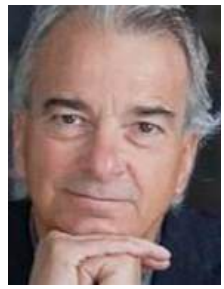
Supplement to
American Journal of
PUBLIC HEALTH
A PUBLICATION OF
AMERICAN PUBLIC HEALTH ASSOCIATION

Racial Disparities in Cancer Care | Access to Care for Transgender Veterans | Hepatitis C Among US Veterans | Battling Tobacco Use at Home | [illegible] | 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

APHA

Vaccines: Containing COVID-19 and Building Long-Term Confidence



On March 18, two months after its installation, the new US presidential administration achieved the symbolic mark of 100 million vaccine shots. The vaccines are safe. Associate editors Wendy Parmet, Daniel Tarantola, and Stella Yu have prepared a special section of *AJPH* showing that the devastation of the COVID-19 pandemic, combined with the scientific and public health successes, open a window of opportunity to change the way society at large and governments assess the cost–benefits of vaccines.

Bloom et al. (p. 1049) stress that, typically, economic evaluation of vaccination focuses on direct health benefits for the immunized, such as avoided deaths or life-years gained or health care cost savings from prevented infections. But when it brutally halted society and the economy at a mindboggling human and material cost, COVID-19 highlighted that getting people vaccinated and achieving herd immunity against COVID-19 can also save jobs, housing, schooling, and more.

The full societal impacts of COVID-19 provide a plethora of positive arguments to convince everyone of the benefit of vaccines. To convince the vaccine hesitant, Broniatowski et al. (p. 1055) propose that social media companies, health agencies, and public health advocates team up to disseminate evidence-based information on social media.

By contrast, in the current context, censoring anti-vaccine misinformation using imprecise algorithms or enforcing vaccination in the workplace can backfire, and, importantly, "a narrow focus on debunking misinformation," Larson and Broniatowski write (p. 1058), "will not address the emotions and concerns of those who distrust COVID-19 vaccination."

Similarly, Rothstein et al. (p. 1061) contrast the risk of hardening vaccine opposition if employers can ask their workers to be vaccinated with the trust-building consequences of workplace campaigns informing employees of the benefits of vaccination and providing time off to get the shot or easy access to it at the workplace.

The long-term success of these trust-building strategies requires not mistaking authorization for approval. As Zuckerman explains (p. 1065), the Food and Drug Administration (FDA) rushed hundreds of tests, personal protection equipment, vaccines, and treatments to the market through Emergency Use Authorizations (EUAs). EUAs should not become the new normal, replacing the gold standard of FDA "approval" and being extended longer than is absolutely necessary.

Equally important to bringing an end to the COVID-19 pandemic is to keep in mind the perspective of rebuilding public health on more equitable foundations. The scientific and technical accomplishments too often obscure the daily resilience of millions of health care (including public health) workers. As Lin (p. 1070) explains, the equitable access to and distribution of vaccines, particularly for disadvantaged US populations, is the responsibility of Federal Health Centers, which operate more than 14 000 primary care clinics and employ nearly 260 000 health care workers.

In their insightful examination of the first weeks of the vaccination campaign, Tewarson et al. (p. 1073) describe the challenges faced by states and territories to cover the "last mile" of COVID-19 vaccine distribution. These challenges of reach, equity, workforce, and communication reveal the structural deficiencies that need to be fixed for the long term.

Yes, the more than 984 US federal, state, and local policies in 13 areas of law can "mess with" an effective national strategy. Operation Warp Speed has constructed a federal database, or "data lake," to monitor vaccine coverage nationwide. But Benjamin-Chung and Reingold (p. 1078) warn that if the data lake is managed separately from existing and experienced state and local immunization information systems, we may lose an opportunity to create a sustainable monitoring system beyond COVID-19.

One hundred million vaccine shots in two months with no vaccine-related deaths is a formidable achievement that has mobilized millions in the private and public workforces. It is also an opportunity to build trust in sustainable vaccination strategies against infectious scourges. AJPH

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

DOI: https://doi.org/10.2105/AJPH.2021.306300

17 Years Ago

Enhancing Public Confidence in Vaccines Through Independent Oversight of Postlicensure Vaccine Safety

The public must know that vaccine safety concerns are taken seriously and investigated by independent professionals whose primary responsibility is safety, not financial gain, public image, or program goals. . . . [T]he Food and Drug Administration (FDA) lacks the resources for adequate postlicensure surveillance and FDA staff members are potentially biased as [it has been said], "their recommendation for approval involves substantial personal identification with that approval, and it is unlikely that those who recommended a drug for approval could later conduct a dispassionate evaluation of possible harm due to that drug." . . . [We propose] a board, modeled after the National Transportation Safety Board (NTSB), with sufficient funds to mount its own ongoing studies or hold open public hearings resulting in recommendations to the FDA. . . . The development of an NVSB [National Vaccine Safety Board] could create a vibrant system for ensuring the safest vaccine system possible and maintaining public confidence in the safety of vaccines.

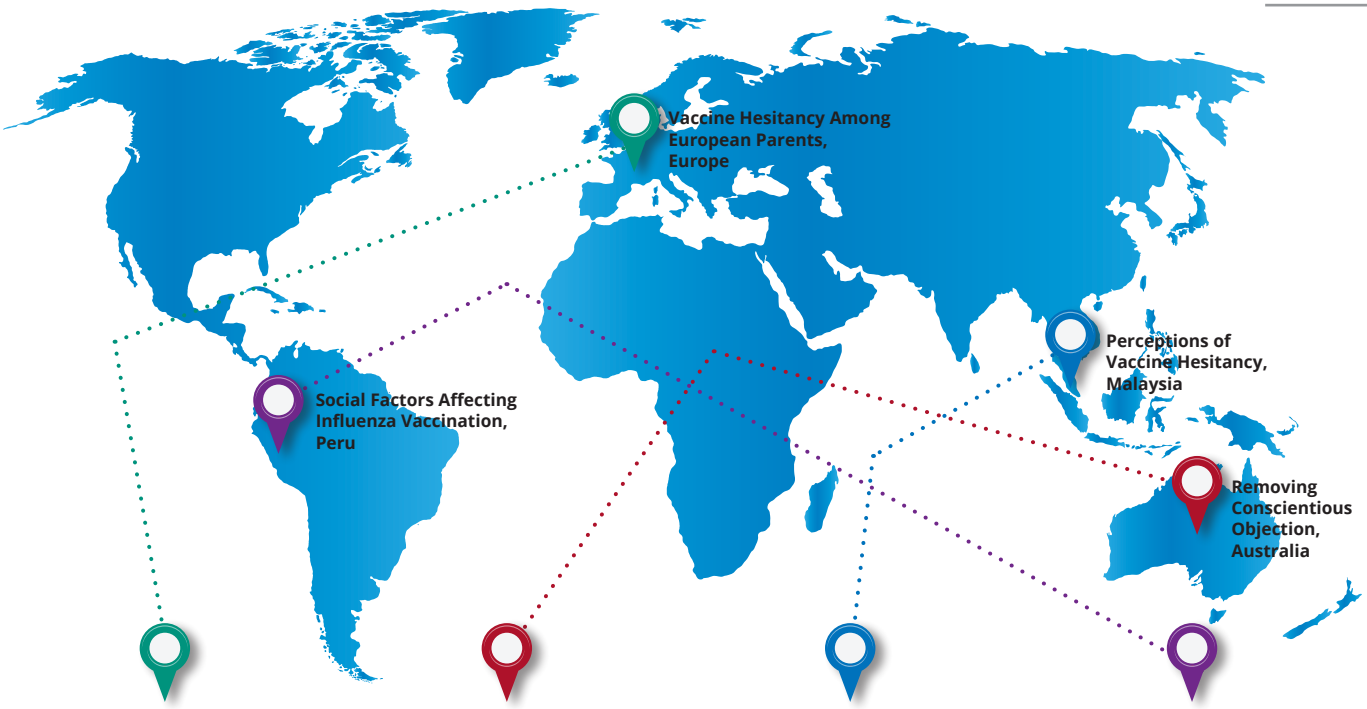
From AJPH, *June 2004, 947–949, passim*

17 Years Ago

Needing a New Paradigm for Vaccine Development

The biotechnology revolution . . . has allowed the unprecedented rational development of new recombinant vaccines that will hopefully help control infectious diseases, including those that appear most complex. . . . However, despite these new tools, the challenges remain formidable. . . . The world vaccine market is estimated at approximately $6.5 billion, a meager 2% of the global pharmaceutical market, making vaccine research and development considerably less attractive to private investors than drug development. Moreover, many of the diseases for which new vaccines are urgently needed mainly affect developing countries whose market characteristics fail to attract private capital investment. . . . In this context, a new paradigm needs to be developed to include and coordinate the actions of the WHO, international and national funding agencies, the pharmaceutical industry and manufacturers in emerging developing countries, nonprofit foundations, and nongovernmental humanitarian organizations.

From AJPH, *November 2004, p. 1935*



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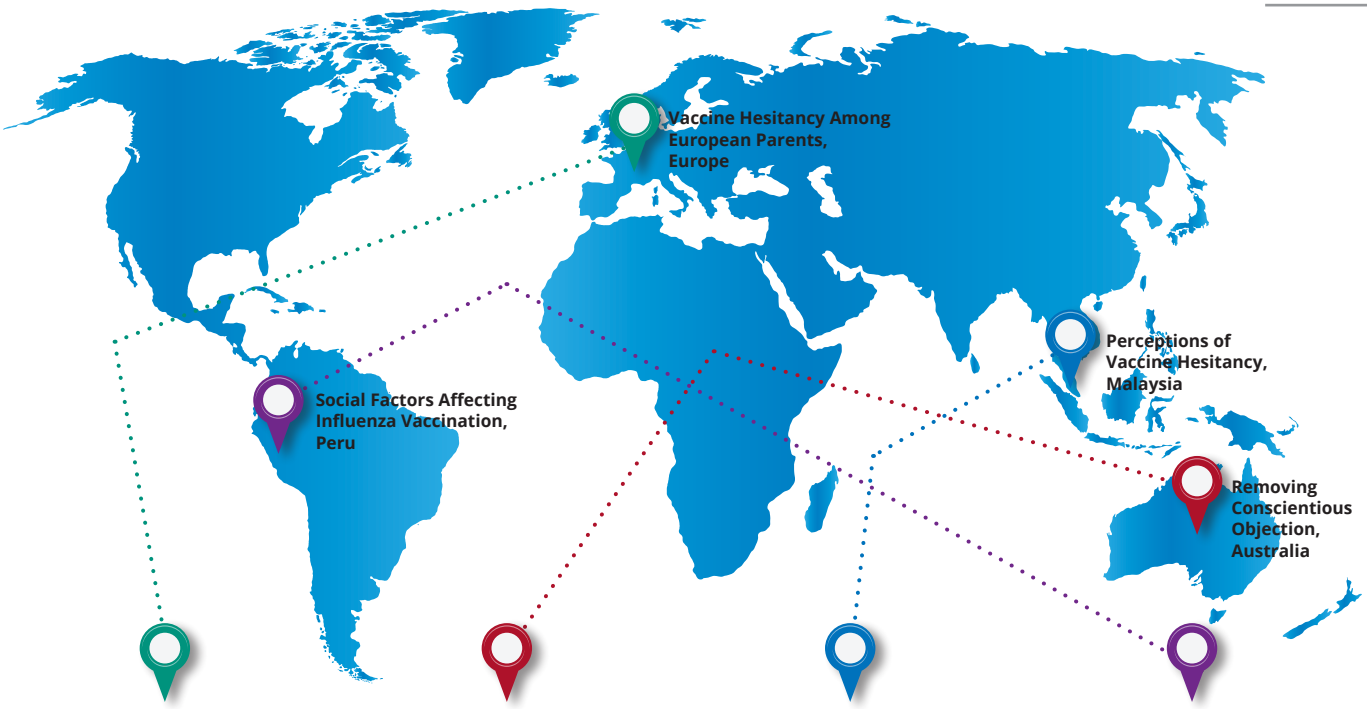

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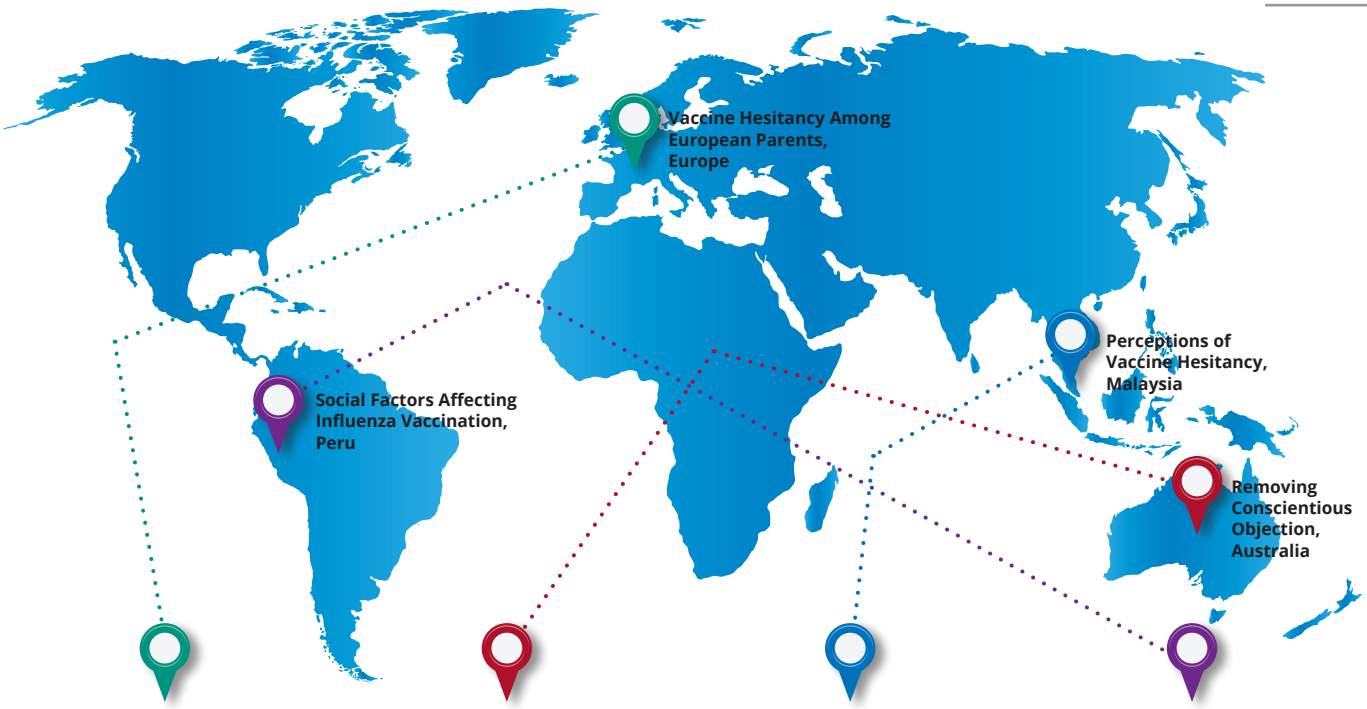

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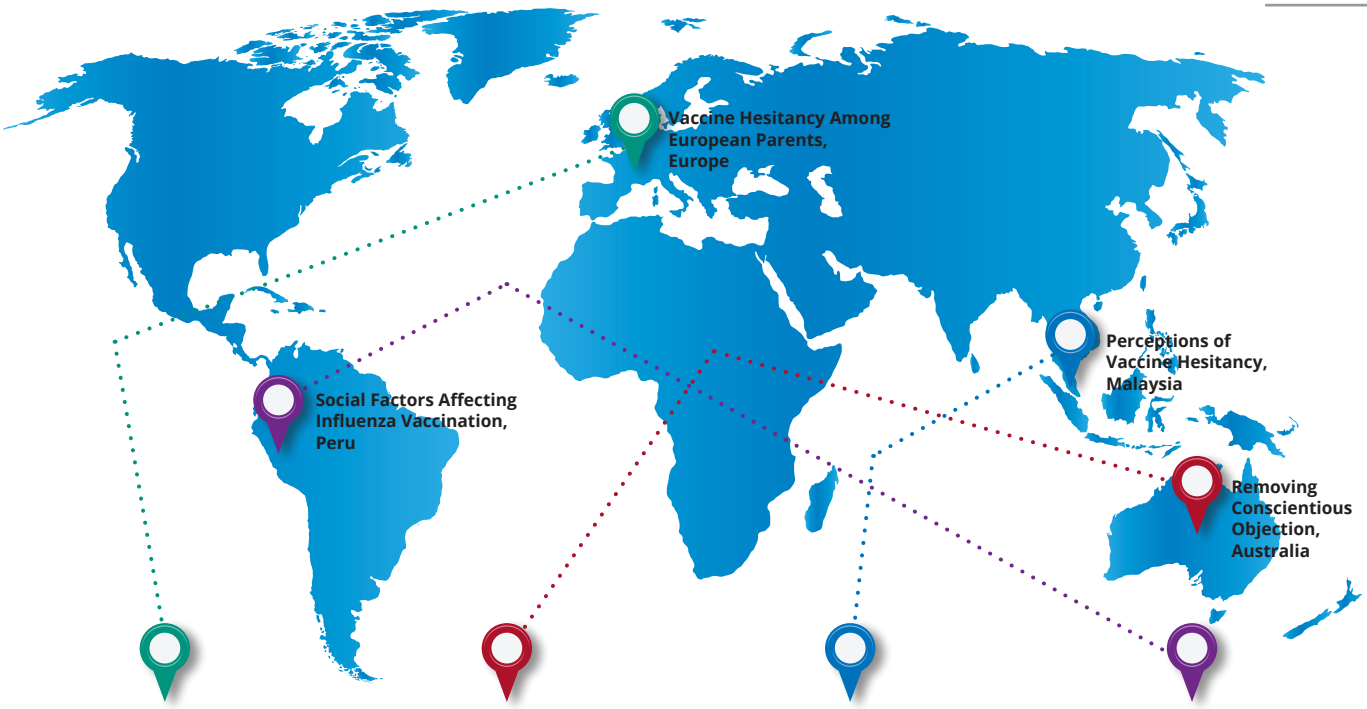

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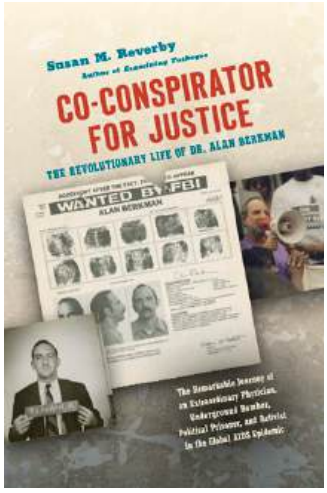
The Revolutionary Sixties Told to Those Who Were Not There

Alfredo Morabia, MD, PhD

ABOUT THE AUTHOR

Alfredo Morabia is the editor-in-chief of AJPH*, Washington, DC.*



Co-conspirator for Justice: The Revolutionary Life of Dr. Alan Berkman (Justice, Power, and Politics)
By Susan M. Reverby
Chapel Hill, NC: University of North Carolina Press; 2020
Hardcover: 408 pp; $30.00
ISBN-10: 1469656256
ISBN-13: 978-1469656250

Susan Reverby's book is about the life of Alan Berkman, MD (1945–2009), whose June 14, 2009, obituary in the *New York Times* stated:

> Physician, fugitive, federal prisoner, clinician to the homeless, advocate for AIDS patients, epidemiologist: That was the arc of Alan Berkman's career. Dr. Berkman, a Vietnam-era radical who spent eight years in prison for armed robbery and possession of explosives and who later founded Health GAP, a leader in the coalition that helped make AIDS medication available to millions in the world's poorest countries, died in Manhattan on June 5. He was 63 and lived in Manhattan. (https://am.ajph.link/ABerkmanObit)

Berkman and I were colleagues at Columbia University around the time of his death and, like many of the other members of the Department of Epidemiology, I discovered Berkman's past reading the *New York Times* obituary. Berkman was not a significant radical historical figure, like, for example, Angela Davis, that the public at large would recognize. A first question when picking up this book is why would he deserve a biography by Reverby, a professor emerita in the history of ideas at Wellesley College and an accomplished historian of public health?

Reverby provides several reasons for having written this biography, which covers, besides Berkman's preactivist youth, his political activism in the 1960s and 1970s, his time in jail in the 1980s, and his global health activism in the 1990s and after. She knew Berkman well from college at Cornell University. She had been studying the story of what she has called "infamous" doctors, and Berkman was one of them. Through Berkman's family, she had access to a trove of documents, including an unpublished prison memoir. But most of all, Berkman's unique journey offered her an opportunity to tell the story of her generation of radical youths of the 1960s.

> I suspect above all I was fascinated because part of his journey was the path I, and others of my generation, had imagined at one time we would take, but ultimately did not. After all, a survey of college students showed that in the late sixties "350,000 considered themselves as revolutionaries." (p. 3)

Berkman's life was typical of a "white American man" (p. 5) among these revolutionaries, but it also was an atypical journey marked by love, activism, violence, disease, and death.

THE EXTRAORDINARY LIFE OF ALAN BERKMAN

Reverby uses written published and unpublished primary sources and interviews as well as her direct experience of the radical left during the 1960s. (Reverby is the narrator, but she is also in the narrative.)

Berkman began as a nonviolent activist reacting to social injustices. But already in this idealistic phase, Berkman showed extraordinary courage. For instance, in 1973, with a guide from the American Indian Movement and two comrades, Berkman took the risk of bypassing stealthily the siege set by the FBI on the Native Americans occupying Wounded Knee, in South Dakota, to

provide medical advice and care to the tribes.

Berkman's political life was transformed when, on October 20, 1981, he was called to provide medical care to a militant wounded by a gunshot during an attack on an armored truck carrying money, which killed the driver. Refusing to provide information about his involvement to the FBI, he was charged with "being an accessory after the fact to robbery and murder, racketeering conspiracy, and obstruction to justice" (p. 118). To escape a pending long jail sentence, he jumped bail in January 1983 and "descended into the political underground" (p. 122). He joined a clandestine political group dedicated to spectacular, allegedly anticapitalistic and anti-imperialistic actions.

After a couple of years of underground activism, Berkman left his fingerprints on a card he lost during an armed action and ended up in jail for eight years (1985–1992). During his incarceration, Berkman survived a cancer diagnosis that initially was not properly treated. Despite the extraordinary physical and psychological hardships of incarceration, he earned the warm friendship and respect of his fellow inmates, for whom he became "Brother Doc."

The HIV/AIDS pandemic exploded in the early 1980s while Berkman was in jail. Persons with HIV and AIDS were disproportionately incarcerated. In a 1995 article in *AJPH*, Berkman stressed the importance of ending mass incarceration and "traditional prison health practices" to effectively challenge the AIDS epidemic.[1] More generally, Berkman came to realize in the 1990s that poor populations affected by the disease could not afford the high cost of the existing treatments. He argued in *AJPH* that integrating prevention and treatment was key to confronting the global epidemic.[2] Through a grassroots organization called Health Global Access Project (Health GAP, healthgap.org), which relied on grants, foundations, and individual donors to sustain its work, Berkman struggled to make HIV/AIDS drugs more available, particularly in Africa. Health GAP claims to have played a key role in winning support for the US President's Emergency Plan for AIDS Relief (aka PEPFAR), which was launched by President George W. Bush in 2003.

In 2003, 10 years after his release from prison, Berkman became an assistant professor and, in 2006, the Vice Chair of the Department of Epidemiology at Columbia's Mailman School of Public Health. As Reverby explains, "After having tried and failed to change the world" (p. 263), public health provided Berkman a way to bring together his medical, political, and organizing talents:

> In the end, Alan came to believe that his medical skills, when shared with activists and those most harmed by the racist, sexist, and neo-imperialist policies, might actually be more revolutionary. His shifted frame of reference never changed his priorities or principles, just the way he accomplished them. He moved from the care of individuals to the care of whole populations. (p. 297)

HISTORY OF A GENERATION

This enthralling biography would deserve a formal literary analysis to do full justice to all its qualities. It reads like a Stendhalian novel, the phases of Berkman's activism evoking those of a hero moving from being idealistic in the 1960s, to erring and undergoing infernal times in jail, and finally to finding redemption in an effective activism that was consistent with his original ideals. Berkman had the uncompromising, permanently untamed, rebellious nature of Julien Sorel in *The Red and The Black* or of Fabrice del Dongo in *The Charterhouse of Parma*. These heroes allow Stendhal to walk us through the psychology and societal context of the first third of the 19th century, in Europe, where the former aristocratic order was being replaced by a new democratic order initiated by the French Revolution and continued through its Napoleonic sequel. In Reverby's biography, the extraordinary life of Berkman, an uncompromising Leftist outlier of the 1960s, provides the backdrop for the social history of a generation of young women and men who were radicals in the 1960s, mostly survived to the present, and have in one way or another striven to sustain their original ideal of a just and equitable society.

This novelistic dimension of Reverby's biography of Berkman may make a difference in the public the book can reach. Histories of activists primarily interest those who were also activists in those years, those "who were there." By contrast, in this riveting book Reverby may have found a Stendhalian way to tell the story of her generation to those who were not there. AJPH

CORRESPONDENCE

Correspondence should be sent to Alfredo Morabia, MD, PhD, Barry Commoner Center for Health and the Environment, Queens College, CUNY, 65-30 Kissena Blvd, Flushing, NY 11367 (e-mail: amorabia@qc.cuny.edu). Reprints can be ordered at http://www.ajph.org by clicking the "Reprints" link.

PUBLICATION INFORMATION

Full Citation: Morabia A. The revolutionary sixties told to those who were not there. *Am J Public Health*. 2021;111(6):984–986.

Acceptance Date: March 17, 2021.

DOI: https://doi.org/10.2105/AJPH.2021.306294

ACKNOWLEDGMENTS

I am grateful to Dan M. Fox, Theodore Brown, Michael C. Costanza, and four reviewers for comments on previous versions of this book review.

CONFLICTS OF INTEREST

The author has no conflicts of interest to declare.

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Timely and Accurate Data From Vital Records Registration, Merged With Disease-Reporting System Data, Can Truly Empower Public Health Officials

Glenn Copeland, MBA

ABOUT THE AUTHOR

Glenn Copeland formerly served as the state registrar for the State of Michigan and the chief of the Division for Vital Records and Health Statistics, Michigan Department of Health and Human Services, Lansing.

See also AbouZahr et al., p. 1123.

The article in this issue of *AJPH* by AbouZahr et al. titled "The COVID-19 Pandemic: Effects on Civil Registration of Births and Deaths and on Availability and Utility of Vital Events Data" (p. 1123) provides an interesting review of the status of civil registration activities worldwide. AbouZahr et al. point out how the pandemic has stopped or curtailed civil registrations over a wide range of countries. The issues identified as interrupting registration include a lack of adequate plans for continuity of operations, the need to set governmental priorities, views that civil registration is not an essential service, and concerns that in-person contacts required for registrations to occur would encourage disease spread. That roughly half the world's population was not covered by systematic vital event registration before the pandemic underscores just how far there is to travel before stable civil vital event registration is available everywhere.

AbouZahr et al. discuss the cost of not having a dependable system for civil registration. They list the administrative uses for these data, such as documentation of identity, maintaining population registries, administering social and health programs, and managing banking and pension systems. The significant value of the resulting data in informing public health officials of the issues and problems of the populations they serve is also discussed. AbouZahr et al. provide an interesting examination of how timely death data can provide valuable information to identify characteristics of a novel disease and how that disease manifests in a population during the initial stages of a pandemic. Examples of innovative uses of these data in New Zealand and Hawaii are described briefly.

Over the past decade, building on initiatives by the National Center for Health Statistics and state vital records offices across the United States, as well as the coordinating efforts of the National Association of Public Health Statistics and Information Systems, there has been a collective quantum leap in the vital records registration methods used in the United States.[1] Individual states' deployment of Web-based birth and death reporting is nearly complete. The effort was undertaken with an eye to improving the timeliness, accuracy, and security of vital event registration. These outcomes were viewed as important to better meet the range of needs for vital records services, whether administrative or analytical.

Because of these advancements, analytical data on deaths are now available roughly seven days from death across most of the United States compared to from 60 to 90 days from death under paper-based registration. Work has been under way since the early part of the past decade at both the state and national levels to radically speed the production of useful information from the timely data now available through these interactive state registration systems. Releases of provisional population-based data on births and deaths, including deaths by cause of death, within months rather than years from the date of death has been taking place for some time now.[2–4]

As COVID-19 began to spread, the efforts to modernize vital records registration created an ideal environment for adapting the handling of these data to provide critical groomed and population-based information on

deaths from this new disease. Accomplishing this early on as the impact of COVID-19 unfolded helped to rapidly identify information critical to public health's understanding of this new disease. With similar efforts at successfully transforming infectious disease reporting systems, states such as Michigan were able to develop and implement routine interfaces between systems, so that mortality data could routinely be screened for reportable infectious conditions and for deaths of persons with a reportable disease. The interface between the Michigan Electronic Death Registration System and the Michigan Disease Surveillance System, finalized just after the COVID-19 pandemic unfolded, enabled augmenting COVID-19 case counts and COVID-19–related deaths by using the mortality files. The linked Electronic Death Registration System data aided in the discovery of COVID-19 cases unknown to the Michigan Disease Surveillance System, providing fact of death and other details on deaths to COVID-19 patients in the Michigan Disease Surveillance System, and allowed the development of information on COVID-19 survivors.

This timely data available in Michigan provided public health officials with critical data that drove public health policy and direction as the pandemic unfolded. As an example, in Michigan it was discovered early on that both COVID-19 case and mortality rates were comparatively high in Michigan's African American population. This discovery led to establishing a task force to examine the problem,[5] formulating strategies to address perceived problems,[6] and setting up a program to direct funds to implement those strategies.[7] In the end, as described in an evaluation by the National Governors Association and the Duke Margolis Center for Health Policy,[8] Michigan experienced a marked reduction in racial disparities relative to both COVID-19 cases and COVID-19–associated mortality.

Concepts underlying Web-based vital event registration can provide an approach that holds the promise of easing the implementation of comprehensive civil registration systems in countries with a poor or no system. The centralized development of such systems with coordinated support and maintenance can significantly ease adoption by countries needing to establish or improve vital records registration. Of note, these systems are generally designed to be paperless, which limits in-person contacts during the registration process, thus complementing stay-at-home orders issued as a disease control measure.

There are surely many success stories regarding how public health officials met the challenge of COVID-19. A full accounting of these success stories is needed, and a picture of the ideal approaches to this crisis does need to be drawn. The implementation of Web-based vital record systems in the United States, although successful, was accomplished largely with state-level funding and without a clear path to fiscal sustainability. These systems are costly to develop and maintain, have a limited shelf life, and significantly reduce the flexibility of the states to adapt to new vital records reporting standards. It is important that efforts to sustain and enhance these new age reporting systems be given priority if we are to be better prepared for the next public health challenge.

The COVID-19 pandemic has exposed several concerns that need the careful attention of governments and public health officials worldwide. It has also provided an opportunity, born of necessity, to demonstrate how timely and accurate data from vital record registration, merged with disease-reporting system data, can truly empower public health officials to rapidly assess problems and develop approaches to best address a public health crisis. AJPH

CORRESPONDENCE

Correspondence should be sent to Glenn Copeland, 7235 West Beard Rd, Shaftsburg, MI 48882 (e-mail: copelandgl@msn.com). Reprints can be ordered at http://www.ajph.org by clicking the "Reprints" link.

PUBLICATION INFORMATION

Full Citation: Copeland G. Timely and accurate data from vital records registration, merged with disease-reporting system data, can truly empower public health officials. *Am J Public Health*. 2021;111(6): 990–992.

Acceptance Date: February 25, 2021.

DOI: https://doi.org/10.2105/AJPH.2021.306255

ACKNOWLEDGMENTS

I acknowledge the assistance provided by Ed Hartwick and Jeff Duncan of the Michigan Department of Health and Human Services. Both provided helpful information on the means and methods used to develop data on COVID-19 in Michigan during the ongoing pandemic.

CONFLICTS OF INTEREST

The author has no potential or actual conflicts of interest to declare.

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Making Meaning of Cumulative Child Welfare System Involvement

Sarah Font, PhD

ABOUT THE AUTHOR

Sarah A. Font is with the Department of Sociology and Criminology, Pennsylvania State University, University Park.

See also Putnam-Hornstein et al., p. 1157.

A new study by Putnam-Hornstein et al., in this issue of *AJPH* (p. 1157), is the latest of many to estimate cumulative incidence rates for child welfare system (CWS) involvement. Whereas previous work relied on synthetic life tables produced from the National Child Abuse and Neglect Data Systems (NCANDS) and the Adoption and Foster Care Analysis and Reporting Systems (AFCARS), this latest work uses linked administrative data from California. It is an important effort to assess the plausibility of previous estimates, and the scientific community will benefit from similar replications in other states. I focus on two issues: (1) discrepancies in estimated cumulative investigation rates, and (2) possible interpretations of the overall rates of CWS involvement.

The authors' estimated prevalence rates for back-end CWS involvement (substantiated CWS investigations, foster care entry, and termination of parental rights) are roughly similar to previous national estimates, thus providing reasonable confidence about the sufficiency of NCANDS and AFCARS data for tracking those outcomes. However, Putnam-Hornstein et al. find a substantially lower rate of exposure to CWS investigations (~26%) than the NCANDS estimates (~37%).[1] They emphasize one possible explanation for the difference in estimates: that NCANDS cannot track children across states (and thus double counts children investigated in multiple states). By contrast, this study is limited to only California-based reports (and thus cannot account for California-born children who are investigated in other states). This explanation seems unsatisfactory for explaining an 11-point gap (a relative difference of 42%). California also does not differ greatly from the nation on investigation rates,[2] so the discrepancy in estimates raises important questions about whether NCANDS identifiers for children in unsubstantiated investigations are reliable (unique) in each state. Further assessment of this issue is warranted, given the attention that cumulative investigation estimates have received to date.

Notwithstanding, the new study likely provides a more accurate estimate of cumulative exposure to a CWS investigation and affirms previously estimated rates of downstream CWS involvement. The question, then, is what do we make of these findings?

Putnam-Hornstein et al. conclude that CWS has limited *specificity*—implying that levels of investigation are disproportionate to the occurrence of maltreatment and ensnare a large number of families for whom maltreatment did not actually occur or who do not require CWS involvement. We cannot draw this conclusion based on available evidence. Cumulative rates of CWS investigation may astonish many, but we should not discount the possibility that it is a reasonable approximation of the prevalence of child maltreatment or imminent risk thereof and that the comparatively low rates of substantiation and subsequent formal intervention indicate limited *sensitivity*.

Some calls to CWS are made simply because reporters do not know how else to connect families to services. Many of the 40% of referrals that are screened out without investigation each year[2] perhaps fall into this category, as, likely, does some proportion of referrals that are investigated. Predictive risk modeling, an area in which Putnam-Hornstein is a leader,[3] is a promising strategy for identifying referrals that can be appropriately and safely diverted to voluntary community resources without an investigation.

Yet the sum of existing evidence indicates that investigations are a reasonable approximation of maltreatment exposure, regardless of the substantiation determination. Estimated rates of child maltreatment exposure derived from surveys and other study methodologies are not consistently lower than the rate of CWS investigation,[4] and a CWS investigation is predictive of a range of adverse outcomes regardless of substantiation and after controlling for socioeconomic factors.[5–7] CWS decisions also occur in a context of high uncertainty, with conflicting or vague child disclosures, lack of direct physical evidence, limited powers to compel

cooperation, inexperienced and poorly trained staff, political pressure to avoid foster care even in the highest risk cases, and limited resources to provide services. These factors imply a tendency not to substantiate or formally intervene even when maltreatment has occurred.

In contextualizing their findings, Putnam-Hornstein et al. further assert that CWS is designed to surveil many but serve few. However, is it true that most investigations result in no intervention? A key distinction here is informal versus formal intervention. CWS frequently provides, refers to, or arranges services or other interventions to children it declines to count as victims. For example, California reportedly provided services to nearly two thirds of children with unsubstantiated investigations in 2019.[2] CWS also relies heavily on informal kinship care as an explicit strategy for avoiding foster care.[8]

Are informal interventions limited to cases in which no maltreatment occurred or in which risk of harm is low? Probably not. Formal interventions (e.g., supervised in-home services, court involvement, and foster care) are comparatively rare by design, as the authors claim. Indeed, it is the expected result of a system that is required to investigate maltreatment but is legally and politically pressured to avoid usurping parental authority. Reliance on informal kinship care, voluntary services, and non-investigative "assessments" to address maltreatment were originally the demands of advocates for CWS reform who wanted a more family-friendly entity.[9] Acquiescence to these demands also serves the interests of government officials, who claim success in reducing child maltreatment on the basis of declining numbers of substantiated victims and foster care caseloads. Whether relying on informal interventions serves the interests of children is not clear. These estimates imply that a substantial proportion of children are born to parents who are, at some point, unable to provide minimally adequate care and for whom existing systems are inadequately resourced to respond.

Lastly, the study also finds disproportionate rates of CWS involvement for Black and Indigenous children, with larger disparities for back-end than front-end involvement. It is worth noting that the landscape of foster care changed drastically during the study period: Black children were 38% of the foster care population in 1999[10] versus 23% in 2019.[11] Regardless, racial disparities certainly remain in various levels of CWS involvement. Because discourse on CWS generally, and foster care and termination of parental rights in particular, often centers on parents rather than children, overrepresentation is often equated to harm. But it matters that disparities in CWS investigation are generally consistent with estimated disparities in child maltreatment,[12] child fatalities,[2] and other metrics indicative of risk to children. It matters because making CWS the problem allows society to ignore or minimize the causes of these disparities—namely, the wholly inadequate efforts to overcome the legacy of de jure segregation, state-sanctioned violence, economic isolation, and discrimination that harms the health and wealth of Black and Indigenous families in the present. Reducing or eliminating CWS will not rectify these broader inequalities and may worsen them, given the intergenerational implications of child maltreatment.

This is not an argument that CWS is performing well—it is not. CWS appears to be frequently ineffective at preventing revictimization or mitigating its effects. Putnam-Hornstein et al. emphasize a lack of specificity in front-end functions as a critical issue undermining CWS effectiveness. Although that is likely at least somewhat true, it is not a complete picture. On the whole, evidence points to both some degree of over-investigation for comparatively low-risk cases and substantial levels of under-intervention in response to high-risk cases. AJPH

CORRESPONDENCE

Correspondence should be sent to Sarah Font, 612 Oswald Tower, University Park, PA 16802 (e-mail: Saf252@psu.edu). Reprints can be ordered at http://www.ajph.org by clicking the "Reprints" link.

PUBLICATION INFORMATION

Full Citation: Font S. Making meaning of cumulative child welfare system involvement. *Am J Public Health*. 2021;111(6):993–995.

Acceptance Date: February 27, 2021.

DOI: https://doi.org/10.2105/AJPH.2021.306268

ACKNOWLEDGMENTS

The author acknowledges the Translational Center on Child Maltreatment Studies at Penn State, funded by the Eunice Kennedy Shriver National Institute on Child Health and Human Development (grant P50HD551411).

CONFLICTS OF INTEREST

I have no conflicts of interest to report.

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Pandemics and History: Context, Context, Context

Judith Walzer Leavitt, PhD

ABOUT THE AUTHOR

Judith Walzer Leavitt is with the Department of Medical History and Bioethics, University of Wisconsin—Madison.

See also Morens et al., p. 1086.

Morens et al. (p. 1086) present a comprehensive medical comparison between the 1918 influenza epidemic and the COVID-19 epidemic in the United States. As scientists, they focus on the viruses and on the science. They identify some similarities and differences, using current knowledge and reflection to find precedent for some of the issues that matter today.

As a public health historian, I examine the uses and meanings that comparisons of epidemic experiences can offer. From the historical perspective, it is essential to locate an epidemic within its full temporal, social, political, economic, and cultural context. It is not sufficient to find, for example, that face masks were used at two different times unless we examine also the significance and meaning those masks had to the people who considered using them. The 1918 epidemic took place during and immediately after World War I, when mask wearing was viewed as a patriotic act. During the 2020 epidemic, powerful political forces have deemed mask wearing an affront to personal liberty.

I draw on my own work on the history of public health in Milwaukee, Wisconsin, to illustrate the importance of the sociopolitical context of the 1918 influenza outbreak.[1] Then, public health in the United States was largely a local matter. Milwaukee, a city of more than 467 000 people in 1918, fared extremely well with influenza compared with other large American cities. With New York City at 452 excess deaths per 100 000 population, Boston, Massachusetts at 710, San Francisco, California at 673, and Philadelphia, Pennsylvania at 748, Milwaukee's rate of 292 was exemplary. Among the 18 American cities of more than 350 000 people, only Minneapolis, Minnesota surpassed Milwaukee with its record 267.[2]

Why was Milwaukee so successful? Public health officials in Milwaukee built a public–private coalition to combat influenza when it arrived in September 1918. Health Commissioner George C. Ruhland acted quickly, consulting the state board of health, which held police powers necessary to protect the public's health. Ruhland requested all physicians to report cases of the disease and appointed an advisory committee of two physicians and two businessmen. He sought money from the common council to prepare hospitals and clinics to receive the sick and enlisted the support of numerous voluntary and religious organizations. He focused his efforts on isolation, the most traditional method of fighting infectious diseases. The health department mobilized an extensive advertising campaign teaching the public how to avoid contagion. In multiple languages in this heavily immigrant city, posters with advice appeared throughout city neighborhoods, newspapers carried lengthy daily accounts and advice, and churches and factories sponsored "four-minute talks" to keep people up-to-date. Ruhland met personally with physicians, clergy, business people, theater managers, newspaper editors, and club representatives. The entire city rallied.

In October, as flu cases increased, Ruhland and his advisors instituted more radical measures. They outlawed public gatherings and closed theaters, movies, public dances, and churches; then they shuttered schools. People were permitted to buy drinks at the neighborhood saloons, but not to stay inside to drink them. The Visiting Nurse Association and women's organizations helped to staff city hospitals and clinics, as did teachers who were idle from their normal duties. Ordinary life was disrupted; businesses lost money; people could not work. After 23 days, Ruhland lifted many of the restrictions, but the victory was short-lived. When cases increased in December, Ruhland again banned public gatherings, closed schools, and imposed a half-capacity rule on theaters and churches. Though reluctant, the public accepted this second round of restrictions. Ruhland allowed some Christmas and New Year's Eve parties to proceed, although he insisted that attendees wear gauze masks. In the new year, influenza waned, schools reopened, and social events were again permitted.

Throughout the crisis, Ruhland consulted with the business community, interacted with health care professionals and hospitals, and scrupulously maintained transparency in his interactions with the public. He credited Milwaukee's relatively low mortality rate to the extreme cooperation of the public and the support of doctors and nurses. In a very short time, the health commissioner had mobilized an army of volunteers, coordinated the efforts of community organizations, plastered the city with educational literature, isolated the sick, and assuaged the doubts of businesspeople and politicians who feared personal loss from the emergency regulations.[1]

Milwaukee's actions to quell influenza were similar to or exactly the same as methods tried by other cities.[3] Along with liberty bond parades (which in Philadelphia demonstrably spread influenza),[4,5] masks carried patriotic value and gave the public a way to exhibit and celebrate their loyalty. Yet Milwaukee's efforts were more successful than elsewhere. Ruhland's achievement did not rest solely on his medical advice or scientific knowledge, which was shared around the country. It was the municipal specificity—the political and social context in which the epidemic occurred—that can help to explain Milwaukee's success. The high level of central coordination and community cooperation might not have been accomplished, even in wartime, unless previous experiences had paved the way. History matters.

Milwaukee had suffered a disastrous smallpox epidemic in 1894, when the city streets had been filled with rioters and disorder reigned for a full month. At the height of that epidemic, the health commissioner had been impeached and thrown out of office, and the social chaos led to a serious reduction in health department funding and authority.[6,7] The turmoil of 1894 informed the 1918 efforts for public cooperation. There were important lessons of what not to do and incentives to remedy lack of transparency and increase public education and trust.

Equally important in explaining Milwaukee's success with influenza was the political reform that was ushered in when the Socialists won the 1910 mayoral and common council elections. Growing in opposition to corrupt and patronage-laden politics, a coalition of ethnic, middle-class, and labor interests joined together under a pragmatic Socialist banner to institute trustworthy, responsive government to address urban problems.[8] Comprehensive and efficient health policies to improve public services, such as infant welfare programs and community clinics, drawing on the advice of experts, aimed to build a healthier city. By 1918, when the Socialists retained the mayoralty but no longer controlled the common council, progressive policies and programs that developed private–public cooperation had achieved citywide trust in local government's attempts to ameliorate urban problems.[9] Socialist mayor Daniel Hoan and wide-ranging community groups actively supported Ruhland in his work. In 1918, Milwaukee's public health structure—a government department laced with pathways to voluntary agencies and community members, born from the struggles of the 19th century and the good-government amalgamations of the early 20th century—provided a stable base on which the city could build its defense against influenza. The specific history of Milwaukee's public health activities and the need to overcome the failings of the past helped build the success of 1918. The health department learned the hard way of the importance of building trust and cooperation, which it reinforced through strong leadership and active communication with the community, to launch a successful attack on disease.

By contrast, the COVID-19 pandemic arrived in the United States at a relative low point in public trust of science and government.[10] This made application of many of the lessons from 1918 difficult to apply. In 2020, there was already a significant history of political wariness of government programs and a diminution of financial support for public health departments at all levels.[11] Thus, institutionally, it became difficult to mount a rapid response to a pandemic crisis. In addition, understanding the responses to the COVID-19 epidemic is incomplete without analysis of medical inequities based on race and class and the prominence of the Black Lives Matter movement.[12,13] Unlike during the 1918 epidemic, African American health disparities and deaths are now a prominent and publicized feature.[14] Because the health system does not serve all populations equally, many Americans feel they cannot trust medical advice about treatment and vaccinations. It is perhaps ironic that masks today, which are so politicized that many supporters of one political party will not wear them, are extremely effective against disease transmission, whereas in 1918, porous gauze masks were probably not very effective against the microscopic virus. But they were more reliably worn by people in 1918 who willingly trusted the word of government health officials. The lessons regarding control of the 1918 influenza epidemic, which depended on a public open to and even eager for government interventions, were received in a very different cultural and political arena in 2020.

Medical and scientific knowledge and capacities today dwarf those of one hundred years ago. Health officials can achieve great success with sophisticated laboratory research, vaccines, isolation, case tracing, and treatment. But they can still come up short, especially in a context of significant health inequities, if the political climate does not emphasize and encourage public trust in government and scientific efforts. Our current situation demonstrates that, as in the past, wide public cooperation based on public trust is an essential element of a successful response to an epidemic. Public trust and cooperation are as important today as in 1918. AJPH

CORRESPONDENCE

Correspondence should be sent to Judith Walzer Leavitt, 1910 Adams St, Madison, WI 53711 (e-mail: judith.leavitt@gmail.com). Reprints can be ordered at http://www.ajph.org by clicking the "Reprints" link.

PUBLICATION INFORMATION

Full Citation: Leavitt JW. Pandemics and history: context, context, context. *Am J Public Health*. 2021;111(6):996–998.

Acceptance Date: March 4, 2021.

DOI: https://doi.org/10.2105/AJPH.2021.306270

ACKNOWLEDGMENTS

I thank Lewis A. Leavitt, MD, for consultation.

CONFLICTS OF INTEREST

The author has no conflicts of interest to report.

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Occupational Health Surveillance as a Tool for COVID-19 Prevention

Marissa G. Baker, PhD

ABOUT THE AUTHOR

Marissa G. Baker is with the Department of Environmental and Occupational Health Sciences, University of Washington School of Public Health, Seattle.

See also Murray, p. 1149.

The workplace is at the center of the COVID-19 pandemic. And although the virus certainly spreads outside the workplace as well, involuntary exposures at work result in its spread, and infection rates in many occupations exceed infection rates in the general population. In limited sample sizes, higher infection rates have been reported in grocery store workers,[1] agricultural workers,[2] construction workers,[3] and health care workers[4] relative to the general population. Recognizing the occupational spread of this disease, 17 states and Puerto Rico have established a presumption of exposure to COVID-19 for worker's compensation coverage for either all occupations (CA, WY) or particularly high-risk or essential occupations (Puerto Rico and the remaining 15 states). During the pandemic, we have called these workers "essential" and applauded them as heroes; yet their exposures, outbreaks, and excess deaths[5] have continued, even as interventions to halt transmission have been implemented.

One intervention strategy adopted piecemeal across the United States early in the pandemic was stay-at-home orders, whereby residents were asked to stay home except to perform essential tasks or go to their employment in essential businesses. To investigate the effectiveness of this type of order on changing behaviors, in this issue of *AJPH* Murray (p. 1149) reports on how Virginia's stay-at-home order affected resident mobility, measured using cell phone data. Murray found that after a declared state of emergency, Virginians decreased time spent at workplaces (–30%) and increased time spent at home (+12%).

The initial decrease Murray reported points to the effectiveness that a stay-at-home order can have for changing the behaviors of able individuals—behaviors that can ultimately decrease disease transmission. However, the 30% decrease in mobility to workplaces shows that many were unable to comply with the stay-at-home order. Murray found that as the stay-at-home order continued, mobility increased back to pre-pandemic levels, and individuals began to spend more time at workplaces and less time at home, indicating that the changes in behavior were not maintained. Although attending social and recreational events during a pandemic is primarily an individual choice, people travel to their workplaces during a pandemic largely owing to economic necessity.

The finding that stay-at-home orders are insufficient to reduce travel to work is congruent with the results of my previous work, which estimated that only 25% of workers can work from home. During the pandemic, the overwhelming majority of the US workforce either continues to work or is unable to continue working, leading to economic insecurity or job displacement.[6] Perhaps unsurprising, the 25% of workers who are able to work from home tend to be higher paid, male, and White, indicating that the risk of exposure to COVID-19 at work, and job displacement because of COVID-19, is not evenly distributed across the US workforce. Risk is influenced not only by occupation but also by social, demographic, and systemic factors.[7] It is the ultimate privilege to work from home during a pandemic—a privilege realized predominantly by higher-paid, White workers.

Murray's findings join a growing body of research recognizing the role of the workplace in spreading COVID-19 and the inability of most workers to stay home. However, despite these recognitions, limited and inconsistent data have been collected during the pandemic to understand the true toll COVID-19 has taken on worker health and to inform appropriate worker controls.

To better understand the role of the workplace in spreading COVID-19 and the burden of COVID-19 on our workforce, thorough and more complete data are needed on where workplace outbreaks have occurred and which workers have become infected. A robust occupational health surveillance system would have allowed us to collect data that could have been used to

immediately improve outcomes among the most vulnerable workers and rapidly deploy appropriate protections for the workers who must continue to travel to work. Occupational health experts and researchers have long argued for a nationally coordinated strategy for occupational health surveillance,[8] and the COVID-19 pandemic has shown us that we are long overdue for implementing these systems and recognizing occupational characteristics as social determinants of health. If such a system had been in place, essential workers would have had improved outcomes during the COVID-19 pandemic.

Standardized information on industry, occupation, employment arrangement (e.g., traditional, independent contractor, temporary worker), and whether the person is traveling to work could have been collected for all individuals at the time of a COVID-19 test and when presenting at a clinic or hospital with symptoms, regardless of whether the source of exposure was assumed to be related to work. Even in states that collect data on occupation or industry of those who test positive for COVID-19, either voluntarily or as a requirement, these data are largely incomplete[9,10] and lack information on employment arrangement and whether the worker is traveling to work. Coupled with this, all workplace outbreaks[11] should be reported to state and federal Occupational Safety and Health Administrations, as this is information that could help them prioritize limited inspection resources. Mobility data, such as those Murray used, could also inform occupational health surveillance systems by helping identify geographic regions where more individuals are traveling to workplaces. These data can be merged with census demographic and employment data to inform locations for testing sites and personal protective equipment and vaccine distribution.

A coordinated occupational health surveillance system is largely achievable and would have value after the COVID-19 pandemic as well. It would require training health care providers on how to collect this information in a standardized manner, uploading the data to a central database, and ensuring that there are trained individuals to rapidly act on the results from these data. These data would be reported daily to local, state, and federal health departments, just like data on the number of infections and hospitalizations.

These data would allow public health officials to rapidly intervene and tailor guidance, deploy necessary personal protective equipment to high-risk workers, or even shut down certain types of workplaces to prevent additional widespread outbreaks. These relatively easily attainable steps will also improve our capacity for ongoing occupational health surveillance, a much needed program in our public health infrastructure.[8] They will also pave the way for all workers to more readily access workers' compensation for occupational illnesses, as surveillance evidence will support links between work exposure and health outcome. Surveillance findings could have also informed shutdown and reopening plans for state governors and vaccine distribution plans and even could have supported policy changes related to hazard pay and paid sick leave.

Working Americans spend about a third of their time at work—an average of 90 000 hours over a lifetime. As Murray showed, even during a pandemic when a stay-at-home order is in place, people must continue to work, primarily for economic reasons. As Murray concluded, for this reason, stay-at-home orders are not enough. To create evidence-based policies to protect workers, increased evidence is needed. A coordinated national occupational surveillance program is an achievable initiative that can be used to understand which occupations are facing the greatest risk of exposure, which workplaces are having outbreaks, and what the occupational characteristics are of exposed workers. This is one additional tool to be used to prevent COVID-19 transmission in the workplace and subsequent transmission in households and communities. AJPH

CORRESPONDENCE

Correspondence should be sent to Marissa G. Baker, 4225 Roosevelt Way NE, Suite 100, Seattle, WA 98015 (e-mail: bakermg@uw.edu). Reprints can be ordered at http://www.ajph.org by clicking the "Reprints" link.

PUBLICATION INFORMATION

Full Citation: Baker MG. Occupational health surveillance as a tool for COVID-19 prevention. *Am J Public Health*. 2021;111(6):999–1001.

Acceptance Date: March 4, 2021.

DOI: https://doi.org/10.2105/AJPH.2021.306269

ACKNOWLEDGMENTS

The author gratefully acknowledges Nicole Errett, PhD, and Noah Seixas, PhD, for helpful feedback on initial drafts.

CONFLICTS OF INTEREST

The author has no real or perceived conflicts of interest to disclose.

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Are Reductions in Immigrants' Supplemental Security Income Participation Beneficial? It Is Not Completely Clear

Leighton Ku, PhD, MPH

ABOUT THE AUTHOR

Leighton Ku is with the Department of Health Policy and Management and the Center for Health Policy Research, Milken Institute School of Public Health, George Washington University, Washington, DC.

See also Muchomba and Kaushal, p. 1106.

The article by Muchomba and Kaushal in this issue of *AJPH* (p. 1106) describes how states' Medicaid expansions led to a reduction in Supplemental Security Income (SSI) payments for nonelderly disabled adults, saving the federal government more than $600 million. The use of SSI fell more for noncitizen immigrants (12%) than for citizens (2%). The authors used difference-in-difference methods to compare results in Medicaid expansion versus nonexpansion states. Using two data sources, they found consistent results, providing strong evidence that Medicaid expansions reduced SSI participation more for noncitizen immigrants than for citizens.

Those who get SSI are usually automatically enrolled in Medicaid. But rigid SSI income and asset eligibility criteria have meant that some disabled adults could be discouraged from working and earning more, because going over the SSI limits (and losing SSI assistance) would trigger the loss of health insurance, which is essential for those with disabilities. The Affordable Care Act allowed states to raise Medicaid income eligibility above SSI levels and eliminated asset tests, so adults with disabilities could keep their health insurance even if they earned more than SSI allows. Previous research has shown how Medicaid expansions improve work incentives and increase employment of disabled SSI recipients.[1,2]

Getting SSI disability benefits is tough; even after providing evidence of disability and economic need, determinations take months, and many are rejected. Immigrants' SSI eligibility is stricter than that for citizens. Those with green cards—lawful permanent residents—do not qualify until they have resided in the United States for more than five years and have 40 quarters of qualifying employment.[3] (Undocumented immigrants cannot get SSI or Medicaid.) In addition, immigrants receiving SSI are considered "public charges" and can be barred from getting green cards, which may discourage SSI use.[4] Muchomba and Kaushal posit that the immigrant restrictions have led to stronger effects for immigrants than for citizens.

The study leaves three lingering questions. First, is the reduction in SSI benefits necessarily a good thing? Although the federal government saved about $600 million, it also means low-income disabled adults received $600 million less. That loss—which might equal a few hundred dollars per month—could be harmful for low-income individuals with disabilities. It could be offset if those losing SSI gained employment and earnings that equaled or exceeded the benefits lost. But some might apply for Medicaid instead of SSI just because applications are simpler and not receive cash assistance for which they are eligible. Unfortunately, Muchomba and Kaushal did not examine whether employment or income changed for those losing SSI, although other previous research indicates that Medicaid expansions led to higher employment for some with disabilities. Without this piece of the puzzle, it is unclear whether the loss of SSI benefits should be considered a net gain or loss for those affected and who the net losers and winners are.

Second, could immigrants' loss of SSI benefits be explained by other factors, such as anti-immigrant policies promulgated by states or the Trump presidential administration? Xenophobic local, state, and federal policies heightened fear in immigrant communities and discouraged many from seeking

public benefits or health services.[5–7] It is not apparent whether "chilling effects" would be higher in Medicaid expansion states, but it is plausible that some refrained from seeking SSI not because they were getting Medicaid but because they were afraid of harmful repercussions.

Third, even if disabled immigrants were more successful in gaining employment during the 2009 to 2018 period of this study because of Medicaid expansion, is this still true today? The economy surged and employment blossomed from 2009 to 2018, but the COVID-19 pandemic had harsh impacts. Between January 2020 and January 2021, unemployment rates grew far more for the disabled and for immigrants than for the nondisabled and native born.[8] Job opportunities for immigrants and those with disabilities are bleaker now, although hopefully prospects will brighten as the nation recovers from the pandemic.

The Medicaid expansions offer new opportunities that let disabled adults keep insurance coverage without the restrictive SSI income and asset eligibility criteria, increasing employment opportunities. Numerous studies have shown a range of positive health and economic effects of Medicaid expansions.[9] But we should be a little more cautious in deciding whether the loss of SSI benefits is beneficial, particularly when considering vulnerable populations like those with disabilities and immigrants. The nation needs to ensure that adequate health coverage, economic assistance, and employment opportunities are available to help all who need them, and immigrants are often at risk. AJPH

CORRESPONDENCE

Correspondence should be sent to Leighton Ku, George Washington University, 950 New Hampshire Ave, NW, Washington, DC 20010 (e-mail: lku@gwu.edu). Reprints can be ordered at http://www.ajph.org by clicking the "Reprints" link.

PUBLICATION INFORMATION

Full Citation: Ku L. Are reductions in immigrants' Supplemental Security Income participation beneficial? It is not completely clear. *Am J Public Health*. 2021;111(6):1002–1003.

Acceptance Date: March 17, 2021.

DOI: https://doi.org/10.2105/AJPH.2021.306295

CONFLICTS OF INTEREST

The author has no conflicts of interest to declare.

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Who Counts and Who Gets Counted? Health Equity in Infectious Disease Surveillance

Grace A. Noppert, PhD, and Lauren C. Zalla, MS

ABOUT THE AUTHORS

Grace A. Noppert is with the Social Environment and Health Group, Institute for Social Research, University of Michigan, Ann Arbor. Lauren C. Zalla is a doctoral candidate in epidemiology at the University of North Carolina at Chapel Hill.

See also Douglas et al., p. 1141.

AJPH June 2021, Vol 111, No. 6

Infectious disease surveillance has long relied on a biomedical paradigm of disease risk, centering the human host and microbial pathogen without ample consideration of the social environment in which they interact. However, the risk of exposure to infectious pathogens, the susceptibility to infection once exposed, and the resulting effects of infection are inextricably tied to the social positions that individuals occupy. Regardless of the disease under surveillance, an individual's education level, residential neighborhood, occupation, race, ethnicity, and other proxies for social position provide essential information about disease risk. This is true across a range of infectious diseases, from those we routinely survey (e.g., influenza, tuberculosis, HIV) to emerging pathogens (e.g., SARS-CoV-2). Consequently, if health equity is not at the core of our surveillance activities, inequities will inevitably arise, persist, and widen over time.

Today, the COVID-19 pandemic is disproportionately burdening racial/ethnic minority groups as a direct consequence of historical and contemporary injustices rooted in the social process of racialization. As Douglas et al. (p. 1141) highlight in this issue of *AJPH*, inadequate reporting of cases and deaths by race/ethnicity continues to mask the true magnitude of inequities owing to COVID-19. In this editorial, we further contextualize their findings by highlighting five shortcomings of current national surveillance activities that have hindered efforts to address racial/ethnic inequities in the impact of COVID-19:

1. Nearly a year into the pandemic, we still lack a funded and enforced federal mandate to report data on race/ethnicity.
2. We lack information about how data on race/ethnicity are collected across contexts.
3. We lack data on the full impact of the pandemic on population health disparities, beyond what can be captured in data on confirmed cases, hospitalizations, or deaths from COVID-19.
4. Suppressing or collapsing data across groups renders smaller racial/ethnic groups invisible.
5. Acknowledgment of the broader social and historical context is often missing from the analysis and interpretation of racial data.

FEDERAL MANDATE TO REPORT RACE/ETHNICITY DATA

The thoughtful collection of data on race/ethnicity has long been recognized as an important part of infectious disease surveillance.[1] Yet, not until June 4, 2020, more than four months after the first documented US case of COVID-19, was there a federal mandate to systematically collect data on race/ethnicity for all reported cases of COVID-19. Unfortunately, the mandate has done little to improve reporting. Of the 15 381 721 cases reported on the Centers for Disease Control and Prevention's (CDC's) COVID Data Tracker between its inception on August 28, 2020 and February 4, 2021, 7 912 371 (51.4%) were missing data on race/ethnicity.[2] Although a federal mandate is a necessary first step to ensure that data are collected, follow-up action is needed to ensure that such a mandate is consistently implemented across contexts. Lack of clear federal guidance and support for implementation reflects a systematic undercounting, and therefore devaluing, of Black and Brown lives.

DIFFERENCES IN COLLECTING RACIAL/ETHNIC DATA

Although the CDC's COVID-19 case report form includes fields for race and ethnicity, it is unclear how this information is collected. Self-report is often the preferred method for ascertaining race/ethnicity.[3] It is unclear, however, if

or how individuals are asked to report their race or ethnicity at testing centers or hospitals. In addition, data on cases, hospitalizations, and deaths may be captured differently across different surveillance systems, with some relying on doctors or medical examiners to assign race/ethnicity and others relying on self-report. To add to this complexity, the racial/ethnic identities reported by health care providers or medical examiners may not match the racial/ethnic identities that are self-reported as part of the US Census. Differential classification of race/ethnicity across data sources may lead to under- or overestimates of disease risk. For example, Indigenous individuals are often misclassified as White in surveillance data, potentially leading to underestimation of the burden of COVID-19 in this population.[4]

POPULATION HEALTH DISPARITIES DATA

SARS-CoV-2 infections are likely to be underdetected in communities that face structural barriers to testing. This is particularly problematic because undetected infections may have long-term health effects. Moreover, our current surveillance activities have focused almost exclusively on the direct effects of the pandemic on population health, measured in terms of SARS-CoV-2 infections or deaths that can be directly attributed to COVID-19. The indirect effects of the pandemic on population health—through mechanisms such as social isolation, job loss, food insecurity, and delayed medical care—have received far less attention. Inequities in the indirect effects of the pandemic are likely to be substantial and will continue to play out long after infections and hospitalizations wane.[5,6]

SUPPRESSING OR COLLAPSING DATA

The practice of suppressing small numbers of cases or deaths makes it difficult to investigate trends in smaller racial/ethnic groups or across multiple axes of identity. Collapsing smaller groups into an "other" category, which often includes cases or deaths missing information on race/ethnicity, does little to address the problem. When determining whether and how to release granular surveillance data, we must balance considerations of individual privacy with considerations of justice. Surveillance data play a central role in guiding the equitable allocation of resources, so the lack of sufficiently granular data inhibits efforts to achieve health equity for smaller groups and multiply marginalized individuals.

ACKNOWLEDGING SOCIAL AND HISTORICAL CONTEXT

The methodological choices we make when analyzing data can profoundly affect the conclusions we draw about the existence, direction, and magnitude of health inequities. Moreover, such choices are not purely objective and value-free; rather, they reflect one's view of the world and judgments about what sources of variation in health status are permissible. Analyses that seek to advance health equity must acknowledge and make explicit the assumptions and values that guide methodological decisions. For example, statistical adjustment for covariates such as age and geography when comparing disease risk across racial/ethnic groups reflects the belief that different distributions of age or geography are not important components of racial disparities in disease risk.[7] By contrast, an analytic approach that seeks to understand *how* racial health inequities are produced might stratify on age and place to assess the roles of age and geography—population characteristics that are themselves shaped by structural racism—in determining the distribution of disease across population groups. Because the analysis and interpretation of surveillance data have real consequences for the subsequent implementation of public health interventions, it is critical that analyses be grounded in an antiracist approach that acknowledges the role of social and historical forces in shaping the distribution of disease.

CONCLUSIONS

Existing inequities in the impact of COVID-19 are likely to be exacerbated by the roll-out of vaccines. Yet, inadequate reporting of race/ethnicity among those vaccinated continues to hamper efforts to measure and alleviate inequities. Of the nearly 13 million individuals who received a first dose of a COVID-19 vaccine between December 14, 2020 and January 14, 2021, data on race and ethnicity were available for only 52%. Among those with available data, 11.5% were classified as Hispanic/Latino and 5.4% non-Hispanic Black, despite these groups comprising 21% and 12% of all COVID-19 deaths, respectively.[8]

Continued gaps in the reporting of inequities in COVID-19 cases, deaths, and now vaccinations are a stark reminder of the structural changes needed in infectious disease surveillance. On the surface, decisions about what data to collect with regard to a nationally notifiable disease may seem purely biomedical in nature, but in practice such decisions reflect underlying power structures that determine

who gets counted and for what purpose. It has perhaps never been more urgent for public health researchers and practitioners to reckon with how our surveillance systems, although powerful tools to improve population health, may insidiously promote inequities in health and perpetuate the notion that not all lives count equally. AJPH

CORRESPONDENCE

Correspondence should be sent to Grace A. Noppert, 426 Thompson St, Ann Arbor, MI 48104 (e-mail: gnoppert@umich.edu). Reprints can be ordered at http://www.ajph.org by clicking the "Reprints" link.

PUBLICATION INFORMATION

Full Citation: Noppert GA, Zalla LC. Who counts and who gets counted? Health equity in infectious disease surveillance. *Am J Public Health*. 2021;111(6): 1004–1006.

Acceptance Date: February 18, 2021.

DOI: https://doi.org/10.2105/AJPH.2021.306249

CONTRIBUTORS

The authors jointly conceptualized the study and wrote the editorial.

ACKNOWLEDGMENTS

G. A. Noppert and L. C. Zalla received support for this work from the National Institute of Aging, National Institutes of Health (NIH; grant K99AG062749).

The authors are grateful to K. A. Duchowny, PhD, for her critical feedback and insights in developing this editorial.

Note. The content of this editorial is solely the responsibility of the authors and does not necessarily represent the official views of the NIH.

CONFLICTS OF INTEREST

The authors have no conflicts of interest to declare.

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Improving American Health, One State at a Time

Sandro Galea, MD, DrPH, and Roger Vaughan, DrPH, MS

ABOUT THE AUTHORS

Sandro Galea is with the School of Public Health, Boston University, Boston, MA. Roger Vaughan is an AJPH *associate editor and is with the Department of Biostatistics, The Rockefeller University, New York, NY.*

The United States, with a population of about 330 million people, is the third most populous country in the world. In the past year there has been substantial discussion about how the United States has fared during the COVID-19 pandemic, informed by the observation that the United States has had substantially more COVID-19 cases than any other country. This has brought to light—belatedly—the condition of US health before the pandemic that did much to shape the country's health during the pandemic. That the underlying health of the US population set us up for poor health during COVID-19 seems to us inarguable, reflecting our decades of systemic underinvestment in the forces that generate health.[1]

And yet, as the COVID-19 picture comes into focus, as we emerge slowly from the fog of the crucial moment, a more complicated picture emerges. There was substantial heterogeneity in how US states fared during the COVID-19 moment. There was, for example, a more than sixfold difference, at this writing, between the state with the highest number of cases per capita (North Dakota) and the one with the lowest (Hawaii). If we considered them as separate countries, the per capita COVID-19 cases in North Dakota would make the state one of the two countries in the world with the highest number of COVID-19 cases; by contrast, Hawaii's case rate positions it in the range of about 85th on the global list of countries with COVID-19.[2]

These differences will, and undoubtedly should, occasion substantial consideration of the factors, both preexisting and concurrent with the pandemic, that brought about these differences. Fundamentally, however, these interstate differences reflect simple observations about American health: the country is composed of tremendously heterogenous states and territories with substantially different health indicators.

HEALTH HETEROGENEITY

By way of example, in a review of trends in the US burden of disease across states between 1990 and 2016, Mokdad et al. found, consistent with previous analyses, substantial variability across states in a range of health indicators.[3] There was a 6.6-year difference in life expectancy at birth in 2016 between the state with the highest (Hawaii) versus the lowest (Mississippi) life expectancy. These differences were not static. Rates of change in health across states also varied, with, for example, reductions in probability of mortality over that period observed for some states and an increase in probability of mortality observed for others. This analysis is well reflected by an article in the April issue of *AJPH* by Farina et al.,[4] who examine differences across US states in life expectancy, disability-free life expectancy, and disabled life expectancy among adults. They found, again, dramatic differences across states. For example, among women, there was more than a six-year gap in disability-free life expectancy between the state that was healthiest (Hawaii) and the state that was least healthy (West Virginia). Consistent with analyses using other metrics, the authors note that the burden of poor health, and shorter lives, is particularly concentrated among Southern states.

These observations make clear that any reckoning with improving American health, particularly in a post–COVID-19 world, where we know that we are experiencing a downturn in a range of health indicators, including life expectancy,[5] must include a consideration of how and why interstate health is so different. Previous work has shown that this state-by-state variation can, if improved, contribute dramatically to national health. For example, focusing on five leading causes of death, the Centers for Disease Control and Prevention showed that improving all states to the levels of the healthiest states could annually prevent more than 90 000 cases of premature heart disease, 84 000 cases of cancer, 28 000 cases of chronic lower respiratory disease, 16 000 cases of stroke, and 36 000 cases of unintentional injury deaths.[6]

A concrete example of how interstate variability in the forces that generate health operate is offered in the article by Baugher et al. in the April issue of *AJPH*.[7] The authors focused on the HIV epidemic and on the factors that may be associated with reduced uptake of preexposure prophylaxis, which can protect against HIV. They compared health care coverage and utilization between men who have sex with men in Medicaid expansion compared with nonexpansion states. This analysis showed elegantly that men who have sex with men in expansion states were more likely to have insurance, discuss preexposure prophylaxis with a provider, and use preexposure prophylaxis . This of course illustrates well why states may differ in HIV prevalence and how this difference may be driven by state-level policy decisions, in this case about Medicaid expansion states.

LEVERS OF CHANGE

The interstate heterogeneity in health, and the forces that may be driving health, suggests to us that any national understanding of the country's health must inevitably deal with the factors at the state level that intersect with decisions that improve or harm health. In the COVID-19 era, we saw this play out visibly, for example, in arguments about state-level use of masks to protect against infectious disease transmission. And yet, although those discussions have been visible and deeply felt, they are simply the tip of the iceberg of more foundational interstate differences in policy and culture that ultimately manifest as different health indicators for each state.

It is, therefore, the task of population health scholarship to better understand, and of public health practice to implement, approaches that may improve health at the state level. Why would some states, for example, not become Medicaid expansion states, given evidence about the benefits that accrue to states that are Medicaid expansion states? What would it take to change the culture around healthy nutrition in some states? The COVID-19 moment has illustrated how far we still have to go to move toward improving health across all the US states. And although there is little question that national action foundationally shapes the ground on which states build their policy architecture, there is clearly much that needs to be done at the state level, absent which we will continue deepening interstate health divides. That recognition should compel us to do the analysis and the work needed to guide scholarship and the practice to improve American health one state at a time. AJPH

CORRESPONDENCE

Correspondence should be sent to Roger Vaughan, The Rockefeller University, 1230 York Ave, New York, NY 10065 (e-mail: roger.vaughan@rockefeller.edu). Reprints can be ordered at http://www.ajph.org by clicking the "Reprints" link.

PUBLICATION INFORMATION

Full Citation: Galea S, Vaughan R. Improving American health, one state at a time. *Am J Public Health*. 2021;111(6):1007–1008.

Acceptance Date: March 10, 2021.

DOI: https://doi.org/10.2105/AJPH.2021.306279

CONTRIBUTORS

The authors contributed equally to this editorial.

CONFLICTS OF INTEREST

The authors have no conflicts of interest to declare.

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The Importance of Federal Waivers and Technology in Ensuring Access to WIC During COVID-19

Shannon E. Whaley, PhD, and Christopher E. Anderson, PhD, MSPH

ABOUT THE AUTHORS

Shannon E. Whaley and Christopher E. Anderson are with Public Health Foundation Enterprises WIC, Irwindale, CA.

The Special Supplemental Nutrition Program for Women, Infants and Children (WIC) is a nutrition assistance program that promotes the health of pregnant and postpartum women, infants, and children up to aged five years who are nutritionally at risk and live in households below 185% of the federal poverty level (FPL).[1] Unlike other federal nutrition assistance programs, WIC reduces structural barriers to healthy eating by providing monthly food benefits while simultaneously promoting good nutrition through regular individualized nutrition counseling and nutrition education. The effectiveness of WIC has been demonstrated by extensive research illustrating improved health outcomes for the women, infants, and children served by the program.[2–5] As the third largest US Department of Agriculture (USDA) nutrition assistance program, WIC served about 6.9 million participants per month in fiscal year 2018, including almost half of all infants born in the United States.[1]

WIC caseloads have been declining in recent years,[6] with recent studies documenting factors such as longer duration of breastfeeding, higher financial need, and relevance of nutrition education associated with program retention.[7,8] The COVID-19 pandemic, however, has substantially increased food insecurity and the need for food assistance across the United States.[9] As the pandemic continues, it has become clear that both federal program waivers enacted by the USDA to allow flexibilities in WIC and technology supporting remote contact with low-income families are essential for continuing to meet the elevated demand for the program while also protecting the health of WIC participants and personnel.

We describe a local WIC agency's response to the pandemic, document the increases in WIC participation observed since March 2020, and describe elements of this response that have been successful in maintaining and expanding access to WIC for low-income families with young children in Los Angeles (LA) County, California.

LA COUNTY AND THE BURDEN OF COVID-19

The PHFE WIC program, a program of Heluna Health, is the largest local agency WIC program in the United States and serves about 20% of California's WIC population. Typically, WIC participants come to their local WIC clinics every one to three months to obtain their WIC benefits and receive nutrition education and counseling. Located primarily in LA County, PHFE WIC closed its doors to the public on March 16, 2020 and began serving all WIC participants remotely to safeguard the health and safety of staff and participants. Ordinances for residents to stay at home were issued on March 19, 2020, for both the City of LA and the State of California.

Before COVID-19, 29.2% of low-income households (< 300% FPL) experienced food insecurity at some point in the past year.[10] Between April and May 2020, in LA County, 39.5% of low-income households experienced food insecurity; nearly half (47%) of households below 100% of the FPL experienced food insecurity. Notable racial and ethnic disparities were evident in household food insecurity: among low-income households in April and May 2020, 38% of Latino and 36% of Black compared with 22% of Asian and 16% of White households experienced food insecurity.[11] The differential burden of food insecurity by racial/ethnic group mirrors the rates of illness from COVID-19 experienced throughout the United States, with COVID-19 disproportionately affecting low-income communities and communities of color.[12]

FEDERAL WAIVERS AND TECHNOLOGY

Federal waivers issued by the USDA have made remote WIC services possible.[13] Physical presence waivers removed requirements for in-person clinic visits at enrollment or recertification and provided the flexibility to postpone bloodwork and weight and height or length measurement requirements typically required during eligibility determination. Remote issuance waivers suspended requirements for in-person pickup of electronic benefit transfer cards (called the "WIC card" in California); new cards were instead mailed to participants and supplemental food package benefits were allowed to be loaded remotely to rapidly meet the needs of families. Extended benefit issuance waivers allowed state agencies to issue up to four months of benefits at once to reduce the frequency of contact needed for benefit issuance.

Although some remote services were available at PHFE WIC before the pandemic, including a sophisticated interactive texting portal and online nutrition education options, the immediate transition of all WIC services to text, telephone, e-mail, and online was unprecedented. PHFE WIC's sophisticated interactive texting system, which resides behind a safe firewall and has the ability to mass text as well as personalize individual responses, has been critical to continue providing the WIC services and foods that families desperately need. Access to online education has also been essential to maintaining this core component of WIC services.

STATISTICAL METHODS

Data for this evaluation originated in the California WIC Management Information System. WIC participation reflects the number of participants receiving benefits. Total eligibility certification events reflect the number of WIC participants who had either initial eligibility certification or annual eligibility recertification.

We used negative binomial regression models for daily eligibility certification events (initial and recertification) to calculate incidence rate ratios comparing the rate of daily certification events following the transition to remote WIC services to before transition. Models included parameters for the date of the event (on or after March 16 or before March 16), type of event (initial or recertification), race/ethnicity and language preference, poverty (< 100% or ≥ 100% FPL), and participant category (woman, infant, or child).

COVID-19 IMPACT ON PARTICIPATION

PHFE WIC participation increased 24% between February and June, concurrent with increases of 21% and 14% for WIC participation in LA County overall and in California, respectively. Total PHFE WIC participation and 60-day running averages of total certification and recertification events (Figure 1a) increased after transitioning to remote-only service on March 16, concurrent with the issuance of the stay-at-home orders for the county and the state. Daily recertification events increased by nearly 150 events from early March through early May (Figure 1a), remaining above pre-pandemic levels at the end of June. Increases in daily recertification events occurred among children of all ages from 1 to 4 years (Figure 1b).

The rates of daily initial certification and recertification increased by 27% and 24%, respectively, after transitioning to remote-only service. We observed significant increases in both initial certifications and recertifications of ongoing WIC participants in nearly all categories of WIC participants (women, infants, and children) and race/ethnicity and income subgroups from before to after the transition to remote services (Table A, available as a supplement to the online version of this article at http://www.ajph.org). Recertification rates increased significantly for English-speaking Asian, non–English-speaking Asian, Black, White, English-speaking Hispanic, and other race children, but not among Spanish-speaking Hispanic children. Increases in recertification were similar for children in households with incomes above or below the FPL.

CONCLUSIONS

It is evident from data in LA County that families with young children are enrolling in and remaining on WIC at unprecedented levels since the start of the COVID-19 pandemic. Children previously on the program are recertifying in unexpectedly large numbers, suggesting that families with young children who may have otherwise left WIC need continued nutrition assistance during the pandemic. Given the dual burdens of food insecurity and COVID-19 illness on low-income communities and communities of color, it is imperative that WIC remain accessible.

Continued extensions of the federal waivers are essential until WIC families and staff can safely return to in-person visits at WIC clinics. While the COVID-19 pandemic persists, and demand for nutrition assistance among low-income families with children remains elevated, USDA-issued waivers afford state and local WIC agencies the flexibility to modify service delivery to meet community needs while reducing infection risks to millions of WIC participants and

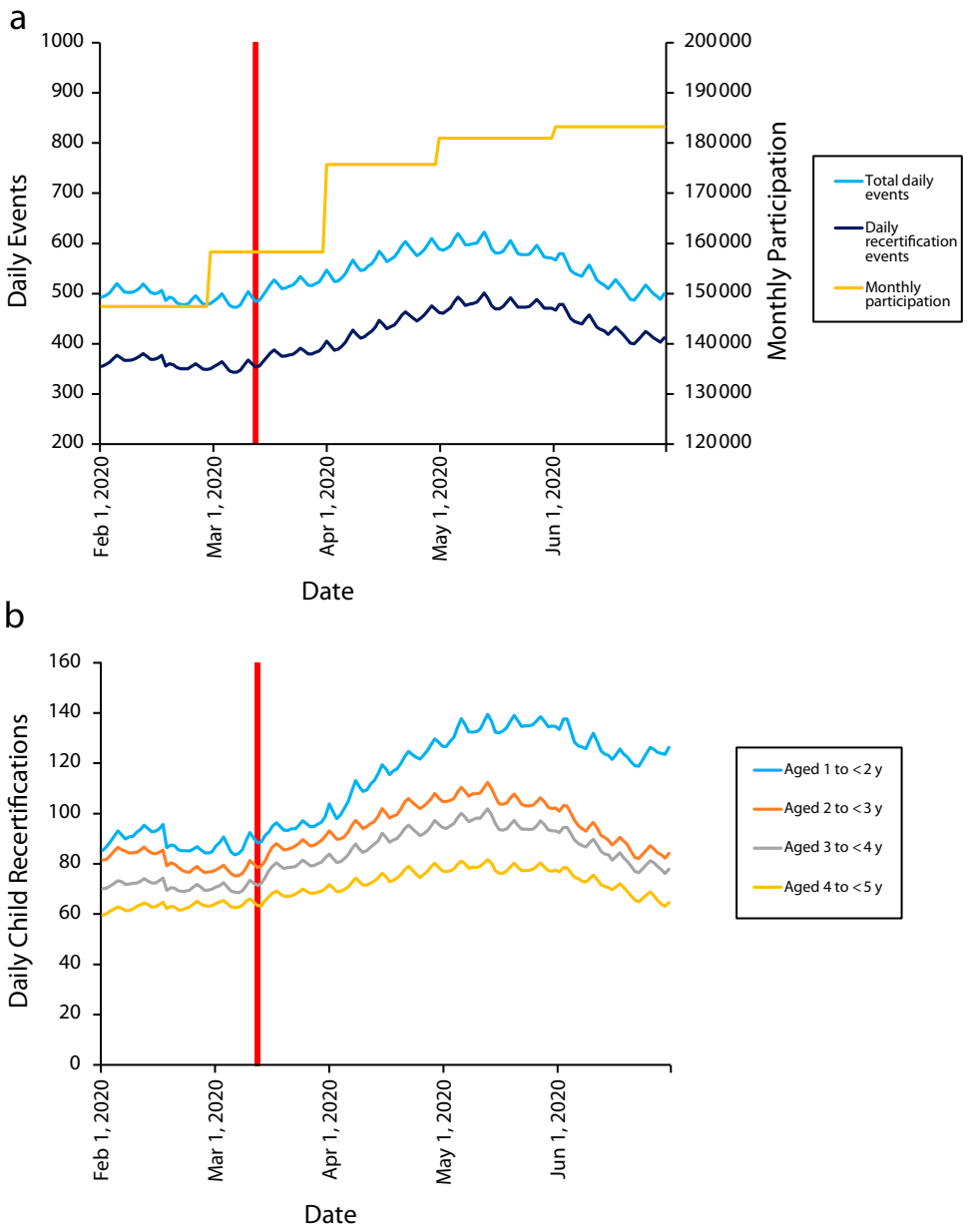

FIGURE 1— PHFE-WIC Participation Data Showing (a) Total Monthly Participation, 60-Day Running Average Daily Recertification, and Total Daily Certification Events, and (b) 60-Day Running Average Daily Child Recertification Events by Age: Southern California, February 1, 2020–June 30, 2020

Note. PHFE = Public Health Foundation Enterprises; WIC = Special Supplemental Nutrition Program for Women, Infants, and Children. Monthly participation indicates the number of WIC participants who received benefits from WIC in a given month. Total daily events is the number (initial eligibility certification or recertification) recorded on a specific date. The vertical red line on the plot corresponds to the last day of in-person WIC service delivery on March 13.

thousands of WIC staff, a majority of whom live in the communities they serve. Future waiver extensions must be considered based on the evolving COVID-19 crisis and the scientific evidence of COVID-19 impacts, particularly on children and families at high risk of disease. Uncertainty about waiver extensions heightens anxiety about whether families will be able to safely access program benefits and keep food on the table.

Renewed USDA investment in technology supporting state and local WIC programs to remotely serve participants while maintaining high-quality services is also a high priority. Technology has been essential for meeting the needs of WIC

families. High-quality WIC services can be maintained remotely with interactive texting platforms that protect the confidentiality of WIC participants, high-quality online education resources, management information systems that enable remote issuance of WIC benefits, and mobile applications that enable participants to check their food balances and interact with WIC program staff. Together, federal waivers and enhanced technology ensure WIC's ability to provide essential WIC services to thousands of families in need of nutrition support.

Finally, although there remains concern about what is "lost" during the pandemic—such as the face-to-face nutrition counseling and breastfeeding support—the substantial increases in participation illustrate how WIC is positioned to reach families in response to changes in the need for nutrition support. This study demonstrates the association of pandemic-related policy waivers with participation but cannot support causal inferences nor speak to the broader participant experience of redeeming benefits with vendors. More research, across multiple states, is needed to address these broader impacts. The reason recertification rates for Spanish-speaking Hispanic children did not increase also merits further investigation.

The pandemic has focused a light on inequities, with families who qualify for WIC representing the groups most disproportionately affected by COVID-19. WIC continues to find innovative ways to provide high-quality nutrition and breastfeeding services to families while reducing food insecurity through the issuance of WIC foods and services. With appropriate USDA-issued waivers, paired with ongoing investments in technology solutions, WIC can continue to rapidly and safely respond to unprecedented increases in need. AJPH

CORRESPONDENCE

Correspondence should be sent to Shannon E. Whaley, Division of Research and Evaluation, PHFE WIC Program, a program of Heluna Health, 12781 Schabarum Ave., Irwindale, CA 91706 (e-mail: Shannon@phfewic.org). Reprints can be ordered at http://www.ajph.org by clicking the "Reprints" link.

PUBLICATION INFORMATION

Full Citation: Whaley SE, Anderson CE. The importance of federal waivers and technology in ensuring access to WIC during COVID-19. *Am J Public Health*. 2021;111(6):1009–1012.

Acceptance Date: January 21, 2021.

DOI: https://doi.org/10.2105/AJPH.2021.306211

CONTRIBUTORS

S. E. Whaley conceptualized the research question. C. E. Anderson conducted the analysis. Both authors designed the study, interpreted the results, and wrote the editorial.

ACKNOWLEDGMENTS

Funding from a research partnership with First 5 LA (contract 07030) supported the analysis time of C. E. Anderson.

The authors would like to thank Lorrene Ritchie, PhD, RD, Cindy Clapp, MA, RDN, IBCLC, Georgia Machell, PhD, Brian Dittmeier, Esq, Denise C. Gee, MPH, RDN, and Kiran Saluja, MPH, RDN, for their careful review and comments on preliminary versions of this editorial.

CONFLICTS OF INTEREST

The authors have no conflicts of interest to declare.

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Expanding Mail-Based Distribution of Drug-Related Harm Reduction Supplies Amid COVID-19 and Beyond

Brian S. Barnett, MD, Sarah E. Wakeman, MD, Corey S. Davis, JD, MSPH, Jamie Favaro, MSW, and Josiah D. Rich, MD, MPH

ABOUT THE AUTHORS

Brian S. Barnett is with the Department of Psychiatry and Psychology, Center for Behavioral Health, Neurological Institute, Cleveland Clinic, Cleveland, OH. Sarah E. Wakeman is with the Division of General Internal Medicine, Massachusetts General Hospital, and the Department of Medicine, Harvard Medical School, Boston. Corey S. Davis is with The Network for Public Health Law, Los Angeles, CA. Jamie Favaro is with NEXT Distro, New York, NY. Josiah D. Rich is with the Departments of Medicine and Epidemiology, Brown University, and the Center for Health and Justice Transformation, The Miriam Hospital, Providence, RI.

One of the most disheartening aspects of the decades-long increase in drug-related harm in the United States is our failure to fully implement the wide array of effective interventions available for reducing that harm. These strategies include broad access to opioid agonist therapy,[1] sterile injection supplies,[2] and naloxone,[3] as well as the establishment of supervised consumption sites.[4] Despite their efficacy, scaling up these interventions has proven a persistent challenge as a result of poorly targeted funding, legal barriers, stigma, and inadequate coordination among stakeholders.

Consequently, thousands in the United States die from drug-related overdoses and contract infectious bloodborne diseases each year, despite the preventable nature of much of this morbidity and mortality; in 2019, 70 630 people died of drug overdoses.[5] As of 2010, more than 140 000 people had contracted HIV through injection drug use, and in 2011, 43 126 of every 100 000 people between 40 and 65 years of age who injected drugs were infected with hepatitis C virus.[6] A lack of access to sterile syringes helped drive the annual incidence of acute hepatitis C virus infection from 0.3 to 0.7 cases per 100 000 people between 2004 and 2014[7] and has also contributed to outbreaks of hepatitis A virus and HIV in multiple states in recent years.

Substance use disorder treatment, as with other areas of medicine, has swiftly adapted to meet the challenges brought on by COVID-19. For example, in response to decreased access to opioid agonist therapy providers and locations caused by the pandemic, the US Substance Abuse and Mental Health Services Administration and the US Drug Enforcement Administration acted quickly to relax certain regulations limiting access to opioid agonist therapy by allowing buprenorphine initiation via telephone and removing some of the limits on "take home" doses of methadone. This rapid adaptation is an example of pivoting service delivery to better meet the needs of patients in the context of a crisis.[8]

Although these efforts to minimize the pandemic's impact on vulnerable individuals with substance use disorders are both necessary and warranted, they are insufficient to counter its acceleration of our overdose crisis.[9] To augment measures taken by the federal government, state governments, and others to address this worsening crisis, we suggest increasing access to harm reduction supplies, such as naloxone and sterile injection supplies, via an additional avenue already capitalized on by our nation to overcome pandemic-related distribution barriers: using the United States Postal Service (USPS) and private courier services to supply these vital items directly to people who use drugs. The volume of mail and parcels processed by the USPS grew by 50% between April to June 2019 and April to June 2020,[10] illustrating the rapid rise in mail and package deliveries during the pandemic. Should providers of harm reduction supplies embrace this distribution approach, there is significant potential to save lives and reduce health care costs associated with substance use.

NEXT DISTRO MODEL OF DISTRIBUTING SUPPLIES BY MAIL

Despite the increasingly critical need for harm reduction supplies since COVID-19's

arrival, access to them has declined, with an April 2020 national survey of 173 syringe service programs (SSPs) revealing that 43% had reduced services because of the pandemic.[11] As a result, some states have removed barriers to mailing these supplies. For example, Maine's governor issued an executive order authorizing SSPs to mail injection supplies to their clients,[12] and Pennsylvania modified its naloxone standing order to permit community organizations to mail naloxone.[13]

Mailing harm reduction supplies to people who use drugs is not new, but the pandemic has provided an opportunity to learn from and build upon preexisting efforts. Since 2017, NEXT (Needle Exchange Technology) Distro, a nonprofit organization based in New York City, has been at the forefront of scaling up mail-based distribution of free naloxone, sterile injection supplies, and educational materials on safer drug use practices nationally. To reduce improperly discarded syringes, the organization also distributes needle clipping devices and sharps containers. Clients order supplies via NEXT Distro's Web site (https://www.nextdistro.org) and learn about its services via Internet searches and word of mouth. As of this writing, NEXT Distro has distributed harm reduction supplies to people in at least 45% of US counties.

NEXT Distro's approach includes not only disseminating harm reduction supplies directly to those in need but also developing a hub and spoke model to grow harm reduction efforts across the country. The organization currently has partnerships in 32 states, primarily with SSPs, to facilitate naloxone distribution and also has partnerships in five states for distribution of sterile injection supplies. Expansion of the latter network has been more difficult because of legal and financial barriers, as well as challenges encountered as SSPs attempt to incorporate a new model of sterile injection supply distribution into their already busy operations.

NEXT Distro also provides infrastructure for health departments and harm reduction programs to begin or scale up their own mail-based efforts. Although its work has primarily been supported by private funding thus far, some health departments, including the Delaware Department of Health and the New York City Department of Health and Mental Hygiene, have partnered with NEXT Distro and are providing support. Other health departments, insurers, and organizations working to prevent overdose deaths and drug-related infectious disease spread should consider working with this organization or replicating its approach.

LIMITATIONS OF RECENT STRATEGIES TO EXPAND ACCESS TO SUPPLIES

Although sterile injection supplies can be purchased online without a prescription through Web sites such as Amazon.com, and naloxone can be purchased in most states through www.naloxoneexchange.com, mail-based distribution of free supplies via SSPs, health departments, and other harm reduction organizations could greatly enhance access given the financial hardships faced by many people who use drugs. States have made helpful efforts to expand access to such supplies, but these dissemination strategies face ongoing barriers, leaving ample opportunity for disruptive innovation via mail-based distribution.

Naloxone access has increased in the United States in recent years as a result of growing recognition of the vital need to have this medication on hand at the scene of an opioid overdose, as well as implementation of legal innovations designed to remove some of the barriers to obtaining it. However, fear of being stigmatized often prevents patients from asking for naloxone prescriptions or obtaining naloxone at a pharmacy or SSP, and although numerous states permit naloxone standing orders, many pharmacies have been slow to embrace this change.[14] A further complication is that even in states permitting standing orders, pharmacists retain discretion over who to dispense naloxone to, allowing the personal beliefs and poor regulatory knowledge of some pharmacists to prevent the benefits of this approach from being fully realized.[15]

Sterile injection supplies, along with naloxone, have long been available via SSPs. However, stigma, legal barriers, financial underinvestment, and community opposition continue to hinder the creation of these organizations and limit their operation. In addition, their harm reduction impact is constrained by distance, as shown by a recent study revealing that the further people who inject drugs live from an SSP, the higher their risk for sharing injection equipment.[16]

Because of these realities, most states have expanded nonprescription sales of sterile injection supplies at pharmacies. The vast majority of pharmacists in one survey strongly agreed that people who inject drugs should always be allowed to purchase nonprescription sterile injection supplies; however, they also reported that restrictive store policies, time limitations, and other structural barriers limited their ability to fully implement this strategy and other harm reduction interventions when interacting with these customers.[17]

Gatekeeping[18] by some pharmacists opposed to sale of nonprescription supplies has also limited the efficacy of this approach, resulting in people who inject drugs regularly being refused sale of nonprescription sterile injection supplies, particularly those who are minoritized populations.[19,20] Quantity limits, age restrictions, and anti-paraphernalia laws also continue to impede nonprescription sales.

ADVANTAGES OF MAIL-BASED DISTRIBUTION OF SUPPLIES

Mail-based distribution of harm reduction supplies circumvents many of these obstacles. For example, fear of being stigmatized is far less of a deterrent for people who use drugs when they can order supplies online for direct delivery instead of having to visit pharmacies or SSPs to obtain them. Although NEXT Distro has primarily partnered with SSPs to distribute harm reduction supplies, allowing clients to order supplies through its own Web site and receive them in discreetly labeled packaging helps attract potential clients who would prefer not to be directly associated with an SSP and those unable to access SSPs owing to physical disability, lack of transportation, or employment during hours of operation.

Mail-based distribution is also immune to the community opposition that often arises when opening an SSP is proposed. Furthermore, it allows supplies to reach remote areas and ones with policies limiting locally based harm reduction efforts, which is particularly helpful in counties (many in predominantly rural areas such as Appalachia) declared by the Centers for Disease Control and Prevention to be vulnerable to rapid dissemination of HIV and hepatitis C virus among people who inject drugs.[21]

BARRIERS TO MAIL-BASED DISTRIBUTION AND POTENTIAL SOLUTIONS

Although several barriers stand in the way of seizing the full potential of mail-based distribution, they are not insurmountable. Unsurprisingly, one of the biggest obstacles is securing financial support. NEXT Distro has found success in partnering with SSPs for distribution, but SSP funding is often limited and tenuous. With significant state budget shortfalls expected from the pandemic, the financial security of many SSPs is at risk, despite our worsening overdose epidemic and the sizeable return on investment provided by SSPs.[22] This reality poses what may be the most serious obstacle for expansion of mail-based distribution of harm reduction supplies in the near term, because the capital necessary for processing supply orders and shipping supplies to clients makes this approach more expensive than in-person distribution.

Because of the funding challenges for SSPs and the relatively small number of programs in the United States, further collaboration between organizations such as NEXT Distro and health departments and the resulting financial support would likely be greatly beneficial with respect to expanding the reach of this strategy. Health departments could also serve as a valuable conduit for mail-based distribution services to increase their client base by displaying and providing written information about them in their clinics. To catalyze these relationships, it is important for states, cities, and counties to gain a better understanding of the need for mail-based distribution of harm reduction supplies. We are unaware of research addressing this important line of inquiry at this time.

However, on the basis of NEXT Distro's experience of rapid client base increases soon after new geographic communities of people who use drugs become aware of its services, coupled with the fact that only 6% of 173 SSPs surveyed in April 2020 reported mailing supplies,[11] potential demand likely far exceeds current capacity. Given the absence of relevant peer-reviewed data, research on need for mail-based services and potential health care savings resulting from this approach could prove vital in demonstrating its merits to governments and other potential funders. Considering the potential of mail-based distribution to significantly increase the life-saving and cost-saving effects of harm reduction efforts, we strongly recommend that both private and public donors increase funding of innovative initiatives employing it.

Retail pharmacies could provide an additional avenue for partially addressing funding limitations. With pharmacists already regularly mailing prescriptions to customers, they could also mail naloxone and sterile syringe supplies to insured customers who use drugs. Although not all insurance covers naloxone or syringes or covers them without a copay, such coverage is something that could be negotiated, advocated for, or mandated by regulation. Given the potential to bill insurers for these supplies, this approach would generate an automatic funding stream and be self-sustaining. If such a strategy were effective, additional external funding could expand it to uninsured patients.

Legal barriers in many jurisdictions also pose challenges to mail-based distribution that must be addressed. Most states continue to criminalize the

possession and distribution of syringes for use in injecting illegal drugs, with limited carve outs for SSPs. Still, these SSP laws sometimes impose requirements that may implicitly forbid mailing syringes to be used for injecting illegal drugs, such as mandating that a person return syringes to receive new ones or that SSPs provide verbal information or referrals to other services to clients. In addition, under current federal law, combining syringes with information on how to use them more safely when injecting illegal drugs might make it easier for federal prosecutors to argue that federal paraphernalia law has been violated by those who mailed them, although this law does not apply to anyone authorized to distribute syringes under federal, state, or local law. To address these regressive barriers, legislatures should repeal paraphernalia laws entirely,[23] exempt injection equipment from their reach, or explicitly permit harm reduction programs to mail supplies to clients.

Confusion about existing laws also presents a hurdle to expansion of mail-based distribution. In many states, laws already allow anyone permitted to dispense or distribute naloxone to ship it, although this may not be common knowledge. At the federal level, noncontrolled prescription medication can be mailed by individuals dispensing the medication to someone under their care, which would likely apply to anyone already authorized under state law to distribute naloxone.

Another challenge for mail-based distribution resides in reaching people who are unhoused. However, the USPS already offers a potential solution. General delivery is a USPS service that allows people without a permanent address to receive mail at a designated post office in their community. It is regularly employed by unhoused clients of NEXT Distro, and the organization's Web site also provides instructions on how to use this service to encourage more unhoused people to become clients.

Recently, prolonged delays have plagued USPS mail delivery in many parts of the country, presenting a previously unencountered obstacle for mail-based distribution of harm reduction supplies. This is unfortunate in that the USPS previously provided the best conduit for shipping these supplies because privacy laws governing its parcel handling are stricter than those applying to private couriers, its prices for low-weight parcels are less than those of its competitors, and its distribution network is unrivaled in size.[24,25] However, with the recent change in presidential administrations and the approval of effective COVID-19 vaccines by the Food and Drug Administration, the reliability of USPS services could soon be restored via potential government action to help bolster the struggling agency and a possible reduction in online shopping parcel volume as vaccinated individuals return to stores.

CONCLUSIONS

With direct deliveries of everything from groceries to ballots being made to millions of Americans daily throughout the pandemic, the renewed prominence of mail and parcel delivery in keeping our society in motion is hard to miss. Amid the reinvigorated epidemic of drug-related harm brought on by COVID-19, we should also be harnessing the public health potential of postal and courier services by using them to distribute harm reduction supplies more widely. In doing so, we can save lives, prevent infectious disease spread, reduce health care costs, and establish a new distribution method for these items that could benefit our country long after the pandemic's conclusion. To put harm reduction supplies in the hands of those who need them, we have sought solutions in many places, but COVID-19 has unexpectedly revealed that an effective one may have been waiting all along in a location many of us in the public health community have not yet checked: our mailboxes. AJPH

CORRESPONDENCE

Correspondence should be sent to Brian S. Barnett, MD, Department of Psychiatry, Lutheran Hospital, 1730 W 25th St, Floor 5E, Cleveland, OH 44113 (e-mail: barnetb3@ccf.org). Reprints can be ordered at http://www.ajph.org by clicking the "Reprints" link.

PUBLICATION INFORMATION

Full Citation: Barnett BS, Wakeman SE, Davis CS, Favaro J, Rich JD. Expanding mail-based distribution of drug-related harm reduction supplies amid COVID-19 and beyond. *Am J Public Health*. 2021; 111(6):1013–1017.

Acceptance Date: February 6, 2021.

DOI: https://doi.org/10.2105/AJPH.2021.306228

CONTRIBUTORS

B. S. Barnett originated the editorial and wrote the first draft. S. E. Wakeman, C. S. Davis, J. Favaro, and J. D. Rich assisted in the development of the concept and helped revise the editorial.

CONFLICTS OF INTEREST

Jamie Favaro is the founder of NEXT Distro.

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To Latinx or Not to Latinx: A Question of Gender Inclusivity Versus Gender Neutrality

Ana María del Río-González, PhD

ABOUT THE AUTHOR

The author is with the Department of Psychological and Brain Sciences, George Washington University, Washington, DC.

I first saw the word "Latinx" at an academic conference a few years ago. As a native Spanish speaker, my first reaction was to squint to confirm I was not making up an "x" where I expected an "o," "a," "o/a," or even "@," as I had seen before. It was not until the speaker clearly pronounced the final "x" (as in \luh-tee-neks\) that I realized what I had read was not a typo, but a new label used to describe people of Latin American origin or descent. Latinx began appearing in social media and on the Internet as a designation that visibilizes gender-expansive people (i.e., those who do not subscribe to the feminine–masculine gender binary or who choose not to be defined by their gender), who are traditionally made invisible by the gendered structure of Spanish grammar.

Despite heated discussions about its pros and cons,[1–5] the use of Latinx in academia has grown dramatically. For instance, a PubMed search of the word Latinx yielded 755 articles, of which 71% were published in 2020 (Figure 1). Clearly, now is the time to answer the following question: Should we be using Latinx at all, and, if so, how? Here I tackle this question by reviewing the meaning of the term Latinx within the context of gender neutrality versus gender inclusivity. In addition, I examine the ways in which Latinx has been used in articles published in *AJPH*. I conclude by providing five recommendations about when and how to use Latinx so that it can live up to its inclusive promise.

GENDER NEUTRALITY DOES NOT EQUAL GENDER INCLUSIVITY

My own reactions to Latinx are a good representation of the conflicting views regarding the term. As a Latina—an identity assigned to me in the United States by virtue of my Colombian origin—I bristle at what feels like an imperialist imposition of the English language's gender neutrality as the grammatical gold standard. As a critical social psychologist interested in the health of transgender and gender-expansive people, I recognize the term's potential for gender inclusivity. To reconcile these conflicting views, I propose a differentiation between gender neutrality and gender inclusivity. Gender neutrality reflects a gender-blind ideology in which gender categories are rendered irrelevant when explaining inequity.[6] Gender inclusivity, on the contrary, acknowledges gender as a source of disadvantage and, most important, explicitly challenges binary notions of gender and recognizes the plurality of identities beyond feminine–masculine dimensions (e.g., gender queer, gender nonbinary, gender fluid, agender). I argue that Latinx should be used as a gender-inclusive label, not as a gender-neutral one.

In many languages—including both English and Spanish—the masculine form is frequently used as a generic form to refer to groups of mixed gender or in cases in which gender is unknown, nonspecific, or deemed irrelevant. A group of 100 people of Latin American origin or descent, for example, will be called "Latinos," even if only one is a man. This gender-neutral use of the masculine form has been strongly criticized as gender biased because it centers men as normative. Several alternatives have been offered to avoid gender-biased language,[7] such as using both the masculine and the feminine words (e.g., he or she, Latina and Latino participants) or using contracted forms that include both (e.g., s/he, Latino/a, Latin@). Although these alternatives are inclusive of men and women, they reify the gender binary and thus fail to acknowledge diversity from a critical gender-inclusive perspective. In this context, Latinx appears as a sociopolitical stance toward increasing the visibility of gender-expansive people of Latin American origin or descent.

Despite this original intent, Latinx has also come to be used as a catch-all generic form to refer to people of Latin American origin or descent, regardless

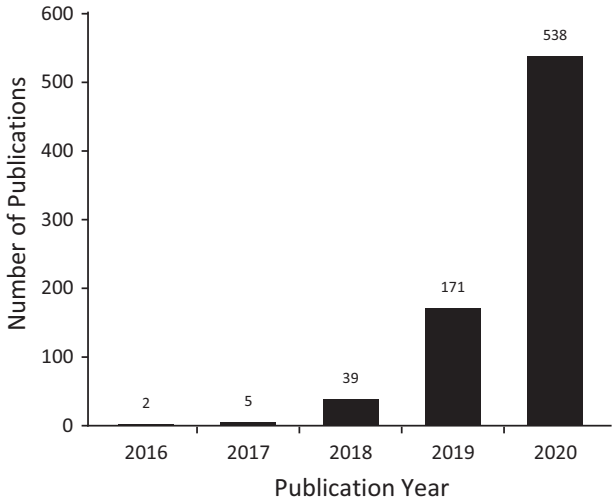

FIGURE 1— Number of Articles per Year in PubMed Including the Word Latinx Through December 31, 2020

of their gender identity. This gender-neutral use of Latinx, however, has some limitations.

For example, few of the people this term describes actually use it or have even heard about it. According to a recent online survey of 3030 Latino and Latina adults in the United States, 23% have heard of Latinx and only 3% actually use it.[8] Moreover, there were important differences in awareness and use of the term across demographic groups in that sample. For instance, 42% of young people 18 to 29 years of age had heard about it, as compared with less than 20% of adults 30 years or older. Similarly, participants with at least some college education (31%) were more likely to have heard about the term than those with a high school education or less (14%). Finally, awareness was twice as high among US-born participants (32%) as among immigrants (16%) and four times higher among English-dominant and bilingual participants (29%) than among monolingual Spanish speakers (7%).[8] Thus, Latinx as a gender-neutral pan-ethnic term fails to represent many people of Latin American origin or descent, particularly those at the intersection of other—mostly marginalized—positions (e.g., immigrants, people with lower educational attainment).

Another limitation of using Latinx as a gender-neutral label is that people who are unaware of the term's meaning are likely to interpret it as just another form of shorthand for Latina and Latino. Thus, this gender-neutral use might continue to marginalize gender-expansive people, albeit in a more "woke" way. To avoid this unintended marginalization, it is important to pair the use of Latinx with an explicit mention of gender diversity that challenges the gender binary.

The use of "they" as a singular pronoun in English may be a good example of this point. This term, used for centuries as a gender-neutral alternative to the masculine generic form,[9] has been gaining increased recognition as a gender-inclusive nonbinary pronoun. Reflecting this recognition, this meaning of singular they was selected "Word of the Year" by the American Dialect Society in 2015[10] and by the Merriam-Webster dictionary in 2019,[11] and its use has been recommended by recent editions of the American Psychological Association's publication manual[12] and the *Chicago Manual of Style*.[13] Rather than simply referring to the original gender-neutral use of the singular they, all of these sources now include definitions that explicitly decenter the gender binary and increase the visibility of gender diversity.

Finally, as some advocates argue, "to demand that everyone identify as Latinx…is counter to the proposal of the term itself"[1(p11)] because it completely erases gender from a gendered language, thereby exacerbating the invisibility of gender diversity. This erasure is the main reason why I identify as Latina and not as Latinx. As a cisgender woman, if I were to identify as Latinx, I feel I would be negating my cisgender privilege rather than using that privilege to challenge the gender binary and uplift gender diversity.

USE OF LATINX IN *AJPH*

To examine how Latinx has been used within the context of public health research, I searched and reviewed all *AJPH* articles published through December 31, 2020, that included the term "Latinx." This search yielded 36 articles, of which two were published in 2019 and the others in 2020 (including those published ahead of print). Eight were research articles, whereas 28 were conceptual or theoretical (e.g., commentaries, editorials).

None of the articles included a definition of Latinx or a specification of whether the term was used to include gender-expansive people. In most of the articles, Latinx was used without explicit mention of gender (n = 27); only three articles mentioned gender diversity, although not in conjunction with the use

of Latinx. Latinx was not used in conjunction with Latina and Latino (e.g., Latina/x/o) in any of the articles. Hispanic/Latino and Latino/a in addition to Latinx were used in nine articles, sometimes interchangeably. In five articles Latinx was paired with an English gendered noun (e.g., Latinx men), three articles focused on single-gender groups (e.g., cisgender women), and in nine articles Latinx was used to describe genderless nouns (e.g., Latinx neighborhoods).

These findings indicate that Latinx was used most frequently as a gender-neutral label, ostensibly meant to be interpreted as gender inclusive. Who was encompassed in this inclusivity, however, was never made explicit, and thus the opportunity to increase visibility and highlight inclusion with respect to gender diversity was squandered.

RECOMMENDATIONS FOR USING LATINX

"Latinx" can be a powerful tool that decenters and challenges the gender binary and provides visibility for gender-expansive people. As public health researchers, however, we are not off to a good start. Expanding the work of other scholars,[1–3,5] I propose the following general recommendations regarding when and how to use the term. Although I limited my search of the term Latinx to articles published in *AJPH*, my recommendations are not limited to *AJPH* but rather include all public health journals, as well as journals in the social and behavioral sciences. It is also important to note that these recommendations do not constitute an endorsement by *AJPH*.

1. Provide a definition of Latinx (e.g., as a label to describe gender-expansive people of Latin American origin or descent) or specify its use as a gender-inclusive term that seeks to increase the visibility of gender-expansive people. Using Latinx without explicitly challenging the dominant binary discourse undermines the inclusiveness and liberatory power the term was meant to have in the first place.
2. Use Latinx only when intentionally acknowledging gender diversity. When gender identity is not known, or when referring to groups of mixed gender, use "Latina, Latinx, and Latino" or "Latina/x/o" to ensure that the visibility of gender diversity is not elided. When gender identity is known, use the label that is most precise: Latinx for gender-expansive people, Latina for women, and Latino for men. In the case of research articles, this requires offering alternatives beyond the gender binary when collecting data on participants' gender identity (e.g., gender nonbinary, genderqueer).[14,15]
3. Do not use Latinx to refer to only men and women (whether cisgender, transgender, or both). Use Latinas/os to convey the use of the gender binary. Using Latinx in conjunction with gendered nouns in English (e.g., Latinx men and women) is not only oxymoronic but goes against the term's original intent of transcending the gender binary.
4. Do not use Latinx when referring to transgender people who identify within the gender binary unless they themselves use the label. Bundling those who have had to fight (quite literally) for their right to define their own gender identity into a genderless category is a microaggression.
5. In empirical studies, provide nonbinary alternatives when assessing ethnic identity (e.g., "Do you identify as Latina, Latino, or Latinx?"). Whenever possible, ask participants how they identify and use those terms to describe them. Some people in Latin America, for example, use the "e" rather than the "x" — which is difficult to pronounce in Spanish—to increase gender inclusivity (e.g., Latines).[16] Moreover, among people of Latin American origin or descent living in the United States, the vast majority agree that pan-ethnic terms such as Hispanics or Latina/x/os merge people from a number of different cultures, and thus many, particularly those who are foreign born, prefer to self-identify using their countries of origin rather than using a pan-ethnic term.[17]

Let us not settle for using Latinx because it is new or to signal political correctness. Let us hold it to a higher standard and properly put it to work. Only then can it truly increase the visibility of gender-expansive people of Latin American origin or descent. AJPH

CORRESPONDENCE

Correspondence should be sent to Ana María del Río-González, PhD, Department of Psychological and Brain Sciences, George Washington University, 2125 G St NW, Washington, DC 20052 (e-mail: amdelrio@gwu.edu). Reprints can be ordered at http://www.ajph.org by clicking the "Reprints" link.

PUBLICATION INFORMATION

Full Citation: del Río-González AM. To Latinx or not to Latinx: a question of gender inclusivity versus gender neutrality. *Am J Public Health*. 2021;111(6): 1018–1021.

Acceptance Date: February 13, 2021.

DOI: https://doi.org/10.2105/AJPH.2021.306238

ACKNOWLEDGMENTS

Work on this article was supported in part by a pilot award from the District of Columbia Center for AIDS Research (P30AI117970) and by a CFAR Adelante Program grant from the National Institutes of Health Center for AIDS Research at Emory University

(P30AI050409), administered in partnership with the District of Columbia Center for AIDS Research.

I acknowledge Rodrigo Aguayo-Romero, Cheriko Boone, Maria Cecilia Zea, Lisa Bowleg, and Mary Beth Hatem for providing feedback and suggestions.

CONFLICTS OF INTEREST

The author has no conflicts of interest to disclose.

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Stigma Is Associated With Widening Health Inequities: Challenges From the Current COVID-19 Pandemic

Ming-Chin Yeh, PhD, MEd, MS, and Ho-Jui Tung, PhD, MPH

ABOUT THE AUTHORS

Ming-Chin Yeh is with the School of Urban Public Health, Hunter College, City University of New York, New York. Ho-Jui Tung is with the Department of Health Policy and Community Health, Jiann-Ping Hsu College of Public Health, Georgia Southern University, Statesboro.

AJPH June 2021, Vol 111, No. 6

In a matter of months, the highly contagious virus that causes coronavirus disease 2019 (COVID-19) spread to infect people of all races and all walks of life on earth. Today, more than 117 million cases and more than 2.6 million deaths have been documented worldwide, teaching us the hard lesson of how vulnerable we are in the face of a global pandemic because viruses do not discriminate. People, however, do. Discriminatory practices have made social and health disparities more visible by worsening the unequal distribution of health-protecting resources and risk-avoiding behaviors.

Racial and ethnic minority populations and other disadvantaged groups have been disproportionately affected by the virus, in part because of conditions such as employment deemed essential that requires in-person attendance or working without adequate protection (e.g., personal protective equipment). Consequently, these groups experienced higher incidence rates, as reflected in more hospitalizations and deaths.[1]

The pandemic created economic devastation in the United States, arguably one of the wealthiest and most scientifically advanced countries, igniting panic and provoking finger-pointing among leaders looking to place blame. Because the virus was first identified in China, the stigmatizing term "Chinese virus" was used by the former president of the United States and has been circulated broadly on conservative news outlets and social media. Asian Americans have been negatively affected by these racial biases and discriminatory behaviors. The use of the term "Chinese virus" implies a pernicious distrust of Asian Americans, portrays them as perpetual foreigners, and creates a sense of not belonging, regardless of birthright citizenship or naturalization.[2]

Stigma goes further than simply creating distrust. It is a significant driver of discriminatory and divisive behaviors, such as the mistreatment of others. When marginalized individuals internalize stigma, it can lead to serious health consequences, such as not pursuing medical treatment or manifesting symptoms of depression.[3] An increase in health disparities impedes efforts to contain a crisis, as seen in the late 1980s during the height of the global HIV/AIDS pandemic.

STIGMA AND HIV/AIDS PREVENTION

The social circumstances surrounding HIV/AIDS provide a good example for studying the effects of stigma on communicable disease control.[4] HIV/AIDS-related stigma has been associated with sexual behaviors (e.g., men who have sex with men), intravenous drug use, race and ethnicity (e.g., Haitian-born Black people were thought to have introduced HIV to North America),[5] and sex work. These social distinctions have been used to divide "us" from "them" and to set hierarchies for exclusion.

Evidence indicates that HIV/AIDS-related stigma has had a detrimental impact on a variety of health-related outcomes among people with HIV/AIDS. At the individual level, health-related stigma and discrimination are barriers to infection-prevention measures, help-seeking behavior, and adherence to treatment.[6] The basic strategy for controlling any communicable disease involves early detection, interruption of transmissions (i.e., identifying and isolating infected cases), and treatment. People infected with HIV, however, faced such great stigma that some chose not to disclose their status to others, including sexual partners, which contributed to the virus's spread. HIV/AIDS stigma and its concomitant social exclusions became a huge barrier to implementing this basic strategy among many socially and politically disadvantaged groups.

NEGATIVE IMPACTS OF STIGMA

The example of HIV/AIDS shows that the stigmatization of socially disadvantaged groups can lead to the widening of health disparities. For example, using social media data, a recent study has indicated that referring to the COVID-19 virus as the "Chinese virus" has had a considerable impact on collective biases toward Asian Americans.[2] COVID-19–related biases and discrimination could reduce access to health services and discourage help-seeking behaviors, which, in turn, could translate into poorer health outcomes, especially among Asian Americans.[7] In fact, preliminary epidemiological data have shown significant disparities in incidence of COVID-19 among disadvantaged racial and ethnic groups.[1] We have seen an increased risk of infection among communities of color. Higher incidence rates have translated into more severe cases and a higher death toll from COVID-19 among ethnic minorities.[8] It is more than evident that this pandemic has made the underlying social and health disparities in our society more visible.

Health is socially determined, and stigma and racial discrimination are rooted in social structures and institutions. Long-standing health disparities across time and societies are the result of an unequal distribution of health chances (e.g., health-protecting and health-enhancing resources) because of sociostructural constraints on economic, racial, and ethnic minorities. To effectively eliminate health disparities, we must confront the upstream sociostructural factors and include multisectoral approaches.[9] To effectively combat the COVID-19 crisis, government action is needed; for example, at the policy level, a national commission should be formed to investigate and mitigate social and health disparities related to COVID-19, and in the justice system, institutional racism and discrimination must be countered.[10] To aid Asian Americans specifically, community-based health care services should be provided in low-resource neighborhoods,[11] and the redistribution of power dynamics should be facilitated (e.g., community mobilization to oppose interpersonal and structural anti-Asian discrimination).[7] The new presidential administration's condemnation of racial stigma and xenophobia is just a beginning.[12] AJPH

CORRESPONDENCE

Correspondence should be sent to Ming-Chin Yeh, PhD, Nutrition Program, Hunter College, City University of New York, 2180 Third Ave, New York, NY 10035 (e-mail: myeh@hunter.cuny.edu). Reprints can be ordered at http://www.ajph.org by clicking the "Reprints" link.

PUBLICATION INFORMATION

Full Citation: Yeh M-C, Tung H-J. Stigma is associated with widening health inequities: challenges from the current COVID-19 pandemic. *Am J Public Health*. 2021;111(6):1022–1023.

Acceptance Date: February 27, 2021.

DOI: https://doi.org/10.2105/AJPH.2021.306265

CONTRIBUTORS

The authors contributed equally to this editorial.

ACKNOWLEDGMENTS

M.-C. Yeh was supported partially by the Temple University/Fox Chase Cancer Center and Hunter College Regional Comprehensive Cancer Health Disparity Partnership (award U54 CA221704(5)) from the National Cancer Institute of National Institutes of Health, National Institutes of Health (NCI, NIH; contact primary investigators [PIs]: G. X. Ma, PhD, and O. O. Ogunwobi, MD, PhD) and partially by the National Institute of General Medical Sciences (NIGMS), NIH (award 5SC3GM131949-02; PI: M.-C. Yeh).

Note. The contents of this editorial are the responsibility of the authors and do not necessarily represent the official views of NCI or NIGMS.

CONFLICTS OF INTEREST

The authors have no conflicts of interest to declare.

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Observing an Anniversary: The 400 Years of Inequality Project

Robert Sember, MA, Robert Fullilove, EdD, Thomas A. LaVeist, PhD, and Mindy Fullilove, MD, MS

ABOUT THE AUTHORS

Robert Sember is with Eugene Lang College, The New School, New York, NY. Robert Fullilove is with the Mailman School of Public Health, Columbia University, New York, NY. Thomas LaVeist is with the Tulane University School of Public Health and Tropical Medicine, New Orleans, LA. Mindy Fullilove is with the Milano School of Policy, Management, and Environment, The New School, New York NY.

In January 2019, *AJPH* published an editorial by three of the present authors in which we called on schools of public health to join the national observance of the 400th anniversary of the arrival in 1619 of the first Africans at Jamestown in the Virginia Colony to be sold into bondage. We proposed that public reflection on this event and the history of inequality that followed would enable us to "acknowledge the errors, the missteps, and the tragedies as well as the triumphs of our nation's past while committing ourselves to a future that fulfills our national aspiration for equality."[1(p84)] We urged that organizations join the 400 Years of Inequality Project in holding observances during 2019.

The 400 Years of Inequality Project was launched in 2016 by five partner organizations: the University of Orange, a people's university in Orange, New Jersey; the New School and Columbia University's Mailman School of Public Health, both in New York City; ONE DC, a Washington, DC–based organization working to advance racial and economic equity; and, Voices of a People's History, a not-for-profit organization located in Brooklyn, New York, that increases awareness of US history through public readings of historical speeches and other texts. This coalition worked to raise awareness of the anniversary, provided educational materials, documented observances, and organized "keynote events" to focus the national project.

In 2017, the project established a Web site and developed the project logo: the number 400 with loops of chain linking the digits (Figure 1). The Web site housed an inequality timeline, "starter kits" that organizations could use to help plan observances, and information about planned or completed anniversary observances. During the 2019 observance year, 110 organizations shared information with us regarding their observances. On the basis of this information, we highlight several observations about these anniversary events.

DIVERSE PARTICIPATING ORGANIZATIONS

Black civil rights organizations and Black churches were expected to participate in large numbers, and they did. We had not anticipated the extent to which "mainstream" organizations of major stature would participate. These included Carnegie Hall, the world-renowned concert music venue in New York City; the Brooklyn Public Library; *AJPH*; and schools of public health.

DIVERSE AND ORGANIZATION-SPECIFIC OBSERVANCES

Organizers used their imaginations, cultural traditions, and resources, including stories from and about their localities, to create observances relevant to their experiences and concerns. The Episcopal Church, for example, called on its congregations throughout the United States to pause in solemn reflection as their church bells rang at 3 PM on August 25, 2019. The Montclair Public Library in New Jersey and its partners commissioned a play based on an archived interview with two formerly enslaved residents. The New School's College of Performing Arts staged a reading from "Voices of a People's History," an anthology of historical testimonials by fugitives from enslavement, citizens of First Nations, union organizers, suffragettes, and other political dissenters and dissidents.

WEAVING PAST AND PRESENT

The observances tracked the evolution of present-day inequality. For example, schools of public health considered how and why structural inequities emerged

FIGURE 1— 400 Years of Inequality Button With Logo

Note. Robert Sember, photographer.

and persist. At Tulane University's School of Public Health and Tropical Medicine, faculty, students, and community representatives discussed concerns related to mass incarceration. They organized lectures and panels, a film screening, and a performance by former members of the Louisiana Correctional Institute for Women Drama Club. Musical performances, grand rounds presentations, and symposia at the Mailman School of Public Health in New York City addressed the legacy of "medical apartheid." The School of Public Health at Boston University hosted a symposium on racism in housing and education, exhibited the 400 Years of Inequality Timeline in its Activist Lab (a venue for developing innovative ways to dismantle the injustices that produce and sustain inequities), and convened storytelling sessions on the topic of inequality with artist-in-residence Rhodessa Jones. Harvard University's T. H. Chan School of Public Health hosted a discussion of medical racism and its roots in chattel slavery. Drexel University's Dornsife School of Public Health hosted a preconference session for the Society for the Analysis of African American Public Health Issues on the public health response to inequities faced by communities in the African Diaspora.

The most dramatic example of this interweaving of past and present was the homily delivered at Riverside Church in New York City by Reverend Dr William Barber, co-chair of the Poor People's Campaign, a national movement led by, and working in the interests of, the poor. Rev Barber delineated "seven sins" that justified slavery and that continue to expose poor- and low-wealth individuals and communities to air and water pollution, poor sanitation, economic exploitation, housing insecurity, and declining life expectancy.

CONTAINERS FOR EMOTIONS

Learning and thinking about 400 years of inequality is emotionally taxing work. Organizations used the arts, religious ritual, and meditation practices to enable people to acknowledge, express, and work through the emotions aroused by the observances. The annual Remembering Rosa concert held in Orange, New Jersey, brings together hundreds of residents for an intergenerational celebration of ancestry and kinship. In 2019, as part of the 400th anniversary observance, families, neighbors, and friends sang "Lift Every Voice," known as the "Black national anthem." In doing so, they recommitted themselves to continuing the racial justice activism begun by earlier generations.

A similar commitment guided the Slave Rebellion Reenactment that, from November 8 to 9, 2019, moved through the Mississippi River parishes that lie between Baton Rouge and New Orleans, Louisiana (Figure 2). Public health researchers and activists call this area "Cancer Alley" because of the correlation between environmental pollutants released by local refineries and chemical plants and the high rates of cancer among the predominantly poor and working-class Black and Latinx residents. Artist Dread Scott organized the observance, which involved hundreds of local residents in a reenactment of the largest uprising of enslaved people in US history.

The 400 Years of Inequality Project demonstrated that many kinds of groups would respond to the call for the observance of the anniversary of Jamestown. Although Black civil rights groups were expected to be involved, a wide array of other groups, including some major mainstream organizations, engaged with the project. These observances offered participants many ways to engage with the history, and to reflect on the emotions they

FIGURE 2— ***Slave Rebellion Reenactment, performance still 1***

Note. Dread Scott, artist; Soul Brother, photographer.

encountered in doing so. The widespread use of the number 400 symbolized a cultural shift, as many more people acknowledged and denounced the centuries of oppression Black Americans have faced. When we published our editorial calling for public health observances of the anniversary, we could not have predicted the specific tragic and epoch-defining events of 2020, among them the emergence of the COVID-19 pandemic and the brutal murders by the police of George Floyd and other Black women and men. We are clear, however, that every group that participated in the observances had useful tools with which to analyze those experiences, and were better prepared to initiate responses. AJPH

CORRESPONDENCE

Correspondence should be sent to Robert Sember, MA, Eugene Lang College, The New School, 66 West 11th St, New York NY 10011 (e-mail: semberr@newschool.edu). Reprints can be ordered at http://www.ajph.org by clicking the "Reprints" link.

PUBLICATION INFORMATION

Full Citation: Sember R, Fullilove R, LaVeist TA, Fullilove M. Observing an anniversary: the 400 Years of Inequality Project. *Am J Public Health*. 2021;111(6):1024–1026.

Acceptance Date: March 15, 2021.

DOI: https://doi.org/10.2105/AJPH.2021.306289

CONTRIBUTORS

All of the authors contributed to the conceptualization, writing, and editing of this editorial.

ACKNOWLEDGMENTS

The 400 Years of Inequality Project was funded by the Blaustein Foundation, Dodge Foundation, Ford Foundation, Kresge Foundation, Mellon Foundation, Robert Wood Johnson Foundation, Surdna Foundation, and the Center for Race, Religion, and Economic Democracy.

CONFLICTS OF INTEREST

The authors have no conflicts of interest to report.

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Career Transition During the COVID-19 Pandemic: A Postdoc Perspective

Elisa Pasqual, MD, PhD, and Ione Avila-Palencia, PhD, MPH

ABOUT THE AUTHORS

Elisa Pasqual is with the Barcelona Institute for Global Health, Barcelona, Spain. Ione Avila-Palencia is with the Urban Health Collaborative, Dornsife School of Public Health, Drexel University, Philadelphia, PA.

On December 3, 2019, I (E. P.) was defending my doctoral thesis in Barcelona, Spain, and everything was set up to continue with my research career in public health: I was supposed to start a postdoctoral position in the United States by May 2020. However, because of the pandemic, as well as travel and visa restrictions, I was not able to start it, so I was back in Italy living with my parents. I was fortunate, because after months of uncertainty, during which I was supported by my family and a short-term scholarship, I started my planned US postdoc in September 2020, working remotely. I also realized that my struggle was not exceptional. My PhD desk-mate (I. A.-P.) in the United States was dealing with the approaching end of her postdoctoral fellowship, which she managed to extend for several months. We shared our own concerns and struggles, and we reflected on the challenges that we, and our peers, were facing. Indeed, our ongoing personal experience of such a tortuous and uncertain career transition during the pandemic is common to many early-career researchers,[1] including those in public health–related disciplines.[2] Many early-career researchers and trainees are currently struggling, as emerged from a recent *Nature* survey, in which 61% of respondents reported that their career prospects had been "negatively impacted" by the pandemic and another 25% said they "possibly" had been.[3]

This pandemic has shown how crucial strong public health research infrastructures are. Researchers have an important role in being consulted by governments, interviewed by the media, and contributing to the advancement of knowledge and to the scientific debate. Paradoxically, however, the current crisis may have negatively affected scientists' career perspectives. The pandemic may have worsened an already existing job precarity, as the availability of PhD and postdoc positions has become more limited through a reduction in university funding or mobility and visa restrictions.[4] The difficulty in advancing research projects—for example, due to delays in data collection—might particularly affect those scientists with short-term contracts whose career advancement depends on delivering results quickly.[3] Additionally, career advancement might be challenged by the lack of traditional networking opportunities, such as in-person conferences or short-term internships. Finally, uncertainty, precariousness, and family or community obligations may affect the motivation and productivity of early-career researchers.[5]

Thus, urgent actions are needed now to support early-career researchers. Public money—for example, from research grants (from international, national, or regional institutions)—has been spent to train this future generation of thinkers, and the investment made should not be lost. In this article, we reflect on the question, "What does academia need to do to support the career development of early-career public health researchers now, during the pandemic?"

Supporting early-career scientists starts with recognizing that their precarious job position is putting them at risk, especially during a crisis. Thus, job security should be reinforced for the current generation of trainees. Funding agencies and research teams should recognize that expecting the same productivity as before the pandemic may be unrealistic. Therefore, under some circumstances, extensions of contracts for early-career researchers or project funding should be considered; however, in the *Nature* survey only 10% of postdocs reported that their contracts had been extended.[3] Establishing positions with the option of remote working, alternative ways for networking, and different strategies for job advertisement and recruiting should be put in place.

In the current situation, where career advancement is particularly challenging, mentors are needed more than ever. Research institutions and scientific societies should strengthen (or create) mentorship programs—for example, by

facilitation of mentor–mentee pairing, regular networking meetings, or career-oriented conversations. Mentors should listen actively, build trust, encourage their mentees, and help them to identify feasible goals given the circumstances. Mentors may help early-career researchers to reimagine their career pathway, by inspiring them to generate new ideas, encouraging them to turn challenges into opportunities, and helping them to build and increase their network.

In securing career perspectives for early-career researchers during the pandemic, additional effort might be required to build and maintain a more diverse workforce.[6] Indeed, the current financial insecurity may particularly affect those who come from an underprivileged background[7]: trainees with financial means might remain in the field whereas trainees with less financial stability might be forced to leave academia. Also, the burden of the COVID-19 pandemic is disproportionally affecting underrepresented communities and women, and diversified actions might be required to address all the different needs. This is crucial: if talent and expertise are lost, society will be less equipped to tackle public health issues.

Effort in securing the researcher's job market should not come without changing the "publish or perish" culture. PhDs and postdocs need to be taught a different story: it is not about the number of publications, but about their quality and societal impact. Indeed, the urgency and the high pressure to publish results are challenging the research community. Poor-quality publications with questionable results present a dilemma, especially if they can influence the management of a public health emergency. Scientific integrity should be cultivated in the future generations of public health scientists, not only through courses on ethics in science but also by making ethical conduct and scientific integrity essential for career advancement.

In conclusion, this pandemic represents a challenge for early-career researchers in public health. Job security, mentorship initiatives, equity, diversity, and research integrity standards should be reinforced during the current situation, so that a force of future public health experts will not be lost. This will make society more empowered and better equipped to respond to this and future emergencies. AJPH

CORRESPONDENCE

Correspondence should be sent to Elisa Pasqual, Barcelona Institute for Global Health (ISGlobal), Campus Mar, Barcelona Biomedical Research Park (PRBB), Dr Aiguader 88, 08003 Barcelona, Spain (e-mail: elisa.pasqual89@gmail.com, elisa.pasqual@isglobal.org). Reprints can be ordered at http://www.ajph.org by clicking the "Reprints" link.

PUBLICATION INFORMATION

Full Citation: Pasqual E, Avila-Palencia I. Career transition during the COVID-19 pandemic: a postdoc perspective. *Am J Public Health*. 2021;111(6):1027–1028.

Acceptance Date: February 27, 2021.

DOI: https://doi.org/10.2105/AJPH.2021.306260

CONTRIBUTORS

E. Pasqual conceptualized this article. I. Avila-Palencia contributed with critical views. Both authors contributed to the writing and editing.

ACKNOWLEDGMENTS

ISGlobal acknowledges support from the Spanish Ministry of Science, Innovation and Universities through the "Centro de Excelencia Severo Ochoa 2019–2023" Program (CEX2018-000806-S), and from the Generalitat de Catalunya through the CERCA Program.

We especially acknowledge Andrè Rose, MD, PhD, who was very supportive for the genesis of this article.

CONFLICTS OF INTEREST

The authors have no conflicts of interest to declare.

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Enhancing Public Health Systematic Reviews With Diagram Visualization

Anke Rohwer, PhD, Melissa Taylor, MSc, Rebecca Ryan, PhD, Paul Garner, MD, and Sandy Oliver, PhD

ABOUT THE AUTHORS

Anke Rohwer is with the Centre for Evidence-Based Health Care, Stellenbosch University, Stellenbosch, South Africa. Melissa Taylor and Paul Garner are with the Department of Clinical Sciences, Liverpool School of Tropical Medicine, Liverpool, UK. Rebecca Ryan is with the Centre for Health Communication and Participation, La Trobe University, Melbourne, Australia. Sandy Oliver is with the Evidence for Policy and Practice Information and Co-ordinating Centre, Social Research Institute, University College London, London, UK, and the Africa Centre for Evidence, University of Johannesburg, Johannesburg, South Africa.

Systematic reviews provide a critical summary of a body of knowledge that links research to decision making, whether to inform public health, clinical medicine, medical education, system-level changes, or advocacy. Good reviews are accessed by a wide range of audiences, including health service users, health service providers, and policy decision makers. Because the topics studied, the thinking behind the review questions, the analytical plan, and the review's interpretation in the broader policy context are often complex, diagrams can play an important role in communicating the review to the reader. Indeed, graphic design is increasingly important for researchers to communicate their work to each other and the wider world.[1] Visualizing the topic under study facilitates discussion, helps understanding by making complexity more accessible, provokes deeper thinking, and makes concepts more memorable.[2] Higher impact scientific articles tend to include more diagrams, possibly because diagrams improve clarity and thereby lead to more citations or because high-impact articles tend to include novel, complex ideas that require visual explanation.[3]

Merriam-Webster's Dictionary defines a diagram as "a graphic design that explains rather than represents, *especially*: a drawing that shows arrangement and relations (as of parts)."[4] Established standards exist for visualizing the flow of studies through a review,[5] risk of bias, and individual study and meta-analysis results in forest plots; these are not the subject of this editorial. We consider diagrams that communicate the conceptual framework underpinning reviews.

Diagrams include "logic models," "framework models," or "conceptual models"—terms that are often used interchangeably and inconsistently in the literature.[6] We examine how diagrams can help review authors and readers and offer guidance for presenting information diagrammatically. We based our work on a purposive search for diagrams from the Cochrane Library and sources of reviews more likely to illustrate conceptual frameworks. Drawing on the data and our own experience, we adapted rapid appraisal methods[7] for analyzing documents, taking an iterative, inductive approach to understand what enhances the clarity and utility of diagrams. We then related this learning to methodological articles of systematic reviewing and science communication (Appendix A, available as a supplement to the online version of this article at http://www.ajph.org). We built on our collective experience of diagrams in reviews and helping others to develop them.

We first describe diagrams' various purposes. Then we discuss what we recognized, as systematic review readers, authors, and editors, as important steps to creating a good diagram. Next, we consider how diagrams can enhance the review process for authors. We discuss these findings in relation to methodologies that routinely integrate diagrams into structure systematic reviews: framework synthesis[8] and logic models of illness or treatment pathways, where principles and agreed good practice are emerging.[9] Finally, we discuss theories underpinning science communication.[10]

WHAT DO DIAGRAMS ILLUSTRATE?

In our rapid appraisal (Appendix A), we found three categories of diagrams illustrating the context and baseline understanding, the review question and scope, and the results. Almost all of them comprised boxes and arrows to indicate causal relationships. This simple design aligns with systematic reviews generating or testing theories about causal relationships. Typically, the authors gave little or no description of how

diagrams were developed, unless they had adapted an existing model. Those developed at the protocol stage illustrated components of the background or review question. Diagrams presenting results were developed at any stage in the review process. For each of the three categories, we describe what the diagrams illustrated or explained and signpost the best examples identified.

DESCRIBING THE CONTEXT

Diagrams visualized important psychological, social, systems, and contextual factors that influence particular behaviors, experiences, or views and the relationships among them. These were predominantly part of qualitative evidence syntheses, in which the diagram illustrates a theory of the phenomenon being reviewed, which may then be updated in light of the findings from the analysis. Factors may be represented visually in such diagrams as opposing forces that influence a chain of events[11] or in ecological hierarchies illustrating at which level factors influence experiences.[12]

For example, one diagram showed potential threats and expectations of engaging in physical activity for those with bipolar disorder; it also showed the modifying factors and behavioral cues that influence the decision to participate.[13] The review authors developed the diagram from existing literature, published it in a protocol, and plan to use it for an ongoing framework synthesis. At the review stage, findings will be mapped to the existing diagram, and when findings do not fit the diagram they will be refined.

DESCRIBING THE REVIEW QUESTION AND SCOPE

In our sample, this was the main purpose of diagrams. Diagrams commonly clarified the review question, although wide variation can be seen in the complexity, depth, and scope of these examples. These diagrams were generally developed as part of comparative effectiveness reviews.

Simpler diagrams depicted the review's participants, intervention, comparison, and outcomes. They tended to be descriptive and display a bird's-eye view of the review question and inclusion criteria using standard headings and formatting. For example, one diagram outlined participants, intervention, comparison, and outcomes for hypertension screening to reduce the burden of disease[14]; another illustrated participants, intervention, comparison, and outcomes for interventions to reduce air pollution and the interventions' effects on respiratory conditions.[15] The researchers described details of the eligible participants, intervention, and expected outcomes in separate boxes that comprised the full diagram.

More advanced diagrams were explanatory; they typically illustrated and explored one aspect of the participants, intervention, comparison, and outcomes in depth, delineating relationships between diagram components. For example, they depicted a pathway of disease progression and manifestation, the development of a series of direct and intermediary outcomes as a result of the intervention, or the components or steps of an intervention.

Some diagrams merged two or more purposes. One showed both the progressive clinical manifestations and the consequences of dementia.[16] The authors then used the disease pathway to map points where the intervention (animal-assisted therapy) may help. Other diagrams illustrated how similar interventions may vary, such as different forms of peer support to improve health literacy[17] or alternative forms of taxes on unprocessed sugar or sugar-added food to tackle obesity.[18]

In addition, we identified three diagrams that combined the two approaches.[19–21] They displayed all elements of the participants, intervention, comparison, and outcomes in a standardized format, with a more explanatory depiction of the series of outcomes resulting from the intervention.

SHOWING RESULTS

For meta-analyses, pathway diagrams may be overlaid with the quantitative results.[22] For qualitative syntheses, diagrams arrange findings into an image of the emerging theory, offering explanations or relationships between or among observations.[23] Diagrams sometimes combine quantitative and qualitative results from paired or mixed studies to generate an integrated understanding.[24]

For example, a diagram that displayed the results of a qualitative synthesis identified factors influencing adherence to antiretroviral therapy in HIV patients.[23] The multiple external and internal influences on an individual, identified through the synthesis, were grouped to demonstrate how they drive engagement and disengagement, as well as good and poor adherence, in a dynamic manner.

WHAT MAKES A GOOD DIAGRAM?

We suggest steps inferred from our analysis and experience as being particularly helpful for developing clear diagrams:

- Choose the purpose of the diagram, whether it is to describe the context,

illustrate the question and scope, or show results of a systematic review, before starting to assemble it.
- Identify the key information to be communicated, and acknowledge the complexity of the review while helping the reader make sense of it. Comprehensive diagrams often obscure the message with too much detail. Instead, focus on the point that is being illustrated, rather than incorporating too many ideas. Combining multiple diagrams in one usually reduces clarity.
- Work as a team to capture and share understanding from various perspectives.
- Start simply and expect at least a few iterations. Using a pen and paper or even a flipchart to draft the initial versions of the diagram, rather than doing this electronically, helps clarify and compile thoughts from team members. Keeping all the draft versions captures the evolution of thinking.
- Give the diagram a clear starting point to help readers navigate the diagram more easily.
- Use visual conventions such as reading from left to right, top to bottom, or both to offer a clear flow of ideas.
- Limit the number of arrows to guide the readers' gaze. Avoid the distraction of multiple, intersecting arrows at various angles. Simplify multiple or complex routes with a topology that allows the reader to pick out pathways clearly.
- Group related information in columns or rows with headings, colors, or shapes to draw attention to key parts, such as activities or outcomes. Use these features selectively to avoid obscuring key relationships with too many layers. For example, employing colors and shapes, rather than colors or shapes, can complicate the picture.
- Use plain language and fewer words without a long legend, key, or acronyms so that the diagram can be understood intuitively.
- Ask others for feedback, including peers and the intended audience, while the diagram is developing.

SIMPLE, CLEAR EXAMPLES

We present three examples showing different sorts of content: (1) the context of a review, (2) the scope and question of a review, and (3) the results of a review. These examples are simple enough to be developed by systematic reviewers without the support of a graphic designer and published without additional color reproduction costs.

Figure 1 demonstrates how diagrams can portray the context of the review. As noted in "Diagrams Describing the Context," context can be presented in a variety of ways. Here it takes the form of a typical logic model that describes a chain of events. It was created during protocol development for a qualitative review exploring factors influencing

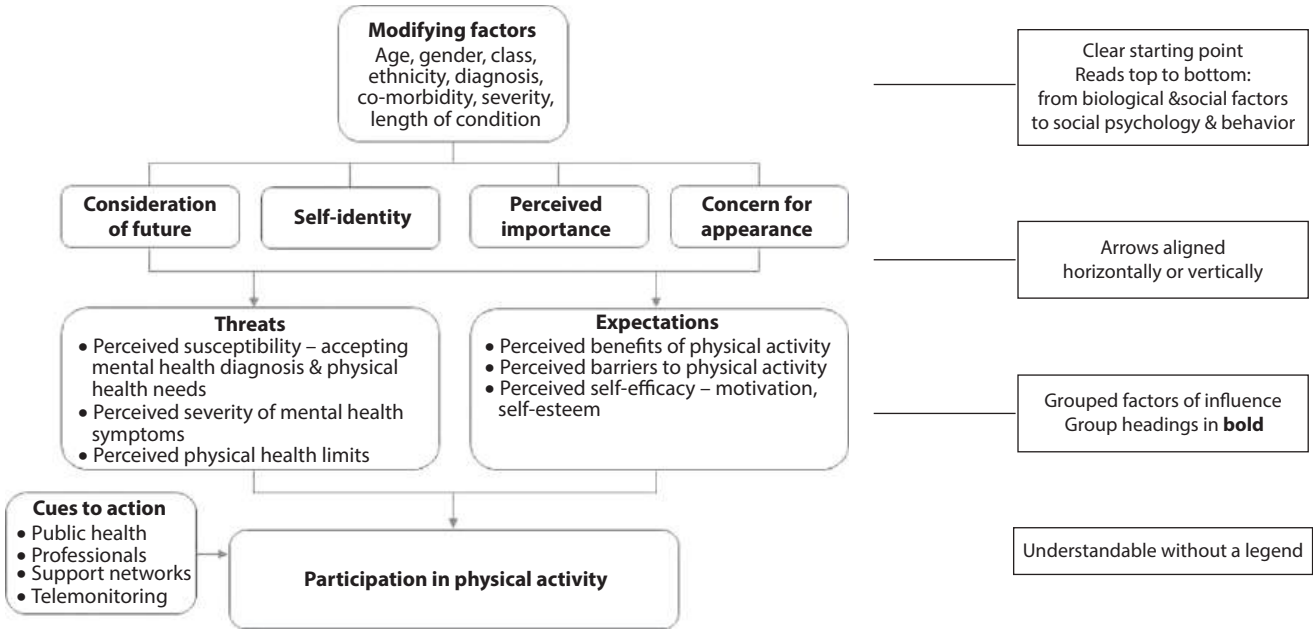

FIGURE 1— Factors That Influence Participation in Physical Activity for People With Bipolar Disorder

Source. McCartan et al.[13]

physical activity in people with bipolar disorder.[13] Related factors are grouped in rows, and the diagram is organized into a hierarchy, with biological and social factors at the start (top) influencing complex psychological factors that subsequently lead to behavior change. Again, the diagram reads top to bottom, and, although there are multiple routes through the diagram, the topology has been simplified and arrows are kept to a minimum. Although there is some detailed information, bold text is used to highlight the key message of each box.

As depicted in Figure 2, a diagram of the effects of mass deworming[24] is easy to interpret, as it has a clear starting point at the top and only three arrows—all of which point downward to indicate a top-to-bottom flow. It can be classed as an example of diagrams that elucidate the review question and scope, as it shows the range of potential outcomes of an intervention (see "Diagrams Describing the Review Question and Scope"). The outcomes are grouped into main effects, mediating pathways, and impacts. These categories are clearly organized in three rows under the appropriate subheading. Language is kept simple, and there is one outcome per box and a maximum of three outcomes per row. Each of these features helps to ensure that the diagram is easy to interpret at first glance, while conveying comprehensive information about intervention effects.

Figure A (available as a supplement to the online version of this article at http://www.ajph.org) depicts a theoretical model of the influences on engagement and adherence to antiretroviral therapy.[23] It is an example of a diagram that displays the results (see "Diagrams Showing Results"). In this case, the review's in-depth qualitative findings were consolidated into one visual image that demonstrates how factors are interrelated. Individual factors are presented in separate boxes, and arrows indicate whether this may lead to engagement or disengagement in the care pathway. Although there are many arrows in the diagram, the authors have ensured that they do not intersect and that the logical flow of the diagram is maintained.

ENHANCING REVIEW DEVELOPMENT

When considering reviews that we have authored or edited, we recognized how the process of constructing a diagram

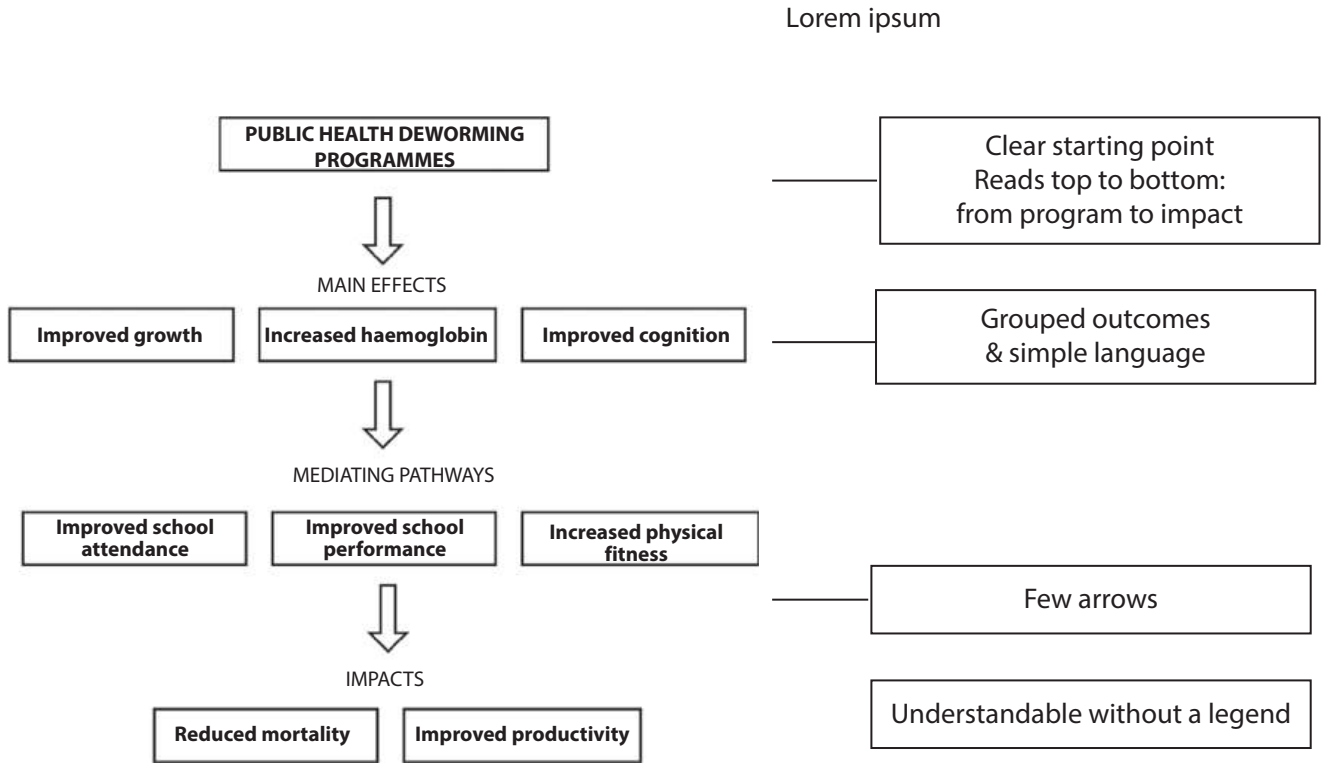

FIGURE 2— The Effect of Public Health Programs That Regularly Treat All Children With Soil-Transmitted Helminth Infection in Endemic Areas

Source. Taylor-Robinson et al.[24]

can be useful for developing the review: conceptualizing the problem or findings, advancing thinking, and framing the analysis. Constructing diagrams as a team can help to develop a common language and understanding of the review.

A review of interventions to improve the involvement of older people with multimorbidity in decisions in primary care provides a good example with its Figure 2.[25] This diagram evolved during the review. Visualizing the range of interventions and processes provided an opportunity to distinguish three main strategies and identify different aims of different components. Later, outcomes were pictured as intermediate or ultimate endpoints. Gradually, likely pathways linked involvement in decision making to outcomes and effects, such as changes to behavior and health.

Recognizing distinct purposes for variations or components of interventions helped authors to group and analyze the interventions in terms of the wider theoretical context of capability, motivation, and opportunity for behavior change.[26] Importantly, the diagram enabled articulation of the links between the different strands of the interventions and the range of outcomes assessed, including those for different actors (i.e., patients, carers, providers, health systems) and reflecting different parts of the pathway between intervention and outcome (e.g., engagement in decision making, health outcomes, treatment burden, evaluation of care, attitudes, resource use, and quality of care).

CONCLUSIONS

We found that diagrams help the reader go straight to the essence of a systematic review. They may illustrate the context and initial understanding as a review begins, the review scope and questions, or the review's findings. Diagrams from Cochrane more often illustrated the review scope and questions ("Diagrams Describing the Review Question and Scope"), whereas diagrams of context and findings generally came from elsewhere ("Diagrams Describing the Context" and "Diagrams Showing Results"), perhaps reflecting the smaller body of qualitative or mixed-methods research currently available in the Cochrane Library. Good examples simplified complexity and variation, facilitated readers' navigation of that complexity, and portrayed a coherent picture. Developing diagrams together also helped authors develop a common understanding and guide the review's development. Good diagrams can, therefore, function as tools for enhancing understanding and for developing reviews.

Authors frequently used diagrams to illustrate their conceptual framework, but they rarely acknowledged or illustrated how diagrams can evolve during the review—a finding that reflects a similar analysis of diagrams in the Cochrane Library and the International Initiative for Impact Evaluation database of systematic reviews.[9] Nevertheless, visualization of conceptual frameworks is common during the development of framework syntheses.[8]

Our rapid appraisal of systematic review diagrams aligns well with good practice and theory of visual communication of science. Whether diagrams are designed for fellow scientists, policy decision makers, or the wider public, principles of good practice from using diagrams in the form of logic models in reviews—and human-centered design theory more broadly—encourage developing diagrams as a team and inviting feedback from the target audience.[9,10] Depicting essential components and relationships, and grouping related concepts, is achieved by keeping the diagram's audience in mind while editing and simplifying, as seen when developing diagrams for systematic reviews, and are fundamental graphic design approaches.[10] Appendix B (available as a supplement to the online version of this article at http://www.ajph.org) distils from our analysis practical tips for a broad range of diagrams to enhance systematic reviews.

Guidance specifically for constructing logic models for systematic reviews is available from the Cochrane Infectious Diseases Group[27] and in the academic literature.[9] AJPH

CORRESPONDENCE

Correspondence should be sent to Sandy Oliver, Social Research Institute, UCL Institute of Education, 20 Bedford Way, London WC1H 0AL, UK (e-mail: sandy.oliver@ucl.ac.uk). Reprints can be ordered at http://www.ajph.org by clicking the "Reprints" link.

PUBLICATION INFORMATION

Full Citation: Rohwer A, Taylor M, Ryan R, Garner P, Oliver S. Enhancing public health systematic reviews with diagram visualization. *Am J Public Health*. 2021;111(6):1029–1034.

Acceptance Date: February 7, 2021.

DOI: https://doi.org/10.2105/AJPH.2021.306225

CONTRIBUTORS

A. Rohwer and M. Taylor identified reviews with diagrams illustrating the substantive focus and applied standardized descriptions. All authors inspected all diagrams and compared them with these descriptions, critiqued the diagrams, contributed to the editorial, and approved the final version.

ACKNOWLEDGMENTS

This editorial is associated with the Research, Evidence and Development Initiative (READ-It). READ-It is funded by the UK government (project 300342-104).

We are grateful to Vittoria Lutje, PhD, for searching the Cochrane Library for systematic reviews with diagrams.

Note. The views expressed is this editorial do not necessarily reflect the UK government's official policies.

CONFLICTS OF INTEREST

The authors have no conflicts of interest from funding or affiliation-related activities

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Recommendations for Delivering COVID-19 Vaccine in Jails: Evidence from Kansas, Iowa, Nebraska, and Missouri

Megha Ramaswamy, PhD, MPH, Catherine L. Satterwhite, PhD, MSPH, MPH, Ashlyn Lipnicky, MPH, Amanda Emerson, PhD, RN, Phil Griffin, BBA, Donald Ash, MBA, and Kevin Ault, MD

We report on data we collected from a 2018 survey examining jails' human papillomavirus virus vaccine delivery capacity and on a secondary analysis we conducted to describe factors similarly associated with delivery planning for the COVID-19 vaccine. We provide recommendations for delivering the COVID-19 vaccine in jails, based on evidence from Kansas, Iowa, Nebraska, and Missouri. Our key finding is that jails have limited staff to implement vaccination and will require collaboration between jail administrators, jail medical staff, and local health departments. (*Am J Public Health*. 2021;111:1035–1039. https://doi.org/10.2105/AJPH.2021.306218)

With the approval of COVID-19 vaccines for emergency use and expanded availability, many Americans are now being vaccinated. As congregate living settings, jails and prisons have been prioritized for early vaccine receipt in many states, with 37 US states and territories prioritizing incarcerated persons for phases 1 and 2 vaccine distribution.[1]

Thirteen million people pass through jails in the United States each year.[2] Jails hold the largest population of those under criminal legal supervision in the United States. These detention centers are also unique in their community embeddedness: they exist in almost every US county. Most people leave jails days or weeks after initial incarceration. Thus, "churning" from detention centers to communities exacerbates COVID-19 spread and amplifies the need for effective jail-based COVID-19 vaccine delivery.[3] Indeed, 80% of the largest COVID-19 outbreaks in the United States have been linked to detention centers. Thousands of correctional employees move between their workplace and community homes daily, potentially passing COVID-19 from communities into jails and back.[3]

Bringing the COVID-19 vaccine to detention settings is critical, but challenges to doing so exist, including lack of local political will, resources, vaccine storage, supply, and county staffing. Detention centers are not well practiced in vaccine delivery. A recent review of domestic and international studies showed that incarcerated persons are underimmunized.[4] Vaccine programs, such as those executed during influenza outbreaks, have been variable and limited in reach. Public health entities face substantial challenges when planning for COVID-19 vaccine delivery in jails.[3]

INTERVENTION

We provide public health planners and jails with a just-in-time snapshot of the infrastructure of, barriers to, and opportunities for COVID-19 vaccine delivery, drawing on data and our shared expertise as jail health researchers and administrators, and state and regional health planners.

PLACE AND TIME

Between November 2017 and October 2018, 192 of 347 invited administrators of local jails in Kansas, Iowa, Nebraska, and Missouri responded to a survey about correctional and public health capacity to deliver human papillomavirus virus (HPV) vaccine in local jails (55% response).

PERSON

All jails were located in a county with a geographically associated health department.[5] The majority were in rural areas (70%). We designed survey items to correspond to consolidated framework for implementation research domains,[6] yielding information for vaccine program implementation.

PURPOSE

Our goal was to provide recommendations for COVID-19 vaccine delivery in jails, extrapolating from data we previously collected with jail administrators to deliver HPV vaccine. We found that half of incarcerated persons report being willing to get a vaccine in jail.[7]

IMPLEMENTATION

Because of the COVID-19 pandemic, the rapid spread of disease in detention settings, and vaccine availability, we conducted a secondary data analysis to repurpose the parent study and offer timely recommendations for COVID-19 vaccine delivery. To provide recommendations for how jails can deliver the COVID-19 vaccine, we analyzed data on facility capacity and operational factors related to vaccine program coordination. Although capacity data are broadly applicable to COVID-19 vaccine planning, we designed operational questions specifically with an HPV vaccine program in mind.

EVALUATION

These data provide some broadly applicable challenges and opportunities pertinent to COVID-19 vaccine delivery.

Capacity for Vaccine Delivery

Administrators reported an average of 20 beds for females (range = 0–180) and 84 beds for males (range = 0–1250). Licensed practical nurses were the most common health care provider onsite (mean = 9 days), followed by registered nurses (mean = 7 days; Table 1). Clinicians were available at the jail more days in urban jails than in rural jails ($P = .001$; Table 2). Medical care was provided by corporations (38%), partnerships with health systems (22%), local providers hired by the jail (18%), and other arrangements (22%). When looking at state differences on selected variables, only Missouri had more jail health care run by a medical care corporation than other states (54% in Missouri, compared with 15% in Iowa, 35% in Kansas, and 33% in Nebraska; $P = .004$). Most jails (72%) dispensed medicines to incarcerated persons on a cart brought to each housing unit. Only 10% of jails reported providing the influenza vaccine, with urban jails more likely to offer vaccine ($P < .001$).

Operational Factors

Most administrators said wardens (51%) or jail medical staff (29%) would coordinate HPV vaccine administration planning. Cost (cited by 66% of administrators), short length of stay of incarcerated persons (62%), and medical staff availability (47%) were the top concerns for providing vaccine. Half of the administrators (52%) had physical safety concerns for staff. Administrators were split on who they would prefer administering HPV vaccine, with 45% saying jail medical staff and 44% saying local health department staff. Urban jails were more likely to say that jail medical staff would offer the vaccine ($P < .001$). There were also differences in expectations for who would pay: incarcerated persons paying out of pocket or through their insurance (54%), local health departments (24%), and jails (17%). To educate about the vaccine, administrators favored written information distributed to incarcerated persons (63%) or education from local health departments (21%). Administrators also wanted direct education for jail medical (25%) and correctional (25%) staff.

ADVERSE EFFECTS

Our study is not without limitations, and we extrapolated data from direct application to HPV vaccine administration to anticipated applicability to COVID-19 vaccine administration. The extent to which empirical research can inform planning efforts is critical to the shared responsibility of counties, local public health systems, and criminal legal systems to best address the jail population and communities.

SUSTAINABILITY

Although the HPV vaccine is clearly different from the COVID-19 vaccine, key similarities suggest that factors associated with HPV vaccine delivery might align with COVID-19 vaccine delivery: two-dose schedules and vaccine hesitancy. We offer the following recommendations:

Capacity (Who, Where, How)

- Given a shortage of jail medical staff and varied organization of medical care, jails will have to negotiate, on a facility-by-facility basis, who is best positioned to deliver the vaccine (jail nurses, local health department nurses, or staff from local safety net clinics). Urban jails will have an advantage in the number of staff available at the jail. Rural jails may have to rely on outside partners.
- The COVID-19 vaccine is likely to be best administered on a medical cart brought to housing units, using an approach possibly aligned with other types of mobile vaccination outreach.

- The first dose of the vaccine should be administered in jail, and incarcerated persons should be given instructions about when to receive a second dose and where (inside the facility through a no-cost health request or outside the facility at a local health department), in addition to a Centers for Disease Control and

TABLE 1— Jail Characteristics and Vaccine Challenges and Opportunities: Kansas, Iowa, Nebraska, Missouri; November 2017–October 2018

Variable	Total (n = 192), No. (Range) or (%)	Iowa (n = 26), No. (Range) or (%)	Kansas (n = 70), No. (Range) or (%)	Missouri (n = 58), No. (range) or (%)	Nebraska (n = 38), No. (Range) or (%)
Providers available, d/mo					
MD and APP	4.0 (0–30)	2.0	5.0	3.5	3.5
RN	7.0 (0–30)	6.5	9.0	5.5	6.0
LPN	9.0 (0–30)	2.5	8.5	13.0	8.0
Exam rooms available	101 (53.4)	10 (40.0)	38 (55.1)	34 (59.7)	19 (50.0)
Entity providing medical care					
Medical care corporation	71 (37.8)	4 (15.4)	24 (34.8)	31 (54.4)	12 (33.3)
Partnership with health system	42 (22.3)	9 (34.6)	17 (24.6)	5 (8.8)	11 (30.6)
Local provider hired by jail	33 (17.6)	3 (11.5)	14 (20.3)	7 (12.3)	9 (25.0)
Other	42 (22.3)	10 (38.5)	14 (20.3)	14 (24.6)	4 (11.1)
Ability to bill third parties	51 (34.2)	4 (21.1)	25 (47.2)	11 (23.9)	11 (35.5)
Coordination of vaccine program[a]					
Warden	81 (50.6)	14 (63.6)	31 (52.5)	20 (40.8)	16 (53.3)
Jail medical staff	47 (29.4)	4 (18.2)	18 (30.5)	17 (34.7)	8 (26.7)
No one	14 (8.8)	2 (9.1)	6 (10.2)	5 (10.2)	1 (3.3)
Don't know	18 (11.3)	2 (9.1)	4 (6.8)	7 (14.3)	5 (16.7)
Challenges to providing vaccines[a]					
Cost	126 (65.6)	16 (61.5)	45 (64.3)	42 (72.4)	23 (60.5)
Medical staffing available	90 (46.9)	13 (50.0)	29 (41.4)	33 (56.9)	15 (39.5)
Not a priority	39 (20.3)	7 (26.9)	14 (20.0)	14 (24.1)	4 (10.5)
Not our responsibility	67 (34.9)	8 (30.8)	25 (35.7)	21 (36.2)	13 (34.2)
Short length of stays for incarcerated persons	118 (61.5)	16 (61.5)	41 (58.6)	38 (65.5)	23 (60.5)
Any security concerns about offering vaccine[a]	100 (52.1)	15 (57.7)	40 (57.1)	29 (50.0)	16 (42.1)
Who would administer vaccine[a]					
Jail medical staff	87 (45.3)	7 (26.9)	34 (48.6)	32 (55.2)	14 (36.8)
Local health department	84 (43.8)	12 (46.2)	28 (40.0)	27 (46.6)	17 (44.7)
Don't know	19 (9.9)	4 (15.4)	6 (8.6)	6 (10.3)	3 (7.9)
Who would pay for vaccine[a]					
Local health department	47 (24.5)	8 (30.8)	19 (27.1)	15 (25.9)	5 (13.2)
Jail health budget	32 (16.7)	8 (30.8)	9 (12.9)	8 (13.8)	7 (18.4)
Incarcerated person/ incarcerated person insurance	104 (54.2)	17 (65.4)	33 (47.1)	38 (65.5)	16 (42.1)
Don't know	49 (25.5)	5 (19.2)	19 (27.1)	13 (22.4)	12 (31.6)

Continued

TABLE 1— Continued

Variable	Total (n = 192), No. (Range) or (%)	Iowa (n = 26), No. (Range) or (%)	Kansas (n = 70), No. (Range) or (%)	Missouri (n = 58), No. (range) or (%)	Nebraska (n = 38), No. (Range) or (%)
Staffing needs for vaccine[a]					
Correctional officers available to escort/guard health department staff	130 (67.7)	18 (69.2)	49 (70.0)	38 (65.5)	25 (65.8)
Jail medical staff supervision/coordination	72 (37.5)	9 (34.6)	28 (40.0)	21 (36.2)	14 (36.8)
Don't know	32 (16.7)	6 (23.1)	11 (15.7)	9 (15.5)	6 (15.8)

Note. APP = advanced practice provider (general nurse practitioner and physician assistant); LPN = licensed practical nurse; MD = medical doctor; RN = registered nurse.

[a]Specifically asked for human papillomavirus vaccine.

Prevention–provided vaccine-tracking card. Entering incarcerated persons should be asked if they have already received their first dose during intake. If eligible for the second dose during their jail term, vaccination should be administered. Administration information for any doses given in jails should be captured in the required immunization information systems per state regulations.

Operational (Costs, Security, and Information)

- The federal government is providing COVID-19 vaccine at no cost to recipients. However, costs of gloves, sharps containers, staff, and administration will have to be negotiated locally.
- Physical security concerns for all parties involved are real, and jails should plan for security staffing needs during vaccine administration in housing units.
- Given the history of vaccine mistrust in the public, health care mistrust in detention settings, and the differential power dynamics of players, information will have to be provided in a transparent, clear, and consistent manner to boost uptake. Jails may ultimately be ill equipped to provide adequate health education and must be supported with clear public health strategies.

PUBLIC HEALTH SIGNIFICANCE

Jails have struggled to limit daily population movement, effectively quarantine incarcerated persons who test positive for COVID-19, refresh staff, and transport sick incarcerated persons to receive medical care during COVID-19.[3] We also know that less than half of inmates are willing to get vaccinated thus far (https://bit.ly/3uOlZwA). Without a plan to vaccinate locally incarcerated persons and correctional officers, the community can expect to continue to be affected by COVID-19 outbreaks in jails. Such superspreader sites can overwhelm local hospitals and put family

TABLE 2— Comparing Selected Variables by Rural Versus Urban Jails: Kansas, Iowa, Nebraska, Missouri; November 2017–October 2018

Variable (n = 185)	Rural (n = 130), No. (range) or (%)	Urban (n = 55), No. (range) or (%)	*P*
No. of days physicians or nurses on site[a]	4.0 (0–30)	8.5 (0–27.8)	≤.001
Medical care corporation providing medical care	32 (25.4)	35 (63.6)	≤.001
Provides flu vaccine	4 (3.1)	14 (25.5)	≤.001
Who would administer vaccines			
Jail medical staff	41 (31.5)	44 (80.0)	≤.001
Local health department	58 (44.6)	24 (43.6)	≥.99
Other	10 (7.7)	2 (3.6)	.51

[a]Combined days for medical doctor, advanced practice provider (general nurse practitioner and physician assistant), registered nurse, and licensed practical nurse.

members and communities at risk.[3] States and local jurisdictions will need to initiate planning that fits with local incarcerated persons' vaccination and engage nontraditional medical partners, such as federally qualified health centers and safety net clinics, when local health departments reach capacity in communities. AJPH

ABOUT THE AUTHORS

Megha Ramaswamy, Ashlyn Lipnicky, and Kevin Ault are with the University of Kansas Medical Center, Kansas City. Catherine L. Satterwhite is with the Office of the Assistant Secretary for Health, US Department of Health and Human Services, Kansas City, MO. Amanda Emerson is with the School of Nursing and Health Studies, University of Missouri-Kansas City. Phil Griffin is with the Bureau of Disease Control and Prevention, Kansas Department of Health and Environment, Topeka. Donald Ash is with the Wyandotte County, Kansas Sheriff's Office, Kansas City, KS.

CORRESPONDENCE

Correspondence should be sent to Megha Ramaswamy, 3901 Rainbow Blvd, MS 1008, Kansas City, KS 66160 (e-mail: mramaswamy@kumc.edu). Reprints can be ordered at http://www.ajph.org by clicking the "Reprints" link.

PUBLICATION INFORMATION

Full Citation: Ramaswamy M, Satterwhite CL, Lipnicky A, et al. Recommendations for delivering COVID-19 vaccine in jails: evidence from Kansas, Iowa, Nebraska, and Missouri. *Am J Public Health*. 2021;111(6):1035–1039.

Acceptance Date: January 31, 2021.

DOI: https://doi.org/10.2105/AJPH.2021.306218

CONTRIBUTORS

M. Ramaswamy designed and obtained funding for the study and wrote the first draft of the article. C. L. Satterwhite provided significant article revisions. A. Lipnicky conducted analyses and wrote corresponding sections. A. Emerson and K. Ault revised the article and collaborated on the original study. C. L. Satterwhite, P. Griffin, and D. Ash provided or agreed with recommendations for the article and participated in editing and approving drafts.

ACKNOWLEDGMENTS

Data collection for this study was funded by the National Cancer Institute, National Institutes of Health (NIH; grant R21 CA204767, "Correctional and public health links to bolster HPV vaccine and cancer prevention" to M. R. [primary investigator]).

Note. The content of this editorial is solely the responsibility of the authors and does not necessarily represent the official views of the NIH.

CONFLICTS OF INTEREST

The authors have no conflicts of interest to declare.

HUMAN PARTICIPANT PROTECTION

This study was approved by the University of Kansas Medical Center institutional review board. All participants gave verbal informed consent to participate, as approved by the institutional review board. Written consent was waived, as the study posed only minimal harm to respondents.

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A Community Health Worker–Led Intervention to Improve Blood Pressure Control in an Immigrant Community With Comorbid Diabetes: Data From Two Randomized, Controlled Trials Conducted in 2011–2019

Jeannette M. Beasley, PhD, MPH, Megha Shah, MD, MSc, Laura C. Wyatt, MPH, Jennifer Zanowiak, MA, Chau Trinh-Shevrin, DrPH, and Nadia S. Islam, PhD, MPhil, MA

AJPH June 2021, Vol 111, No. 6

Evidence-based strategies addressing comorbid hypertension and diabetes are needed among minority communities. We analyzed the outcome of blood pressure (BP) control using pooled data from two community health worker interventions in New York City conducted between 2011 and 2019, focusing on participants with comorbid hypertension and diabetes. The adjusted odds of controlled BP (< 140/90 mmHg) for the treatment group were significant compared with the control group (odds ratio = 1.4; 95% confidence interval = 1.1, 1.8). The interventions demonstrated clinically meaningful reductions in BP among participants with comorbid hypertension and diabetes. (*Am J Public Health*. 2021;111:1040–1044. https://doi.org/10.2105/AJPH.2021.306216)

Although clinical and lifestyle recommendations are in place to promote hypertension control for individuals with diabetes, there is a gap in the implementation of evidence-based strategies to address comorbidities, particularly among minority communities that may face social and cultural barriers to optimizing chronic disease management. We report on the impact of blood pressure (BP) control among individuals with comorbid hypertension and diabetes in two community health worker (CHW)-led interventions in the South Asian community (Table 1),[1,2] an immigrant population with a high risk of cardiovascular disease.[4]

INTERVENTION

We conducted a secondary analysis of two patient-centered lifestyle interventions utilizing CHWs among South Asians. The DREAM Project enrolled Bangladeshi individuals diagnosed with type 2 diabetes into a culturally adapted diabetes management intervention conducted in community and clinical settings (n = 336).[1] Project IMPACT enrolled South Asian individuals with uncontrolled hypertension into a hypertension management intervention in clinical settings (n = 304).[2] Both studies randomized participants into treatment and control groups after all participants had received the first educational session. Treatment group participants then received four additional group educational sessions led by the CHW (Table 1).[1,2]

PLACE AND TIME

Both studies were conducted in New York City. DREAM was conducted from April 2011 to November 2016, and IMPACT was conducted from February 2017 to May 2019.

PERSON

The analytic sample included the subset of South Asian individuals from the DREAM and IMPACT studies with comorbid

TABLE 1— Overview of Study Characteristics: IMPACT and DREAM Studies, New York City, 2011–2019

	IMPACT	DREAM
Disease focus	**Hypertension**	**Diabetes**
Recruitment setting	Community-based primary care practices (n = 14) in New York City primarily serving South Asians	Safety-net hospitals in New York City (n = 2) and community-based primary care practices (n = 2)
Recruitment process	(1) Identified through EHR and mailed a recruitment letter; (2) tabling and outreach at sites; (3) referral by provider	(Same as for IMPACT)
Eligibility criteria	(1) South Asian ethnicity (defined as self-identified Asian Indian, Bangladeshi, Pakistani, Nepali, Sri Lankan, or of Indo-Caribbean descent); (2) hypertension diagnosis through EHR or uncontrolled BP reading; (3) aged 18–85 years; (4) not pregnant at screening	(1) Self-identified as Bangladeshi; (2) physician diagnosis of type 2 diabetes verified through patient medical record; (3) aged 21–85 years
Randomization	After outreach by CHW, consent and completion of session 1	(Same as for IMPACT)
CHW curriculum: group-based educational sessions	5 monthly, 60-minute, group-based health education sessions delivered in English or South Asian language by a CHW using a culturally adapted curriculum over the 6-month study period (treatment); 1 60-minute group-based health education session delivered in English or South Asian language by a CHW using a culturally adapted curriculum at the start of the study period (control)	(Same as for IMPACT)
CHW curriculum: coaching and goal-setting follow-up	10 biweekly follow-up calls for action-planning and goal-setting to improve hypertension management, conducted by CHWs in participants' preferred language using standardized scripts and documentation forms	2 in-person 1-on-1 visits for action-planning and goal-setting to improve diabetes management, conducted by CHWs in participants' preferred language using standardized documentation tools
CHW training	Core competency-based training, 105 hours[3]	(Same as for IMPACT)
CHW characteristics	3 women and 3 men	2 women and 2 men
Languages used to deliver curriculum	Bengali, Punjabi, Urdu–Hindi, English	Bengali, English
Session location	Community-based primary care practices and community organizations	Safety-net hospitals, community-based primary care practices, and community organizations
In-person data collection	Surveys and BP collected at baseline and months 3 and 6, with both treatment and control groups by CHWs	(Same as for IMPACT)

Note. BP = blood pressure; CHW = community health worker; EHR = electronic health record; PCP = primary care practice.

hypertension and type 2 diabetes who had uncontrolled BP (≥ 140/90 mmHg) at screening: 187 individuals from DREAM and 167 individuals from IMPACT.

PURPOSE

Most CHW interventions address risk factors associated with a single morbidity. However, more than two thirds of US adults with diabetes have hypertension, and half are not meeting BP goals despite antihypertensive treatment.[5] The purpose of this analysis was to ascertain whether individuals with comorbid diabetes and hypertension could benefit from a CHW intervention.

IMPLEMENTATION

For both studies, BP measurements were collected by the CHW; in IMPACT, missing follow-up BP measures were obtained directly from patients' medical records. Diabetes diagnosis was self-reported for IMPACT; for DREAM, it was verified by the patient's electronic medical record.

EVALUATION

We compared demographics among the treatment and control groups at baseline using descriptive statistics; Pearson λ^2 tests and two-tailed Student *t* tests were used to determine statistically significant differences ($P < .05$) between the groups. To test within-group differences, we used two-tailed paired *t* tests and McNemar tests. To assess change across groups for each continuous outcome, we ran generalized estimating equation (GEE) models for repeated

TABLE 2— Changes in Blood Pressure and Proportion With Controlled Blood Pressure at Baseline and 6-Month Follow-Up for Treatment and Control Groups, Overall and Stratified by Study: IMPACT and DREAM Studies, New York City, 2011–2019

	Intervention Group (n = 159), Mean ±SD or No. (%)			Control Group (n = 133), Mean ±SD or No. (%)			Intervention Effect or OR	
	Baseline	6-Month	*P*	Baseline	6-Month	*P*	Unadjusted (95% CI)	Adjusted[a] (95% CI)
SBP (mmHg)								
Overall	135.9 ±18.2	130.2 ±14.8	< .001	137.3 ±17.8	137.3 ±18.6	.98	−6.0 (−10.2, −1.9)	−6.2 (−10.4, −2.1)
DREAM	134.3 ±18.3	126.2 ±16.7	< .001	135.7 ±15.6	129.1 ±15.2	.013	−2.3 (−8.6, 4.0)	−2.5 (−8.8, 3.8)
IMPACT	137.2 ±18.0	133.5 ±12.1	.017	138.7 ±19.5	144.6 ±18.4	.007	−9.4 (−14.5, −4.2)	−9.3 (−14.5, −4.2)
DBP (mmHg)								
Overall	82.7 ±11.3	78.5 ±9.0	< .001	81.3 ±11.6	81.3 ±13.3	.1	−4.0 (−6.3, −1.6)	−4.0 (−6.3, −1.7)
DREAM	80.5 ±11.0	76.1 ±10.1	< .001	76.9 ±10.9	74.4 ±12.4	.08	−1.1 (−4.6, 2.4)	−1.1 (−4.6, 2.4)
IMPACT	84.5 ±11.2	80.5 ±7.4	< .001	85.2 ±10.9	87.4 ±10.9	.06	−6.1 (−9.2, −3.1)	−6.1 (−9.1, −3.1)
BP < 140/90								
Overall	76 (47.8)	114 (71.7)	< .001	67 (50.4)	74 (55.6)	.2	1.4 (1.1, 1.8)	1.4 (1.1, 1.8)
DREAM	42 (58.3)	53 (73.6)	< .001	35 (56.5)	46 (74.2)	.07	1.3 (0.9, 2.0)	1.3 (0.8, 1.9)
IMPACT	34 (39.1)	61 (70.1)	< .001	32 (45.1)	28 (39.4)	> .99	1.5 (1.0, 2.2)	1.5 (1.0, 2.3)

Note. BP = blood pressure; CI = confidence interval; DBP = diastolic blood pressure; OR = odds ratio; SBP = systolic blood pressure.

[a]Adjusted for gender and age.

measures, including study arm, time point, and the interaction between study arm and time point. Adjusted models for this complete case analysis included gender and age. The study arm × time point interaction tests the intervention effect, and the B coefficients computed by GEE represent the change in slope within the two study arms over time. For BP control (< 140/90), we ran GEE models using a binomial distribution to estimate odds ratios. We used SAS version 9.4 (SAS Institute, Cary, NC) for analyses.

This was a secondary analysis of two randomized, controlled trials having more than 80% retention. To assess selection bias, we compared participants having six-month BP measurements with those who did not, but there were no significant differences between these groups. We ran models adjusting for session attendance and using 130 over 80 millimeters Mercury as the cutpoint for BP control,[6,7] but inferences were similar for session attendance and nonsignificant for 130 over 80 millimeters Mercury (data not shown). Our intervention was delivered in both clinical and community settings, further supporting generalizability.

Of the 354 individuals with comorbid hypertension and diabetes, 60.7% were female, and the mean age was 58.5 years (SD = 9.6). All were foreign-born, mean years lived in the United States was 13.7 years (SD = 9.9), and 37.4% spoke English very well or well. Most (89%) were married or living with a partner, and 40.8% had less than a high school education. Most were taking diabetes (89.5%) and hypertension (96.6%) medications. There were no statistically significant differences by randomization group. Compared with IMPACT participants, DREAM participants were significantly more likely to be female and to be married, and had higher education (Table A, available as a supplement to the online version of this article at http://www.ajph.org).

Most (n = 292, 82.5%) had complete BP data at baseline and six-month follow-up. We compared participant characteristics among individuals with complete BP versus no BP data at follow-up, and there were no significant differences by group.

Table 2 presents changes in BP between baseline and six-month follow-up among individuals with complete data. In the treatment group, mean systolic BP and diastolic BP decreased significantly over time. No change in systolic BP and diastolic BP was seen for the control group.

GEE models present the difference in slope both within and between the study groups over time. Greater improvement in systolic BP and diastolic BP was seen in the treatment group compared with the control group; the difference in slopes was −6.2 millimeters Mercury (95% confidence interval

[CI] = −10.4, −2.1) and 4.0 millimeters Mercury (95% CI = −6.3, −1.7), respectively, in adjusted analyses.

BP at six months was controlled among a significantly greater percent of individuals in the treatment group (71.7%) than in the control group (55.6%), when BP control was defined as lower than 140 over 90 millimeters Mercury. The odds ratio of controlled BP from baseline to six months for the treatment group was 1.4 times the odds ratio for the control group in adjusted analysis (95% CI = 1.1, 1.8). When BP control was defined as lower than 130 over 80, comparisons between intervention and control groups were nonsignificant.

We conducted a stratified analysis by DREAM and IMPACT study populations and found that the magnitude of results was greater in the IMPACT population for reductions in systolic BP and diastolic BP, although treatment group participants in both studies experienced reductions (Table 1).

Limitations include that the two studies had some differences by demographic characteristics, and some differences were noted in stratified analyses conducted by study. However, study differences were in magnitude only, indicating that both interventions improved BP control. Our intervention was evaluated in an urban setting, but results from rural settings[8] and lower-income countries[9] suggest that findings may be generalizable.

ADVERSE EFFECTS

We are not aware of any adverse events of this program, but such considerations are critically important for the development and implementation of any new behavioral intervention program.

SUSTAINABILITY

The CHWs delivering both interventions were hired through grant resources. However, both projects employed a community-engaged approach and included partnerships with diverse stakeholders, including community organizations, clinics, and payers, which facilitated the sustainability of the workforce. For example, several project CHWs were subsequently supported by the New York University Langone Community Service Plan to continue providing BP and diabetes education in faith-based settings. In addition, we are pursuing sustainability funding for CHW programs in partnership with a Medicaid payer. Finally, additional funding was acquired, and CHWs are currently engaged in another study.

PUBLIC HEALTH SIGNIFICANCE

Among South Asian immigrants with multiple chronic diseases, this CHW intervention led to clinically meaningful BP reductions[10] compared with the control group. The CHW intervention also improved the proportion of participants with controlled BP, defined as lower than 140 over 90 millimeters Mercury. These findings are consistent with a recent meta-analysis (standardized mean differences for systolic BP and diastolic BP = –0.32 and –0.35, respectively).[9]

We demonstrated that an integrated CHW-led intervention targeting chronic disease reduction among South Asians in New York City can significantly reduce BP in patients with comorbid diabetes and hypertension. Health systems and primary care practices aiming to improve the care of immigrant and minority patients with multiple comorbidities may consider this study as supportive evidence for the addition of trained CHWs. AJPH

ABOUT THE AUTHORS

Jeannette M. Beasley is with the Department of Medicine and Laura C. Wyatt, Jennifer Zanowiak, Chau Trinh-Shevrin, and Nadia S. Islam are with the Department of Population Health, New York University School of Medicine, New York. Megha Shah is with the Department of Family and Preventive Medicine, Emory University, Atlanta, GA.

CORRESPONDENCE

Correspondence should be sent to Jeannette M. Beasley, New York University School of Medicine, Division of General Internal Medicine and Clinical Innovation, 462 First Ave CD 673, New York, NY 10016 (e-mail: jeannette.beasley@nyulangone.org). Reprints can be ordered at http://www.ajph.org by clicking the "Reprints" link.

PUBLICATION INFORMATION

Full Citation: Beasley JM, Shah M, Wyatt LC, et al. A community health worker–led intervention to improve blood pressure control in an immigrant community with comorbid diabetes: data from two randomized, controlled trials conducted in 2011–2019. *Am J Public Health*. 2021;111(6):1040–1044.

Acceptance Date: January 31, 2021.

DOI: https://doi.org/10.2105/AJPH.2021.306216

CONTRIBUTORS

J. M. Beasley, L. C. Wyatt, and N. S. Islam drafted the manuscript. J. Zanowiak, C. Trinh-Shevrin, and N. S. Islam conceptualized and conducted the interventions. L. C. Wyatt analyzed the data. All authors edited and approved the manuscript.

ACKNOWLEDGMENTS

This study was supported by the Centers for Disease Control and Prevention (grant U48DP001904) and the National Institutes of Health (grant 3U54MD00053817S1). NI's time is partially supported by the National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases (grants R01DK110048-01A1, R18DK110740 and P30 DK111022R01DK11048), National Institute on Minority Health and Health Disparities (grant U54MD000538), National Heart, Lung, and Blood Institute (grant 1UG3HL151310), and National Center for Advancing Translational Science (grant UL1TR001445). We gratefully acknowledge IMPACT and DREAM community health workers, HealthFirst, and our network of primary care practice sites for their partnership in implementing the intervention.

CONFLICTS OF INTEREST

The authors have no conflicts of interest to disclose.

HUMAN PARTICIPANT PROTECTION

These studies were approved by the New York University Institutional Review Board.

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Delivering Preexposure Prophylaxis to People Who Use Drugs and Experience Homelessness, Boston, MA, 2018–2020

Katie B. Biello, PhD, MPH, Angela R. Bazzi, PhD, MPH, Seamus Vahey, BA, Mary Harris, BA, Leah Shaw, MPH, and Jennifer Brody, MD

Despite high need, HIV preexposure prophylaxis (PrEP) utilization among people who use drugs (PWUD) remains low. Boston Health Care for the Homeless Program implemented an innovative "low-threshold" PrEP Program for PWUD experiencing homelessness in Boston, Massachusetts. From October 1, 2018 to February 29, 2020, 239 clients were linked to PrEP services, and 152 were prescribed PrEP (mean = 8.9/month), over twice the number of PrEP prescriptions over the previous 12 months (n = 48; mean = 4/month). The cumulative probability of remaining on PrEP for 6 months was 44% (95% confidence interval = 36%, 52%). (*Am J Public Health*. 2021;111:1045–1048. https://doi.org/10.2105/AJPH.2021.306208)

Recent HIV outbreaks and clusters among people who use drugs (PWUD) and experience homelessness threaten to reverse previous success in lowering HIV incidence among PWUD in the United States. As such, there is an urgent need to expand access to HIV prevention options for PWUD experiencing homelessness. Antiretroviral preexposure prophylaxis (PrEP) is an efficacious and recommended daily HIV prevention medication; however, despite high levels of need, PrEP utilization in this socially marginalized population remains low.[1] Among several important challenges to PrEP implementation for PWUD experiencing homelessness[2] is the widespread belief among providers, likely grounded in overlapping stigmas, that PWUD are not good PrEP candidates.[3] Moreover, PWUD have described multilevel perceived barriers to PrEP use—for example, competing health needs, provider stigma, and lost or stolen medications resulting from homelessness.[2] However, studies indicate that PWUD can adhere to daily medications (e.g., for HIV and hepatitis C virus treatment) with appropriate supports and programming innovation.[2,4]

INTERVENTION

Prior to October 1, 2018, at Boston Health Care for the Homeless Program (BHCHP), PrEP care was provider initiated and required in-person clinic visits with multiple steps over multiple days to receive a prescription (e.g., labs drawn, results received, prescription provided) and follow-up monitoring with a provider. Additionally, systematic navigational and adherence supports were lacking.

In 2018, in response to increasing rates of HIV transmission locally,[5,6] BHCHP implemented an innovative PrEP Program for PWUD experiencing homelessness. This PrEP Program utilizes a "low threshold" care model, which is characterized by highly accessible, harm reduction–oriented approaches (e.g., care is not contingent on abstinence from substance use). One key innovation involves intensive, flexible PrEP navigation services, which include the following: obtaining guideline-recommended intake and follow-up laboratory data through outreach-based phlebotomy; following up closely with clients through phone- and street-based outreach; accompanying clients to appointments; assisting with medication pickup and delivery; and making referrals to other services as needed or desired. Navigation intensity is tailored to clients' needs but often involves weekly check-ins and lab follow-ups at four weeks and every three months thereafter. A panel of "PrEP champions" (i.e., clinicians) and a PrEP nurse provide brief in-person or phone visits to review clients' assessments and prescribe same-day PrEP when appropriate. Clinician visits are scheduled every three months, but missed appointments do not necessitate medication discontinuation if appropriate lab follow-up can be performed. Additional innovations include safe same-day starts (prior to HIV status confirmation), short-interval

prescriptions (seven to 14 days, to mitigate impact of lost or stolen medication and support adherence through more frequent contact), and on-site medication storage at BHCHP and affiliated venues.

For more details on the program, please contact the authors.

PLACE AND TIME

BHCHP is a federally qualified health center serving more than 10 000 individuals experiencing homelessness in Suffolk County, Massachusetts, an Ending the HIV Epidemic priority jurisdiction. BHCHP utilizes highly accessible, harm reduction–oriented approaches to care.

BHCHP's PrEP Program was initiated inside the health center and in nonmedical settings (e.g., homeless shelters, syringe service programs, street venues) on October 1, 2018, and is ongoing; we present data through February 29, 2020.

PERSON

Candidates for BHCHP's PrEP Program include individuals with sexual (e.g., transactional sex, condomless sex) or drug-using (e.g., syringe sharing) behaviors that increase HIV risk, who are referred by BHCHP HIV counselors, clinicians, or partner agencies. Client sociodemographics are described in Table 1.

PURPOSE

The overarching goal of BHCHP's PrEP Program is to increase PrEP use among PWUD experiencing homelessness, eventually decreasing HIV incidence. We hope that this report can motivate and inform other programs regionally and nationally, especially where HIV clusters and outbreaks have emerged in this marginalized population.

IMPLEMENTATION

BHCHP provides PrEP navigation and low-threshold care by staff trained in engaging PWUD experiencing homelessness, and its PrEP Program was built on long-standing relationships with outreach staff based in shelters and harm-reduction interventions to facilitate building trust with clients.

EVALUATION

For this posthoc evaluation of BHCHP's PrEP Program, we drew on pharmacy and electronic medical records to confirm PrEP medication pickup, and on program-specific tracking information from the first 17 months of the program's implementation. From October 1, 2018 to February 29, 2020, BHCHP linked 239 PWUD experiencing homelessness to PrEP services (i.e., referred to PrEP navigator), of whom 152 (64%) were prescribed PrEP (mean = 8.9 prescriptions/month), more than 2 times the mean number of PrEP prescriptions in the year preceding implementation of this low-threshold program (n = 48; mean = 4.0/month).

Of those prescribed PrEP and who had reached each respective milestone, 85% (129/152) picked up their initial prescription, and 67% (96/144) picked up a refill at three weeks, 40% (42/105) at three months, and 25% (22/88) at six months. Using the Kaplan–Meier method, we estimated that the cumulative probability of obtaining PrEP prescriptions for six months was 44% (95% confidence interval = 36%, 52%; Figure 1).

Notably, we could not collect data on clients who may have received PrEP

TABLE 1— Patient Characteristics: Boston Health Care for the Homeless Preexposure Prophylaxis Program, Boston, MA, October 2018–February 2020

	Mean ±SD or No. (%)
Age, y	38.5 ±9.3
Gender	
Male	138 (57.7)
Female	77 (32.2)
Transgender female	21 (8.8)
Nonbinary	1 (0.4)
Race/ethnicity	
Non-Hispanic White	139 (58.2)
Non-Hispanic Black	33 (13.8)
Hispanic/Latino/a	51 (21.3)
Other/unknown	16 (6.7)
Primary language	
English	222 (92.8)
Spanish	16 (6.8)
Vietnamese	1 (0.4)
History of injection drug use	169 (70.6)
Current primary care provider at BHCHP	170 (71.1)

Note. BHCHP = Boston Health Care for the Homeless Program. The sample size was n = 239.

outside of BHCHP (though this is uncommon), did not collect adherence data, and were limited in the data available in the years leading up to this program because detailed tracking was initiated as part of the program.

ADVERSE EFFECTS

There were no episodes of HIV seroconversion with development of drug resistance or flares of chronic hepatitis B infections associated with the PrEP Program. Other potential social or emotional adverse events were not systematically collected.

SUSTAINABILITY

BHCHP implemented an innovative "low threshold" PrEP Program for PWUD experiencing homelessness. This program had rates of PrEP initiation (i.e., initial prescriptions picked up) and persistence (i.e., prescription refills over six months) comparable to those documented among other populations, including among men who have sex with men attending sexual health clinics, a group for which PrEP has been targeted for nearly a decade.[7] Our findings suggest that BHCHP's innovative strategies can successfully engage this population in PrEP care. Despite this success and the efforts of the PrEP navigators, rates of PrEP discontinuation remained high, a pattern that has been seen with other treatments (e.g., buprenorphine). We did not collect reasons for PrEP discontinuation from the PWUD sample; however, the PrEP navigators report that high levels of mobility and PrEP interruptions due to incarceration and drug treatment were common reasons for disengagement.

Because of its initial success, the BHCHP PrEP Program is ongoing. To mitigate current and future HIV outbreaks, these approaches should be considered in a range of service settings (e.g., syringe service programs, mental health treatment programs, shelters), and should be accompanied with other harm reduction–focused interventions such as low barrier access to medications for opioid use disorder, wound care, and viral hepatitis vaccination and treatment. Moreover, this program relied on a full-time PrEP navigator; as such, local, state, and federal public health departments must invest resources in such programs to ensure sustainability and advocate for making PrEP navigation a billable service.

PUBLIC HEALTH SIGNIFICANCE

This evaluation adds to the growing literature indicating that PWUD can successfully engage in PrEP care when it is provided in low barrier settings with appropriate supports. Clinical providers should not assume that PWUD experiencing homelessness are uninterested in or unable to use PrEP. Funding for PrEP navigation for vulnerable populations should be expanded in both clinical and nonclinical settings where PWUD seek care, and PWUD should be better represented in research on PrEP and other emerging biomedical HIV prevention technologies. AJPH

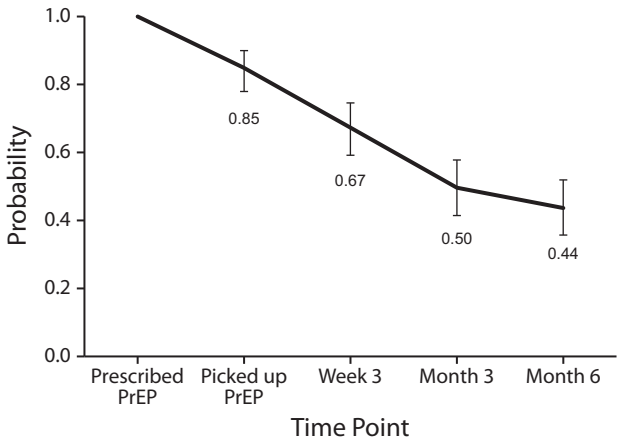

FIGURE 1— Cumulative Probability of Picking Up Preexposure Prophylaxis (PrEP) Prescription and Remaining on PrEP (if Prescribed PrEP) Over 6 Months: Boston Health Care for the Homeless PrEP Program, Boston, MA, October 2018–February 2020

Note. Error bars = 95% confidence intervals. The sample size was n = 239.

ABOUT THE AUTHORS

Katie B. Biello is with the School of Public Health, Brown University, Providence, RI. Angela R. Bazzi is with the School of Public Health, Boston University, Boston, MA. Seamus Vahey, Mary Harris, Leah Shaw, and Jennifer Brody are with the Boston Healthcare for the Homeless Program, Boston.

CORRESPONDENCE

Correspondence should be sent to Katie B. Biello, Brown University School of Public Health, 121 South Main St, Box G-S121-8, Providence, RI 02912 (e-mail: katie_biello@brown.edu). Reprints can be ordered at http://www.ajph.org by clicking the "Reprints" link.

PUBLICATION INFORMATION

Full Citation: Biello KB, Bazzi AR, Vahey S, Harris M, Shaw L, Brody J. Delivering preexposure prophylaxis to people who use drugs and experience homelessness, Boston, MA, 2018–2020. *Am J Public Health*. 2021;111(6):1045–1048.

Acceptance Date: January 19, 2021.

DOI: https://doi.org/10.2105/AJPH.2021.306208

CONTRIBUTORS

S. Vahey, M. Harris, L. Shaw, and J. Brody contributed to the design and implementation of the research, K. B. Biello led the analysis of the results. K. B. Biello and A. R. Bazzi led the writing of the manuscript. All authors reviewed and approved drafts of the manuscript.

ACKNOWLEDGMENTS

This work was supported by the National Institutes of Health (NIH; grants K01DA043412, P30AI042853, and R01DA051849).

An earlier version of this analysis was presented as a poster (#LBPEE45) at the 23rd International AIDS Conference, July 6–10, 2020.

Note. The content is solely the responsibility of the authors and does not necessarily represent the official views of the NIH.

CONFLICTS OF INTEREST

The authors have no conflicts of interest to declare.

HUMAN PARTICIPANT PROTECTION

This study was reviewed and determined to be exempt by the Boston University Institutional Review Board because data were obtained from secondary sources.

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The Societal Value of Vaccination in the Age of COVID-19

David E. Bloom, PhD, Daniel Cadarette, and Maddalena Ferranna, PhD

See also Morabia, p. 982, and the Vaccines: Building Long-Term Confidence section, pp. 1049–1080.

In recent years, academics and policymakers have increasingly recognized that the full societal value of vaccination encompasses broad health, economic, and social benefits beyond avoided morbidity and mortality due to infection by the targeted pathogen and limited health care costs. Nevertheless, standard economic evaluations of vaccines continue to focus on a relatively narrow set of health-centric benefits, with consequences for vaccination policies and public investments.

The COVID-19 pandemic illustrates in stark terms the multiplicity and magnitude of harms that infectious diseases may inflict on society. COVID-19 has overtaxed health systems, disrupted routine immunization programs, forced school and workplace closures, impeded the operation of international supply chains, suppressed aggregate demand, and exacerbated existing social inequities.

The obvious nature of the pandemic's broad effects could conceivably convince more policymakers to identify and account for the full societal impacts of infectious disease when evaluating the potential benefits of vaccination. Such a shift could make a big difference in how we allocate societal resources in the service of population health and in how much we stand to gain from that spending. (*Am J Public Health*. 2021;111:1049–1054. https://doi.org/10.2105/AJPH.2020.306114)

There is a rapidly growing body of evidence demonstrating that vaccination yields sizable and diverse health, economic, and social benefits, including herd protection, increased work hours and productivity, enhanced cognitive function among healthy children, and potentially improved social equity. Despite increasing recognition of vaccination's full value, standard economic evaluations in health systems around the world typically focus on a relatively narrow set of health-centric benefits. This has consequences for decisions made by public authorities regarding vaccination funding, distribution, and reimbursement.

The staggering health and economic effects of COVID-19 (and of the nonpharmaceutical interventions implemented to control it) show the limits of such evaluation methods. This deficiency leads to underestimating the value of countermeasures, including vaccines, against both endemic and epidemic infectious diseases. Here we discuss the importance of adopting a broad societal perspective as an appropriate standard for health technology assessment and the potential role of COVID-19 in advancing this perspective.

THE STANDARD (NARROW) APPROACH TO VACCINE EVALUATION

Standard economic evaluations of vaccination typically rely on health-centric cost-effectiveness analyses and focus on 2 sets of benefits: (1) the direct health benefits of vaccination (e.g., the number of avoided deaths or the number of quality-adjusted life-years gained) for those who are immunized and (2) net reductions in health care costs resulting from the decreased need for treatment of disease caused by the target pathogen.[1] A vaccine being assessed under such an approach is considered cost effective, and therefore sufficiently valuable to merit allocation of public resources, if the health benefits per dollar spent, net of health care cost savings, are sufficiently high (e.g., if they are above a prespecified threshold or if they rank above alternative uses for health sector funds and fit within the budget).[2]

This narrow health-centric approach to economic evaluation falls short of capturing the full range of health, economic, and social benefits of vaccination.[3] Recent empirical research has shown that these benefits can be sizable in magnitude and that properly accounting for them may significantly change the way vaccines are valued in

certain contexts. In fact, failing to consider the broad benefits of vaccination may translate into socially inefficient levels of resources being devoted to vaccine development, manufacturing, and delivery. Adopting a broader societal perspective could help address the gap between the narrow health benefits included in standard evaluations and the wider benefits vaccination actually confers, leading to better-informed vaccine investment, distribution, recommendation, and reimbursement decisions. In the following sections, we review some of the broader benefits of vaccination and how they relate to COVID-19.

THE BROAD SOCIETAL PERSPECTIVE

The broad benefits of vaccination fall into 3 categories: (1) health benefits beyond reductions in mortality and morbidity directly attributable to preventing cases of the vaccine-targeted disease among those who have been immunized, (2) economic benefits beyond direct reductions in treatment costs, and (3) social benefits. Broad benefits may accrue to immunized individuals, their families and households, the health sector, or society as a whole.

Examples of broader health benefits include prevention of nosocomial infections among hospitalized patients, prevention of complications and long-term sequelae such as reduced lung capacity among children who have suffered from pneumococcal pneumonia, and, potentially, prevention of such complications and sequelae among COVID-19 patients.[4] In addition, even vaccines that are less than 100% effective in preventing disease may reduce the severity of illness when vaccinated individuals become infected. There is also evidence that some vaccines protect against pathogens beyond their intended targets; for example, measles vaccination can protect against the loss of acquired immune memory that may occur with measles infection.[5] In addition, vaccination can preserve individuals' microbiomes (i.e., prevent dysbiosis) and reduce antimicrobial resistance by decreasing the need for antimicrobial treatment.[6,7]

Narrowly focused, traditional cost-effectiveness analyses also sometimes neglect the herd protection conferred by vaccination. Herd protection refers to a phenomenon in which nonvaccinated individuals gain some protection against disease caused by the target pathogen because vaccination reduces the likelihood of transmission in their community.

By improving people's health, vaccination also contributes to enhanced individual and societal economic well-being.[8] Vaccinated adults are more likely to participate in the labor force and tend to work more hours and be more productive than their unvaccinated counterparts.[9] In addition, vaccinated adults of retirement age may participate in economically valuable nonmarket activities such as looking after grandchildren and volunteering.[10] On average, vaccinated children attend school more regularly, have better cognitive function, and attain higher levels of schooling than otherwise comparable unvaccinated children.[11] Ultimately, all of these impacts translate into higher individual incomes and better lifelong opportunities.

Vaccination can also have significant positive economic effects at the household level. The increased income stemming from the educational, labor force participation, and productivity gains associated with vaccination can lead to more savings and accumulated wealth. Vaccination can also protect against catastrophic health care spending and the risk of falling into poverty, especially in countries without universal health care coverage.[12] In addition, vaccines generate health and economic gains for informal caregivers, for example by promoting parental peace of mind and preventing unpaid leaves of absence to care for ill relatives.

The economic impacts of vaccination may also be felt at the macroeconomic level.[13] Vaccination can increase tax receipts by positively affecting labor force participation and productivity and reduce governmental spending by protecting population health. A healthy working population is also able to attract more foreign direct investment, which is often accompanied by technology transfer and trade, all of which serve to promote economic growth.

Moreover, in low-income settings, improvements in children's survival through vaccination tend to reduce fertility rates, as couples realize they can reach their desired number of surviving children with fewer pregnancies and as the opportunity cost of child rearing increases with economic development. In turn, reduced fertility allows countries to escape the burden of youth dependency and to increase living standards for their people, thereby realizing a "demographic dividend."[14] Vaccination against pathogens with outbreak potential can also help protect specific economic sectors, such as travel, hospitality, brick-and-mortar retail, transportation, and entertainment, that are particularly vulnerable to shutdowns or diminished patronage caused by fear of disease spread.[15]

Finally, vaccination may have significant social benefits. At the household level, vaccination can have positive intergenerational effects by preventing premature disability or death among parents and grandparents who care for

children. For example, human papillomavirus vaccination plays an important role in preventing premature mortality among mothers.[16] At the population level, vaccination can reduce inequalities and promote social equity insofar as it prevents diseases that disproportionately harm those who are socioeconomically disadvantaged.

The call to assess vaccination from a full societal perspective is not specific. The same approach can and should be applied to all health interventions, including medical devices, pharmaceutical drugs, and the reform of health care institutions. It should also be applied to nonhealth interventions, such as schooling, transport, and energy, to support transparent and fully rational decisions about the best use of constrained public resources.

However, relative to most other health interventions, vaccination tends to be disadvantaged by the narrow health perspective that dominates health technology assessment. For example, the narrow perspective does not reflect the time horizon for enjoying the benefits of avoiding childhood infectious disease, which tends to be much longer than for the prevention and treatment of disease among older people. It also neglects that relatively large populations can benefit from vaccines and that vaccination against infectious diseases tends to have substantially larger externality benefits than interventions against noncommunicable diseases. In addition, many nonhealth interventions, such as environmental policies, are already evaluated from a societal perspective.

Several economic tools are available to evaluate vaccination from a societal perspective.[1,6] The range of vaccine impacts included in cost-effectiveness analyses can be broadened to take into account indirect health gains resulting from herd protection as well as avoided economic consequences such as transportation or day care costs. Another possibility is benefit-cost analysis (BCA), in which all outcomes, including health outcomes, are quantified in monetary terms, summed, and compared with the costs of vaccination. An advantage of BCA relative to cost-effectiveness analysis is that it expresses all impacts in a single metric (e.g., dollars), thereby facilitating inclusion and comparison of all relevant costs and benefits.

One challenge with respect to BCA is monetizing impacts that are not naturally monetary. A large and growing literature has been devoted to resolving this challenge, for example by estimating the value of a statistical life.[17] Nevertheless, there may be situations in which it is impractical to measure and monetize all relevant vaccination impacts because of lack of data or methodological constraints. There are also ethical objections to BCA on the grounds that it accords higher value to interventions that prevent or treat diseases affecting people with higher incomes unless equity concerns are explicitly taken into account.

COVID-19 AND THE VALUE OF VACCINATION

The direct health effects of the COVID-19 pandemic are substantial, with a global death toll of more than 2.7 million people as of March 2021.[18] But the pandemic also drives home the point that the effects of infectious disease encompass more than the poor health of infected individuals.

With respect to broad health outcomes, COVID-19 has overburdened some health systems or threatened to do so, resulting in delay or cancellation of non-COVID-19-related visits.[19] In certain locales such as New York City, which suffered a large outbreak early in the pandemic, reduced willingness to seek care out of fear of infection has also been apparent.[20] In addition, people who have lost private insurance coverage as a result of COVID-19-induced unemployment may be refraining from interacting with the health system—at least in the United States—as a result of financial concerns.[21]

COVID-19 has disrupted routine immunization activities across the country income spectrum, which threatens to elevate rates of vaccine-preventable diseases and their physical, mental, and cognitive health sequalae throughout the life cycle. For example, the World Health Organization, the United Nations Children's Fund, and Gavi reported that the pandemic had forced 80 million children to forgo vaccine protection against one or more pathogens, at least temporarily.[22] This corresponds to roughly 60% of the world's annual birth cohort.[23]

The economic damage wrought by COVID-19 has been well documented. The pandemic has forced countries to close workplaces and schools, driving massive unemployment and permanent business closures and increasing learning gaps between rich and poor children.[24] In the United States, nearly 50 million workers filed for unemployment over the 16-week period after a national state of emergency was declared in mid-March 2020.[25]

The pandemic has also impeded the operation of international supply chains, suppressed aggregate demand, and exacerbated existing inequities.[26] In October 2020, the World Trade Organization projected that global trade could fall by roughly 9% for the year as a result of the pandemic.[27] Likewise, the International Monetary Fund projected a global economic contraction of 4.4%

for the year (4.3% in the United States), with some countries, such as Italy, Spain, and India, anticipated to experience more than 10% reductions in gross domestic product.[28] The COVID-19 pandemic is expected to have long-lasting consequences, with economies slowly returning to prepandemic growth trajectories once the pandemic is over and potentially with permanent changes in our way of living (e.g., more teleworking and fewer business trips).[29]

Negative social impacts of COVID-19 have also been widely experienced.[30] They include, for instance, loss of social connections, strain on families, postponement or cancellation of once-in-a-lifetime ceremonies such as graduations and marriages, and preclusion of personal contact with sick or dying loved ones. Health care workers, in particular, have suffered high rates of COVID-19-related stress and occupational burnout. School closures in some areas may stunt social development among children in addition to harming their future economic prospects.

Many of these health, economic, and social impacts are mediated by or dependent on political and social responses to the disease. For example, delayed and insufficient testing in the United States has amplified certain impacts (e.g., unchecked local spread of disease) relative to countries that implemented effective test-and-trace regimens early in the pandemic.

The COVID-19 pandemic makes it obvious that infectious diseases have broad impacts beyond their direct health impacts. Given the scale of morbidity and mortality directly attributable to COVID-19 alone, accounting for these broad impacts almost certainly would not make a meaningful difference in decisions with respect to COVID-19 vaccine development, manufacturing, and delivery: the prevailing wisdom is virtually assured to be something along the lines of "invest whatever it takes," whether or not anything beyond direct health outcomes is taken into consideration.[31]

However, the fact that the COVID-19 pandemic illustrates in stark terms the multiplicity and magnitude of harms that infectious diseases can inflict on society could plausibly have implications for future investment decisions regarding vaccination in general. If COVID-19 convinces more policymakers to identify and account for the full health, economic, and social impacts of infectious disease when evaluating the potential benefits of vaccination and other relevant interventions, this could make a big difference in how we allocate societal resources in the service of population health and in how much we stand to gain from that spending.

The COVID-19 pandemic has also highlighted 2 key aspects of infectious diseases that should be factored into assessments of the value of vaccination. First, the value of most vaccines depends on the proportion of the population with natural immunity to the disease and the rate at which this proportion is changing (e.g., whether it is endemic or we have an outbreak, whether natural infection does or does not confer substantial immunity, whether we are close to achieving meaningful herd protection or far from doing so). It also depends on the availability of alternative countermeasures and policies to control or mitigate the pandemic. For example, if an effective and relatively inexpensive treatment for COVID-19 were identified before a vaccine was developed or becomes widely available globally, the demand for a vaccine and its value would necessarily be reduced. Likewise, the value of a specific vaccine may depend on the properties of competitor vaccines.

Moreover, in the absence of a vaccine and of extensive virology and serology testing for active or past infection by the virus that causes COVID-19, countries may rely on widespread, untargeted lockdowns and physical and social distancing measures to curtail the spread of the infection. The high costs of these alternative policies should clearly be added to the benefits of vaccination.

Second, the distribution of disease impacts and vaccination benefits may have a bearing on the way we assess overall value. In the case of COVID-19, the risks of infection and mortality and the pandemic's economic and social consequences fall disproportionately on certain groups. For instance, fatality risks are higher among older people, whereas economic and educational disruptions primarily affect younger adults and children. The risk of being infected is greater for individuals of low socioeconomic status who cannot work from home and tend to live in more crowded housing; the economic and social costs of the pandemic (e.g., unemployment and challenges with online learning) are also felt mainly by those of low socioeconomic status absent government intervention.[32] In the United States, infections and deaths have occurred disproportionately among minority groups, especially African Americans, Hispanics, and Native Americans.[33]

Traditional methods used in health technology assessments often neglect the distributional implications of interventions such as vaccines, as well as the distribution of their costs (e.g., whether vaccine doses are paid for out of pocket or are fully covered by tax-supported national programs or social insurance). Other factors being equal,

expanded access to and more equitable distribution of vaccination and its benefits (including willingness to receive the vaccine) will increase aggregate value.

CONCLUSIONS

The COVID-19 pandemic is an epic catastrophe for global well-being. In addition to imposing tremendous health, economic, and social harm, COVID-19 could spur health researchers and policymakers around the world to significantly rethink the way they understand and quantify the value of infectious disease countermeasures, especially vaccination. Insofar as this shift leads societies to invest more money in the development, production, and widespread delivery of vaccines, theoretical and empirical research indicate that we will naturally reap greater societal benefits as a consequence.

It is also plausible that the effects of COVID-19 on people's daily existence will promote greater social acceptance for and appreciation of the value of vaccination. However, this is not certain. Evidence from the psychology and behavioral economics literature shows that simply presenting new factual information that counters antivaccine sentiments entrenched in some segments of the population is unlikely to be effective and may even backfire.[34] Beyond hardline "anti-vaxxers," the implications of the pandemic for vaccine acceptance depend on the events of the coming months and years. Public acceptance of a COVID-19 vaccine likely will depend in part on the transparency and trustworthiness of the political leaders charged with overseeing the government's role in the vaccine research and development, manufacturing, and delivery process and with recommending vaccination. It also surely will depend on legitimate assessments of the safety profiles of any vaccines brought to market.

Although there is obviously a tremendous need to produce effective COVID-19 vaccines as quickly as possible, compressing the timeline for vaccine clinical trials, regulatory reviews, and widespread distribution is not altogether without risks. Indeed, hastening the approval and distribution of a COVID-19 vaccine that later proves to be unsafe or ineffective could have disastrous public health consequences, including undermining public confidence in vaccination generally.

To the extent that vaccine hesitancy persists or grows in force during and after the pandemic, it may substantially reduce the value of vaccination by decreasing the resulting aggregate benefits (e.g., because fewer cases and deaths are avoided) and increasing aggregate costs (e.g., if additional public expenditure to promote vaccine uptake is required). Ensuring that people have adequate information, giving them the tools to process it accurately, and ensuring that they have a say in their health are key elements in reducing vaccine hesitancy. Providing evidence of the broad benefits of vaccination and properly including these benefits in economic evaluations are also part of this process.

Given the high value that accompanies widespread and equitable access to vaccination, society would benefit from increased investment in mechanisms designed to advance vaccine access. For example, it may be appropriate to increase funding for Gavi, which has subsidized the purchase and delivery of vaccines for poor countries since 2000. In addition, during the pandemic, Gavi, the World Health Organization, and the Coalition for Epidemic Preparedness Innovations are co-leading COVAX, an international facility that is pooling resources from countries across the income spectrum to make advanced purchase commitments for COVID-19 vaccines and ensure that a portion is available for lower-income countries.[35] COVAX, or a similar initiative, could be maintained and expanded after the pandemic to incentivize the development and production of future vaccines against both epidemic and endemic pathogens and ensure equitable access.

Tools for making vaccine investment decisions based on a full societal perspective are available and are already being used in some countries, including Norway and the Netherlands.[36] What remains needed in many contexts, in addition to appropriate data for the implementation of those tools, is the political will to adopt them. The COVID-19 pandemic, and the light it is shedding on the broader societal effects of infectious disease, could be a game changer with respect to convincing national health authorities and other policymakers of the importance of recognizing the full value of vaccination. AJPH

ABOUT THE AUTHORS

The authors are with the Department of Global Health and Population, Harvard T. H. Chan School of Public Health, Boston, MA.

CORRESPONDENCE

Correspondence should be sent to David E. Bloom, PhD, c/o Harvard T. H. Chan School of Public Health, 665 Huntington Ave, Boston, MA 02115 (e-mail: dbloom@hsph.harvard.edu). Reprints can be ordered at http://www.ajph.org by clicking the "Reprints" link.

PUBLICATION INFORMATION

Full Citation: Bloom DE, Cadarette D, Ferranna M. The societal value of vaccination in the age of COVID-19. *Am J Public Health*. 2021;111(6): 1049–1054.

Acceptance Date: December 11, 2020.

DOI: https://doi.org/10.2105/AJPH.2020.306114

CONTRIBUTORS

All of the authors contributed to research and analyses and to writing and editing the article.

ACKNOWLEDGMENTS

This work was supported by the Value of Vaccination Research Network (VoVRN) through a grant from the Bill & Melinda Gates Foundation (OPP1158136).

We thank Robert Steinglass for helpful comments. We also thank the reviewers and editors for their feedback and assistance.

Note. The content is solely the responsibility of the authors and does not necessarily reflect the views of the VoVRN or the Bill & Melinda Gates Foundation.

CONFLICTS OF INTEREST

D. E. Bloom. has received travel grants, grants, or personal fees from Pfizer, GSK, Sanofi Pasteur, and Edwards Life Sciences.

HUMAN PARTICIPANT PROTECTION

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

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"First Do No Harm": Effective Communication About COVID-19 Vaccines

David A. Broniatowski, PhD, SM, Mark Dredze, PhD, and John W. Ayers, PhD, MA

ABOUT THE AUTHORS

David A. Broniatowski is with the Institute for Data, Democracy, and Politics, and the Department of Engineering Management and Systems Engineering, School of Engineering and Applied Science, The George Washington University, Washington, DC. Mark Dredze is with the Department of Computer Science, Johns Hopkins University, Baltimore, MD. John W. Ayers is with the Division of Infectious Diseases and Global Public Health, Department of Medicine, and the Center for Data Driven Health, Qualcomm Institute, Department of Engineering, University of California San Diego, La Jolla.

See also Morabia, p. 982, and the Vaccines: Building Long-Term Confidence section, pp. 1049–1080.

With effective COVID-19 vaccines in hand, we must now address the spread of information on social media that might encourage vaccine hesitancy. Although misinformation comes in many forms,[1] including false claims, disinformation (e.g., deliberately false information), and rumors (e.g., unverified information), social media companies now seek to interdict this objectionable content—for the first time in their history—by removing content explicitly containing conspiracy theories and false or debunked claims about vaccines. Concurrently, social media users routinely disparage "anti-vaxxers" online, conflating a large group of vaccine-hesitant individuals who may be using social media to seek information about vaccination with a potentially much smaller group of "vaccine refusers."[2] Both strategies could cause more harm than good, necessitating a change in strategy informed by a large body of scientific evidence for making online communications about COVID-19 vaccines more effective.

WHEN CONTENT REMOVAL BACKFIRES

On December 3, 2020, Facebook stated that they would start removing false claims about COVID-19 vaccines. On December 16, 2020, Twitter followed suit. The scope of Facebook's content removal has since expanded, stating that they would remove false claims about vaccines more broadly on February 8, 2021. Other social media companies have taken a broader stance to remove even more content.

Although well intentioned, some evidence suggests that such censorship can be ineffective and counterproductive, raising questions regarding whether the risks outweigh the benefits: Can platforms effectively define and remove offending content? Does its removal actually reduce exposure to information that might encourage vaccine hesitancy? Does this censorship change how the public appraises removed information? How will this censorship be interpreted? We can begin to answer these questions by examining other areas where content removal has been applied.

Historically, content violating governing laws (e.g., child pornography) or platforms' terms of service has been removed haphazardly. Purveyors of this content have, on occasion, also been suspended inconsistently. For instance, one study found that roughly 10% of accounts on Twitter are bots that violate the platform's terms of service.[3] It follows that removing content about vaccines would similarly miss some objectionable content. On the other hand, acceptable content (e.g., a sincere question from a vaccine-hesitant person or a response to vaccine misinformation) might also be deleted as collateral damage. For example, Facebook was forced to apologize to an African American activist after her account was erroneously deleted as she tried to address racism on her Facebook page.[4]

Even if the algorithms were perfect, social media companies lack formal training and clear accountability mechanisms for differentiating between blatantly false content and legitimate scientific uncertainty. In general, platforms' policies for content removal are perceived to be unfair, such as when a 2017 ProPublica report found that Facebook's hate speech censorship rules ". . . tend to favor elites and governments over grassroots activists and racial minorities."[5] When censorship cannot be carried out with precision, it can discourage the vaccine hesitant from genuinely seeking quality information, with the damage possibly outweighing the benefits.

Censorship often yields unintended consequences, even if implemented as intended. First, censored content may be more sought out and more

persuasive, thus undermining the credibility of evidence-based information. This is because censorship can lead to outrage, encouraging some people to desire censored information more—the so-called "Streisand Effect."[6] Second, censorship may be ineffective in a world where multiple social media platforms exist. Platforms such as Gab,[7] Rumble, and Telegram welcome content banned by larger platforms. Thus, vaccine-related content, including antivaccine content, can still be found when it is inevitably sought out. Third, the act of censorship may make the public more likely to believe censored information. In multiple experiments,[8] participants were more likely to change their opinions in favor of content that they had been told was banned—even if they had only been exposed to the title of the censored content rather than the content in full! Thus, public awareness of censored content that promotes vaccine refusal may increase vaccine hesitancy, even if the public never sees it. Fourth, experiments show that efforts to debunk are less persuasive if the material being debunked is a target of censorship.[8] Thus, censoring potentially harmful information about vaccines may reduce the efficacy of high-quality, evidence-based communications. Finally, censorship promotes a narrative—that has increasingly been embraced by vaccine opponents[9]—portraying social media platforms and the public health establishment as authoritarian and paternalistic, thus eroding confidence in these critical institutions.

USING SOCIAL MEDIA TO ENGAGE WITH THE VACCINE HESITANT

To date, public health communicators do not frequently engage with the vaccine hesitant online. This has left a void on social media, which has been filled by vigilantes who are not trained in effective communication, and who mischaracterize the vaccine hesitant as stupid, science deniers, or conspiracy theorists. Thus, some of the most popular provaccine Facebook fan pages promote discord by mocking those with whom they disagree and stigmatizing those who have real questions about vaccines. Examples include pages with names such as "Refutations to Anti Vaccine Memes" (323 340 followers as of March 13, 2021), "Things Anti Vaxers [sic] Say" (156 070 followers), and "Detox, Antivax, and Woo Insanity" (114 653 followers). While perhaps well intentioned, these pages violate a basic principle of persuasion by relying on ad hominem attacks. A messenger who is well-liked is statistically significantly more likely to be persuasive, irrespective of the message content.[8] By contrast, demeaning provaccination messages may be ineffective and possibly harmful, making everyone more vulnerable. For example, Russian Twitter "troll" accounts weaponized demeaning provaccine messages as frequently as vaccine refusal narratives when conducting a broad campaign to promote discord in American society.[10]

To fill this void, resources spent on censorship could instead be directed to collaborations with public health partners to help craft evidence-based, positive interventions with demonstrated efficacy. Currently, interventions focus on broadcasting promotional messages, or correcting or debunking falsehoods. This approach places the debunker in a position of authority relative to the audience, potentially engendering resistance. Although these strategies are important components to any public health campaign, communications must also address rationales for vaccine hesitancy that vary among communities. The messages must therefore be targeted and tailored, communicating the gist of why people should vaccinate in a manner that is comprehensible, but not simple-minded, and connecting rationales for vaccination to culturally contingent values.[11]

The messenger matters: although trust in government institutions may be at an all-time low, trust in physicians remains high.[12] Platforms could therefore draw upon the expertise of trained medical and public health professionals, and trusted community leaders, to developed targeted and tailored provaccination messages, interjecting these into contested online spaces and disseminating messages that meet the needs of specific communities. Such messages, if appropriately crafted, can go viral on social media.[13] However, not all physicians will be equally appealing to all audiences. Here, we may take advantage of social media platforms' main strength: they excel at microtargeting and could leverage their technological prowess to empower trusted community advocates to connect with public health agencies. Rather than eroding the public's access to critical health communities, platforms could thus promote a two-way dialogue between community advocates, public health agencies, and physicians on one hand, and the vaccine hesitant on the other, helping to build trust where it may be lacking.

In general, social media platforms facilitate the exchange of medical information among peers, even information that is private or sensitive.[14] Action that shuts down these spaces could both deprive participants of a community upon which they have come to rely and make members of these communities harder to reach. If communities on

popular, and relatively well-regulated, social media platforms are shut down, members of the public may fill their need for community in less reachable venues, or in private settings where there is no opportunity for public health advocates to encourage evidence-based behaviors.

Cynics might question whether even the most effective communicator can change the minds of "antivaccination crusaders." We certainly will not if we do not try. Even controversial opinions that seem firmly entrenched can change when contact opens one's mind to different perspectives. In our opinion, a large social media cluster hosting objectionable conversations about vaccines represents an untapped opportunity to encourage both participants and bystanders to engage in healthy behaviors, building trusting relationships, and potentially changing minds. Social media platforms, working in close collaboration with health experts, could implement targeted and tailored campaigns that could reach clusters of vaccine-hesitant users that would otherwise be unreached.

It is reasonable for the public to have questions in the midst of a pandemic that has left many anxious, or even panicked.[15] We must meet the public where they are: reaching out to the vaccine hesitant on social media rather than imposing a blanket ban—enforced by imprecise algorithms—that could backfire and undermine the persuasive power of public health communications. A strategy modeled on evidence-based practices that combines the resources of social media companies, health agencies, and public health advocates could significantly accelerate the uptake of COVID-19 vaccines, potentially ending the pandemic. A necessary first step is systematically appraising our current social media strategies and changing course to align them with evidence-based practices. AJPH

CORRESPONDENCE

Correspondence should be sent to David A. Broniatowski, Associate Professor, 800 22nd St NW #2700, Washington, DC 20052 (e-mail: broniatowski@gwu.edu). Reprints can be ordered at http://www.ajph.org by clicking the "Reprints" link.

PUBLICATION INFORMATION

Full Citation: Broniatowski DA, Dredze M, Ayers JW. "First do no harm": effective communication about COVID-19 vaccines. *Am J Public Health*. 2021;111(6): 1055–1057.

Acceptance Date: March 15, 2021.

DOI: https://doi.org/10.2105/AJPH.2021.306288

CONTRIBUTORS

D. A. Broniatowski and J. W. Ayers wrote the first draft of the article. M. Dredze critically revised the article. All authors have full access to all the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.

ACKNOWLEDGMENTS

This work was supported by a grant from the John S. and James L. Knight Foundation to the George Washington University Institute for Data, Democracy, and Politics; the John and Mary Tu Foundation; and the Burroughs Wellcome Fund.

We thank Davey Smith, MD, MAS, and Eric C. Leas, PhD, MPH, (both with University of California San Diego) for comments on earlier versions of our editorial.

Note. The funders played no role in the decision to publish, nor the conceptualization, preparation, or revision of this work.

CONFLICTS OF INTEREST

D. A. Broniatowski received a speaking honorarium from the United Nations Shot@Life Foundation—a nonprofit organization that promotes childhood vaccination. M. Dredze holds equity in Good Analytics and has received consulting fees from Directing Medicine and Bloomberg LP. J. W. Ayers owns equity positions in Directing Medicine, Health Watcher, and Good Analytics. J. W. Ayers and M. Dredze previously advised GlaxoSmithKline on social media communication strategies for vaccines.

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Why Debunking Misinformation Is Not Enough to Change People's Minds About Vaccines

Heidi J. Larson, PhD, MA, and David A. Broniatowski, PhD

ABOUT THE AUTHORS

Heidi J. Larson is Director of the Vaccine Confidence Project, Department of Infectious Disease Epidemiology, London School of Hygiene & Tropical Medicine, London, UK, and the Department of Health Metrics Sciences, University of Washington, Seattle. David A. Broniatowski is with the Department of Engineering Management and Systems Engineering, Institute for Data, Democracy & Politics, George Washington University, Washington, DC.

See also Morabia, p. 982, and the Vaccines: Building Long-Term Confidence section, pp. 1049–1080.

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It's too new. Made too fast. Don't know enough about long-term possible effects.

Don't trust the system—or the motives of the government, big business, or the big funders.

Don't tell me what to do. It's my choice.

It's not natural, it's going to manipulate my DNA.

These are among the myriad of concerns and conspiracy theories driving COVID-19 vaccine hesitancy and refusal. These concerns vary across population groups, political contexts, and personal and collective histories. They particularly thrive in the context of uncertain science and a dynamic and ever-evolving new virus.

One of the strongest underlying drivers that determines whether individuals or groups are vaccine confident or vaccine hesitant is the level of trust—or distrust—in the individuals and institutions that discover, develop, and deliver vaccines. Higher levels of trust mean willingness to accept a level of risk for a greater benefit. Those with lower levels of trust are less likely to accept even the smallest perceived risk.[1]

The messenger matters as much as the message. Particularly in vulnerable populations characterized by attributes associated with race, economic status, and immigrant status, familiar community members or local leaders are likely to be more trustworthy than those from outside the community. Successful initiatives have involved bringing relevant community members together with health authorities to cocreate communication and engagement strategies.

There is a confusing landscape of evolving scientific information, as well as mis- and disinformation, about COVID-19. Vaccines have been a particular focus of conspiracies and mis- and disinformation. The threat of viral misinformation spread through social media was recognized well before this pandemic struck.[2] The World Health Organization named "vaccine hesitancy" as one of the top 10 global health threats in 2019 and pointed to the risks of an "infodemic." To combat this threat, public health organizations have created content designed as corrective information (e.g., "myth busters"). Although a welcome addition to the arsenal of countermisinformation efforts, such debunking strategies are inadequate to address the deep-seated emotions and drivers of dissent.

Vaccine information does not exist in isolation. Vaccine views exist in a contentious landscape, whereby people make sense of this information in terms of political, cultural, and social values that set the stage for whether individuals or communities trust or distrust authority. As human beings, we are constantly trying to make sense of our environment. Mysterious and unexpected events, such as the COVID-19 pandemic, seem to come out of nowhere, defying explanation. Under these circumstances, it is only rational for members of the public to ask, "Why is this happening?" Unfortunately, there are no easy answers; the state of scientific knowledge is simply too limited, albeit evolving. These uncertain times are fertile ground for rumors and conspiracy theories, allowing outlandish and implausible claims that seek to explain misfortune to become compelling.

Consider the case of someone who has been exposed to misinformation claiming that a COVID-19 mRNA vaccine can "change your DNA." Like most misinformed rumors, this false claim is rooted in a misinterpretation of the truth. Specifically, this misinformation originated as a consequence of a

metaphor used by Moderna—one of the primary manufacturers of COVID-19 mRNA vaccines—which states that they "set out to create an mRNA technology platform that functions very much like an operating system on a computer . . . the 'program' . . . is our mRNA drug."[3]

This statement is accompanied by an explanatory figure (Figure 1) making explicit the analogy between computer software and mRNA, describing mRNA medicines as "the software of life."

Correctly interpreting this metaphor requires university-level knowledge of biology and computer science. This information is easy to *mis*interpret. If one takes seriously the idea that mRNA is the software of the human body, then the vaccine can easily be misconstrued as an attempt to "program" vaccinated individuals: to rob them of their autonomy.

What makes this misinformation compelling? First, it must be plausible that pharmaceutical companies seek to challenge the autonomy of the average person. To many, this narrative is plausible: it is precisely the narrative that those trying to undermine confidence in vaccines are promoting on social media.[4] Second, the misinformation contains a gist—a compelling, simple, bottom-line meaning—that interprets the facts in light of political, cultural, and social values held in long-term memory by its audience.[5] In the midst of a pandemic marked by repeated restrictions on movement, the value of personal autonomy is even more pronounced. Under these circumstances, in which individuals may feel their personal autonomy under threat, it is not only reasonable but rational to experience fear and anxiety at the prospect of being vaccinated.

Attempts to debunk this rumor are likely to be ineffective unless they provide a more compelling gist. Consider that a simple search on Google using the terms "vaccine mRNA" immediately yields a "COVID-19 alert" with several "common questions," including "Could an mRNA vaccine change my DNA?" Clicking on this question yields the following answer: "An mRNA vaccine—the first COVID-19 vaccine to be granted emergency use authorization (EUA) by the FDA [US Food and Drug Administration]—cannot change your DNA" (https://bit.ly/3uzxpnP). This decontextualized factual statement might lead this person to draw several erroneous conclusions: (1) mRNA vaccines are new, (2) the first mRNA vaccine was granted an emergency use authorization by the FDA and therefore might not have been tested fully, and (3) several people are asking Google whether mRNA vaccines can change one's DNA, lending the question social validity. Even a more detailed factual response, such as the statement provided by the Centers for Disease Control and Prevention that "mRNA from the vaccine never enters the nucleus of the cell and does not affect or interact with a person's DNA" (https://bit.ly/2Pc95tn) may be misconstrued because it assumes that the listener possesses, and can contextualize, knowledge of cell biology. Worse, these points do not address the fundamental concern of the vaccine-hesitant individual: a perceived threat to their value of personal autonomy.

Decades of empirical research in experimental psychology, and especially medical decision making,[6] demonstrates conclusively that providing detailed factual information is not an effective antidote to vaccine safety concerns. When asked in an experimental or didactic setting, individuals may repeat these facts in the short term but, on their own, easily forget, with relatively small impacts on intentions or behaviors. This same research shows that

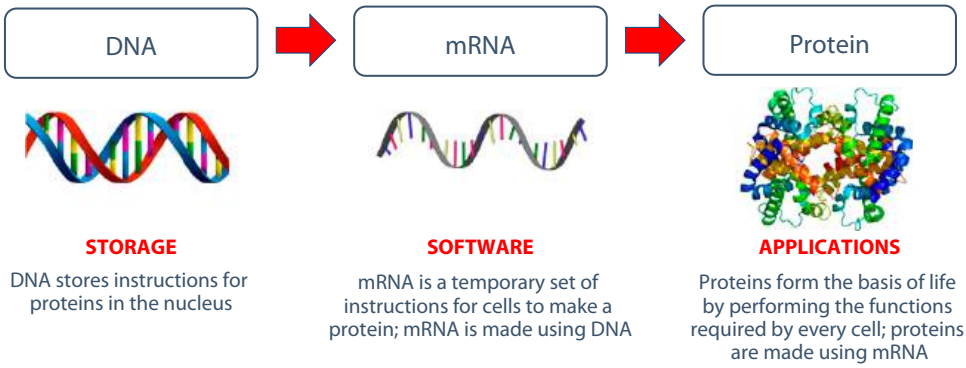

FIGURE 1— Image That Could Be Misinterpreted to Falsely Suggest That mRNA Vaccines Program (and Therefore Change) One's DNA

Source. Image adapted from Moderna.[3]

messages are more compelling when they communicate a gist or simple bottom-line meaning that helps the listener make sense of the message.

To adequately address misinformation and build trust, it is crucial to directly address the concerns of audiences. In the words of a recent article published in the *Proceedings of the National Academy of Sciences*, "Science communication needs to shift from an emphasis on disseminating rote facts to achieving insight, retaining its integrity but without shying away from emotions and values."[5(p1)] Thus, rather than simply debunking the decontextualized claim that "mRNA vaccines can change your DNA"—which, if done inappropriately, may simply trigger a negative response to authority—health communicators must understand the context that gave rise to the claim and recontextualize their response in terms of the values of the vaccine-hesitant individual.

For example, one might point out that the software metaphor is actually an inaccurate description—rather than forcing the human body to follow a program, it is actually the vaccine that will give the body the ability to defend itself naturally. This statement is factual, meaningful, and relevant to the listener's core values of autonomy and self-reliance.

The above example highlights the importance of empathy. A decontextualized debunking strategy does not engage with the substance of the listener's concern, the debunker's job is to educate or otherwise fill an information gap. A more effective response to misinformation is more compassionate; it starts from the premise that the misinformed individual has legitimate concerns and feelings. Listening plays an important role in understanding those concerns. By seeking to get the gist of their concerns—that is, to understand what they mean, how it makes them feel, and why it is important to them—it demonstrates a motive of caring and can contribute to building trust.[7]

The implications of this reality are that simply responding to misinformation with factual corrections is not likely to turn the tide of public dissent. There are deeper issues at play: building trust means changing perceptions of risk and requires being responsive to felt needs and concerns, putting facts in context, and ultimately building relationships.

This is just the beginning: our handling of the COVID-19 vaccine rollout will be foundational for future vaccine confidence as several new vaccines are introduced around the world. A recent study conducted in Africa found that 42% of respondents reported that they were exposed to a lot of misinformation. Correcting misinformation, one piece at a time, is important for today, but only if we address the underlying issues driving misinformation will we be able to build vaccine confidence for the longer term.

We still have time to get it right. AJPH

CORRESPONDENCE

Correspondence should be sent to Heidi J. Larson, Department Infectious Disease Epidemiology, London School of Hygiene & Tropical Medicine, Keppel St, London WC1E 7HT, United Kingdom (e-mail: Heidi.Larson@LSHTM.ac.uk). Reprints can be ordered at http://www.ajph.org by clicking the "Reprints" link.

PUBLICATION INFORMATION

Full Citation: Larson HJ, Broniatowski DA. Why debunking misinformation is not enough to change people's minds about vaccines. *Am J Public Health*. 2021;111(6):1058–1060.

Acceptance Date: March 16, 2021.

DOI: https://doi.org/10.2105/AJPH.2021.306293

CONTRIBUTORS

The authors contributed equally to the editorial.

ACKNOWLEDGMENTS

This work was supported by a grant from the John S. and James L. Knight Foundation to the George Washington University Institute for Data, Democracy, and Politics.

CONFLICTS OF INTEREST

H.J. Larson has received research grants from GlaxoSmithKline (GSK), Johnson & Johnson, and Merck and serves on the Merck Vaccine Confidence Advisory Board. She has received honoraria for speaking at training seminars hosted by GSK and Merck. D. A. Broniatowski received a speaking honorarium from the UN Shot@Life Foundation—a nonprofit organization that promotes childhood vaccination.

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Employer-Mandated Vaccination for COVID-19

Mark A. Rothstein, JD, Wendy E. Parmet, JD, and Dorit Rubinstein Reiss, LLB, PhD

ABOUT THE AUTHORS

Mark A. Rothstein is with Institute for Bioethics, Health Policy and Law, University of Louisville School of Medicine, Louisville, KY. Wendy E. Parmet is with School of Law, Northeastern University, Boston, MA. Dorit Rubinstein Reiss is with University of California Hastings College of the Law, San Francisco. Wendy E. Parmet is also an AJPH *associate editor.*

See also Morabia, p. 982, and the Vaccines: Building Long-Term Confidence section, pp. 1049–1080.

When the US Food and Drug Administration (FDA) decided to grant emergency use authorization (EUA) for the first two vaccines for COVID-19, the United States' response to the pandemic entered a new phase. Initially, the greatest challenge is having enough doses of vaccine and administering them to all who want it. Yet even while many wait expectantly for their turn to be vaccinated, a significant minority of Americans are hesitant. Lack of information or misinformation about the vaccine, a long-standing and well-entrenched antivaccination movement, distrust of public health officials, and political polarization have left many people ambivalent or opposed to vaccination. According to a poll by the Kaiser Family Foundation taken in late November and early December 2020, 27% of respondents surveyed stated that they would "probably" or "definitely" not be willing to be vaccinated.[1] Reflecting the sharp partisan divide that has characterized views about the pandemic, Democrats (86%) were far more likely than Republicans (56%) to be vaccinated.

The prospect of numerous Americans declining vaccination has raised the issue of whether vaccination could or should be mandated for education, travel, or other activities.[2] This editorial focuses on some of the legal and public health policy issues related to employer-mandated vaccination.

THE LEGAL FOUNDATIONS FOR VACCINE MANDATES

Vaccine mandates in the United States date back to 1827, when Boston, Massachusetts, became the first jurisdiction to require that children be vaccinated against smallpox to attend school.[3] In the years that followed, such mandates became common, and they were almost always upheld by the courts.

The US Supreme Court did not consider mandatory vaccination until its 1905 decision in *Jacobson v Massachusetts*.[4] The Court rejected the claim that a Cambridge, Massachusetts, regulation that required residents to be vaccinated against smallpox (then epidemic) or pay a $5 fine violated the Due Process clause of the Fourteenth Amendment. The Court nevertheless recognized that state vaccine mandates could be unconstitutional if they were unrelated to their public health goals, oppressive to particular individuals, or imposed a "plain and palpable violation of fundamental law."[3]

For over a century, *Jacobson v Massachusetts* has been the leading authority for the state's ability to require vaccination. In 1922, the Supreme Court relied on this case to uphold a law requiring that children be vaccinated to attend school, even though there was no outbreak at the time of the mandate.[5] In a 1944 case concerning child labor laws, the Supreme Court explained that religious freedom "does not include liberty to expose the community or the child to communicable disease."[6] In 1990, the Supreme Court further secured states' right to mandate vaccination against claims of religious freedom by holding that generally applicable state laws that do not discriminate against religion do not violate the Constitution's protection for religious liberty.[7] Since then, courts have rejected most constitutional challenges to state vaccine laws, even those without a religious exemption.[8]

Whether the courts will adhere to this precedent, however, is uncertain. On November 25, 2020, in *Roman Catholic Diocese of Brooklyn v Cuomo*,[9] the Supreme Court granted an injunction against New York's COVID-related restrictions on in-person worship. Although the Court had previously refused to enjoin state restrictions of religious services during the pandemic, with Justice Amy Coney Barrett on the Court, a new majority ruled that New York had violated the First Amendment by regulating worship more strictly than some secular activities. In a concurring opinion, Justices Gorsuch and Alito questioned the applicability of *Jacobson v Massachusetts* to religious liberty claims. In a later case, the same justices suggested that in some settings, such as

education, public health laws without exemptions might violate the Free Exercise clause of the First Amendment even if they do not discriminate against religion. If the majority adopts that approach, religious challenges to state vaccine laws would receive new life.

Even when the First Amendment does not prohibit state or federal vaccine mandates, Religious Freedom Restoration Acts (RFRAs)—either at the state or federal level—may. The federal RFRA requires that laws imposing a substantial burden on religion must be the least restrictive means for protecting a compelling state interest. In dissenting to the Supreme Court's decision in *Hobby Lobby v Burwell*, which held that the Affordable Care Act's contraceptive mandate violated the federal RFRA, Justice Ginsburg presciently raised the specter that the majority's holding might impact coverage for vaccines.[10] The majority dismissed those concerns, stating there was no reason to believe that employers would object to paying for vaccines.

EMERGENCY USE AUTHORIZATION

Scientists have focused on creating a COVID-19 vaccine since early in the pandemic, when the United States provided grants for vaccine development and manufacture to several candidates.[11] Operation Warp Speed—the federal task force coordinating vaccine funding, development, and distribution—was announced on May 15, 2020.[12] Despite its somewhat unfortunate name—which implies the rushing of vaccines—such coordination was critical.[13] Operation Warp Speed involved members from multiple agencies, including scientists with extensive experience in vaccine development as well as participants from industry. In addition, in April 2020, the Advisory Committee on Immunization Practices established a working group dedicated to following COVID-19 vaccines through their development and preparing recommendations for their deployment once the FDA granted an EUA.

During discussions before federal advisory committees, officials from the Centers for Disease Control and Prevention and the FDA stated consistently that COVID-19 vaccines authorized via an EUA cannot be mandated. The law, however, is not clear on this point. The relevant provision of the Food, Drug, and Cosmetic Act[14] provides that the required conditions of an EUA include informing individuals that they can accept or refuse an EUA product, and of any consequences of refusal. Officials interpreted this as a prohibition of mandates, but the statutory language says nothing about employers or even states. It is directed only at vaccine recipients and providers and declares that there can be consequences for refusal. Potentially, such consequences may include discharge or exclusion from work, thereby allowing workplace mandates.

This view is reflected in guidance from the Equal Employment Opportunity Commission (EEOC), which clearly assumes that vaccines approved under an EUA can be mandated under the same terms as other vaccines.[15] The best argument against mandating an EUA vaccine is that the vaccine is still experimental; however, that argument has not been tested in court, and a long tradition of allowing workplace mandates and the lack of clear statutory prohibition on mandates by private actors work against it.

EMPLOYER MANDATES

Many private-sector employers want their employees to be vaccinated against COVID-19 to prevent the spread of the virus, reassure employees and customers that the premises are safe, avoid potential liability for transmission of the virus, and advance public health. Private-sector employers are generally free to use any hiring criteria and impose any condition of employment unless doing so violates federal or state law (public employers are subject to the constitutional limits applicable to states). Bills introduced in more than a dozen state legislatures would prohibit employers from mandating vaccination for COVID-19.[16]

The Americans with Disabilities Act (ADA) and its state law analogs prohibit discrimination in employment because of disability. If employees assert that the vaccine would cause a severe adverse reaction, they would first have to prove that they are covered under the ADA by having a physical or mental impairment that constitutes a substantial limitation of a major life activity, such as breathing. Even if the mandate burdens employees who are covered under the ADA, an employer can still mandate vaccination to prevent a direct threat to the employee or others.[17] Courts are likely to find this in many work settings if a vaccine reduces infectiousness. Even if a lack of vaccination creates a direct threat, the employer would need to provide covered employees who are unable to be vaccinated for medical reasons with "reasonable accommodation," such as working remotely or using additional personal protective equipment. Reasonable accommodation is not required if it would cause an undue hardship to the employer, which is defined as "significant difficulty or expense." For example, an employer is not required to create new positions or fundamentally alter job duties.

According to the EEOC, if an unvaccinated employee cannot be accommodated, an employer may "exclude" the employee from the workplace.[16] Exclusion is especially appropriate for health care workers and other employees who have direct contact with the public. Granting leave without pay for the duration of the direct threat is preferable to discharge.

Employees might also assert that a vaccination requirement conflicts with their religion and is therefore in violation of Title VII of the Civil Rights Act of 1964 or similar state laws, which prohibit religious discrimination and require employers to provide reasonable accommodations to an employee's religious beliefs. The courts have interpreted reasonable accommodation under Title VII as less demanding on employers than under the ADA, only requiring employers to incur de minimis costs.[18] Although the employee need not be a member of a traditional religion, a "personal philosophy" (such as veganism) does not qualify.[19] Furthermore, the accommodation must be reasonable—not unduly burdensome for the employer. Recent decisions of the Supreme Court, however, indicating a heightened concern for religious liberty,[8] could presage decisions requiring employers to make greater accommodation to employees' religious beliefs and practices.

Under the National Labor Relations Act, private sector employers with unionized workforces are required to "bargain" with the union before making unilateral changes in working conditions. A vaccination requirement would be considered a mandatory subject of bargaining. Even nonunionized employees are protected from discharge or discipline if they engage in "concerted activity for their mutual aid or protection," as when employees submit a list of COVID-19 concerns to their employer. All employers would be wise to consult with their employees before formulating and implementing a vaccination plan.

OSHA-MANDATED VACCINATIONS

The Occupational Safety and Health Administration (OSHA) is likely to promulgate an emergency temporary standard for COVID-19, which could require face masks, other appropriate personal protective equipment, physical distancing, and similar measures. It also might require that some or all employees be vaccinated. Under the Occupational Safety and Health Act, the Secretary of Labor may issue an emergency temporary standard "if employees are exposed to grave danger from substances or agents determined to be toxic or physically harmful or from new hazards."[20]

An OSHA standard requiring employers to ensure that all employees are vaccinated might face two types of legal challenges. First, a court might hold that there is no "grave danger" justifying the requirement for workers who do not face heightened risks of exposure. Second, a standard could be challenged if it does not generally permit employees to decline vaccinations or does not include medical and religious exemptions. OSHA's blood-borne pathogen standard requires employers to offer vaccination for hepatitis B to exposed health care employees, but employees can decline vaccination for any reason. Although a verified medical exemption from COVID-19 vaccination probably would involve a small number of employees, religious exemptions might be claimed more broadly, and not allowing them might raise issues under the First Amendment and RFRA.

PUBLIC HEALTH STRATEGY

The development of multiple safe and effective vaccines in record time provides hope that the horrible human and economic consequences of the coronavirus pandemic may begin to abate and, ultimately, end. Many employers may view mandated universal employee vaccination as a way to keep their workplaces safe and mitigate their financial losses, but premature and inflexible vaccination mandates raise numerous legal issues. Employment policies on vaccination also need to align with public health strategies.

Without a sufficient uptake of the vaccine, it will be impossible to develop the herd immunity necessary to end the pandemic. Yet those reluctant to be vaccinated have a variety of reasons, including concerns about safety and efficacy. Pregnant women, children younger than 16 or 18 years (depending on the vaccine), elderly people in nursing homes or similar facilities, and immunocompromised individuals and those with severe allergies were excluded from vaccine trials. In addition, the first approved vaccines have been shown to prevent moderate and severe cases of COVID-19, but it is not known whether they prevent infection or whether a vaccinated person can infect others. These determinations go to the heart of employer mandates—the ability to protect others—and are critical for deciding the law and ethics of vaccine mandates.

We believe that rigid, coercive approaches enforced by employers could harden the opposition of individuals who are currently unsure about the vaccine. Rather than rushing to compel

vaccination, employers should help educate their employees about the benefits of vaccination, and help employees, to the extent possible, get vaccinated (e.g., offering on-site vaccination or giving employees time off for vaccination).

The most hopeful scenario is that support for vaccination will continue to grow with the lack of serious adverse events and additional evidence of the vaccine's effectiveness as shown in declining rates of infection, serious illness, and death. Support from vaccinated peers and family members—together with consistent, positive messaging from the government, public health officials, and employers—may appeal to all but those with the most entrenched views. Americans frequently have demonstrated an ability to change their prevailing opinions in a short time, and a sound public health strategy for workplace-based vaccination should be predicated on prevention and persuasion grounded in science before resorting to compulsion. AJPH

CORRESPONDENCE

Correspondence should be sent to Mark A. Rothstein, JD, Institute for Bioethics, Health Policy and Law, University of Louisville School of Medicine, 501 East Broadway #310, Louisville, KY 40202 (e-mail: mark.rothstein@louisville.edu). Reprints can be ordered at http://www.ajph.org by clicking the "Reprints" link.

PUBLICATION INFORMATION

Full Citation: Rothstein MA, Parmet WE, Reiss DR. Employer-mandated vaccination for COVID-19. *Am J Public Health*. 2021;111(6):1061–1064.

Acceptance Date: January 3, 2021.

DOI: https://doi.org/10.2105/AJPH.2020.306166

CONTRIBUTORS

All authors contributed to the conceptualization, research, writing, and editing of the article.

CONFLICTS OF INTEREST

M. A. Rothstein and W. E. Parmet have no conflicts of interest to disclose. D. R. Reiss owns stock in GSK, which has a COVID-19 vaccine candidate in early stages of testing. She also served as a volunteer, nonpaid participant in an ethics panel advising Moderna on allocation of COVID-19 vaccines.

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Emergency Use Authorizations (EUAs) Versus FDA Approval: Implications for COVID-19 and Public Health

Diana M. Zuckerman, PhD

ABOUT THE AUTHOR

Diana M. Zuckerman is president of the National Center for Health Research, Washington, DC.

See also Morabia, p. 982, and the Vaccines: Building Long-Term Confidence section, pp. 1049–1080.

In response to the COVID-19 pandemic, the Food and Drug Administration (FDA) rushed hundreds of medical products for testing, prevention, and treatment onto the market through Emergency Use Authorizations (EUAs), rather than FDA approval. This policy began on February 4, 2020, when Health and Human Services Secretary Azar announced that the pandemic justified the authorization of emergency use of in vitro diagnostics for detection or diagnosis of the virus.[1] As the virus spread rapidly, and health care personnel and morgues became overwhelmed, the FDA responded by specifying policies and standards for a wide range of essential medical products, including diagnostic tests, treatments, masks, and vaccines. To what extent did reliance on EUA lower standards—in some cases with no review by the FDA at all—benefit public health or put it at unnecessary risk in 2020 or in the future? Answering this question requires an understanding of EUA standards compared with FDA approval standards, how and why EUA standards changed during 2020, and the quality of EUA products used by millions of Americans.

FDA APPROVAL VS EMERGENCY USE AUTHORIZATION

The FDA was created in 1906, but the EUA provision was not added until 2004, to respond to chemical, biological, nuclear, or radiation threats. The track record of early EUAs has implications for how COVID-19 EUAs affect access to urgently needed medical products and information about their risks and benefits.

The FDA's first EUA was in 2005, for anthrax prevention for military personnel,[2] and the FDA later approved a reformulation. Two other EUAs, issued in 2008 and 2016 for doxycycline products for postanthrax exposure, are still active; the FDA never approved those drugs for that purpose, although doxycycline is approved for other infections.

The FDA's first EUAs for civilians were in 2009, during the H1N1 (swine flu) pandemic, authorizing two previously approved flu medications—Tamiflu and Relenza—and a new drug, Rapivab. The EUAs expired in 2010.[3] In 2014, Rapivab was approved for the treatment of acute, uncomplicated cases of influenza types A and B, including H1N1; but not for hospitalized patients.

In 2013 and 2014, the FDA authorized two diagnostic tests for a coronavirus called Middle East Respiratory Syndrome (MERS). Both EUAs are still active; neither test has received FDA approval. From 2014 to 2018, the FDA issued 11 EUAs for Ebola diagnostic tests; one was subsequently cleared for market, whereas the other 10 are still active EUAs. From 2016 to 2017, the FDA issued 20 EUAs for diagnostic tests for Zika; only four of those tests were subsequently allowed on the market permanently, one was withdrawn, one was discontinued, and 14 EUAs remain active.

These examples indicate that (1) EUA products were not previously widely used in the United States and (2) most EUA products were not subsequently approved. Since medical products authorized through EUAs are not typically covered by Medicare or health insurance, and since the FDA can withdraw EUAs at any time, companies have financial incentives to gather additional data to transition from EUA to FDA approval. If approval never happens, is that a red flag? Perhaps subsequent evidence indicates that the products are not proven safe or effective, or possibly companies determine that the cost of conducting additional research needed for approval outweighs the incentive of selling more products. Either way, unanswered questions about safety and

efficacy remain. Since the stakes are much higher during the current pandemic than for previous EUAs, public health would benefit if the FDA improved incentives for COVID-19 EUAs to transition to approval on the basis of additional research needed to more definitively prove risks and benefits.

Standards for FDA approval vary for different types of medical products; devices rarely require clinical trials, whereas drugs and biologics usually require randomized clinical trials proving safety and efficacy. EUA policies typically require data supporting—not proving—safety and effectiveness, with lower standards and faster reviews than FDA approval. Although consistently less stringent than approval standards, EUA standards for COVID-19 products varied considerably, in some cases not requiring any FDA review of safety or efficacy.

COVID-19 VACCINES

The FDA issues Guidance documents to provide companies with research guidelines for specific types of applications. In a June 2020 Guidance, the FDA specified standards for approval of COVID-19 vaccines, recommending that thousands of adults diverse in race, ethnicity, and age be studied in Phase 3 randomized double-blind clinical trials to determine benefits and risks. Clinical trials "should continue as long as feasible, ideally at least one to two years."[4] In contrast, the FDA's EUA Guidance for COVID-19 vaccines, published in October, specified that data from double-blind randomized "Phase 3 studies should include a median follow-up duration of at least two months," which the FDA described as the minimum needed "to achieve some confidence that any protection . . . is likely to be more than short-lived."[5]

EUA vaccine applications met that minimum follow-up and were quickly authorized. Pfizer-BioNTech submitted its EUA on November 20, 2020, FDA's Advisory Committee reviewed it at a public meeting on December 10, and the FDA authorized it for adults aged 16 years and older the following day.[6] Moderna submitted its EUA on November 30; the FDA's Advisory Committee[7] reviewed it on December 17, and the FDA authorized it for adults aged 18 years and older the following day.

Safety data were based on thousands of adults in each study, and serious (potentially life-threatening) adverse events were rare. Systemic adverse events such as fatigue, fever, chills, and headache were common, but fewer than 18% of Moderna's vaccinated patients reported that "at least one" of these adverse events interfered with daily life.[7] Pfizer did not calculate how many participants reported "at least one" adverse event that interfered with daily life.[6]

COVID-19 cases were defined as a positive diagnostic test and at least one symptom after the second dose. Pfizer's 95% efficacy was based on only 162 placebo cases and eight vaccinated cases, and Moderna's 94% efficacy was based on 185 placebo cases and 11 vaccinated cases.

Janssen's COVID-19 vaccine was authorized on February 27, the day after their data were reviewed by the FDA's Advisory Committee. The study was similar in design, sample size, and seven-week median follow-up, but because their data were collected during the surge in cases in December and January, the data included 464 cases in the vaccinated and placebo groups, including the South Africa variant.[8]

The FDA's decisions to authorize COVID vaccines were carefully worded to reflect uncertainties: "it is reasonable to believe" that the vaccine "may be effective."[8] Although the efficacy data for all three vaccines were more impressive than the 50% efficacy EUA guidelines required, the FDA acknowledged that lack of data on asymptomatic patients and short follow-up meant that it was not possible to determine if the vaccines prevent asymptomatic COVID-19, or how long immunity lasted. It stated that two-month median follow-up was insufficient to answer key public health questions: how long these vaccines prevent moderate and severe COVID for which patients, and if and when booster shots are needed. Although FDA advisors urged longer follow-up, the vaccine companies did not agree. Pfizer announced on their vaccine Web site that study participants have the option of being unblinded and vaccinated in March 2021; Janssen and Moderna made similar public statements.

COVID-19 DIAGNOSTIC TESTS AND ANTIBODY TESTS

Prior to COVID-19, diagnostic tests for other coronaviruses could not be marketed until approved by the FDA based on proven accuracy. In February 2020, with no tests available because of problems with the Centers for Disease Control and Prevention's COVID-19 diagnostic test, the FDA temporarily lifted the agency's requirement that COVID-19 diagnostic tests be validated before they are marketed. That policy was modified in May with the announcement that companies could sell their COVID-19 diagnostic tests for only 15 business days prior to submitting EUA applications. However, sales continued for months before the FDA completed reviewing each application.[9]

The first authorized diagnostic tests were polymerase chain reaction (PCR)

tests, requiring nasopharyngeal swabs. In April, the FDA authorized the first saliva-based test. As of January 7, 2021, 203 COVID-19 PCR or saliva tests were authorized.[10]

Antibody tests were intended to evaluate previous exposure to the novel coronavirus. In March 2020, those tests could be sold without submitting EUAs, but after the FDA noted "that a concerning number of commercial serology tests" were "performing poorly based on an independent evaluation by the NIH [National Institutes of Health]," the FDA revised its policy to require commercial entities to submit an EUA within 10 days, but allowed certified laboratories to market antibody tests without an EUA.[11] With hundreds of different tests submitted for EUAs, there were lengthy delays as the FDA reviewed the data.

By May 2020, the FDA had temporarily authorized diagnostic and antibody tests for 84 different labs and companies; more than 400 additional applications were awaiting FDA review.[12] Neither the 84 that were authorized nor the other 400 had proven accuracy that was independently verified by the FDA or another entity. Doctors were reporting many false negatives and false positives, and a review of published studies of various diagnostic tests found that the "probability of a false-negative result in an infected person decreases from 100% on day 1 to 67% on day 4."[13] On the day of symptom onset, the median false negative rate was still 38%.

By February 1, 2021, the FDA had rejected 225 antibody tests and placed 88 firms on alert for violations.[14] To date, many COVID-19 tests are still not independently validated on patients to ensure accuracy, and the reported range of accuracy varies considerably.

In medicine, many screening tests have substantial false positives and false negatives; however, there are no biopsies to provide definitive confirmation for COVID-19 results as there are for cancer screening tests, for example. Retesting with PCRs is an option, but with results often delayed, infected people who tested negative do not self-quarantine and are likely to spread the virus. Similarly, because the media had reported that people previously infected with the virus were probably immune, those whose antibody test results indicated that they were previously infected were likely to assume they could therefore be less careful about avoiding future exposures.

TREATMENTS

Early in the pandemic, with vaccines months away, there was tremendous political and medical pressure to find effective treatments as quickly as possible. Hydroxychloroquine was an FDA-approved drug for malaria, lupus, and rheumatoid arthritis; the FDA authorized it for COVID-19 in March 2020. That EUA was based primarily on anecdotal clinical reports from France and pressure from the White House, despite known risks of heart failure and potentially fatal heart arrhythmia.[15] Although preliminary data from randomized trials soon suggested the risks outweighed the benefits, the FDA did not withdraw that EUA until June 15, 2020.

Remdesivir was authorized on May 1, 2020, and approved in October 2020 for hospitalized COVID patients. Approval remains controversial because the World Health Organization recommended against its use, stating that clinical trials failed to prove clinically meaningful benefits.[16]

In August, the Trump administration pressured the FDA to issue an EUA for convalescent plasma, which is antibody-laden plasma from someone who survived COVID-19. Despite a published study finding no benefit for hospitalized patients,[17] the FDA issued a broad EUA, undermining efforts to conduct randomized clinical trials. In February 2021, a smaller study found a benefit for older hospitalized patients only if it was given within 72 hours of mild symptoms.[18]

In August, the FDA authorized investigational monoclonal antibodies for hospitalized patients, despite lacking data. In November, the FDA authorized the monoclonal antibody bamlanivimab for mild to moderate COVID-19 in high-risk adults and children, based on interim results from a Phase 2 randomized dosing trial.[19] That EUA was revoked in April, but a February 2021 EUA is still in effect for bamlanivimab in combination with the monoclonal antibody etesevimab for the same indication, based on a double-blind randomized trial of over 1000 adults.

Overall, research standards have improved for treatment EUAs, but we will never know if research could have determined effective treatments sooner had EUAs not made unproven treatments widely available.

PERSONAL PROTECTIVE EQUIPMENT

The FDA has the authority to regulate face masks used "for medical purposes," defined as providing protection from infection anywhere, not only in medical settings. The FDA had required companies to submit evidence proving the safety and effectiveness of these products, or their substantial equivalence to other products on the market. However, in response to dangerous shortages of

personal protective equipment (PPE) in April 2020, the FDA announced it would not enforce its usual requirement that companies submit applications with scientific evidence before marketing face masks, surgical masks, and respirators.[20] The FDA later issued EUAs requiring safety data for respirators and surgical masks, which are made from nonwoven plastic material, but not for cloth face masks.

CONCLUSIONS

The FDA justified authorizing hundreds of different COVID-19 tests, treatments, and vaccines to show its commitment to "expediting the development and availability of potential COVID-19 treatments and providing sick patients timely access to new therapies where appropriate, while at the same time supporting research to further evaluate whether they are safe and effective."[21] To address urgent shortages, PPE that was not evaluated by the FDA became widely available, apparently assuming that even poorly designed PPE was better than nothing.

Balancing urgent needs and unproven benefits is challenging. EUAs are available as short-term emergency solutions, but most are renewed for years without data to warrant FDA approval. "Gaiter" masks are a simple example of a product that is still sold despite evidence that it is less effective than other masks. Similarly, hundreds of different COVID-19 diagnostic tests are being sold, although some are proven to be much less accurate than others. Vaccines rushed to market give hope and protection to many, but FDA scientists stated that vaccine efficacy has not yet been proven to last, and specified that FDA approval would require longer-term data than a median of two months.[8] I agree with the FDA staff and advisors who expressed concerns that we might never get the longer-term data that would determine which vaccines last longest or are most effective against specific variants if participants drop out of clinical trials as EUA vaccines become widely available.

The failure to replace EUAs with more stringent FDA approval is less problematic when products are no longer urgently needed. Indefinitely renewing EUAs for Zika, Ebola, and anthrax has not attracted concerns because few Americans are exposed, but this track record raises important questions about the hundreds of unproven COVID-19 tests, PPE, and treatments currently on the market. EUA treatment standards have generally improved over the past year, but standards for tests remain inconsistent, and standards for many types of PPE are not enforced. Vaccines' data are very encouraging, but primarily based on two-month data on small numbers of COVID patients.

The tragic death toll from the pandemic has resulted in greater flexibility and faster FDA decisions, and has also resulted in hundreds of EUA products subsequently found not to benefit patients, consumers, or public health. We will never know if the pandemic's toll would have been lower if EUA standards had been higher, but it is essential to ensure that COVID-19 EUAs supplement and not replace the gold standard of FDA approval, and not be extended longer than is absolutely necessary, whether during the height or waning of the COVID-19 public health emergency. AJPH

CORRESPONDENCE

Correspondence should be sent to Diana M. Zuckerman, 1001 Connecticut Ave, NW, Suite 1100, Washington, DC 20036 (e-mail: dz@center4research.org). Reprints can be ordered at http://www.ajph.org by clicking the "Reprints" link.

PUBLICATION INFORMATION

Full Citation: Zuckerman DM. Emergency use authorizations (euas) versus FDA approval: implications for COVID-19 and public health. *Am J Public Health*. 2021;111(6):1065–1069.

Acceptance Date: March 7, 2021.

DOI: https://doi.org/10.2105/AJPH.2021.306273

ACKNOWLEDGMENTS

Funding for this manuscript was from general support funds of the National Center for Health Research.

I thank Nina Zeldes, PhD, and Meg Seymour, PhD, for their assistance in reviewing the history of Emergency Use Authorizations prior to COVID-19.

CONFLICTS OF INTEREST

The National Center for Health Research does not accept funding from companies that make pharmaceuticals, medical devices, or biologics. D. M. Zuckerman owns stock in Johnson & Johnson.

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Equitable Access and Distribution of COVID-19 Vaccines for US Vulnerable Populations: Federal Health Center Program Perspective

Sue C. Lin, PhD, MS

ABOUT THE AUTHOR

Sue C. Lin is with the Bureau of Primary Health Care, Health Resources and Services Administration, US Department of Health and Human Services, Rockville, MD.

Note. The views expressed in this editorial are the author's and not necessarily those of the Health Resources and Services Administration or the US Department of Health and Human Services.

See also Morabia, p. 982, and the Vaccines: Building Long-Term Confidence section, pp. 1049–1080.

In October 2020, the National Academies of Sciences, Engineering, and Medicine released the Framework for Equitable Allocation of COVID-19 Vaccine to guide government agencies on vaccine administration and prioritization for equitable distribution.[1] In addition, the Advisory Committee on Immunization Practices (ACIP), which provides national guidance on vaccine-preventable diseases, recommended vaccine allocation based on the following four ethical principles: (1) maximize benefits and minimize harms, (2) promote justice, (3) mitigate health inequities, and (4) promote transparency.[2]

With respect to equity and social justice, how can equitable vaccine allocation and access be accomplished and operationalized? The mortality and disease burden of COVID-19 among vulnerable populations and underserved communities in the United States have further magnified health disparities among individuals from racial/ethnic minority groups, adults with multiple chronic conditions, individuals experiencing housing instability, and those with limited English proficiency, low socioeconomic status, or one or more disabilities.[3–7] On January 21, 2021, the National Strategy for the COVID-19 Response and Pandemic Preparedness called upon the Health Resources and Services Administration (HRSA) Health Center Program to launch a new federal vaccination program to provide HRSA-supported health centers direct access to the vaccine supply and ensure equity in vaccine distribution.[8]

US PRIMARY CARE SAFETY NET

To answer why the HRSA Health Center Program was given the charge is to understand the history of the health center movement, the vulnerable populations served, and the primary care safety net infrastructure built to date. Starting in 1965 as a small demonstration program from President Lyndon B. Johnson's Office of Economic Opportunity with two small health centers in Mississippi and Massachusetts, HRSA-supported health centers have activated and sustained community-driven social changes to improve the health of vulnerable populations.[9]

Today, the Health Center Program operates more than 14 000 primary care clinics with the federally qualified health center designation in every US state and territory and employs nearly 260 000 health care workers. The Health Center Program has provided health care to nearly 30 million patients, including more than 2.9 million older adult patients—or one in 11 people across the nation—regardless of their ability to pay.[10] More than 90% of health center patients live at or below 200% of the federal poverty level; 63% are from racial/ethnic minority groups; and nearly 25% are patients with limited English proficiency.[10] Finally, health centers provide primary care to statutorily defined special populations that include more than 1.0 million agricultural workers and their families, more than 1.4 million individuals experiencing homelessness, and more than 5.1 million public housing residents.[10]

Over the past decade, health centers have strengthened the primary care safety net infrastructure through accelerating comprehensive primary care integration by placing medical, oral health, mental health, substance use disorder, and patient services under one roof; they have also advanced high-quality care through patient-centered medical home transformation. Health centers have delivered key

enabling services that address social determinants of health, including case management, patient navigation, language interpretation, transportation, eligibility assistance, health education, and outreach that facilitate access to care for vulnerable populations. In addition, investments in health information technology have resulted in electronic health record implementation at nearly all health centers, enhanced medical information exchange, advanced interoperability with external health information systems, and supported the collection of patient social risk factor data to inform patient-centered treatment plans.[10,11] Jointly, patient-centered medical homes, comprehensive primary care integration, enabling services, and health information technology have enhanced the provision of holistic patient care and further strengthened trusting doctor–patient relationships, which are key to strategically addressing vaccine confidence and administration.

Health centers have worked diligently to address medical distrust resulting from historical and ongoing discrimination by providing high-quality, patient-centered care and serving as patient-trusted partners in health.[12] Health centers have also played a critical role in responding to the COVID-19 pandemic by increasing COVID-19 testing capacity since the beginning of the pandemic, which has resulted in nearly nine million patients tested to date. In protecting underserved communities and vulnerable populations, more than 38 000 health center staff have tested positive for COVID-19 and hundreds of clinical sites have temporarily closed.[13] Finally, an estimated 14.1 million, or 47% of, health center patients have met the ACIP criteria for phase 1 based on age and high-risk medical conditions and are thus in critical need of vaccination.[14]

ADVANCING EQUITABLE VACCINE ACCESS AND UPTAKE

For more than five decades, health centers have worked in underserved communities to tackle the socioeconomic circumstances that adversely affect health; increase patients' knowledge, improve their attitudes, and motivate them; and develop interventions that respond equitably to diverse patients' needs.[10] Challenging long-term structural factors drive health disparities. However, immediate efforts guided by the socioecological model (Figure A, available as a supplement to the online version of this article at http://www.ajph.org) could quickly expand COVID-19 vaccine administration capacity and uptake in underserved communities, with health centers and state primary care associations as key partners.[15] Primary care associations have long facilitated and advocated collaboration between member health centers and governors, Medicaid directors, and state health departments on primary care and public health priorities as well as in response to state and local public health emergencies.

At the system, community, and organizational levels, strategic engagements among federal public health agencies, state health departments, local public health departments, primary care associations, health centers, and other key stakeholders in statewide vaccine distribution microplanning improve the continual coordination of COVID-19 vaccine administration to vulnerable populations. Through federal funding and state-level partnerships with primary care associations earlier in the pandemic, health centers demonstrated their ability to rapidly initiate and expand COVID-19 testing capacity to enhance testing accessibility and affordability to racial/ethnic minority groups. At the organizational level, health center workforces have continued to provide necessary preventive and chronic care to patients during the pandemic, simultaneously answering their communities' call to serve at the front lines of the COVID-19 public health emergency. At the system level, on February 9, 2021 President Biden announced the launch of the Health Center COVID-19 Vaccine Program to ensure that underserved communities and those disproportionately affected by COVID-19 are equitably vaccinated against COVID-19.[16]

HRSA and the Centers for Disease Control and Prevention launched a program to directly allocate COVID-19 vaccine to HRSA-supported health centers starting the week of February 15. This program design complements existing jurisdictional efforts to ensure equitable and effective access by providing an additional vaccine supply directly to HRSA-supported health centers that specialize in caring for disproportionately affected populations. In the optimization of vaccine administration, health centers will leverage existing electronic health record systems. Additionally, effectively designed electronic clinical workflows and decision supports can help primary care team members do the following: quickly identify patients meeting ACIP's vaccination guidance criteria, schedule appointments, create standing orders, and provide patient reminders and outreach in support of vaccine administration.

With the health information technology and data analytic capacity to swiftly assess vaccination uptake patterns and monitor patient well-being, health centers can seamlessly integrate COVID-19 vaccination information with routine immunizations and identify

undervaccination among patient subpopulations who may require additional outreach and the systematic delivery of enabling services to address social determinants of health.

At the individual level, health center staff have gauged their patients' knowledge, attitude, and motivation regarding COVID-19 vaccination; there are initial indications of heterogeneity across vulnerable population subgroups in COVID-19 vaccination understanding and acceptance. Although efforts to tailor health education and communication on vaccination administration, planning, and prioritization of high-risk populations are under way, we need continual efforts to pilot test and refine outreach interventions as well as address factors influencing vulnerable population's willingness and adoption of COVID-19 vaccine. Targeted strategies could focus on disseminating observable evidence of vaccine efficacy and safety, highlighting success stories that describe the economic and other benefits of safely returning to work and school. It is of paramount importance that all approaches demonstrate respect for the dignity and autonomy of individuals from vulnerable populations.

CONCLUSIONS

Vulnerable populations have shouldered a disproportionate burden of COVID-19–related morbidity and mortality. Ensuring equity in vaccine access and administration for them will safeguard their health and the nation's health. Health centers serve patients who are among the most vulnerable populations. The health center workforce, many of whom are members of the underserved communities, have an acute understanding of the social needs and COVID-19–related concerns as their patients' medical home throughout the pandemic. The Health Center COVID-19 Vaccination Program has activated and mobilized strategic partnerships among the primary care safety net system, underserved communities, and public health systems to advance health equity for the nation's most vulnerable populations. Moving forward, the collaboration, systematic planning, and coordination will serve as a blueprint for future public health emergency responses, address social determinants of health of vulnerable populations, and improve overall population health outcomes. AJPH

CORRESPONDENCE

Correspondence should be sent to Sue C. Lin, Health Resources and Services Administration, Bureau of Primary Health Care, 5600 Fishers Ln, Room 16W54, Rockville, MD 20857 (e-mail: slin@hrsa.gov). Reprints can be ordered at http://www.ajph.org by clicking the "Reprints" link.

PUBLICATION INFORMATION

Full Citation: Lin SC. Equitable access and distribution of COVID-19 vaccines for US vulnerable populations: federal health center program perspective. *Am J Public Health*. 2021;111(6):1070–1072.

Acceptance Date: March 3, 2021.

DOI: https://doi.org/10.2105/AJPH.2021.306267

CONFLICTS OF INTEREST

The author has no conflicts of interest to declare.

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State Strategies for Addressing Barriers During the Early US COVID-19 Vaccination Campaign

Hemi Tewarson, JD, MPH, Katie Greene, MPP, and Michael R. Fraser, PhD, MS

ABOUT THE AUTHORS

Hemi Tewarson and Katie Greene are with the Duke-Margolis Center for Health Policy, Washington, DC. Michael R. Fraser is with the Association of State and Territorial Health Officials, Arlington, VA.

See also Morabia, p. 982, and the Vaccines: Building Long-Term Confidence section, pp. 1049–1080.

Under Operation Warp Speed (OWS), the US government invested an unprecedented $10 billion to speed the development, manufacturing, and distribution of a COVID-19 vaccine, resulting in emergency use authorizations for two effective vaccine products in a record-breaking 11-month time frame.[1] Although this is a remarkable scientific accomplishment, the United States now faces the urgent task of ensuring widespread acceptance and uptake of COVID-19 vaccines to contain the COVID-19 pandemic, and begin to resume normal economic, educational, and social activities. The operational responsibility for ensuring that COVID-19 vaccines are safely and efficiently delivered in a jurisdiction falls largely on state, territorial, tribal, and local governmental public health systems that support jurisdiction-wide vaccination efforts for a variety of immunizations, including childhood diseases and seasonal influenza. Ultimately, state and territory governors are responsible for the "last mile" of COVID-19 vaccine distribution in their states and ensuring that vaccination is efficiently prioritized for those who need it most, as well as administered, tracked, and reported to the federal government. Although all states and territories have developed plans to increase capacity, enhance data systems, and develop partnerships to support this complex effort, the initial rollout of vaccine allocations did not match federal projections and public expectations; states reportedly distributed roughly one third of allocated doses in the first two weeks of the program.[2]

Although vaccine distribution speed and the number of doses delivered on a weekly basis dominated media coverage of the early rollout, the actual overall public health goal of the COVID-19 campaign is to reach herd immunity in the United States, whereby enough people have immunity from COVID-19 to protect against community transmission, as soon as possible.[3] The importance of this goal has been heightened, given new COVID-19 variants and the need to prevent infection while vaccines are still efficacious against the strains most prominent worldwide. Experts estimate that as much as 80% to 85% of the population (or 300 million) will need to receive a COVID-19 vaccine to achieve this goal—a task made even more urgent, as confirmed cases of more transmissible COVID-19 variants spread in the United States.[4] The development of three authorized vaccines, with more vaccine products in the pipeline, provides hope that this goal will be achieved, but the supply of vaccine and the rate of vaccination are limiting factors.

States are working to increase their vaccination capacity by setting up community "megaclinics" capable of vaccinating thousands of individuals in a day, but their ultimate success depends on having sufficient supply to meet demand. States are also addressing the logistical problems involved in scheduling vaccine appointments across multiple sites, which may include hospitals, pharmacies, state or local governmental public health clinics, federally qualified health centers, and other venues with independent scheduling systems. States also must balance vaccinating quickly with vaccinating equitably—first providing vaccines to those who need it most, not just those who can schedule an appointment first.

OWS officials predicted that states would distribute vaccines to 20 million individuals by the end of December, 2020, with supply ramping up in subsequent months.[5] The first vaccine in the United States was administered on December 14, 2020. A little over two weeks later (January 1, 2021), 4.2 million people

had received their first dose according to data reported to the US Centers for Disease Control and Prevention (CDC).[6] On January 12, 2021, Trump administration officials announced a number of changes to speed vaccine delivery, including recommending expanding eligibility to all Americans who were 65 years or older and to those with chronic conditions that placed them at increased risk of COVID-19 complications.[7] The administration also committed to releasing vaccines to states, instead of holding half back, to ensure that sufficient vaccine was available for second doses to those who had received their first dose 21 days (Pfizer) or 28 days (Moderna) before.[8] However, federal officials subsequently determined that no second doses were actually held back and that OWS was allocating available doses directly to states. On January 15, the incoming president-elect's transition team announced a national COVID-19 vaccination plan that recommended expanding eligibility to individuals who were 65 years and older as well as to frontline workers.[9] Although they support the push to expand eligibility and to get all vaccines available into the arms of willing Americans, state health officials remain concerned about staying true to the equity principles that were part of the federal phased recommendations (as detailed in "Speed, Efficiency, Priority Groups, Equity"), as well as ensuring that there will be sufficient supply to provide second doses to all who need them in accordance with the US Food and Drug Administration's emergency use authorization for both the Pfizer and Moderna vaccines.

We look back on the first two months of vaccine distribution (December 2020 and January 2021) and consider the challenges experienced at the state level as the country looks ahead to the long-term campaign to vaccinate everyone in the United States. We identified these challenges by reviewing each jurisdictions' COVID-19 vaccine plan[10] as well as by conducting interviews with state and local leaders, making all-jurisdiction planning calls, and reviewing media reports covering COVID-19 vaccination planning and implementation. Three key challenges for states emerged from reviews of state plans and the actual experience in the first weeks of the COVID-19 vaccination effort: (1) needing to balance speed, efficiency, equity, and protection of vulnerable populations; (2) expanding the vaccination workforce and state and local capacities to vaccinate; and (3) addressing communication and vaccine hesitancy. Each of these challenges is being addressed by states, and by federal and local partners, as public health leaders and policymakers seek to vaccinate as many people as possible in the coming months. Understanding these challenges more deeply and incorporating lessons learned from early rollout experiences into future planning are essential to improving vaccine distribution in the months ahead.

SPEED, EFFICIENCY, PRIORITY GROUPS, EQUITY

The early planning efforts of state health agencies in October 2020 using the CDC's *COVID-19 Vaccination Program Interim Playbook for Jurisdictional Operations* assumed a limited initial supply of vaccines.[11] Accordingly, states outlined plans for prioritizing early access to certain populations who were most vulnerable to virus exposure or who were most likely to experience severe illness if infected. Adapting to unpredictable shifts in vaccine supply and changes in federal policy in the early weeks of the campaign, and working to quickly respond to emerging logistical challenges have become a daily challenge for state immunization programs. In no instance has this task been more difficult than in identifying who should be first in line to receive the vaccine in a manner that is fair, efficient, and clear to the public. Early uncertainty in priority groups and in vaccine supply availability meant that state plans needed to be iterative, high-level documents that addressed categories of operations and not detailed logistics. These initial documents were not specific tactical plans that could estimate the throughput needed and staffing capacity week by week.

With the authorization of both the Pfizer and Moderna vaccines, the CDC's Advisory Committee on Immunization Practices (ACIP) recommended a detailed prioritization scheme for delivering limited vaccine to health care workers, elderly individuals, those at risk for severe illness, and essential workers at high risk for exposure.[12] ACIP's recommendations, however, are just that—recommendations—and governors ultimately decided what groups would be eligible to receive a vaccine on a state-by-state basis. Although states consistently adopted ACIP's recommendations for the first phase of the campaign (phase 1a), which prioritized health care workers and long-term care residents and staff, states developed significantly more varied approaches for phases 1b and 1c, which included categories or subcategories of individuals older than 65 years, individuals with comorbidities, and a broader group of essential workers.

Early in the rollout, as states faced hesitancy in some communities and sites reported difficulty in filling vaccination slots because of scheduling,

demand, and the complexities associated with thawing and storing the vaccine and the delivery of vaccine in very specific quantities, many states shifted to broadening eligibility categories to ensure that vaccine could be delivered to others to avoid waste or unused dosages. Spurred by changes in federal policy in the last week of the Trump administration, which proposed to tie states' future vaccine allocations to a state's performance in administering and reporting vaccinations, a number of states further expanded eligibility categories to rapidly expand the flow of vaccines into their population. Although the Biden administration did not implement such a performance-based policy, it did continue to push for a more flexible interpretation of ACIP guidelines and suggested that states could speed up vaccination efforts if they expanded beyond initial eligibility groups (i.e., hospital and frontline health care workers and residents of long-term care facilities).

Additionally, although flexibility in prioritization and allocation has allowed states to develop strategies that can meet each state's unique public health infrastructure and needs, shifting approaches and variability across states has contributed to confusion and difficulty in communicating vaccine eligibility and availability to the public. As vaccine supply becomes more predictable, and as state and local tactical plans shift toward expanding the number of vaccination sites in retail pharmacies and additional public health clinics, a more predictable schedule of what priority groups will be vaccinated and when is anticipated. This will not, however, address interstate variation in eligibility, as these are state decisions, nor will it address vaccine availability, as the federal government has assumed procurement of available vaccine on behalf of all states.

To help provide the public with up-to-date information, a number of states have developed scheduling systems and information campaigns to help individuals determine when they can expect to receive the vaccine. Additionally, some states have begun allowing individuals to preregister through state portals, which will provide up-to-date information on current eligibility and appointments for vaccination. The ability to schedule appointments online is important, but also needs to be complemented by phone and in-person sign-ups for individuals who lack Internet access or are not fluent in using online systems.

VACCINATION WORKFORCE AND CAPACITY

Many state immunization programs already have networks of providers and health systems enrolled as vaccine providers who are very familiar with typical vaccination activities as part of their day-to-day operations. However, this provider capacity is not sufficient to support the rapid distribution of COVID-19 vaccine at scale, and states need to continue to expand their workforce to increase the numbers of vaccinators and sites for vaccine distribution. In the initial phase 1a rollout, many states partnered with health systems in their states for the initial distribution to health system staff. States also had the option of participating in a federal government pharmacy program in which the federal government partnered with pharmacy companies CVS and Walgreens to provide the capacity for vaccinating long-term care staff and residents in every state.

States have considered a variety of approaches for expanding their pools of potential vaccinators. Although the federal government has already authorized pharmacists to procure and administer COVID-19 vaccines, several states are examining expanding their scope of practice or licensure for COVID-19 vaccine administration by nontraditional providers, such as advanced emergency medical technicians, paramedics, and medical and nursing students. Additionally, several states have identified plans or announced emergency waivers allowing nontraditional partners, such as respiratory therapists, dentists and dental hygienists, podiatrists, midwives, and veterinarians, to provide additional support and capacity.[13] States and local health agencies are mobilizing volunteers through public health efforts such as the Medical Reserve Corps.[14]

To boost capacity, states are considering or have announced plans for deploying their National Guard to assist with vaccine administration and other logistical efforts.[15] States are also examining a variety of vaccine delivery modalities to address barriers facing underserved populations. These include using seasonal influenza and drive-through testing sites as large-scale community vaccination sites, encouraging pharmacies to set up outreach clinics, and using other sites such as mobile health clinics, federally qualified health centers, Indian Health Service clinics, homeless shelters, harm reduction sites, churches, and primary care offices.

COMMUNICATIONS AND VACCINE HESITANCY

Across the country, states have observed hesitancy among health care

workers and nursing home staff, which are disproportionately composed of individuals of color. According to recent research,[16] a significant percentage of Black and Latinx community members reported concerns about safety or side effects, preferring to take a wait and see approach that would allow others to go first. Other respondents reported a significant distrust of public health authorities, rooted in both historical trauma and contemporary concerns, which contributes to vaccinate hesitancy. Ensuring that communities have access to culturally appropriate resources and information, delivered through trusted messengers, is critical to addressing ongoing disparities in the impact of COVID-19.

To address these challenges, states have employed different strategies, as outlined in their vaccination distribution plans and refined in response to actual events. States are launching public information campaigns to communicate with the public about COVID-19 vaccine availability and safety. Some states have engaged communication firms to design and implement these strategies, and others will work through existing communications resources and partnerships, including federal efforts currently under way. States are also drawing on or building partnerships with community leaders, faith-based leaders, and trusted community organizations to reach critical populations, minimize misinformation, and increase public acceptance among communities of color.

MEETING THE CHALLENGE

An accurate forecasting of supply remains a critical issue to be addressed at the federal level, as week-to-week changes in supply continue to severely challenge logistical planning efforts. The recent announcement of $3 billion in federal funding to support vaccination activities in the states and territories will provide welcome relief to public health agencies strained from months of pandemic response, as will the Biden administration's initiative to expand the support provided to states for vaccination efforts.[17] However, states will need to act quickly and judiciously in dispersing new funding to support urgently needed communications, outreach efforts, and technology solutions; mobilizing mass vaccination clinics; and hiring trained personnel to support these efforts. States will also turn to strategies to increase clinic capacity so more individuals receive the vaccine more quickly. Such efforts include setting up mass vaccination clinics that states will need to partner with a number of different organizations.

The media and some federal and state policymakers have scrutinized the early weeks of the COVID-19 vaccine rollout as failing to meet initial expectations for numbers of individuals vaccinated. The reasons for the perceived slow start to this unprecedented COVID-19 vaccine rollout are complex and multifaceted, and health officials predicted many of them before December 2020.[17] These include shifting supply projections and uncertainty in weekly total allocations of vaccine to states, a lack of commitment of federal funding to states to support vaccine distribution at scale until two weeks into the rollout itself, delays in the reporting of doses administered as new tracking systems were set up, delays in provider reporting of the number of individuals vaccinated in their clinics, vaccine hesitancy among many groups eligible to be vaccinated including health care workers and residents and staff of long-term care facilities, and many other challenges that can accompany the launch of a public health campaign of this scale and complexity.

States are now expanding partnerships and collaborations with key stakeholders, such as pharmacies, community health centers, community organizations, and employers, to address challenges and ensure that vaccines are distributed in an equitable and fair manner in every jurisdiction. As reported by the Association of State and Territorial Health Officials, most states predict a rapid increase in the number of individuals a state will be able to vaccinate after expected problems and early issues with the vaccine rollout.[18] However, the vaccine production and supply required to meet demand remain a concern. The early challenges of the vaccine rollout are important to address as states and territories collaborate with local and federal partners to improve vaccine distribution in the months ahead. AJPH

CORRESPONDENCE

Correspondence should be sent to Michael R. Fraser, ASTHO, 2231 Crystal Dr, Suite 450, Arlington, VA 22202 (e-mail: mfraser@astho.org). Reprints can be ordered at http://www.ajph.org by clicking the "Reprints" link.

PUBLICATION INFORMATION

Full Citation: Tewarson H, Greene K, Fraser MR. State strategies for addressing barriers during the early US COVID-19 vaccination campaign. *Am J Public Health*. 2021;111(6):1073–1077.

Acceptance Date: February 13, 2021.

DOI: https://doi.org/10.2105/AJPH.2021.306241

CONTRIBUTORS

The authors contributed equally in the preparation of this article.

CONFLICTS OF INTEREST

The authors have no conflicts of interest to declare.

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Measuring the Success of the US COVID-19 Vaccine Campaign—It's Time to Invest in and Strengthen Immunization Information Systems

Jade Benjamin-Chung, PhD, MPH, and Arthur Reingold, MD

ABOUT THE AUTHORS

Jade Benjamin-Chung and Arthur Reingold are with the Division of Epidemiology & Biostatistics, University of California, Berkeley.

See also Morabia, p. 982, and the Vaccines: Building Long-Term Confidence section, pp. 1049–1080.

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With the recent US Food and Drug Administration approval of the Pfizer-BioNTech and Moderna SARS-CoV-2 vaccines, the United States has begun COVID-19 vaccine dissemination. The vaccination program is historic in its massive scope and complexity. It requires accurate, real-time estimates of vaccine coverage to assess progress toward achieving herd immunity. Under Operation Warp Speed, the US Centers for Disease Control and Prevention (CDC) has constructed a federal database, or "data lake," to monitor vaccine coverage nationwide and ensure that recipients receive both of the necessary doses. The data lake will be managed separately from existing state and local immunization information systems (IISs), which house vaccine data in all 50 states, five cities, the District of Columbia, and eight territories. In an open letter to the Director of the CDC in late 2020, four organizations representing immunization managers and public health officials expressed concerns about the plan to include vaccine recipients' personal identifier information in the data lake.[1] They also urged stronger coordination with IISs.

We wholeheartedly agree with both points. While some IISs have limitations, including incomplete data and poor linkage with electronic health records (EHRs), they also have a track record of success, as during the 2009 H1N1 influenza pandemic.[2,3] The current moment demands that IISs be strengthened. With enhanced IIS data quality, we can reduce health inequities and conduct more rigorous evaluations of vaccine campaigns. Given the current limitations of IISs, the planned data lake may be a necessary stopgap for the COVID-19 vaccine program. However, the pandemic has radically increased public awareness about the value of the public health enterprise. We must seize this unprecedented opportunity to achieve long-standing goals to increase funding and streamline policies for IISs.

THE COVID-19 DATA LAKE

Operation Warp Speed's data lake is managed federally, but it relies on state and local IISs to collect data. IISs, on the other hand, are managed by the very people who are responsible for administering vaccines and have thus established relationships with vaccine providers. Perhaps the most controversial aspect of the data lake is the plan for inclusion of identifiers (name, sex, date of birth, address, and race/ethnicity) of vaccine recipients. Identifiers are typically stored in IISs and are not reported to federal organizations. Trump Administration officials stated that identifiers are required to coordinate the administration of multidose vaccines, estimate vaccination coverage, and monitor adverse reactions, but these are standard functions of IISs. Concerns about how identifiers may be used by the federal government (e.g., to deport people) could undermine public trust and threaten the vaccine program's success. The Biden Administration's 200-page national strategy for COVID-19 response includes a goal to modernize data collection and reporting to guide pandemic response, but it does not explicitly mention IISs.

HOW TO STRENGTHEN IISs

According to the Advisory Committee on Immunization Practices (ACIP), IISs have the potential to ensure proper vaccination dosage, generate reminders about upcoming vaccinations, minimize vaccine waste, reduce time spent locating vaccination records, and evaluate

vaccine campaigns. We believe there are three key improvements that, if undertaken, will unlock this potential.

First, IISs must receive all vaccination records, including those of older children and adults. A 2012 study estimated that 42% of states and localities operating IISs lacked a reporting mandate for vaccine providers.[3] Without reporting mandates, data are typically incomplete, and IISs cannot reliably evaluate vaccination campaigns. While reporting to IISs is high for young children's vaccination records (96% in 2019), it is lower for older children and adults (82% for 11–17 years and 60% for ≥ 19 years in 2019).[4] The pandemic response effort will require immunization data for all ages, especially older adults, who are more vulnerable to COVID-19.

Second, IISs require more complete demographic information. Race/ethnicity, occupation, and residence type (e.g., long-term care) data are needed to facilitate prioritized SARS-CoV-2 vaccine administration. Occupation and residence type are not included in the CDC's recommended core IIS data elements, although the CDC's pandemic plans prioritize risk groups by occupation. Race/ethnicity data are included but are incomplete in some IISs, preventing the examination of vaccination disparities based on these variables.[5] Vaccine hesitancy is greater in Black populations, and minorities have been disproportionately impacted by the pandemic.[6] Identifying gaps in vaccination coverage by race/ethnicity is essential to reducing such inequities.

Third, increased linkage between IISs and EHRs is needed to support more rigorous evaluations, thereby increasing vaccine campaign effectiveness. If linked with EHR data, IIS data could be used to help assess SARS-CoV-2 vaccine effectiveness and safety within age and race/ethnicity subgroups. The unprecedented speed of SARS-CoV-2 vaccine development makes postlicensure evaluation especially important. Such data linkage would also benefit evaluations of school-based influenza and human papillomavirus vaccination programs, among others. However, interoperability between IISs and EHRs is often limited because of conflicting regulations governing IISs and patient privacy.[3]

POLICY REFORM AND INCREASED FUNDING

The solutions for strengthening IISs are clear: policy reform and increased funding. IISs are governed by over 984 federal, state, and local policies in 13 areas of law.[2] This often overlapping and contradictory hodgepodge of regulations creates confusion and hampers IIS effectiveness. The CDC, ACIP, and National Vaccine Advisory Committee provide best practices and guidance for IIS managers, but we need to reform laws to make them clear and uniform across all IISs in the following ways.

First, policies to protect patient privacy must be standardized to reduce confusion. Currently, patient privacy protections are specified not only by state and local IIS-specific regulations but also federal laws, such as the Health Insurance Portability and Accountability Act, resulting in confusion. Vaccine providers' liability concerns contribute to inadequate reporting to IISs.[2] Streamlining these policies could thus increase reporting to IISs and protect privacy and public health.

Second, all states need policies authorizing and facilitating data transfers between IISs. Vaccine administration increasingly occurs across multiple localities and states. To accurately capture vaccination in different locations, IISs need to share data across city and state lines, but only about half do so.[2] In some states, IISs do not have the legal authority to share data with other IISs[3]; in others, data exchange agreements are needed to share data, which can slow or prevent data sharing.

Third, policies must encourage rather than hinder IIS innovation. There is no shortage of technological innovations to increase reporting to IISs (e.g., the integration of smartphone apps with IISs, as is done in Canada); however, the complexity of current policies relating to vaccine data privacy and transfer hampers innovation.

Improvements to IISs will require additional funding to support IIS computing infrastructure and staff time. Historically, IISs have been funded by federal, state, and local governments and foundations. Since 2014, the annual federal budget appropriation for immunization programs under Section 317 of the Public Health Service Act has remained the same at approximately $611 000.[7] This pales in comparison with the billions of dollars of federal funding devoted to SARS-CoV-2 vaccine development. The March 2020 Coronavirus Preparedness and Response Supplemental Appropriations Act provided the CDC with $500 million to modernize public health data systems, and the December 2020 coronavirus stimulus bill included $8.75 billion in CDC funding to support COVID-19 vaccine dissemination and measurement of vaccination coverage. However, public CDC documents do not indicate whether any of these funds will be allocated specifically to strengthen IISs. Without increased and sustained funding, IISs will not realize their full potential, even if the policy reforms outlined above are achieved.

CONCLUSIONS

The public health departments that run IISs cannot lobby legislatures responsible for IIS policy. However, physicians, epidemiologists, and public health professionals can use their voices to express the importance of IISs, particularly during the COVID-19 pandemic, to advocate for policy reform and increased funding.

The recommendations to make IISs more effective are not new,[2,3] but the opportunity to achieve them is. We must capitalize on this moment to strengthen our public health systems so that we may save more lives in a more equitable manner in the current pandemic and beyond. AJPH

CORRESPONDENCE

Correspondence should be sent to Jade Benjamin-Chung, PhD, MPH, Division of Epidemiology & Biostatistics, University of California, Berkeley, 2121 Berkeley Way Rm 5302, Berkeley, CA 94720-7360 (e-mail: jadebc@berkeley.edu). Reprints can be ordered at http://www.ajph.org by clicking the "Reprints" link.

PUBLICATION INFORMATION

Full Citation: Benjamin-Chung J, Reingold A. Measuring the success of the US COVID-19 vaccine campaign—it's time to invest in and strengthen immunization information systems. *Am J Public Health*. 2021;111(6):1078–1080.

Acceptance Date: January 11, 2021.

DOI: https://doi.org/10.2105/AJPH.2021.306177

CONTRIBUTORS

J. Benjamin-Chung wrote the first draft of the manuscript. A. Reingold reviewed and revised the manuscript.

ACKNOWLEDGMENTS

J. Benjamin-Chung was supported by the National Institute of Allergy and Infectious Diseases, National Institutes of Health (grant K01AI141616).

We thank Casey Wright of Flu Lab for thoughtful comments on the manuscript.

Note. Research reported in this publication was supported by the National Institute of Allergy and Infectious Diseases of the National Institutes of Health under award number K01AI141616. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

CONFLICTS OF INTEREST

J. Benjamin-Chung has no conflicts of interest to declare. A. Reingold is the Chair of the California State COVID-19 Vaccine Workgroup and a Director of the California Emerging Infections Program.

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COVID-19—The Case for Rethinking Health and Human Rights in Prisons

Jörg Pont, MD, Stefan Enggist, MSc, Heino Stöver, PhD, Stéphanie Baggio, PhD, MSc, Laurent Gétaz, MD, and Hans Wolff, MD, MPH

This article considers health and human rights implications for people deprived of liberty during the COVID-19 crisis. The health risks of incarceration for individual and community health, particularly in overcrowded and underresourced prisons and detention centers, are well known, but with the COVID-19 pandemic have become a public health emergency.

Physical distancing in prisons is hardly manageable, and protective means are poor or lacking. Emergency releases have been shown to be feasible in terms of public safety but lack sustainability in reducing the number of people living in detention, and, globally, only a small proportion of them have been released. Without controlling the infection inside prisons, global efforts to tackle the spread of the disease may fail. People living in detention are not only more vulnerable to infection with COVID-19 but they are also especially vulnerable to human rights violations induced by inappropriate restrictions under the pretext of infection control. Therefore, alternatives for detention should be promoted and the number of incarcerated people radically decreased.

This article calls on policymakers and all professionals involved in public health and criminal justice not to waste the opportunities provided by the crisis but to act now. (*Am J Public Health*. 2021;111:1081–1085. https://doi.org/10.2105/AJPH.2021.306170)

The COVID-19 pandemic is imposing excessive health problems upon persons living in detention (PLDs) and to those working in detention settings. The prepandemic health risks of incarceration for individual and community health including high prevalence of infectious diseases in PLDs, increased risks of transmission, insufficient screening and health care in prison, and spread of infectious diseases to the community by released PLDs have been clearly documented.[1,2] Similar health risks are found in detention settings worldwide even if the magnitude of health risks may differ between detention settings and penitentiary systems and depending on countries' imprisonment and occupancy rates and staffing levels as well as prison health care governance.[3] The risks are particularly high in overcrowded and underresourced detention centers, a pattern that is repeated, sadly, in the majority of countries worldwide.[4,5] Hence, the demands of the International Covenant on Economic, Social, and Cultural Rights, "the right of everyone to the highest attainable standard of physical and mental health"[6] are rarely, if ever, met in persons deprived of liberty.

The number of PLDs worldwide is growing at a rate that exceeds the rate of population growth, recently topping 11 million. The global numbers of persons in pretrial detention,[7] of imprisoned females,[8] and of aging imprisoned persons[9] are also constantly increasing and this also has to be assumed for detained refugees and asylum seekers for whom no global numbers are available. In 2020, at least 124 countries exceeded their maximum occupancy rates, in 23 by more than 200%. The rising numbers of PLDs and prison overcrowding are not a consequence of rising crime rates but of current criminal justice policies including overuse of pretrial detention,[10,11] of the war on drugs that lapsed into a war on drug users who worldwide now represent a major proportion of PLDs, and of applying incarceration for failure to pay a fine.

The impact that prison health has on community health has been demonstrated and proclaimed by the World Health Organization (WHO).[2,12] For effectively fighting HIV, hepatitis C, and tuberculosis infection, the inclusion of PLDs in public health programs has become indispensable,[2,13–16] and a clear relationship between prison population growth and increased incidence of tuberculosis and drug-resistant

tuberculosis in the communities has been documented.[17]

THE COVID-19 PANDEMIC

The chronic health plight of PLDs and the consequences on public health have now, with the COVID-19 pandemic, become an acute public health emergency. Throughout the pandemic, physical distancing has been the backbone for controlling the spread of COVID-19, a measure hardly manageable in custodial settings, particularly in overcrowded ones. In prisons and detention centers the provision of protective means is often poor or lacking and poor ventilation increases the transmission risk of airborne infections. Health care professionals in custodial settings are often understaffed, and the increasing age of PLDs,[18] high prevalence rates of chronic health problems,[1] and inadequate provision of health care[19] increase susceptibility to severe COVID-19 disease.[20] The WHO has warned that global efforts to tackle the spread of the disease may fail without controlling the infection inside prisons.[21]

By July 2020, internationally, 102 000 PLDs tested positive for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), and 1500 deaths from COVID-19 had been reported.[22] Lack of testing, symptom-based rather than mass testing,[23] insufficient data collection, and deficient transparency of reporting suggest that the true number of cases and deaths was much higher.[24] The highest national numbers as of September 2020 stem from US prisons where 155 000 persons had tested positive and more than 1000 died of COVID-19. The rate of COVID-19 cases in prisons was more than 4 times the rate of US residents, and the average COVID-19 mortality in prisons was twice as large as the mortality in the general population, adjusted for sex, age, and race/ethnicity.[25]

Emergency reactions undertaken by penitentiary administrations included compulsory isolation; quarantine for newly admitted, suspected, and infected imprisoned persons; and restricted activities with persons circulating between community and prison while custodial staff continued circulating between in- and outside. The suspension or denial of personal visits by families, who provide badly needed mental support and often also livelihood for PLDs, brought on violent riots in several countries[21] with high death rates.[26]

Many states resorted to reducing PLD numbers by emergency releases. International organizations[21,24,27] recommend prioritizing release of offenders in pretrial detention, older and ill persons, juveniles, pregnant women, breastfeeding women, mothers with children, and persons imprisoned for minor offenses and nonviolent crimes. However, only a fifth of the countries engaging in early release strategies included women, and in 28 countries, PLDs with drug-related offenses have been excluded despite the small risk they pose for public safety.[24] Although some countries released tens of thousands of PLDs, not more than 5.8% of the global prison population had been released by July 2020.[24]

It is a matter of great concern that some countries have been reported to select only nonpolitical PLDs for release while keeping political PLDs in detention.[28] The selective exposure of political PLDs to the COVID-19 risk in prisons with insufficient care conditions may be seen as an equivalent of a biological weapon against political opponents and a severe human rights violation.

THE HUMAN RIGHTS DIMENSION

According to the European Committee for the Prevention of Torture and Inhuman or Degrading Treatment or Punishment, "Protective measures must never result in inhuman or degrading treatment of persons deprived of their liberty."[27] The WHO pointed out that "people in prisons and other places of detention are not only likely to be more vulnerable to infection with COVID-19, they are also especially vulnerable to human rights violations."[21]

Lockdown measures inside the locked prison environment further reducing the scanty movement and activities of PLDs and restrictions of contacts with families and legal representatives can easily amount to human rights violations.

According to the International Covenant on Civil and Political Rights, the right to liberty may be derogated in times of public emergencies. However, any restriction or limitation on the grounds of health needs to be temporary, necessary, proportionate, nondiscriminatory, legally authorized, subject to review, and the least-restrictive alternative.[29,30]

The human rights challenge in infection control measures in prison is twofold: (1) not ensuring optimal protection of PLDs' health amounts to a human rights violation, and (2) inappropriate restrictions of PLDs' rights under the pretext of health protection also result in a human rights violation.

Compulsory measures restricting liberty belong to the basic methods of control of infectious diseases.[31] Even though the suspension of human rights in times of emergency is explicitly recognized in the International Covenant on Civil and Political Rights, coerced quarantine, isolation, and other restrictions of liberty implicitly raise disputes between public health and human rights positions, particularly in the coercive environment of a prison. The United Nations Office of the High

Commissioner of Human Rights Working Group on Arbitrary Detention recently set a benchmark by emphasizing "that the prohibition of arbitrary deprivation of liberty is absolute and universal. Arbitrary detention can never be justified, whether it be for any reason related to national emergency, maintaining public security or health."[30(p2)]

Restrictive measures in addition to those intrinsic in prison run the risk of infringing on human dignity of PLDs by making them become mere objects of administrative procedures rather than subjects of individualized sentence plans allowing them to perceive themselves as individuals. This may amount to a violation of Article 3 of the European Convention of Human Rights: "No one shall be subjected to torture or to inhuman or degrading treatment or punishment."[32(p7)] Lack of personal space and movement of prisoners have been frequently judged as violations of Article 3 by the European Court of Human Rights.[33]

Mann et al. wrote in 1994,

> At present, an effort to identify human rights burdens created by public health policies, programs and practices, followed by negotiation towards an optimal balance whenever public health and human rights goals appear to conflict, is a necessary minimum. An approach to realizing health objectives that simultaneously promotes - or at least respects - rights and dignity is clearly desirable. . . .[34]

And, in 1997, Mann wrote, ". . . it will require innovation, experiment, and risk-taking."[35]

In tackling the current pandemic and anticipating future pandemics, this is even more true. The revision of incarceration policies and the introduction of new policies that are potentially more effective, such as abstaining from incarceration whenever possible, also provide an opportunity for improving individual and community health while staying in line with human rights.

POSSIBLE INTERVENTIONS AND STRATEGIES

International organizations providing guidance for prevention and control of COVID-19 in prisons[21,24,27] recommend an array of interventions including strengthening the resources for health care in prison and the reduction of PLD numbers. However, in light of the long-standing demands and unmet needs of proper staffing and financial support of prisons, it seems unlikely that just in times of the pandemic-caused economic crisis the strengthening of human and material resources will be accomplished and the long-standing recruitment problems for prison staff will improve given their high risk of infection.

The recommended reduction of PLD numbers should be achieved by (1) applying pretrial detention only as a rare exception, (2) releasing vulnerable PLDs and those sentenced for minor and nonviolent crimes, and (3) introducing noncustodial sentences whenever possible and applying incarceration only as a last resort. The attained space and resources will allow for better physical distancing and better access to health protection and care of the remaining PLDs.

Recent reports show that releases are feasible in terms of public safety.[36,37] However, releases reduce PLD numbers and overcrowding only temporarily without a sustainable effect. For remedying the intolerable health situation of overcrowded and understaffed prisons and for being prepared for future epidemic outbreaks, sustainable measures reducing incarceration rates by systemic and long-term reforms are needed including the following:

- Prevention of crimes through social measures without recourse to criminal law (e.g., using restorative justice approaches);
- Diversion of minor offenses by warnings and cautions, mediation, fines, restorative justice, and referral to treatment;
- Reducing pretrial detention by enforcing time limits of criminal proceedings, bail, and alternatives to pretrial detention;
- Abandoning imprisonment as a standard sanction by training of judges, electronic supervision, community sentences, fines, and assistance of offenders to comply with them;
- Abandoning imprisonment of children, juveniles, caretakers of children, mentally ill persons, and drug-addicted persons by diversion to education, restorative noncustodial measures, and medical or other care;
- Reducing sentence lengths legislatively and by practice; and
- Strengthening parole systems for early release and assistance to released PLDs by placement in supervised community accommodation.[38]

Published recommendations to reduce overcrowding in prisons[5] provide detailed proposals in this regard. There is an, albeit slow, increase of sanctions without deprivation of liberty in Europe, whereas noncustodial measures as an alternative to pretrial detention are still seldom used.[39]

Main barriers to effectively reducing prisoner numbers are overuse and

misuse of pretrial detention[10] and the tenacious, media-fueled belief of the public and politicians in deterrence by tough incarceration practices, which have not shown any demonstrable effect on reduction of crime but have induced the current global prison crisis.

Strategies chosen should have a sustainable effect and take into account the prepandemic global health plight in prison. The frequently expressed wish for a "return to normality" after the COVID-19 crisis is, in the prison health context, a threat rather than a desirable aim.

PRISON ABOLITIONISM MOVEMENTS

The lack of evidence that incarceration achieves reduction of crime and human rights concerns has motivated the development of a global penal abolitionism movement during the past decades,[40,41] and concerns on health in prisons contributed to it. Positions within the movement differ in their philosophical and political backgrounds and in the extent of their demands. Their common denominator is a radical reduction of PLDs and replacement of the current criminal law practices by restorative and transformative justice.

The global emergency situation in prisons because of the pandemic on top of the global prison crisis gives reason for urgently transferring the theoretical philosophical considerations of the abolitionism movement to a practical political discourse. As Mann wrote in "Health and Human Rights: If Not Now, When?" ". . . it will require innovation, experiment, and risk-taking."[35]

CONCLUSIONS

The impact the COVID-19 pandemic has had on our current prison systems is a humanitarian disaster. It is a reminder that we should take note of the long-standing principle that incarceration for any legal purpose should be the very last resort and be applied only if absolutely unavoidable as a rare exception rather than as standard penal procedure. With the COVID-19 pandemic, this principle became an indispensable necessity for individual and public health. Instead of deprivation of liberty as a punishment for whatever offense or crime, new ways of restorative and transformative justice are needed, focusing more on the victims rather than only on the perpetrator, more on responsibility rather than on guilt, and more on penitence by indemnification rather than by taking away liberty. We must urge policymakers, governments, penitentiary and public health legislators, judges, penitentiary practitioners, and other detention authorities not to waste the opportunities provided by the crisis but to act now. AJPH

ABOUT THE AUTHORS

Jörg Pont, retired from the Medical University Vienna, Austria, is a consultant for prison health care. Stefan Enggist is with the Swiss Federal Office of Public Health, Bern, Switzerland. Heino Stöver is with the University of Applied Sciences, Faculty of Health and Social Work, Frankfurt am Main, Germany. Stéphanie Baggio, Laurent Gétaz, and Hans Wolff are with the Division of Prison Health, Geneva University Hospitals and University of Geneva, Geneva, Switzerland.

CORRESPONDENCE

Correspondence should be sent to Jörg Pont, Brachtlgasse 20a, 1230 Vienna, Austria (e-mail: joerg.pont@meduniwien.ac.at). Reprints can be ordered at http://www.ajph.org by clicking the "Reprints" link.

PUBLICATION INFORMATION

Full Citation: Pont J, Enggist S, Stöver H, Baggio S, Gétaz L, Wolff H. COVID-19—the case for rethinking health and human rights in prisons. *Am J Public Health*. 2021;111(6):1081–1085.

Acceptance Date: January 9, 2021.

DOI: https://doi.org/10.2105/AJPH.2021.306170

CONTRIBUTORS

J. Pont led the writing, and all authors made substantial contribution to the conceptualization and analysis of the work, revised it critically, and approved the final version of the article.

CONFLICTS OF INTEREST

None of the authors has any potential and actual conflicts of interest.

HUMAN PARTICIPANT PROTECTION

No protocol approval was necessary because data were obtained from secondary sources.

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A Centenary Tale of Two Pandemics: The 1918 Influenza Pandemic and COVID-19, Part I

David M. Morens, MD, Jeffery K. Taubenberger, MD, PhD, and Anthony S. Fauci, MD

See also Leavitt, p. 996.

Separated by a century, the influenza pandemic of 1918 and the COVID-19 pandemic of 2019–2021 are among the most disastrous infectious disease emergences of modern times. Although caused by unrelated viruses, the two pandemics are nevertheless similar in their clinical, pathological, and epidemiological features, and in the civic, public health, and medical responses to combat them. Comparing and contrasting the two pandemics, we consider what lessons we have learned over the span of a century and how we are applying those lessons to the challenges of COVID-19. (*Am J Public Health*. 2021;111:1086–1094. https://doi.org/10.2105/AJPH.2021.306310)

AJPH June 2021, Vol 111, No. 6

It was the best of times when renowned artist Marilee Shapiro Asher finally left the hospital, in April 2020, after five days of struggling with COVID-19 (caused by severe acute respiratory syndrome coronavirus 2 [SARS-CoV-2]).[1] We know that Asher was glad to be home, looking forward to returning to her studio and her exhibitions, because she had already written about what it was like surviving an eerily similar respiratory illness as a 6-year-old girl: her most vivid memory was not the days in bed, but finally being allowed to get up one morning and join her family at the breakfast table, a joyous event signaling recovery.

That joyous breakfast was in 1918, when Marilee survived the so-called "Spanish" influenza, estimated to have killed at least 50 million people worldwide, one of the deadliest single events in all of human history.[2] Recovering from COVID-19 last year, Asher, then in her 108th year, was among a dwindling cohort of 1918 pandemic survivors who not only still remembered it but who also were now facing another lethal pandemic: COVID-19. Childhood memories like Asher's were supplemented by an enormous body of medical, scientific, public heath, and societal information concerning that earlier pandemic. It is worth reflecting on this body of collective memory as we travel through the dark uncertainty of another pandemic that threatens and impacts millions of lives. From the vantage point of an additional century of medical and social progress, it is hoped that we are mastering history's lessons.

THE 1918 INFLUENZA PANDEMIC

Before 1918, influenza was a poorly understood disease of unknown cause. The 1918 pandemic appeared suddenly in a few populous cities including in China in June[3] and in Northern Europe in July–August 1918.[4] It rebounded over most of the world (in both the Northern and Southern Hemispheres) in September–November 1918, featuring from one to several additional recurrences beginning in late 1918–early 1919.[2,5,6] In the United States, an estimated 675 000 people died in the first year, equivalent to about 2.16 million deaths in today's much larger population, an approximate 1% case–fatality ratio.[2] The explosivity of the pandemic was staggering. Bodies were sometimes "stacked like cord wood" in hospitals, or by roads outside of cemeteries; coffins had to be mass produced on a large scale (Figure 1).

Over a few years, the 1918 pandemic settled into a pattern of less fatal annual seasonality. Human influenza A viruses were first isolated in 1933.[7] At that time, isolation materials from the 1918 pandemic were thought not to exist; however, decades later (1996–2005) the viral genome was fully sequenced from RNA fragments in pathological materials of 1918–1919 pandemic victims; soon thereafter, it was reconstructed as a fully infectious virus and studied experimentally.[7] Viral descendants of the 1918 "founder" virus are still circulating today as seasonal influenza A viruses; subsequent pandemics in 1957, 1968, and 2009 all resulted from genetic

FIGURE 1— Both the (a) 1918 and the (b) 2020 Pandemics Featured Hastily Assembled Cemeteries, Mass Graves, and Collections of Unburied Bodies

Note. Photo by Willy Kurniawan, courtesy of Reuters. Printed with permission.

updating of the 1918 virus via a mutational mechanism called gene segment reassortment.[8] Over the period of a century, viral descendants of this single emergent virus have caused tens of millions of additional deaths, adding to the tragic losses of 1918. Fortunately, to date, there is evidence that public health restrictions to control COVID-19 (e.g., social distancing, mask wearing, business closures) are controlling influenza as well. As we are in the early second year of the COVID-19 pandemic, we cannot predict with certainty whether the virus will persist as the 1918 influenza virus did, or die out in the face of growing population immunity associated with natural infection and new COVID-19 vaccines.

CLINICAL AND PATHOLOGICAL COMPARISONS

Although caused by unrelated viruses, the two diseases are similar in their clinical features (Figure 2). Both are respiratory viruses transmitted and acquired via respiratory inoculation, and both emerged in global populations with little or no preexisting immunity. Typical signs and symptoms of both full-blown diseases include fever, chills, fatigue, muscle aches, nasal congestion or rhinorrhea, headache, and cough, with variable sore throat, dyspnea, and nausea, vomiting, or diarrhea. Both diseases feature many mild, atypical, and asymptomatic

Comparing pandemics: 1918 influenza and 2019 COVID-19

Variable	1918 Influenza	2019 COVID-19
Infectious Agent	Novel respiratory virus	Novel respiratory virus
Mechanism of emergence	Host switching	Host switching
Source of emergence	Wild waterfowl (*Anseriformes*)	**Wild *Rhinolophus* bat**
Cell receptor	**Sialic acids on respiratory epithelia**	**ACE2 receptor on multiple cells, multiple organs**
Viral preadaptation	Virus preadapted or quickly adapted to human spread	Virus preadapted or quickly adapted to human spread
Clinical & Pathological Disease		
Clinical	Upper respiratory disease, pneumonia	Upper respiratory disease, pneumonia
	No viremia, no systemic disease	**Viremia with systemic disease, vascular damage**
Complications	Secondary bacterial pneumonia, empyema	**Secondary bacterial pneumonia less frequent; Multisystem disease**
Pulmonary pathology	Viral pneumonia, DAD, edema	Viral pneumonia, DAD, edema
	Microthrombi, variable hemorrhage in some	Microthrombi, variable hemorrhage in some
	Aberrant immune response	Aberrant immune response
	Massive neutrophilic infiltrates in some	Neutrophilic infiltrate **less frequent**
Epidemiology		
Preexisting immunity	Possible immunity in older persons	**Prior immunity status not yet certain**
Mortality	Case–fatality ratio about 1% in United States	Case–fatality ratio estimated around 1% in United States
	Higher mortality in infants, elderly, chronically ill	**Children and young adults: lower incidence & severity**
	Pregnant women/fetuses	**No extreme mortality in pregnant women/fetuses?**
	Mortality peak in adults aged 20–40 years	**No mortality peak in adults aged 20–40 years**
Morbidity	Morbidity peak in school-aged children	**Low morbidity in children & young adults**
Origin & spread	Spread by travel, from big cities, spread outward	Spread by travel, from big cities, spread outward
	R_0 estimated to be about 1–2	R_0 about 1–2, but varies greatly
	Spread by droplet, aerosol, hands and fomites	Spread by droplet, aerosol, hands, and fomites
	Asymptomatic carriers	Asymptomatic carriers
	Super spreaders probable	Super spreaders
	Induces full or partial protective immunity	Induction of full or partial protective immunity not established
	Persisted by means of viral evolution	Persistence potential not yet established
Public Health Responses	Closures, isolation, social distancing, masks	Closures, isolation, social distancing, masks
	Bacterial vaccines	Bacterial vaccines, SARS-CoV-2 **viral vaccines**
Treatment	Supportive care, plasma therapy, no ICUs	Supportive care, plasma therapy, **ICUs**
	No antibiotics or antivirals	**Antibiotic, antivirals, glucocorticoids**
	Quack and untried remedies	Quack and untried remedies
Psychosocial Reactions	Widespread disease fear	Widespread disease fear
	Common defiance of public health recommendations	Common defiance of public health recommendations
	Altruism and helping others was common	Altruism and helping others was common

FIGURE 2— Comparing Pandemics: 1918 Influenza and 2019 COVID-19

Note. DAD = diffuse alveolar damage; ICU = intensive care unit; SARS-CoV-2 = severe acute respiratory syndrome-2.

infections, but also complicating, sometimes fatal, pneumonias in about 2% of those clinically ill. In the case of COVID-19, unusual as well as late complications are being noted with increasing frequency, including tissue and organ damage, neurological complications, and inflammatory syndromes. It is not clear to what extent, if any, such complications occurred with 1918 influenza, although, curiously, neurological complications were said to be prominent in the 1889 influenza pandemic.

Typical influenza pneumonia in 1918 occurred in a bronchopneumonic pattern associated with secondary bacterial pneumonias caused by pathogens carried silently in the upper respiratory tract, including *Streptococcus pneumoniae*, *Streptococcus pyogenes,* and

Staphylococcus aureus.[9,10] Initial autopsy data from COVID-19 patients suggest a similar histologic picture of viral pneumonic damage with, however, fewer secondary bacterial pneumonias,[11] perhaps in part reflecting widespread use of broad-spectrum antibiotics not available in 1918.

In both diseases, severe pneumonias have been associated histologically with diffuse alveolar damage, hyaline membrane formation, pulmonary edema, and, often, neutrophilic infiltrates[11,12] (Figure 3). Autopsy studies of COVID-19 patients reveal widespread medium- and small-vessel thromboses[13]; pulmonary small-vessel thrombosis was prominent in 1918 influenza as well[14,15]; however, it has been less frequently observed in more recent influenza autopsies (e.g., during the 2009 H1N1 pandemic[16,17]). In contrast to 1918, in which tissue damage was mostly pulmonary, in COVID-19, tissue damage has been observed in tissues and organs systemically.[18]

Important pathological differences between the two infections (Figure 2) include the following: influenza infects primarily by binding to sialic acid receptors found on respiratory epithelial cells, whereas SARS-CoV-2 infects various cells of the respiratory tract, gastrointestinal enterocytes, and arterial and venous endothelial cells, as well as arterial smooth-muscle cells, presumably by binding to ACE2 receptors.[19] As influenza caused by human-adapted influenza viruses is not associated with viremia, live influenza virus has little direct interaction with the systemic immune system, explaining in part why natural and vaccine-induced protective immunity against influenza is often imperfect. Preliminary data from COVID-19, however, suggest systemic infection of multiple organs,[20–22] which can potentially elicit protective immunity more durable than that of influenza, although duration of COVID-19 protection remains to be determined, and reinfections have been documented.[23]

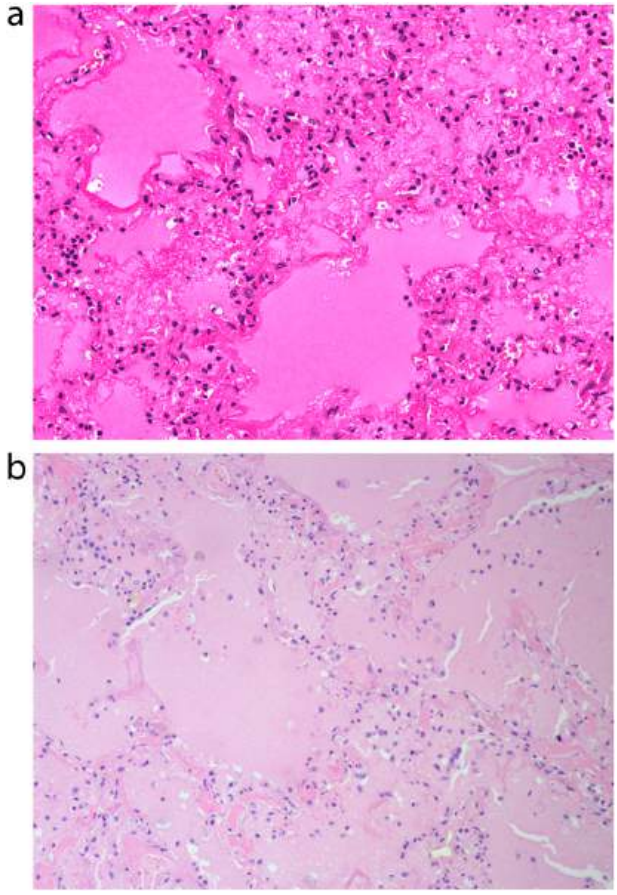

FIGURE 3— Representative Pulmonary Histopathology of (a) Fatal 1918 Influenza and (b) Fatal SARS-CoV-2 Infection Showing Acute Diffuse Alveolar Damage With Pulmonary Edema and Hyaline Membranes

Source. Sauter et al.[11] and Sheng et al.[12]
Note. SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2. The histologic patterns of acute diffuse alveolar damage are virtually indistinguishable.

EPIDEMIOLOGICAL COMPARISONS

It is extremely difficult to know the exact origin of any pandemic disease, because emerging infectious agents arise via host switching from an animal to a human, after which successful adaptation associated with human-to-human transmission occurs.[24–26] This process necessarily takes time: by the time the new disease is eventually recognized, its occult beginnings are unlikely to be discovered. In this regard, it is noteworthy that over many centuries, from the 1500s until the modern era, almost all influenza pandemics were first recognized in Asia or Southeast Asia, and then spread westward to Europe and, at some point after the 16th century, from Europe or Asia to the Western Hemisphere.[27] As some of the earliest evidence of the existence of the 1918 pandemic came from China,[28] this same historical pattern remains plausible, although the geographic

origin of the 1918 pandemic remains unknown, with hypotheses ranging from China to Europe to the United States.[28–30]

When the 1918 pandemic was first recognized clinically and epidemiologically in July 1918, and again in September–November 1918, it was robustly emerging almost simultaneously in large populous cities all over the globe, in both the Northern and Southern Hemispheres. This pattern indicates that rather than spreading from city to city along travel routes at the time of such explosive emergence, many regions of the world must have been seeded by the virus previously.[2] Presumably, the relatively slow global spread of infections by ship, rail, and other means of human travel went undetected until international metropolitan mortality data began to show excess respiratory mortality increases. From these large cities, the disease spread outward to smaller towns and to rural areas, and also caused additional rounds of global spread by ships.

Because of modern international air travel, COVID-19 spread slightly more rapidly than 1918 pandemic influenza; however, the patterns of spread were probably very similar: (1) local emergences and initial spread that went undetected because of low case–fatality, followed by (2) local, national, and eventually international movement of infectious persons, leading to seeding of cases in crowded metropolitan areas, followed by (3) clusters of respiratory disease mortality that were eventually detected in sensitive metropolitan mortality data, followed quickly by (4) massive global emergence.[31]

SARS-CoV-2 was first detected in Wuhan, Hubei Province, China, and spread simultaneously outward within China and via international air routes. It is highly likely that SARS-CoV-2 emerged from within a tight phylogenetic cluster of *Sarbecoviruses* infecting *Rhinolophus* (horseshoe) bats found mostly in Southwest China and contiguous areas of Cambodia, the Lao PDR, Myanmar, and Vietnam.[26,32,33] How the virus got to the place of its initial detection, at least 850 miles away in Wuhan, remains unknown; possible explanations include the mobility and long-distance ranges of various bat species, undetected cross-infection from *Rhinolophus* to other bat species, or infection and movement of secondarily infected animal hosts or of humans.

EMERGENCE VIA ANIMAL-TO-HUMAN VIRAL HOST SWITCHING

The 1918 pandemic "founder" virus was genetically and functionally very similar, in sequences of all eight genes, to avian viruses that then existed, and that still exist, in the global reservoir of wild waterfowl (*Anseriformes*).[34] It is unknown whether an avian virus host-switched directly into humans or first switched into a different host, perhaps another mammal, and from there to humans.[35] However, phylogenetic analysis of the human virus suggests that emergence must have occurred in or shortly before 1918.[2]

SARS-CoV-2 is very close genetically to numerous enzootic *Sarbecoviruses* of *Rhinolophus* bats found in Southwest China and contiguous areas, suggesting one of three possibilities[32,36–38]: (1) an as-yet-undiscovered enzootic *Sarbecovirus* identical to SARS-CoV-2 emerged into humans directly; (2) a different but closely related *Sarbecovirus* emerged directly into humans and spread silently for some period of time, accumulating new mutations as it adapted to human transmission; or (3) humans were infected via an intermediate animal host that had originally been infected by a *Rhinolophus*-transmitted *Sarbecovirus*.[36,37,39] Thus, 1918 influenza and SARS-CoV-2 share the same origin mysteries of direct versus indirect emergence from a natural animal host, and of extent of postemergence genetic adaptation to humans.

Both 1918 influenza and COVID-19 are among the deadliest examples of viral emergences from the animal–human interface.[33] How this happens and what we can do to prevent it from happening are among the most important areas of research in the study of emerging infections.[33,40] The host-switching ability of both viruses may be an established evolutionary mechanism: both 1918 influenza and SARS-CoV-2 are promiscuous in their ability to infect mammals, facilitating broad epidemicity and epizooticity. In 1918, the human virus was quickly transmitted to pigs,[41] while housecats were sometimes infected by their owners (as seen in previous influenza pandemics). A century later, humans and pigs are still frequently exchanging their influenza viruses.[42] Unexpected deaths of chimpanzees and gorillas in 1918 were thought to be attributable to influenza. Horses, dogs, seals, and other animals have also been involved in influenza virus exchanges.[43] SARS-CoV-2 has infected not only *Rhinolophus* bats, their reservoir host, but also cats, dogs, minks, and other animals[44]; closely related SARS-like viruses have infected pangolins (*Manis javanica*, a species of anteater).[32] Such efficient intra- and interspecies exchanges may have enhanced evolution and survival of both viruses.

VIRAL TRANSMISSION

Both viruses are transmitted by the respiratory route via large droplets,

fine-particle (< 5 μm) aerosols, or by hands or fomites contaminated with respiratory secretions. Both viruses spread by silent transmission—that is, transmission by presymptomatic (incubating) people, by asymptomatic infected people, by people with mild or atypical symptoms who are not recognized as being potentially infectious, and, less commonly, by people who have recovered from illness but may still be excreting virus.[39,45] Unlike influenza, SARS-CoV-2 infects enteric cells, but gastrointestinal transmission has not yet been shown to be important.

Preliminary evidence suggests roughly equivalent effects of environmental variables on spread of both viruses (e.g., effects of airflow, temperature, and humidity). This has important implications for COVID-19 public health control measures such as social distancing and controlling airflow in hospitals, nursing homes, workplaces, and recreational venues, such as restaurants and bars.

Regarding seasonality, 1918 pandemic influenza was first detected in the early summer of the Northern Hemisphere and did not spread globally until September–October 1918. When it did so, it aggressively spread not only in the Northern Hemisphere but also in the Southern Hemisphere's spring season (e.g., in South Africa[46] and in New Zealand[47]). Five hundred years of observation[48] suggest that influenza pandemics can appear at any time of year, but when they arrive in summer they are likely to be somewhat blunted until they rebound more forcefully in the fall; when pandemics arrive at other times of year, summers seem to temporarily slow viral spread.[48] This pattern was seen in both the 1957 and 2009 influenza pandemics; in the United States, both pandemics arrived in the spring, slowed down in the summer, and then picked up in the fall. The presumed reasons for this pattern include physical effects of temperature and humidity on viral spread and more summer hours spent outdoors where airflow is optimal and crowding usually less extreme. To date, seasonal effects on COVID-19 spread have not been fully documented because few regions have been in the throes of COVID-19 for much more than a full calendar year. Moreover, the effects of season and of often-intermittent and incomplete public health control efforts are hard to disentangle.

PATTERNS OF MORBIDITY AND MORTALITY

In all circumstances studied over the past 130 years, except in 1918–1920, patterns of age-specific morbidity, mortality, and case–fatality for pandemic influenza have been similar. Because influenza pandemics emerge when all or most of the global population lacks immunity to the new pandemic virus, moderately high attack rates within the first year, usually between 30% and 60% of the population, are common. Age-specific morbidity patterns have been highly similar for known influenza pandemics, featuring peak morbidity rates in school-aged children and young adults, slightly lower rates in both very young children and in adults aged 30 to 55 years, and much lower rates at older ages (Figure 4). This pattern presumably reflects exposure risks related to school, work, and other congregating activities, as well as the possibility of prior exposure to related influenza viruses within the older age group.

Overall influenza mortality varies significantly, with some pandemic viruses being highly pathogenic (approximate 1% case–fatality in the United States in the 1918 pandemic vs less than 0.05% case–fatality in the 2009 pandemic). The elderly; people with serious respiratory, cardiac, metabolic, and other diseases; and pregnant women are always at elevated mortality risk from influenza.

With the exception of 1918–1920, pandemic and seasonal influenza exhibit a characteristic mortality pattern. Age-specific influenza mortality is classically U-shaped, with elevated mortality in infants and young toddlers and the elderly, but with very low mortality at all ages in between. A different pattern was seen in 1918–1920: a W-shaped pattern (Figure 4) featured a third mortality peak in those aged 20 to 40 years. This pattern, never seen before or since, disappeared entirely in the early 1920s.[50,51] It remains unexplained, and, while likely not a signature of the 1918 virus, it may be related to preexisting age cohort–specific, cross-protective immunity.

In the early stages of the COVID-19 pandemic, morbidity and mortality patterns are still not fully established, in part because of the relatively high percentage of asymptomatic infections coupled with underdiagnosis of cases. Overall case– and infection–fatality ratios, which are population structure–dependent, have been estimated from as high as 3% to well below 1%.[52] Speculative theories to explain low morbidity and mortality in the young include (1) protection afforded by prior and recent exposure to circulating endemic coronaviruses, two of which—HCoV-HKU1 and HCoV-OC43—are β-coronaviruses, albeit not closely related to SARS-CoV-2; (2) increased exposures to other infectious agents that stimulate generic innate immune responses; or (3) immune enhancement mechanisms.[39]

In contrast to influenza, which causes high mortality and high fetal loss, significant COVID-19 mortality in pregnant

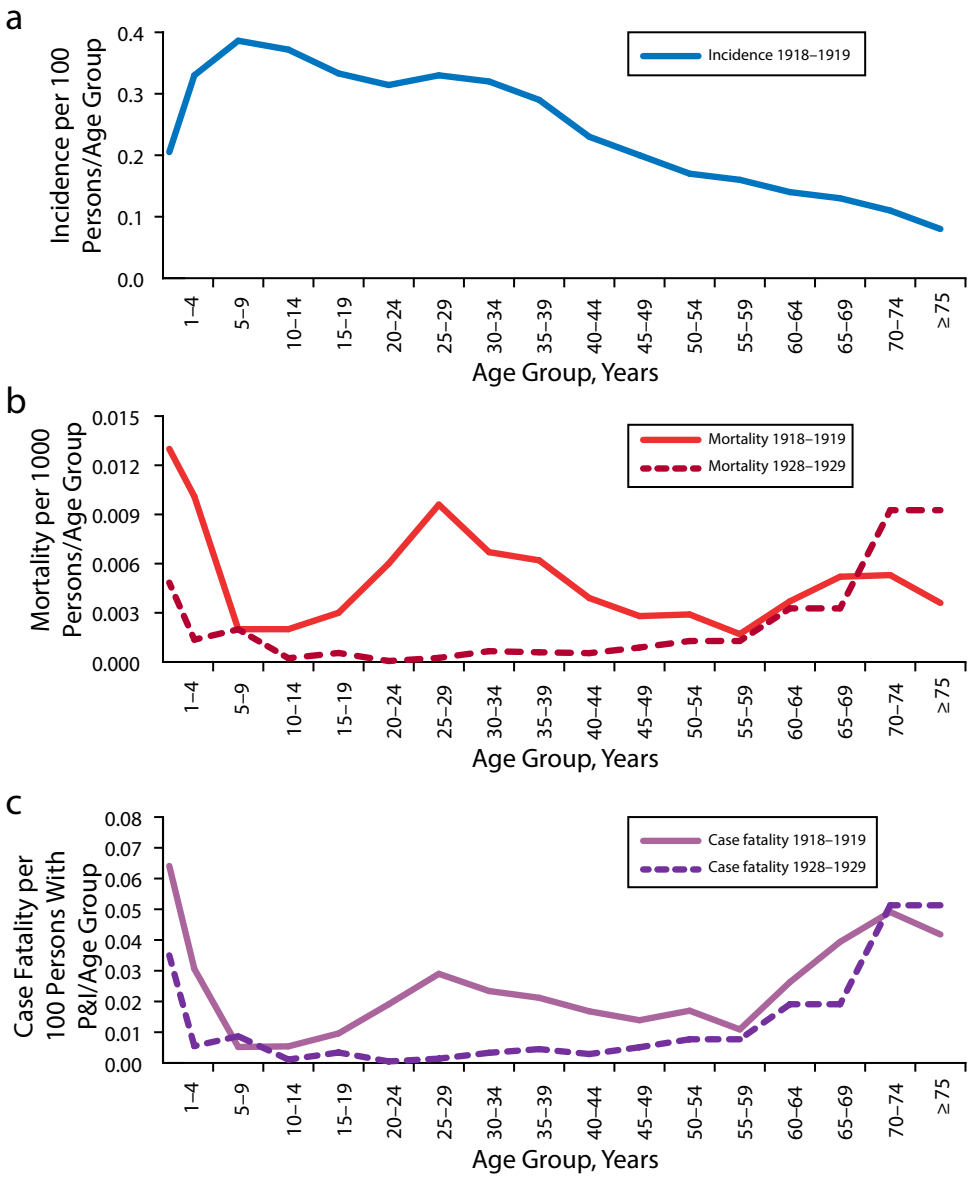

FIGURE 4— Age-Specific Morbidity and Mortality of Influenza in 1918–1919 and, for Comparison, in 1928–1929, as Determined by US "P and I" Data by (a) Incidence per 100 Persons Ill With Pneumonia and Influenza per Age Group; (b) Mortality per 1000 Persons per Age Group; and (c) Case–Fatality

Source. Morens and Taubenberger.[49]
Note. P and I = pneumonia and influenza. Parts b and c compare the W-shaped curves of age-specific mortality and case–fatality seen in 1918–1919 with more typical U-shaped curves from 1928 to 1929. Between 1889 and the present time, U-shaped curves have been seen in all pandemics and seasonal epidemics except for 1918 and the several years thereafter. Morbidity and mortality data reflecting diagnoses of pneumonia and influenza (so-called "P and I") are still widely used today for epidemiological purposes (e.g., for estimating total influenza deaths during periods of influenza prevalence) because incomplete morbidity reporting and imperfect death certificate accuracy greatly underestimate infections and deaths from influenza and its secondary bacterial complications. National or large-population data permitting similar calculations for COVID-19 are not yet available, although preliminary data suggest that age-specific mortality is very low in infants and children, rising regularly with age thereafter.

women and their fetuses is only now beginning to become better appreciated, although the extent of maternal and fetal risks remains to be fully established.[53–56] In 1918, as in 2020,[57] mortality was higher in the poor, in African Americans and Native Americans, in health care workers, and in workers in crowded occupations.[50,58–60] These patterns, observed for most infectious diseases, reflect societal inequalities and inadequate occupational safety measures.

As descendants of the 1918 influenza virus persist to this day,[8] a question

arises about whether SARS-CoV-2 will do the same. Furthermore, a possibility to be considered is whether, similar to influenza, it will elicit a weakly protective immune response and then circumvent that response with further viral evolution by antigenic drift or other mechanisms such as viral genetic recombination. The recent (in late 2020) emergences of SARS-CoV-2 genetic variants, some apparently associated with increased transmissibility and immune escape,[61] may be an early answer to this question, auguring future COVID-19 reemergences caused by antigenically drifting strains, in a manner analogous to the genetic drift of influenza A viruses. Descendants of the 1918 virus still circulate; we can only speculate whether SARS-CoV-2 or its descendants will still be circulating in 2120. (Continued in Part II.[62]) AJPH

ABOUT THE AUTHORS

David M. Morens and Anthony S. Fauci are with Office of the Director, National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health, Bethesda, MD. Jeffery K. Taubenberger is with Viral Pathogenesis and Evolution Section, Laboratory of Infectious Diseases, NIAID.

CORRESPONDENCE

Correspondence should be sent to David M. Morens, MD, Senior Advisor to the Director, National Institutes of Health, National Institute of Allergy and Infectious Diseases, Bldg 31, Room 7A-03, 31 Center Drive, Bethesda, MD 20892-2550 (e-mail: dm270q@nih.gov). Reprints can be ordered at http://www.ajph.org by clicking the "Reprints" link.

PUBLICATION INFORMATION

Full Citation: Morens DM, Taubenberger JK, Fauci AS. A centenary tale of two pandemics: the 1918 influenza pandemic and COVID-19, part I. *Am J Public Health*. 2021;111(6):1086–1094.

Acceptance Date: January 14, 2021.

DOI: https://doi.org/10.2105/AJPH.2021.306310

CONTRIBUTORS

All authors contributed equally to the content and writing.

ACKNOWLEDGMENTS

This work was supported by the intramural research program of the National Institute of Allergy and Infectious Diseases, National Institutes of Health.

CONFLICTS OF INTEREST

The authors have no conflicts of interest.

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The Challenges of Conducting Intrastate Policy Surveillance: A Methods Note on County and City Laws in Indiana

Lindsey Sanner, MPH, Sean Grant, DPhil, MSc, Heather Walter-McCabe, MSW, JD, and Ross D. Silverman, JD, MPH

Policy surveillance is critical in examining the ways law functions as a structural and social determinant of health. To date, little policy surveillance research has focused on examining intrastate variations in the structure and health impact of laws. Intrastate policy surveillance poses unique methodological challenges because of the complex legal architecture within states and inefficient curation of local laws.

We discuss our experience with these intrastate policy surveillance challenges in Indiana, a state with 92 counties and several populous cities, a complicated history of home rule, systemically underfunded local governments, and variations in demography, geography, and technology adoption. In our case study, we expended significant time and resources to obtain county and city ordinances through online code libraries, jurisdiction Web sites, and (most notably) visits to offices to scan documents ourselves.

A concerted effort is needed to ensure that local laws of all kinds are stored online in organized, searchable, and open access systems. Such an effort is vital to achieve the aspirational goals of policy surveillance at the intrastate level. (*Am J Public Health*. 2021;111:1095–1098. https://doi.org/10.2105/AJPH.2021.306227)

AJPH June 2021, Vol 111, No. 6

It has been said "All public health is local."[1]

The design, interpretation, and enforcement of county and municipal law significantly affect local public health.[2] Legal epidemiology—"the scientific study and deployment of law as a factor in the cause, distribution, and prevention of disease and injury in a population"[2(p136)]—is critical in examining how such law functions as a structural and social determinant of health.[3]

A core legal epidemiology practice is policy surveillance: the ongoing, systematic collection, analysis, and dissemination of information about health-related laws and other policies.[4] Much of this work has focused on interstate surveillance, comparisons across major metropolitan areas, or variations within substructures of a particular city or county. To date, little policy surveillance research has attempted to comprehensively assess local law variations across an entire state.[5]

Conducting intrastate policy surveillance poses unique sets of methodological challenges.[6] One set results from the complex legal architecture within each state.[7] Researchers must understand the intricacies of the particular state's local autonomy rules to determine which governance powers have been delegated to which governmental authorities (state, county, municipality). Concurrently, local jurisdictions may have to defer to state authorities in circumstances in which the state prohibits local public health agencies from exerting influence over particular issues or industries (preemption). As described subsequently, a second set of challenges relates to information technology and infrastructure: how researchers obtain access to the local laws themselves.[8]

Policy surveillance requires identifying and assessing relevant content within laws of the target jurisdictions. This process relies on comprehensively cataloging primary source documents. A researcher can find legal documents curated in costly but searchable, centralized, fastidiously updated, and

topically indexed commercial databases (e.g., Westlaw, Lexis). Several commercial enterprises index and publish local laws (e.g., Municode, American Legal, Code Publishing); however, such collections are neither as comprehensive nor as reliably updated as state law sources. Researchers interested in statewide analyses therefore cannot rely on such sources to contain all of a particular state's local laws.

Consequently, researchers must employ less efficient methods, including combing unorganized documents on governmental Web sites and hand searching at physical offices. Similar to searching for and selecting studies in systematic reviews of research documents,[9] acquiring and examining legal documents through these inefficient means has significant implications for the scalability and utility of intrastate policy surveillance.

SURVEILLING 1 STATE

We faced such challenges in the Indiana Addictions Law and Policy Surveillance Project. Indiana local laws are a complex web of local-level ordinances, orders, and resolutions: the state has 92 counties, a complicated history of home rule, systemically underfunded local governments, and variations in demography, geography, and technology adoption. How Indiana localities choose to store and organize their laws also complicates surveillance. Currently, county governments can fulfill their obligation to publish, record, and maintain a permanent public record of local laws through keeping official copies in a book in their offices. Furthermore, unlike state statutes, most counties organize their laws chronologically by passage date as opposed to topically. In the sections to follow, we detail how these challenges complicated the process of building a database of potentially relevant local laws for intrastate policy surveillance.

ACQUIRING DATA ON INDIANA'S LOCAL LAWS

To examine the health-related laws covering the largest possible share of the state population in the least number of discrete jurisdictions, we focused on gathering all local laws from Indiana's 92 counties and 20 largest municipalities (112 jurisdictions in total, with municipalities located across 15 counties; Figure 1). Local laws from 77 of the 112 jurisdictions included (68.8%; 57 counties, 20 cities) were available online. Forty-two jurisdictions (37.5%; 27 counties, 15 cities) contracted with a commercial enterprise to index and publish their laws. Thirty-seven jurisdictions (33%; 32 counties, 5 cities) published local laws on their local government Web sites, although there was variation in resource ease of access, organization, and completeness. Of the 77 jurisdictions with information available online, 65 (84.4%; 45 counties, 20 cities) had their laws codified by topic, and 19 (24.6%; all counties) stored individual ordinances as discrete PDFs.

Thirty-five jurisdictions (29.5%; all counties) did not have their laws available online. By contacting county auditors, we were able to obtain ordinances for 27 of these counties. For 6 counties, we sent the auditors a prepaid, self-addressed envelope and a blank flash drive. Three auditors shared their informal index of ordinances and resolutions, allowing us to view the titles and request the text of any materials that would have been relevant to the project.

Six counties for which we could not obtain ordinances did not respond to our outreach, 4 stated they were converting to an electronic storage system and would soon be able to share electronic files, and 3 gave us permission to scan the documents. Two counties did not allow us to scan documents but offered us the use of their equipment to copy or print documents for $0.25 to $1.00 per page.

In the case of the other 18 counties, we acquired data on laws by visiting local county offices and scanning documents. Visiting offices and scanning physical documents into a searchable PDF format was resource and time intensive. We purchased a notebook computer and 2 portable scanners (we burned out the first) and rented a university vehicle to drive to local county offices. Source documents required delicate handling, including removing (and then replacing) staples and placing pages in (and taking them out of) binders and protective covers. Documents that could not be scanned as a result of their fragility or size had to be captured with a telephone scanning app and concatenated with the appropriate scanned files. Database curation required that we keep source materials in the proper order and save files systematically using titles that included the jurisdiction name, ordinance indicator, and year (e.g., Franklin_O_2005.pdf), after which we uploaded files from the notebook computer to a secure shared drive.

Because documents were chronologically organized, we could not efficiently or consistently assess any particular law's potential topical relevance (e.g., substance use, social determinants of health) on site. Consequently, we scanned all local laws back to a predetermined date, leaving determinations regarding relevance to our project to a subsequent scoping process. We scanned more than 25 000 pages of primary source documents from 18 counties. Our scanning efforts halted when COVID-19 orders were imposed.

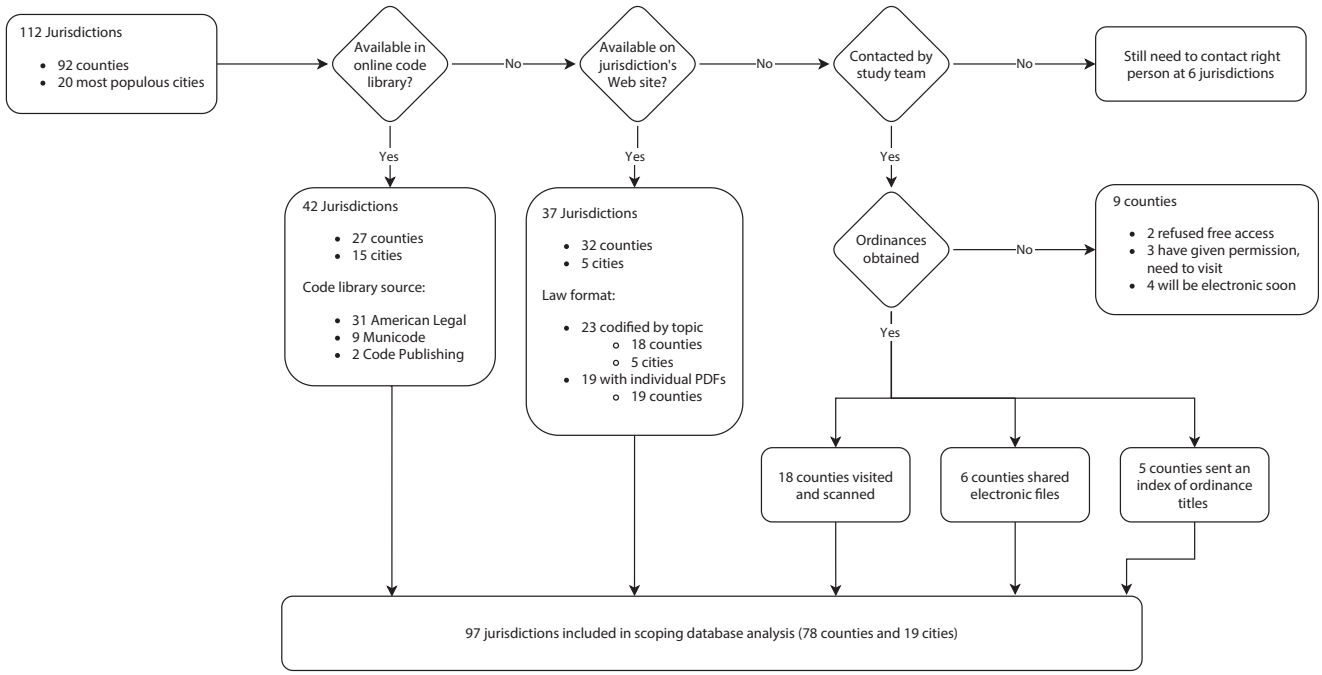

FIGURE 1— Flow Diagram: Obtaining Copies of County and City Laws in Indiana

Many counties have limited resources and do not have the ability to convert all of their files to electronic storage. As some auditors indicated that our scanning would allow them to put their ordinances online, we loaded their scanned county files onto a flash drive we gave to them. In addition to contributing to our searchable database of local legislation, we hope that converting paper documents to electronic files will help facilitate open government initiatives, easing residents' access to the laws that govern them.

INTRASTATE POLICY SURVEILLANCE IMPLICATIONS

To assess the impact of law on public health, researchers must be able to obtain accurate, up-to-date, and comprehensive data on local-level laws. Indiana is not unique in the varied ways local governments publish and store laws. To improve access to and assessment of local public health laws, we recommend that (1) local laws of all kinds be online; (2) online systems be standardized across jurisdictions, organized, and searchable; and (3) online systems be freely and openly accessible. These recommendations not only would assist researchers in examining the public health impact of laws but would facilitate transparency and accountability. A concerted effort to fund and implement such an approach to local legal publication will pay dividends in public health and democratic engagement with local government. AJPH

ABOUT THE AUTHORS

Lindsey Sanner is with the Center for Health Policy, Richard M. Fairbanks School of Public Health, Indiana University, Indianapolis. Sean Grant is with the Department of Social and Behavioral Sciences, Richard M. Fairbanks School of Public Health, Indiana University, Indianapolis. Heather Walter-McCabe is with the Department of Social Work and Law and the Robert H. McKinney School of Law, Indiana University, Indianapolis. Ross D. Silverman is with the Department of Health Policy and Management, Richard M. Fairbanks School of Public Health, and the Robert H. McKinney School of Law, Indiana University, Indianapolis.

CORRESPONDENCE

Correspondence should be sent to Ross D. Silverman, JD, MPH, Health Sciences Building, 1050 Wishard Blvd, Indianapolis, IN, 46202 (e-mail: rdsilver@iu.edu). Reprints can be ordered at http://www.ajph.org by clicking the "Reprints" link.

PUBLICATION INFORMATION

Full Citation: Sanner L, Grant S, Walter-McCabe H, Silverman RD. The challenges of conducting intrastate policy surveillance: a methods note on county and city laws in Indiana. *Am J Public Health*. 2021; 111(6):1095–1098.

Acceptance Date: February 6, 2021.

DOI: https://doi.org/10.2105/AJPH.2021.306227

CONTRIBUTORS

L. Sanner and R. D. Silverman made substantial contributions to the conception, data collection, analysis, and interpretation involved in the work and to the drafting and revision of content. S. Grant and H. Walter-McCabe made substantial contributions to the analysis and interpretation of the work and the drafting and revision of content.

ACKNOWLEDGMENTS

This project was funded by a grant from the Indiana University Responding to the Addictions Crisis Grand Challenge program.

CONFLICTS OF INTEREST

S. Grant's spouse is a salaried employee of Eli Lilly and Company and owns stock. He has accompanied his spouse on company-sponsored travel.

HUMAN PARTICIPANT PROTECTION

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

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Ten Urgent Priorities Based on Lessons Learned From More Than a Half Million Known COVID-19 Cases in US Prisons

Elizabeth Barnert, MD, MPH, MS, Ada Kwan, PhD, and Brie Williams, MD, MS

COVID-19 is ravaging US prisons. Prison residents and staff must be prioritized for vaccination, but a rapidly mutating virus and high rates of continued spread require an urgent, coordinated public health response.

Based on knowledge accumulated from the pandemic thus far, we have identified 10 pressing public health priorities for responding to COVID-19 in prisons: (1) accelerate population reduction coupled with community reentry support, (2) improve prison ventilation systems, (3) ensure appropriate mask use, (4) limit transfers between facilities, (5) strengthen partnerships between public health departments and prison leadership, (6) introduce or maintain effective occupational health programs, (7) ensure access to advance care planning processes for incarcerated patients and delineation of patient health care rights, (8) strengthen partnerships between prison leadership and incarcerated people, (9) provide emergency mental health support for prison residents and staff, and (10) commit to public accountability and transparency.

Dedicated prison leaders cannot accomplish these public health priorities alone. We must mobilize prison leaders, staff, and residents; public health departments; community advocates; and policymakers to work together to address the pandemic's outsized impact in US prisons. (*Am J Public Health*. 2021;111: 1099–1105. https://doi.org/10.2105/AJPH.2021.306221)

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The 1918 influenza pandemic demonstrated the calamitous consequences a highly transmissible respiratory pathogen can have in overcrowded prisons, jails, juvenile detention centers, and immigration detention centers (herein referred to as "prisons").[1] Yet when the COVID-19 pandemic arrived in early 2020, the United States had experienced 5 decades of growth in imprisonment rates. Approximately 2.3 million people were incarcerated (7 times the number held in 1972) across the nation's 7000 facilities, with many prisons populated well above 100% capacity.[2,3] Intersecting risks related to poverty, racial inequity, and overcrowding and high infection transmissibility of COVID-19 make residents and staff particularly vulnerable to COVID-19. As the pandemic has raged in US prisons, lessons have emerged that can inform a life-saving public health response.

TOLL OF COVID-19 IN US PRISONS

Over the 6 months following the publication of our July 2020 *AJPH* article, "Prisons: Amplifiers of the COVID-19 Pandemic Hiding in Plain Sight,"[4] the pandemic took a devastating toll on people who lived or worked in US prisons. Confirmed cases continue to rise at a breathtaking rate, affecting prison residents, staff, their families, and their communities, and challenging the capacity of local health care systems.[4,5] In January 2021, 10 months since the United States reported its first death of an incarcerated patient,[4] more than 510 000 cases of COVID-19 had been reported in prisons, more than double the number reported only 2 months earlier.[5] COVID-19 has claimed the lives of at least 2200 US prison residents and staff.[5] In the few states that publicly report cases among youths in juvenile detention centers, at least 3360 cases have been confirmed.[6] The majority of the United States' largest outbreaks have occurred in prisons. Now, nearly 1 year into the COVID-19 pandemic, it is imperative that we integrate lessons learned from the responses and calls to action into strategic steps to protect prison residents and staff.

Ten Lessons Learned From COVID-19 in Prisons

Lesson	Key Strategies
1. Accelerate population reduction coupled with community reentry support to make space for physical distancing and areas for quarantine and medical isolation	• Pursue evidence-based decarceration strategies informed by public health professionals and prison leaders and prevent new incarceration by promoting alternatives to incarceration
	• Bolster reentry supports by educating people leaving prisons about COVID-19, ensuring access to health insurance, and promoting linkages to community and social services
2. Improve ventilation in housing units and common spaces	• Maximize ventilation with outdoor air
	• Ensure that air ventilation systems meet standards to prevent the spread of COVID-19 in housing units and common spaces and that MERV 13 or higher air filters are used (or the highest MERV-rated filter that the HVAC systems can allow)
	• Ensure that medical isolation units and quarantine cells are available, when needed, to prevent the spread of COVID-19
3. Ensure appropriate mask use among staff and residents	• Ensure access to masks for residents and staff
	• Ensure that universal mask use with proper fit is nonnegotiable
	• Provide health education about mask importance, use, and fit
4. Limit transfers between facilities	• Avoid transfers between facilities
	• If a transfer must take place, allow medical staff involvement in transfer policies, use PPE, ensure that screening protocols are in place (i.e., that the resident being transferred does not have COVID-19 or COVID-19 exposure after test administration), and require a 14-day quarantine
5. Strengthen partnerships between public health departments and prison leadership	• Encourage frequent, regular meetings between prison and public health leaders to manage COVID-19
	• Develop and implement coordinated pandemic preparedness plans for current and future waves
6. Introduce or maintain thoughtful occupational health programs	• Promote occupational health programs that are accessible to prison staff by bolstering funding, ensuring access to PPE, ensuring affordability for staff, and applying a nonpunitive approach
	• Promote a culture of health among prison staff that encourages symptom reporting and behaviors informed by health evidence to prevent COVID-19 transmission
7. Ensure access to advance care planning processes for incarcerated patients and delineation of health care rights	• Ensure that advance care planning processes are developed and accessible for residents
	• Ensure that hospitals caring for prison residents are aware of advance care plans and know patient rights
8. Strengthen partnerships between prison leadership and incarcerated people	• Encourage a culture and infrastructure to support partnership with prison residents in responding to COVID-19
9. Provide emergency mental health support for prison residents and staff	• Recognize that COVID-19 in prisons is a significant source of stress and psychological trauma
	• Provide trauma-informed mental health support, including via expanded telehealth mental health visits, and deploy heightened surveillance for suicidality
10. Commit to public accountability and transparency	• Mandate data reporting on COVID-19 prison cases
	• Publicly report procedures for combatting COVID-19
	• Promptly conduct outreach to affected families

Note. HVAC = heating, ventilation, and air conditioning; MERV = minimum efficiency reporting value; PPE = personal protective equipment.

URGENT PRIORITIES

National COVID-19 guidelines issued by the Centers for Disease Control and Prevention (CDC) have provided some guidance to prison leadership during the pandemic.[7] However, system discoordination and variation between prisons by prison type, population size, population health status, degree of overcrowding, and quality of facility infrastructure (many buildings are archaic)

have resulted in jurisdictions and facilities using trial and error approaches with varying degrees of success. With the recent availability of vaccines, health experts have called for prison residents and staff to receive priority vaccination.[8] However, viral mutations, lags in vaccine distribution, and vaccine hesitancy mean that COVID-19 mitigation techniques will be required for months, and likely years, to come. To supplement prompt vaccine education and delivery to staff and residents, we summarize 10 key public health priorities (see box on p. 1100) needed to respond to COVID-19 in prisons:

1. Accelerate population reduction coupled with community reentry support to make more space for physical distancing and areas for quarantine and medical isolation,
2. Improve ventilation in housing units and common spaces,
3. Ensure appropriate mask use among staff and residents,
4. Limit transfers between facilities,
5. Strengthen partnerships between public health departments and prison leadership,
6. Introduce or maintain thoughtful occupational health programs,
7. Ensure access to advance care planning processes for incarcerated patients and delineation of health care rights,
8. Strengthen partnerships between prison leadership and incarcerated people,
9. Provide emergency mental health support for prison residents and staff, and
10. Commit to public accountability and transparency.

Population Reduction and Community Reentry Support

Many jurisdictions, especially early in the pandemic, enacted decarceration strategies to enhance the ability of residents and staff to comply with physical distancing measures to prevent COVID-19 spread.[2] The National Academy of Sciences declared decarceration the most important public health strategy to minimize the devastating impact of COVID-19 in prisons.[2] Decarceration can be achieved through a variety of mechanisms, including commutation or release, furlough, or home confinement. Yet, between January and August 2020, population size in postconviction state prisons decreased by only 4%,[9] a small reduction insufficient for achieving community standard guidelines for physical distancing. A decarceration strategy, informed by public health professionals and prison leaders, is also needed to ensure that sufficient quarantine and medical isolation rooms are available for outbreaks.[10]

To drive decarceration, prison health professionals can advocate patients' health needs; public health practitioners can promulgate decarceration policy and alternatives to incarceration to prevent new incarceration; and, when necessary, health care professionals can serve as medical experts in litigation to improve prison conditions or achieve decarceration. Academic and community clinicians can advise on prognostication and medical documentation for courts to guide decarceration efforts.[11,12]

Rapid decarceration must go hand in hand with adequate reentry support and planning.[12,13] Before the COVID-19 pandemic began, the risk of death among formerly incarcerated individuals within 2 weeks of release was 12.7 times higher than that among other state residents.[14] During the pandemic, mortality risk is further heightened, as discharges may be rushed, community resources may be limited, and community COVID-19 transmission may occur. Roadmaps for emergency discharge planning during the pandemic have been developed.[2,12] Priorities include educating people leaving prisons about COVID-19, activating public health insurance benefits for eligible individuals, and ensuring linkages to community health services.[9,12] We recommend prioritizing addiction treatment and taking advantage of prescribing flexibilities during the pandemic, such as using televisits for prescribing treatment of opioid use disorder. Assistance with accessing community resources—such as food stamps, housing, and crisis support to prevent drug overdose, suicide, or recidivism—is also crucial.[12] Although decarceration should be prioritized in the pandemic, it is equally important to bolster reentry supports to prevent COVID-19 transmission, serious adverse health outcomes, and recidivism.

Ventilation in Housing Units and Common Spaces

In many prisons, residents share a small (~4 by 10 foot) cell, oftentimes with a barred door, leaving few options to achieve the physical distance recommended for the general public. Further, even single cells with solid doors can function like a shared dorm if heating, ventilation, and air conditioning (HVAC) units are not up to code. Many residents actively participate in limiting the spread of COVID-19 through cleaning and disinfection efforts. However, given the importance of preventing aerosol transmission of COVID-19, sweeping structural measures in many facilities

are urgently needed to maximize ventilation with outdoor air and upgrade HVAC system filters to minimum efficiency reporting value (MERV) 13 air filters or to the highest MERV-rated filter that the HVAC system can allow.[15] Such measures are of particular importance in cells designated for medical isolation or quarantine. To halt COVID-19 spread, HVAC systems should be upgraded to hospital-level quality to ensure that residents and staff are not breathing inadequately filtered air.

Appropriate Mask Use Among Staff and Residents

Although mask wearing has become politicized, proper mask use must be nonnegotiable in prisons because it can prevent COVID-19 transmissibility by greater than 70%.[16] Depending on degree of spread in facilities and HVAC system adequacy, many prisons are opting for KN95 or N95 mask use. Staff should wear masks properly at all times, including in breakrooms unless staff are alone, and remove them only for eating and drinking. For residents, mask wearing at all times is infeasible (e.g., when eating, bathing, or sleeping). Inability to adhere to universal masking mandates because of dormitory living further justifies decarceration during the pandemic. Simultaneously, encouraging mask wearing in prisons via public health education about mask use importance and fit, consistent guidelines, incentivization efforts, and, if needed, reasonable disciplinary action for staff and residents who refuse masks is needed so that proper mask use becomes an expected and explicit norm.[17]

Transfers Between Facilities

Prison-to-prison transfers (and facility-to-facility transfers within prisons) have led to numerous COVID-19 outbreaks. Between June and August 2020, San Quentin California State Prison, which held 3362 people and was at 109% design capacity in mid-July,[18] had one of the largest outbreak clusters of COVID-19 in the United States at the time, with confirmed cases in at least 2 of 3 residents and 28 resident deaths.[19] The outbreak began when 121 patients from another state facility with an outbreak were transferred to the COVID-naïve San Quentin facility.[19] Data across facilities indicate that transfers should stop, with few being absolutely necessary.[20] Prison medical staff should be consulted on transfer decisions and protocols. Transfers should be accompanied by rigorous testing strategies, use of personal protective equipment during transfer, screening protocols, and 14-day quarantine.

Public Health and Prison Partnerships

The COVID-19 pandemic has brought to the fore the importance of agile coordination between prison leadership and public health departments. Many local public health departments have been in near-constant communication with area prisons to coordinate testing. Yet, many states have tested less than 10% of their prison populations and others have not made testing results public, obscuring the true scope of the pandemic in prisons and hampering community health system responses.[21] During the pandemic, prison health should be an active concern of public health departments, especially regarding rapid testing, data transparency, vaccination distribution, emergency workforce replacement for health care staff sick days, coordination of hospital transfers, and emergency access to Medicaid and housing when needed for people released to the community. Such partnerships can turn their attention after the pandemic to optimizing future preparedness and addressing health disparities plaguing residents of the justice system.[4]

Thoughtful Occupational Health Programs

When the pandemic began, many prison occupational health programs were unequipped to respond to a health crisis of such magnitude.[4,22] Prison medical directors were called on to protect the health of prison residents *and* staff (essentially doubling patient care responsibilities). Decisions regarding staff exposures, symptom monitoring, testing, and guidance regarding return to work or mask wearing needed to be made quickly, although there was insufficient infrastructure support. Many prison medical leaders have also been tasked with vaccine education and delivery for prison staff. Funding to bolster prison occupational health programs is crucial. At a minimum, prison occupational health programs should guarantee that prison staff have access to adequate personal protective equipment as well as sick days and free or affordable health services, and encourage staff to report symptoms and stay home when sick or exposed.[22]

Planning and Delineating Health Care Rights

Older adults and people with significant medical conditions (i.e., those with highest risk of developing a severe case of COVID-19) comprise a growing proportion of the US prison population.[4] The pandemic has reinforced the importance of access to advance care planning for incarcerated patients, especially for older adults and people with

serious illnesses. Such advance care planning processes should include clear, in-depth conversations with a primary health care professional to clarify patients' health care wishes and to guide them in the selection of a medical proxy decision maker in case of future need.

The pandemic has also demonstrated the importance of community hospital health care professionals understanding the rights of hospitalized incarcerated patients. For example, confusion exists among hospitalists about whether and when hospitalized incarcerated patients can communicate or visit with loved ones. Guidelines exist for community health care professionals to clarify the tenets of ethical care for incarcerated patients.[23] A structured partnership and clear communication between prison leaders, prison health care professionals, and community hospital administrators are needed. These will ensure that adequate advance care plans can be accessed upon hospital transfer and are systematically communicated with community health care professionals upon hospitalization and that protocols and procedures to provide access to family and loved ones are in place for incarcerated patients hospitalized with COVID-19.[23] Moreover, many national standards limit or prohibit the use of shackles for pregnant women in custody who are in labor in community hospitals. The pandemic has made clear the vital need for medical professionals to enact similar limits on the use of shackles for people who are dying or seriously ill in community hospitals.[24]

Partnerships with Prison Residents

Partnerships forged between prison residents and prison leaders can be key to safeguarding health in a prison, especially during a pandemic. At a minimum, prison administrators' recognition of failures to treat residents and families with respect is a necessary component of quality medical care, as is proper representation of patients' voices, acknowledgment of power imbalances, and identification of shared health-related goals. Collective practices, such as the meaningful use of ideas generated in inmate advisory councils and family councils, can help shift prison culture toward productive partnerships. Residents are living with constant fear of COVID-19, and it is imperative that prison and medical leadership engage in meaningful dialogue with residents and families to elicit ideas that can improve day-to-day life and the physical and mental health of residents.

Emergency Mental Health Support

Because they have higher rates of mental health challenges and substance use disorders compared with the general US population, many prison residents and staff, who are already overburdened by traumatic experiences, are suffering the compounded, exhausting effects of enduring the pandemic in prisons. Prison staff are putting themselves, their households, and their communities at risk, which further exacerbates the stress of working in prisons. In response to the constant stress and fear associated with living and working in infection hotbeds, emergency mental health support services for residents and staff are needed. Expanded telehealth mental health visits and heightened surveillance for suicidality should be deployed. Community mental health agencies can also assist. Although the acknowledgment of ongoing stress and the provision of online resources are a start, our consultation with experts suggests that a prompt and proactive trauma-informed response is needed.

Public Accountability and Transparency

Many prisons have made great efforts to adhere to emerging CDC recommendations regarding COVID-19 in prisons.[7] The National Commission of Correctional Health Care also provided early guidance on standards of care related to COVID-19[25]; however, accreditation with the commission is voluntary and most US prisons are not accredited. Residents, family members, advocates, and attorneys have voiced concerns about variation in practice across prisons and lack of transparency regarding COVID-19 infection control measures in US prisons. In particular, the lack of information available about COVID-19 prevention and care approaches in immigration detention centers underscores the urgent need for improved transparency from these agencies. Some prisons and related government agencies published early tracking of COVID-19 testing and policies.[4,19] These positive outliers demonstrate that it is possible to increase transparency and accountability in maintaining standards of care during the pandemic. Researchers and public health departments can use such data to measure the pandemic's scope and guide resource allocation to optimize a coordinated, data-driven response. Experiences to date suggest that government mandates through legislation are worth pursuing to achieve timely and accurate reporting about COVID-19 in prisons.

CONCLUSIONS

The COVID-19 pandemic has created an infectious disease crisis in the setting of what was already a public health travesty—mass incarceration. As the public health community battles the pandemic and prepares for a resurgence of COVID-19, addressing the poverty, racial inequality, and historical oppression that fuel mass incarceration will be crucial. If public health lessons learned from the pandemic in prisons are properly applied, COVID-19 can be an impetus to promulgate overdue justice reform and interventions that promote health equity. As the world awaits widespread distribution of vaccines and more effective antiviral therapies, the public health community has a vital role to play in creating the conditions that best protect the human rights and health of prison residents and staff in all types of prison settings. Many of these lessons could have been learned after the 1918 influenza pandemic. We must not squander the lessons learned from the 2020 COVID-19 pandemic. AJPH

ABOUT THE AUTHORS

Elizabeth Barnert is with the Department of Pediatrics, University of California, Los Angeles. Ada Kwan and Brie Williams are with the Department of Medicine, University of California, San Francisco.

CORRESPONDENCE

Correspondence should be sent to Elizabeth Barnert, UCLA Department of Pediatrics, 10833 Le Conte Ave, 12-467 MDCC, Los Angeles, CA 90095 (e-mail: ebarnert@mednet.ucla.edu). Reprints can be ordered at http://www.ajph.org by clicking the "Reprints" link.

PUBLICATION INFORMATION

Full Citation: Barnert E, Kwan A, Williams B. Ten urgent priorities based on lessons learned from more than a half million known COVID-19 cases in US prisons. *Am J Public Health*. 2021;111(6): 1099–1105.

Acceptance Date: February 3, 2021.

DOI: https://doi.org/10.2105/AJPH.2021.306221

CONTRIBUTORS

E. Barnert prepared the first draft of the article. A. Kwan and B. Williams contributed substantially to revisions.

ACKNOWLEDGMENTS

E. Barnert's efforts were funded by the National Institute on Drug Abuse, National Institutes of Health (grant K23 DA045747-01), the California Community Foundation (grant BA-19-154836), and the University of California, Los Angeles Children's Discovery and Innovation Institute. B. W.'s efforts were supported by the National Institute on Aging, National Institutes of Health under the Aging Research in Criminal Justice Health Network (grant R24AG065175) and the University of California, San Francisco Pepper Center (grant P30 AG044281).

We offer our deep appreciation and gratitude to all frontline staff, leadership, prison residents, families, and advocates working to respond to COVID-19 in US prisons. We thank Cyrus Ahalt for his conceptual contributions.

Note. The content is solely the responsibility of the authors and does not necessarily represent the official views of the funders.

CONFLICTS OF INTEREST

The authors have no conflicts of interest to declare.

HUMAN PARTICIPANT PROTECTION

No protocol approval was necessary because no human participants were involved in this study.

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Medicaid Expansions and Participation in Supplemental Security Income by Noncitizens

Felix M. Muchomba, PhD, MPH, and Neeraj Kaushal, PhD

See also Ku, p. 1002.

Objectives. To estimate the effect of Medicaid expansion on noncitizens' and citizens' participation in the Supplemental Security Income (SSI) program. The Affordable Care Act (ACA) expanded Medicaid eligibility to cover low-income nonelderly adults without children, thus delinking their Medicaid participation from participation in the SSI program.

Methods. Using data from the Social Security Administration for 2009 through 2018 (n = 1020 state-year observations) and the Current Population Survey for 2009 through 2019 (n = 78 776 respondents), we employed a difference-in-differences approach comparing SSI participation rates in US states that adopted Medicaid expansion with participation rates in nonexpansion states before and after ACA implementation.

Results. Medicaid expansion reduced the SSI (disability) participation of nonelderly noncitizens by 12% and of nonelderly citizens by 2%. Estimates remained robust with administrative and survey data.

Conclusions. Medicaid expansion caused a substantially larger decline in the SSI participation of noncitizens, who face more restrictive SSI eligibility criteria, than of citizens. Our estimates suggest an annual savings of $619 million in the federal SSI cost because of the decline in SSI participation among noncitizens and citizens. (*Am J Public Health*. 2021;111:1106–1112. https://doi.org/10.2105/AJPH.2021.306235)

AJPH June 2021, Vol 111, No. 6

Immigrants' eligibility for and participation in Medicaid are highly controversial. They have evoked concerns relating to the fiscal consequences of providing public health insurance to noncitizens, as well as policy actions to classify certain groups of immigrants as public charges if deemed to become eligible for Medicaid.[1–3] Noncitizen's eligibility for Medicaid, however, may lower their participation in other means-tested programs, which will reduce Medicaid's net fiscal impact. In this article, we studied the impact of Medicaid eligibility on participation in the Supplemental Security Income (SSI) program by noncitizens and citizens.

The Affordable Care Act (ACA) expanded Medicaid eligibility to cover low-income nonelderly adults without children. Prior to the ACA, their Medicaid eligibility was linked to participation in the SSI program, which required an arduous and lengthy disability application process. People with disabilities, who have higher levels of medical need, were effectively locked into poverty to maintain Medicaid eligibility because of the low-income and assets limits of SSI.[4–7]

The SSI eligibility criteria are considerably more restrictive for noncitizens who face additional eligibility requirements, including work experience in the United States of at least 40 quarters.[8,9] Thus, if Medicaid expansions under ACA caused lower SSI participation, the decline should be much higher among noncitizens. There is, however, no systematic research on the effect of Medicaid expansions on the SSI participation of noncitizens, a highly vulnerable group with relatively low incomes that also experienced a substantial rise in Medicaid eligibility after the ACA expansions. Previous research documents that immigrants in the United States are more likely than similarly placed natives to be low income and to work in jobs that do not offer employer-sponsored insurance. From 2011 through 2013 (the 3 years prior to ACA implementation),

foreign-born adults aged 19 to 64 years with incomes less than 300% of the federal poverty line had an uninsurance rate of 49% compared with a 28% uninsurance rate among similar US-born adults; of those with incomes less than 150% of the federal poverty line, the uninsurance rate was 55% among the foreign-born and 33% among the US-born.[10]

Two previous studies estimated the effect of Medicaid expansions on SSI use among all US residents and found a small decline in SSI participation associated with Medicaid expansions.[11,12] One study used 1 year of post-ACA data and the other used 2 years of post-ACA data. Arguably, these studies did not have sufficient post-ACA expansion data to yield the full impact of Medicaid expansions on SSI participation. In this study, we used 6 years of post-ACA data and estimated change in SSI participation among noncitizens and citizens separately. Specifically, we compared SSI participation in states that adopted ACA Medicaid expansion before and after ACA implementation and compared it with the corresponding change in nonexpansion states to study how Medicaid expansions affected SSI participation among noncitizens and citizens.

Medicaid and SSI eligibility are restricted to citizens, lawful permanent residents, and certain other noncitizens, a category that includes refugees and asylees. Undocumented immigrants and temporary residents are ineligible for SSI and Medicaid. Further, the ACA, following the guiding principle of the Personal Responsibility and Work Opportunity Reconciliation Act of 1996, restricted Medicaid eligibility to lawful permanent residents who have been in the United States for more than 5 years, but a few states have exemptions to cover certain excluded populations.

The postulated mechanism we studied is the ACA's introduction of a pathway to Medicaid eligibility based on income alone (Medicaid) versus a pathway that combines a restrictive employment, financial means, and disability test (SSI). Because noncitizens face a more restrictive process of SSI eligibility, we hypothesized that the Medicaid expansions would cause a larger reduction in their SSI participation.

We performed empirical analyses with 2 sets of data: the reports of the Social Security Administration on SSI[13] for 2009 through 2018 and the Annual Social and Economic Supplement of the Current Population Survey (CPS)[10] data for 2009 through 2019, covering a period of 5 years before and 6 years after implementation of the ACA.

Our analysis of the Social Security Administration data provided evidence that Medicaid expansions indeed lowered SSI participation among noncitizens by a much larger proportion than among citizens (US-born and naturalized). We found that between 2013 and 2018, in Medicaid expansion states, the proportion of noncitizens receiving SSI fell 22%; among citizens the decline in SSI participation was a mere 4%. The declines in SSI participation of citizens and noncitizens in Medicaid nonexpansion states were much smaller in magnitude. Our back-of-the-envelope estimates suggest an annual savings of $619 million in SSI costs because of the decline in SSI participation among noncitizens and citizens in Medicaid expansion states.

METHODS

Our primary analysis was based on data from Social Security Administration reports. These reports include counts of SSI recipients by age (0–17, 18–64, and ≥65 years), citizenship status (citizens and noncitizens), state of residence, and year. We used the SSI data for nonelderly adults (18–64 years), yielding 510 observations for noncitizens and citizens each. Our outcome variable was SSI participation rate (number of SSI recipients divided by total population of each group). We computed nonelderly adult population size by citizenship status, state, and year from the American Community Surveys of the US Census Bureau. The advantage of using administrative data is that our analysis was not affected by underreporting of benefit receipt in government-administered surveys, including the CPS, as reported in recent studies.[14]

In supplementary analysis, we tested our findings from the administrative data using the CPS survey data. The CPS includes data on respondents' age, number of children, and income-to-poverty level ratio, which we used to restrict the sample to nonelderly childless adults with incomes below the federal poverty level. The CPS data are rich in individual characteristics, such as citizenship status, year of immigration, gender, educational attainment, marital status, household size, and state of residence, which were used as control variables or to stratify the sample. In some analyses, we used information on whether the respondent had a serious physical or cognitive limitation to further restrict the sample to adults reporting having a disability. We excluded noncitizens who immigrated to the United States less than 5 years prior to the CPS interview, because immigrants who have lived as permanent residents in the United States for less than 5 are ineligible for SSI. This yielded a sample of 73 001 citizens and 5775 noncitizens.

Our outcome variable was a binary indicator for receiving any SSI income payments in the previous calendar year.

We used a difference-in-differences[15] method to compare SSI recipiency in Medicaid expansion states and in states that did not expand, before and after 2014. Medicaid expansion states were Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, the District of Columbia, Hawaii, Illinois, Indiana, Iowa, Kentucky, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Dakota, Ohio, Oregon, Pennsylvania, Rhode Island, Vermont, Washington, West Virginia, and Wisconsin. Nonexpansion states were Alabama, Florida, Georgia, Idaho, Kansas, Maine, Mississippi, Missouri, Nebraska, North Carolina, Oklahoma, South Carolina, South Dakota, Tennessee, Texas, Utah, Virginia, and Wyoming. In sensitivity analyses, we excluded Louisiana and Montana because they expanded Medicaid in 2016 but the results were unaffected. Excluding Wisconsin, which we categorized as an expansion state because it received approval to provide coverage to childless adults with incomes up to 100% of the federal poverty line, also did not affect results.

We estimated separate multivariable linear models on noncitizen SSI recipiency and citizen SSI recipiency, and controlled for state unemployment rate, population size of the group (citizens and noncitizens) in the state, and state and year effects. During the period of our study, the noncitizen population in the United States was subject to a number of policies that may have affected their health, well-being, and participation in SSI.[16] To account for these changes in policies, for the noncitizen SSI recipiency, we estimated a second model that additionally controlled for a range of time-varying state-level policies toward immigrants—namely, enforcement of Section 287(g) of the Illegal Immigration Reform and Immigrant Responsibility Act, the Secure Communities Program, state Dream Act policy, eligibility of undocumented immigrants to obtain a driver's license, and state implementation of E-Verify.

For the supplementary analyses based on CPS data, we estimated linear probability models and also controlled for the following demographic characteristics: age, gender, educational attainment, marital status, household size, period of arrival to the United States, and years since migration. Linear probability models give consistent estimates of average causal effects and have an intuitive interpretation.[17]

Our analytical approach yields unbiased estimates of the causal effect of Medicaid expansion on the assumption that the trend in SSI recipiency in expansion and nonexpansion states would have been similar if Medicaid expansion had not occurred. We examined this parallel trends assumption first visually and then statistically, as in previous research on the effects of Medicaid expansion.[18] The statistical approach used data for the pre-ACA period (2009–2013) and tested whether the difference in SSI recipiency between expansion and nonexpansion states was constant over time. We used models similar to those in our main analysis, except that state Medicaid expansion status was interacted with year of observation. If the parallel trends assumption holds, there should be no statistically significant interaction between state Medicaid expansion status and year in the pre-ACA period. Estimates presented in Figure A (available as a supplement to the online version of this article at http://www.ajph.org) suggest that to be the case. Estimated coefficients of the interactions in the Medicaid expansion dummy variable and year dummy variables were negligible and statistically insignificant for both citizens and noncitizens.

We conducted all analyses using Stata version 16 (StataCorp LP, College Station, TX). We used robust standard errors clustered on state of residence to account for arbitrary correlation of observations within each state.

RESULTS

In this section, we present results from descriptive analysis followed by results of the multivariable analysis.

Descriptive Results

The SSI receipt rate among noncitizens was substantially lower than that among citizens even prior to the ACA. Between 2009 and 2013, 0.8% of noncitizens aged 18 to 64 years received SSI, which was less than a third of the receipt rate of 2.5% among citizens (Table 1). The former also experienced a decline in SSI receipt rate after the ACA. Overall, between the pre-ACA period (2009–2013) and the post-ACA period (2014–2018), nationally, the SSI receipt rate increased 2% among citizens but decreased 13% among noncitizens. Between those same 2 periods, the SSI receipt rate among citizens fell 0.03 percentage points in Medicaid expansion states compared with nonexpansion states, whereas the corresponding decline among noncitizens was 0.1 percentage points. These statistics do not adjust for changes in demographics. The multivariable analysis, presented in the next subsection, adjusts for a rich set of demographics.

TABLE 1— Percentage of Citizens and Noncitizens Aged 18–64 Years Who Were Supplemental Security Income (SSI) Recipients, Before and After Medicaid Expansion: United States, 2009–2018

	Citizens, % (95% CI)		Noncitizens, % (95% CI)	
	2009–2013	2014–2018	2009–2013	2014–2018
Medicaid nonexpansion states	2.42 (2.04, 2.80)	2.50 (2.12, 2.88)	0.64 (0.37, 0.92)	0.59 (0.33, 0.86)
Medicaid expansion states	2.53 (2.19, 2.87)	2.58 (2.25, 2.90)	0.94 (0.74, 1.13)	0.79 (0.61, 0.96)
All states	2.49 (2.23, 2.75)	2.55 (2.30, 2.80)	0.83 (0.67, 1.00)	0.72 (0.57, 0.86)

Note. CI = confidence interval.

Source. SSI receipt data are from the Social Security Administration SSI Annual Statistical Reports, 2009–2018. Population sizes are from the American Community Survey, 2009–2018.

Figure 1 shows the trends in the SSI receipt rate of citizens and noncitizens by Medicaid expansion versus Medicaid nonexpansion states. For citizens, the SSI receipt rate peaked in 2013, followed by a modest fall in both expansion and nonexpansion states. For noncitizens, SSI receipt also peaked in 2013, followed by a sharp decline in expansion states (from 0.9% to 0.7%) compared with nonexpansion states (0.7% to 0.6%).

Figure 1 also shows that trends in SSI recipiency rates in expansion states were similar to those in nonexpansion states in the pre-ACA period, which is consistent with the parallel trends assumption. Statistical tests also found no statistical difference in pre-ACA trends between expansion and nonexpansion states. Results are available in Figure A.

Difference-in-Differences Regression Results

Next, we used a multivariable regression framework to compute the difference-in-differences estimates of the effect of Medicaid expansion on SSI receipt. This involved comparing change in SSI receipt before and after ACA implementation in Medicaid expansion and nonexpansion states. We did these analyses using administrative SSA data as well as survey data; the results are presented in Tables 2 and 3, respectively.

Analyses based on SSA data adjusted for state-level characteristics suggested that the SSI receipt rate among citizens fell 0.05 percentage points (or 2% of the preexpansion mean for citizens) in Medicaid expansion states compared with nonexpansion states (Table 2). The corresponding decline in the SSI receipt rate among noncitizens was of a much higher magnitude: 0.1 percentage points, or 12% of the preexpansion mean for noncitizens. Estimates remained robust in models that controlled for a rich set of policies toward noncitizens that can potentially affect the utilization of means-tested programs (model 2).

We conducted regression analysis with survey data on 2 samples of adults with incomes below the poverty threshold: nonelderly childless adults and nonelderly childless adults with disabilities. Estimates based on the sample of nonelderly childless adults suggest that, compared with nonexpansion states, SSI receipt among citizens fell 0.6 percentage points (or 5% of the pre-ACA mean) in Medicaid expansion states; the decline was 2.6 percentage points (or 72% of the pre-ACA mean) for noncitizens (Table 3).

Narrowing the sample to nonelderly childless adults with disability—the population whose SSI recipiency was most affected by the Medicaid expansion—increased the size of the effects: compared with nonexpansion states, SSI receipt among citizens fell 3.1 percentage points (or 9% of the pre-ACA mean) in Medicaid expansion states; the decline was 15.4 percentage points (or 62% of the pre-ACA mean) for noncitizens.

DISCUSSION

In this quasi-experimental study, we found that Medicaid expansion led to meaningful reductions in SSI recipiency among noncitizens. Noncitizens experienced a sharper decline in SSI receipt after ACA implementation than citizens. For noncitizens, SSI receipt peaked in 2013—just prior to ACA implementation—followed by a 12% decline in Medicaid expansion states compared with nonexpansion states in the post-ACA period. SSI receipt among citizens similarly peaked in 2013, but the corresponding decline was a modest 2%.

In the United States, noncitizen participation in welfare programs is highly controversial. A number of recent studies have stressed the increase in immigrant participation in Medicaid and its fiscal implications.[19,20] Our analysis, however, suggested that by focusing entirely on Medicaid participation, these previous studies did not capture the full impact of Medicaid expansions on the exchequer.

Our analysis suggested that Medicaid expansion, by creating an avenue for public health insurance for low-income families, reduced their SSI receipt. Given these findings, inferences on the fiscal effects of ACA expansions, including the

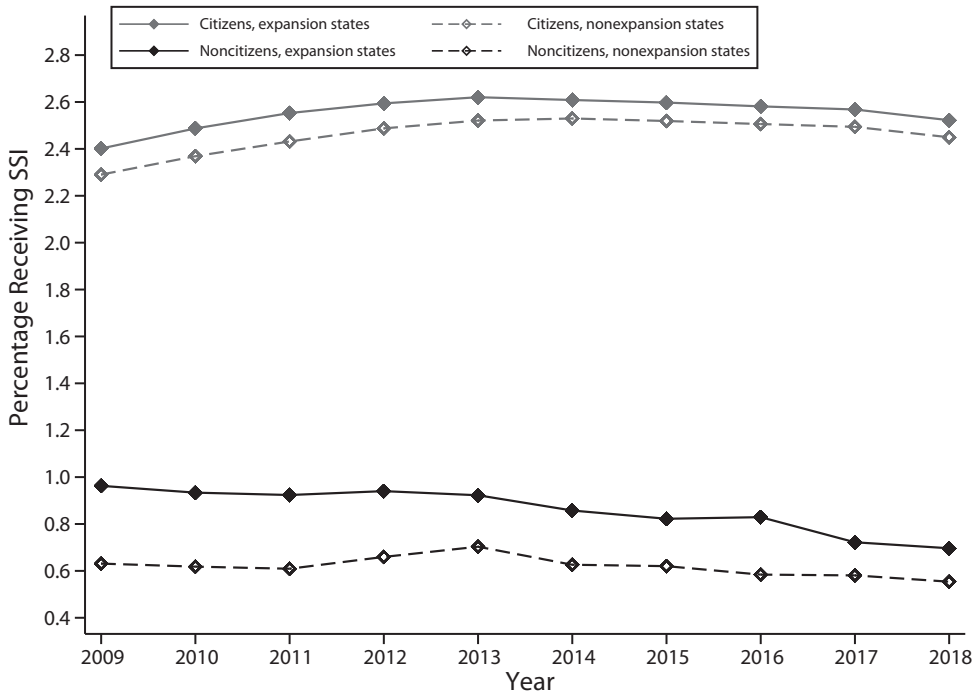

FIGURE 1— Trends in Average Percentage of Citizens and Noncitizens Aged 18–64 Years Who Were Supplemental Security Income (SSI) Recipients, by State Medicaid Expansion Status: United States, 2009–2018

Source. Authors' analysis of data from the Social Security Administration SSI Annual Statistical Reports, 2009–2018. Population sizes are from the American Community Survey, 2009–2018.

effects of immigrant insurance coverage, should be adjusted for the spillover effect of decline in SSI receipt. Our back-of-the-envelope estimates suggest an annual savings of $122 million in federal SSI costs because of the decline in SSI participation among noncitizens in Medicaid expansion states ($122 million = $260 [monthly benefit] × 12 × 39 311 [number receiving SSI in 2013 minus number receiving SSI in 2018 among noncitizens aged 18–64 years in Medicaid expansion states]), assuming that noncitizens who exited SSI received a third of the maximum SSI benefit of $771 in 2019. These savings are in addition to the corresponding savings due to the decline in SSI participation among citizens, a much larger population: $497 million ($260 [monthly benefit] × 12 × 159 528).

TABLE 2— Effect of Medicaid Expansion on Percentage of Adults Aged 18–64 Years Receiving Supplemental Security Income (SSI), by Citizenship Status: United States, 2009–2018

	Citizens	Noncitizens	
	Model 1, b (95% CI)	Model 1, b (95% CI)	Model 2, b (95% CI)
Medicaid expansion state	−1.72 (−1.79, −1.65)	0.79 (0.72, 0.86)	0.81 (0.70, 0.93)
Post-ACA	0.10 (0.00, 0.19)	−0.19 (−0.35, −0.04)	−0.19 (−0.34, −0.03)
Medicaid expansion state × post-ACA	−0.05 (−0.11, 0.00)	−0.10 (−0.18, −0.02)	−0.09 (−0.17, −0.01)
No. of observations	510	510	510

Note. ACA = Affordable Care Act; CI = confidence interval. The dependent variable is percentage of adults aged 18–64 years receiving SSI. All models controlled for number of noncitizens aged 18–64 years in the state, state unemployment rate, state fixed effects, and year fixed effects. Model 2 (for noncitizens) additionally controlled for state policies toward immigrants—namely, enforcement of Section 287(g) of the Illegal Immigration Reform and Immigrant Responsibility Act, the Secure Communities Program, state Dream Act policy, eligibility of undocumented immigrants to obtain driver's license, and state implementation of E-Verify.

Source. SSI receipt data are from the Social Security Administration SSI Annual Statistical Reports, 2009–2018. Population sizes are from the American Community Survey, 2009–2018.

TABLE 3— Effect of Medicaid Expansion on Probability of Low-Income Adults Aged 18–64 Years Receiving Supplemental Security Income, by Citizenship Status: Current Population Survey, United States, 2009–2019

	Citizens	Noncitizens	
	Model 1, b (95% CI)	Model 2, b (95% CI)	Model 3, b (95% CI)
Low-income and childless			
Medicaid expansion state	0.0868 (0.0761, 0.0975)	−0.0022 (−0.0228, 0.0184)	−0.0140 (−0.0354, 0.0075)
Post-ACA	−0.0093 (−0.0314, 0.0128)	−0.0458 (−0.0855, −0.0061)	−0.0450 (−0.0964, 0.0063)
Medicaid expansion state × post-ACA	−0.0060 (−0.0166, 0.0047)	−0.0258 (−0.0466, −0.0051)	−0.0284 (−0.0566, −0.0002)
Pre-ACA mean of outcome variable	0.118	0.036	0.036
No. of observations	73 001	5 775	5 775
Low-income, childless, and disabled			
Medicaid expansion state	0.1504 (0.1152, 0.1856)	−0.6217 (−0.8145, −0.4289)	−0.4555 (−0.7442, −0.1669)
Post-ACA	−0.0202 (−0.0869, 0.0465)	−0.3351 (−0.6583, −0.0119)	−0.3286 (−0.7657, 0.1085)
Medicaid expansion state × post-ACA	−0.0305 (−0.0614, 0.0004)	−0.1536 (−0.2720, −0.0352)	−0.1960 (−0.3909, −0.0011)
Pre-ACA mean of outcome variable	0.343	0.247	0.247
No. of observations	17 418	513	513

Note. ACA = Affordable Care Act; CI = confidence interval. Sample is restricted to childless adults aged 18–64 years in households with incomes below the federal poverty threshold.[10] All models controlled for age (categories: 18–26 [ref], 27–34, 35–42, 43–49, 50–57, and 58–64 years), gender (female [ref], and male), educational attainment (categories: high school or lower [ref], some college, and associate degree or higher), marital status (categories: married [ref], married but spouse absent, separated, divorced, widowed, and never married or single), household size (categories: 1 [ref], 2, 3, and 4 or more), number of (non)citizens aged 18–64 years in the state, state unemployment rate, state fixed effects, and year fixed effects. Models 2 and 3 additionally controlled for period of arrival to the United States and years since migration. Model 3 additionally controlled for state policies toward immigrants—namely, enforcement of Section 287(g) of the Illegal Immigration Reform and Immigrant Responsibility Act, the Secure Communities Program, state Dream Act policy, eligibility of undocumented immigrants to obtain driver's license, and state implementation of E-Verify.

Source. Authors' analysis of data from the Current Population Survey, 2009–2019.

These estimates suggest that any discussion of the fiscal implications of Medicaid expansions should take into account savings from other means-tested programs, in particular declines in SSI participation. Our analysis contributes to other research that documents that access to public health insurance reduces health care expenditures by ensuring timely health care and thus avoiding expensive emergency public health care that is generally available to immigrants.[21–23]

Although a reduction in SSI participation represents savings to the federal government, it is a loss of benefits to potential beneficiaries. Previous research documents higher employment rates in Medicaid expansion states than in nonexpansion states among adults aged 18 to 64 years with disabilities, which suggests that a reduction in SSI benefits may be offset, at least in part, by earned income.[4,5] Further research on the net financial gain to individuals is warranted.

Limitations

Our study has limitations. First, unobserved bias from time-varying factors that differentially affect expansion and nonexpansion states cannot be definitively excluded. We supported the validity of our findings by showing that our data are consistent with the parallel trends assumption in the pre-ACA period. We also performed robustness checks by fitting models with a rich set of controls, which produced similar estimates.

Second, our analyses based on SSA administrative data are at the state level, which could mask changes in the composition of the population within states. This would be a concern if changes in state composition were correlated with Medicaid expansion. To address this concern, we estimated models using individual-level survey data, which yielded similar conclusions. Previous research also finds that the level of generosity of a state's social programs does not influence the residency patterns of immigrants.[24,25]

Public Health Implications

The COVID-19 pandemic has revealed the serious implications of a large population without health insurance to overall public health. Note that because immigrants, on average, are

younger and healthier than natives, they are likely to have lower health care utilization than natives; therefore, immigrant Medicaid eligibility is likely to be a cost-effective policy for society.[26–28]

For the SSI population specifically—the focus of this study—the effect on Medicaid expansions on the economy is likely to be even greater, as these expansions also provided opportunities to low-income adults to increase work effort and accumulate savings and assets without the risk of losing public health insurance.[4,5,7,12] An increase in work effort, and therefore in income, would further increase fiscal windfalls from Medicaid expansions. AJPH

ABOUT THE AUTHORS

Felix M. Muchomba is with the School of Social Work, Rutgers University, New Brunswick, NJ. Neeraj Kaushal is with the School of Social Work, Columbia University, New York, NY, and the National Bureau of Economic Research, Cambridge, MA.

CORRESPONDENCE

Correspondence should be sent to Felix M. Muchomba, PhD, MPH, 120 Albany St, Tower One—Suite 200, New Brunswick, NJ 08901 (e-mail: felix.muchomba@rutgers.edu). Reprints can be ordered at http://www.ajph.org by clicking the "Reprints" link.

PUBLICATION INFORMATION

Full Citation: Muchomba FM, Kaushal N. Medicaid expansions and participation in Supplemental Security Income by noncitizens. *Am J Public Health*. 2021;111(6):1106–1112.

Acceptance Date: February 14, 2021.

DOI: https://doi.org/10.2105/AJPH.2021.306235

CONTRIBUTORS

Both authors contributed to the conceptualization of the study, the analysis and interpretation of the data, and the writing and revision of the article.

ACKNOWLEDGMENTS

This study was funded by the Eunice Kennedy Shriver National Institute of Child Health and Human Development (grant 1R03HD102466-01A1).

CONFLICTS OF INTEREST

The authors have no conflicts of interest to declare.

HUMAN PARTICIPANT PROTECTION

This study was reviewed by the Rutgers University Institutional Review Board and considered exempt from ethics review because it was based on anonymized secondary data.

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A Spatiotemporal Tool to Project Hospital Critical Care Capacity and Mortality From COVID-19 in US Counties

Alexis Zebrowski, PhD, Andrew Rundle, DrPH, Sen Pei, PhD, Tonguc Yaman, MPH, Wan Yang, PhD, Brendan G. Carr, MD, MS, Sarah Sims, BS, Ronan Doorley, PhD, Neil Schluger, MD, James W. Quinn, MA, Jeffrey Shaman, PhD, and Charles C. Branas, PhD

Objectives. To create a tool to rapidly determine where pandemic demand for critical care overwhelms county-level surge capacity and to compare public health and medical responses.

Methods. In March 2020, COVID-19 cases requiring critical care were estimated using an adaptive metapopulation SEIR (susceptible–exposed–infectious–recovered) model for all 3142 US counties for future 21-day and 42-day periods from April 2, 2020, to May 13, 2020, in 4 reactive patterns of contact reduction—0%, 20%, 30%, and 40%—and 4 surge response scenarios—very low, low, medium, and high.

Results. In areas with increased demand, surge response measures could avert 104 120 additional deaths—55% through high clearance of critical care beds and 45% through measures such as greater ventilator access. The percentages of lives saved from high levels of contact reduction were 1.9 to 4.2 times greater than high levels of hospital surge response. Differences in projected versus actual COVID-19 demands were reasonably small over time.

Conclusions. Nonpharmaceutical public health interventions had greater impact in minimizing preventable deaths during the pandemic than did hospital critical care surge response. Ready-to-go spatiotemporal supply and demand data visualization and analytics tools should be advanced for future preparedness and all-hazards disaster response. (*Am J Public Health*. 2021;111:1113–1122. https://doi.org/10.2105/AJPH.2021.306220)

The World Health Organization declared severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) a public health emergency of international concern on January 30, 2020, and a pandemic on March 12, 2020.[1] By March 26, 2020, and for months after, the United States had the highest number of confirmed cases of COVID-19, the disease caused by SARS-CoV-2, of any country in the world.[2] The nationwide increase in COVID-19 cases created a demand on the US health care system not seen for a generation in other large-scale disasters.

The COVID-19 pandemic also presented an opportunity for health care and public health to work together to meet the demands of local communities. Concern for local medical system response capacity was almost immediate along with expectations that the supply of hospital critical care resources would be exceeded. Critical care is perhaps the most important medical system choke point in terms of preventing deaths in disaster scenarios such as the COVID-19 pandemic.[3,4] A wide range of critical care infrastructure, from intensive care units to operating rooms and long-term acute-care facilities, can be drafted in crisis care surge situations, potentially increasing hospital capacity by significant amounts.[5–8]

Despite the increased need for critical care during disaster events, the full extent of surge capacity in the US health care system remains unknown. The COVID-19 pandemic presented a never-before-experienced opportunity to study the boundaries of the US hospital system in terms of the extent to which its supply of medical resources could be expanded to meet a predictable growth in critical care demand by COVID-19 patients. We created a spatiotemporal disaster response tool that combined previously established disease modeling

estimates[9,10] of COVID-19, various contact-reduction intervention assumptions, and county-level estimates of the potential critical care surge response[4] as a methodologic test case of how emerging and existing data could be used to provide meaningful, real-time public health policy guidance during a pandemic.

Our objectives in creating this tool were to be able to quickly highlight where demand for critical care beds would overwhelm surge capacity limits, provide real-time estimates for counties in terms of when they would exceed critical care surge capacity limits, and estimate the mortality that would result from exceeding available critical care surge capacity in these counties. The tool is intended for use by the US medical and public health systems under various disaster conditions—pandemic, natural disaster, or mass casualty trauma. It can estimate the system's ability to meet local demands with existing and quickly deployable health care resources while accounting for the implementation of interventions such as nonpharmaceutical reductions in contact transmission. By combining these inputs, the tool provides hospitals adequate time to prepare and minimize preventable mortality.[11,12]

METHODS

All US counties were included as our primary units of analysis[13] along with the District of Columbia. Counties were further aggregated into US regions using Census Bureau standards as Northeast, Midwest, South, and West[14] and urban or nonurban using the 2013 US Department of Agriculture Rural–Urban Continuum Classification, which considers population size and proximity to metropolitan areas. Urban counties had Rural–Urban Continuum Classification codes 1 through 3, and nonurban counties had codes 4 through 9.[15]

We estimated data for all continental US counties in the early months of the US pandemic, specifically both spatiotemporal COVID-19 demand and medical system critical care supply. We completed all mapping by using ArcGIS Pro 2.5 (ESRI Inc, Redlands, CA).

Demand Estimates of COVID-19

We used a previously reported, metapopulation SEIR (susceptible–exposed–infectious–recovered) model to simulate the spatiotemporal dynamics of COVID-19 infections.[9,10,16–20] This model structure was previously validated for forecasting the spatial spread of influenza and other respiratory and infectious diseases.[10,21–24] Compared with simple compartmental models developed for single locations, the metapopulation model has demonstrated superior performance in predicting the spatial progression of infectious disease[10]; homogeneous compartment models cannot represent the heterogeneity of disease transmission across different locations. The same model has been used to simulate counterfactual and future COVID-19 cases and deaths in the United States,[18] and a similar metapopulation model has been used to study COVID-19 in China.[9] Here we generated ensemble projections using 100 simulations for each scenario. The data assimilation method we used to calibrate the model is also widely used in weather[25] and infectious disease prediction for generation of probabilistic forecasts.[26–30]

We separated documented and undocumented infected individuals into 2 classes with separate rates of transmission, and we used Census Bureau commuting data and a multiplicative factor to estimate the daily number of people traveling between counties. Intercounty commuting in the model is reduced by 50% starting from March 14, 2020, to May 3, 2020, because of the introduction of stay-at-home orders. After this end date, near-real-time human mobility data were available and incorporated to measure intercounty movement along with data that quantified the number of visitors to nonresidential points of interest (e.g., parks, restaurants, stores)[31] on a county-by-county basis.

Transmission dynamics were simulated for all US study counties from February 21, 2020, to April 2, 2020, using an iterated filtering-ensemble adjustment Kalman filter framework.[32–34] This combined model-inference system estimated 4 population trajectories in each county—susceptible, exposed, documented infected, and undocumented infected—while simultaneously inferring model parameters for the average latent period, the average duration of infection, the transmission reduction factor for undocumented infections, the transmission rate for documented infections, the fraction of documented infections, and the travel multiplicative factor. To account for delays in infection confirmation, we employed a time-to-event observation model using a gamma distribution with a range of reporting delays and different maximum seeding. We used log-likelihood to identify the best-fitting model-inference posterior.[9,19]

We projected public health measures to control the spread of SARS-CoV-2 forward in time using the optimized model parameter estimates for 21-day and 42-day time horizons beginning on April 2, 2020, and ending on April 22,

2020, and May 13, 2020, respectively.[19] Because of a roughly 2-week lag between infection acquisition and case confirmation, we initiated the projections on March 19, 2020, using the parameter estimates made with confirmed case data through April 2, 2020. We considered 2 types of movement—daily work commuting and random movement. Control measures included travel restrictions between areas, self-quarantine and contact precautions that were publicly advocated or imposed, and greater availability of rapid testing for infection. We also considered changes in medical care seeking attributable to increased awareness of COVID-19 and increased personal protective behavior (e.g., use of facemasks, social distancing, self-isolation when sick).

We projected four adaptive scenarios of contact reduction to simulate the measures implemented by state and local governments (e.g., school closures, work from home) and personal protective behavior (mask wearing, social distancing): 0% (no contact reduction via social distancing controls or behavior change), 20%, 30%, and 40% contact reduction.[35] Upon initiation of projections on March 19, 2020, we assigned US counties with at least 10 confirmed cases 0%, 20%, 30%, or 40% contact rate reductions, and we applied no contact reduction to remaining counties. In each subsequent week, we assigned counties exceeding 10 confirmed cases for the first time a 0%, 20%, 30%, or 40% contact rate reduction, depending on the projection scenario. For counties with increasing confirmed case counts and 10 previously confirmed cases, we applied multiplicative contact rate reductions of 0%, 20%, 30%, or 40%, depending on the projection scenario. We applied no contact reduction to counties with fewer than 10 confirmed cases. This multiplicative ratcheting of contact reduction levels was meant to represent increasing reactive social distancing imposed within counties as long as confirmed weekly cases of COVID-19 continued to rise. These adaptive control measures were intended to reflect county-level reactions and adaptations to the introduction of COVID-19. Over the same period studied here, the average contact reduction percentage in the United States, as measured by visitors to nonresidential places such as parks, grocery and pharmacy stores, retail and recreation, workplaces, and transit stations, was 30.2% according to independent data, justifying the chosen range of 20% to 40%.[35]

We also compared actual hospital critical care case counts with projected critical care case counts, as described previously, for all US counties. We calculated mean percentage errors (MPEs) for the study period (beginning April 5, 2020) extending to June 10, 2020, the most recent date of data availability. We reported the MPEs, the average percentage differential between actual and projected values with both positive and negative values, as summary measures over time.[36] We chose the single intervention scenario for each projection date that most closely matched the actual case counts in calculating MPE (minimum MPE), and the median of all intervention scenarios for each projection date (median MPE). We computed the minimum MPE and median MPE across both projection time horizons as means with confidence intervals for all US counties and for counties separated into urban and nonurban classifications.

Supply Estimates of Hospital Capacity

We derived critical care bed counts for all US counties from the linkage and harmonization of different data sets:

1. the 2020 Centers for Medicare and Medicaid Services (CMS), Health Care Information System Data File, Sub-System Hospital Cost Report (CMS-2552–96 and CMS-2552-10), Section S-3, Part 1, Column 2;
2. the 2018 American Hospital Association Annual Survey;
3. the 2020 US Department of Health and Human Services Health Resources and Services Administration, Area Health Resources Files; and
4. the 2017–2019 CMS Medicare Provider of Services file, Medicare Cost Report, Hospital Compare Files.

To account for the reallocation of resources during surge, we calculated critical care bed supply from 4 hospital bed types: intensive care unit (ICU) beds, operating room (OR) beds, postanesthesia care unit (PACU) beds, and step-down beds. We summed critical care bed counts for all US civilian hospitals within each county, including pediatric medical–surgical hospitals and long-term acute-care facilities. We did not include Veterans Affairs or military medical hospital facilities. We summed counts of ICU beds per hospital as any reported

1. general medical–surgical ICU beds,
2. surgical ICU beds,
3. coronary ICU beds,
4. burn care ICU beds,
5. pediatric ICU beds, and
6. other ICU beds.

We excluded neonatal ICU beds. Counts of ICU beds were the highest number of ICU beds reported by each US hospital across the 4 primary sources of data listed previously. We used step-down bed counts where reported; if hospitals did not report step-down beds, we assumed a 1-to-4 step-down-to-ICU-bed

ratio, and we multiplied ICU bed counts by 1.25. We assumed 1 bed per OR. For hospitals that did not report PACU beds, a 1.5-to-1 PACU beds-to-OR ratio was assumed, and ORs were multiplied by 1.5. We assumed 1 ventilator per critical care bed except in the highest surge scenario in which we doubled the number of available ventilators as an estimate of additional resources that were acquired by health systems to meet high-volume demands by creating double occupancy in critical care units or converting space to serve these needs.[4–8,37–40]

We estimated baseline critical care bed availability at 30% of the total ICU beds in each county. We created 4 critical care bed scenarios to account for surge response in each US county: very low, low, medium, and high (see box on p. 1117). Each scenario created an increase in the number of available beds with the very low scenario assuming only the baseline 30% of critical care beds available, the low scenario incorporating extra beds through discharge or other clearing, the medium scenario increasing bed counts through the use of specialized non-ICU beds, and the high scenario assuming twice the number of ventilators in the medium scenario could be ascertained, therefore doubling critical care capacity.[6,41–44] In this way, we incorporated existing critical care bed availability rates and occupied critical care bed clearance rates for purposes of meeting high-volume patient surges in disasters into our estimates.

To estimate preventable deaths attributable to lack of critical care supply, we aggregated the number of new cases requiring critical care beds that could not be admitted once a hospital reached capacity minus discharges at the county, regional, and national levels. If we recorded no bed counts in any of the 4 data sets, we did not include the county in calculating the time to exceed critical care capacity. We calculated daily critical care bed need and discharge rates for each day of the study period using a typical ICU length of stay for COVID-19 patients.[19] Previous reports of the hospital course for COVID-19 patients showed that the majority of those admitted to the ICU were critical, and survival for critical patients was 1 in 5. Thus, the survival of critically ill patients treated outside of the ICU should be much lower, approximately 5%; we therefore assumed a 95% mortality for patients requiring a critical care bed but who did not receive one because their local capacity had been exceeded.[45]

RESULTS

Of the 3142 US counties included in our analysis, 217 (6.9%) were in the Northeast, 1055 (33.6%) were in the Midwest, 1422 (45.3%) were in the South, and 448 (14.2%) were in the West. In addition, 1166 (37.1%) were urban and 1976 (57.9%) were nonurban.

Critical care surge response ranged from 77 588 available critical care beds in the very low to 278 850 in the high scenario. Mean available critical care beds in the very low scenario was 24.0 per county (SD = 88.8), whereas the mean critical care bed availability in the high surge response was approximately 3.5 times this with 86.2 available beds per county (SD = 307.7). Baseline critical care bed availability and gain in beds for surge response estimates were highly correlated (medium response vs baseline; r = 0.97). For each baseline critical care bed, 4.61 (95% confidence interval = 4.57, 4.65) additional critical care beds could be gained under the medium critical care surge capacity scenario. The counties that could generate the largest gains in beds under these surge capacity scenarios were typically urban counties that already had substantial hospital infrastructure.

Contact Reduction, Surge Response, and Capacity

Urban, Northeastern, and Southern counties exceeded critical care bed capacity in greater numbers than their nonurban, Western, and Midwestern counterparts. Regionally, these findings were consistent across all surge response scenarios including those with increased contact reduction (Appendix Tables A and B, available as supplements to the online version of this article at http://www.ajph.org). However, the disparity between urban and nonurban counties was reduced in the high scenario. More urban counties consistently exceeded critical care bed capacity compared with nonurban counties. As time progressed from the 21-day through the 42-day scenario, larger numbers of counties outside of the Northeast exceeded their critical care capacity (Figures 1 and 2).

Contact reduction interventions of 40% over the 42-day scenario prospectively produced decreases in the number of counties with unmet critical care demand between 81.5% and 87.3% compared with 24.6% to 48.0% reductions from high-intensity patient surge responses. The percentages of lives saved from high levels of nonpharmaceutical public health interventions were 1.9 to 4.2 times greater than high levels of hospital surge response. By increasing contact reduction strategies from 0% to 40% over the 42-day period, a high of 185 192 deaths could be averted in the Northeast, and a low of 33 986 deaths could

Hospital Critical Care Surge Response Scenarios, by Ascending Intensity: United States

1. Very-low-intensity patient surge response
   a. 30% of existing ICU beds are unoccupied and available.
   b. 50% of existing ICU beds can be cleared and made available.
2. Low-intensity patient surge response
   a. 30% of existing ICU beds, step-down beds, OR beds, and PACU beds are unoccupied and available.
   b. 30% of existing ICU beds, step-down beds, OR beds, and PACU beds can be cleared and made available.
3. Medium-intensity patient surge response
   a. 30% of existing ICU beds, step-down beds, OR beds, and PACU beds are unoccupied and available.
   b. 50% of existing ICU beds, step-down beds, OR beds, and PACU beds can be cleared and made available.
4. High-intensity patient surge response
   a. 30% of existing ICU beds, step-down beds, OR beds, and PACU beds are unoccupied and available.
   b. 50% of existing ICU beds, step-down beds, OR beds, and PACU beds can be cleared and made available.
   c. All available ICU and step-down units can be modified for double occupancy with double the number of ventilators procured.

Note. ICU = intensive care unit; OR = operating room; PACU = post-anesthesia care unit.

be averted in the Midwest under medium hospital surge conditions (Appendix Table B).

As a gauge of aggressive critical care surge actions, the difference between the high and the very low critical care surge response scenarios ranged from an estimated 4507 to 104 120 deaths averted over the 42-day period. As a gauge of redeploying non-ICU beds for critical care surge response, the difference between the medium and the very low critical care surge response scenarios ranged from 2807 to 57 662 deaths averted over the 42-day period. Differences between the high and the medium critical care surge response scenarios ranged from 1700 to 46 458 deaths averted over the 42-day period under the assumption that hospitals acquired twice the number of available ventilators (Appendix Table B).

Projected Versus Actual Estimates

In comparing projected versus actual COVID-19 case demands for critical care beds, we noted little difference in MPE for the 21-day and the 42-day estimates when we used the estimates that most closely matched the actual case counts (minimum MPE). There was a greater range for median MPEs for the 42-day estimates with smaller deviations typically seen in urban settings (Figure 3).

DISCUSSION

The pandemic supply and demand tool created and showcased here was able to rapidly determine, with reasonable accuracy, which US counties were imminently at risk for exceeding their medical capacity limits because of COVID-19 cases over 3- to 6-week time horizons. The tool successfully combined real-time disease modeling of the growth of severely ill COVID-19 cases and the hospital critical care demand these would create, with the actual supply of hospital critical care that existed and could be created in all counties across the United States. A ready-to-go tool like this could be of great value as subsequent waves of COVID-19 occur and as future large-scale disasters, including pandemics, emerge.

The value of "flattening the curve"—that is, even a relatively small 20% contact reduction—is potentially sizeable and results in a greater number of deaths averted than even the highest health care surge response scenarios. Nonpharmaceutical interventions, such as social distancing, not only save lives as stand-alone interventions but they also provide the US medical system, especially the choke point of hospital critical care, the necessary time to prepare and be able to handle a manageable throughput volume of severely ill people with COVID-19. This case study clearly shows the importance of nonpharmaceutical public health measures, with up to 4 times more deaths averted through contact-reduction strategies (mask wearing, travel restrictions, social distancing) than from high levels of critical care surge response.

The number of deaths in urban counties remained high compared with nonurban counties throughout the 6-week period in which the tool was applied. Although greater numbers of hospital beds were typically found in urban locations, these counties also experienced or were predicted to

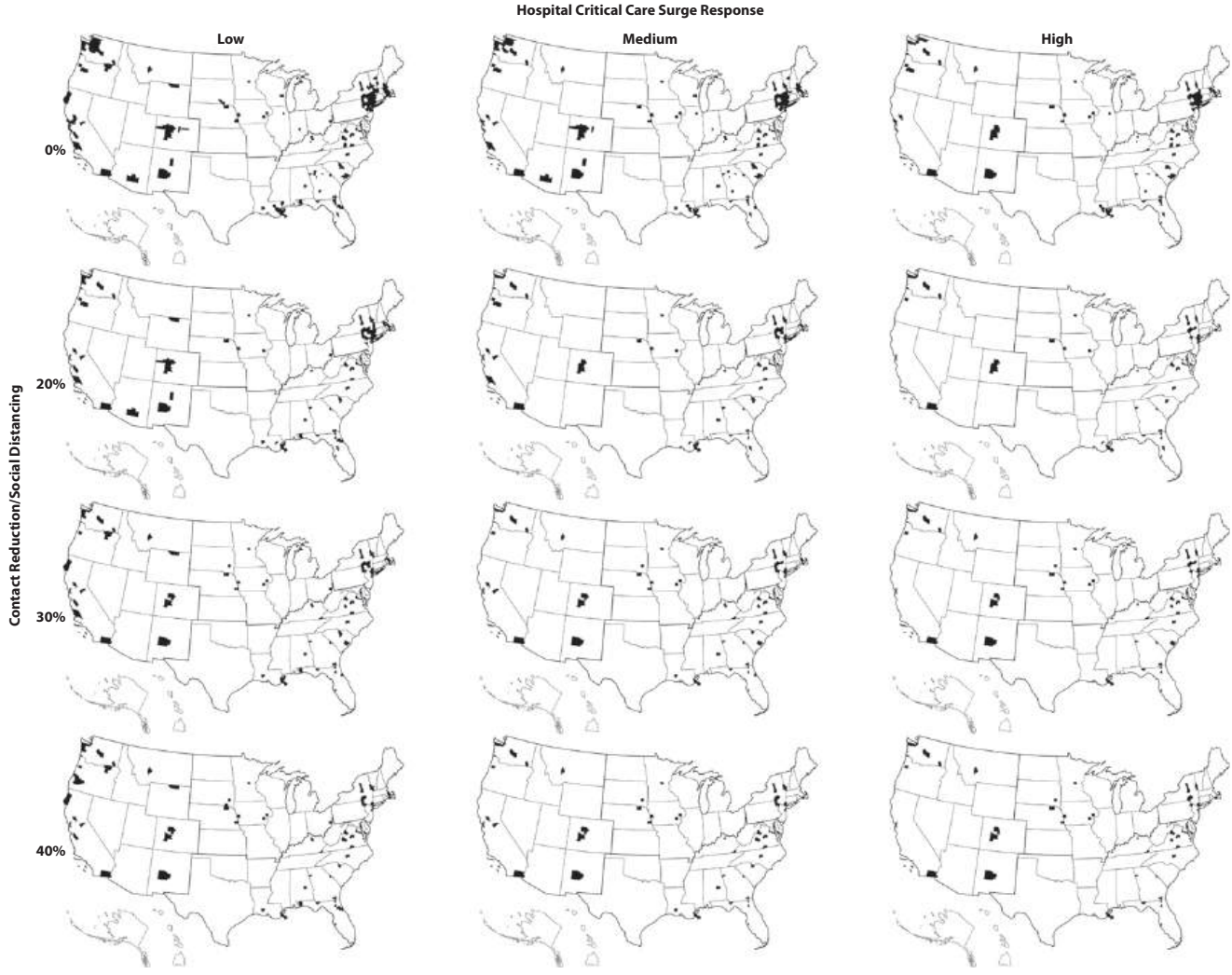

FIGURE 1— US Counties Exceeding Hospital Critical Care Surge Limits Within a 21-Day Time Period Under Different Surge Response and Contact Reduction Scenarios, Shown in Black: April 2, 2020–April 23, 2020

experience larger increases in COVID-19 cases, as well as to receive transfers from their rural counterparts. Therefore, the ability of the health care system within urban counties to meet the demand from critically ill patients remains of primary concern. This may be exacerbated by the inability of urban residents to remain socially distant given increased population density. At the same time, less extensive hospital resources in many nonurban counties may not have been able to keep pace with the growth in severe COVID-19 cases. The relocation or travel of urban residents with undetected COVID-19 infection to nonurban areas that appear to be relatively unaffected may exacerbate this and overwhelm the relatively limited critical care capacity in otherwise isolated nonurban regions.

Limitations

Several qualifications of the county-level supply and demand tool are worth noting. Optimizing the model projections using observations of confirmed cases by county, and representing infections that were acquired by individuals approximately 2 weeks earlier, potentially during a time before the implementation of many of the social distancing and isolation measures that had been put in place by the end of March 2020, is a recognizable delay. Because of this delay between infection acquisition and case confirmation, certain aspects related to flattening of the curve attributable to these effects may not get communicated to the model in a timely way. For instance, with the implementation of many new control policies after mid-March, the 20% to 40% contact reduction projections likely

FIGURE 2— US Counties Exceeding Hospital Critical Care Surge Limits Within a 42-Day Time Period Under Different Surge Response and Contact Reduction Scenarios, Shown in Black: April 2, 2020–May 13, 2020

depict paths that multiple counties may have already been following. Second, variability in population density, control measures, and testing practices adds uncertainty to model optimization and potentially magnified projection errors in nonurban, as opposed to urban, counties. Despite this, for the most part, our models exceeded expectations and did not "always overshoot" as some anticipated,[46] posting relatively small percentage errors in projecting critical care cases and likely resulting in even greater accuracy for projected mortality estimates, as a subset of these cases.

The health care system capacity estimates presented here are based on long-standing federal and professional agency databases of US hospitals. However, a limitation of these databases is their lack of robust information on health care human resources, staffing, and equipment, such as ventilator supplies, dialysis machines, heart–lung bypass support, and others. Health care workers, especially those involved in critical care, are at high risk for COVID-19 infection, and shortages that reduce the ability to staff critical care beds made available during critical incident surge response times limit effective patient care and endanger health care worker safety. Hospitals under surge conditions may be unable to accept patients, not because of lack of beds, but because of lack of staff to cover those beds. Although the tool and models developed here cannot account for the innovation, ingenuity, and perseverance of medical staff, many of whom are trained to work in crisis situations, they should endeavor to incorporate staffing and equipment data for medical system surge into future models, as they become known.[47] Recent and emerging work has shown

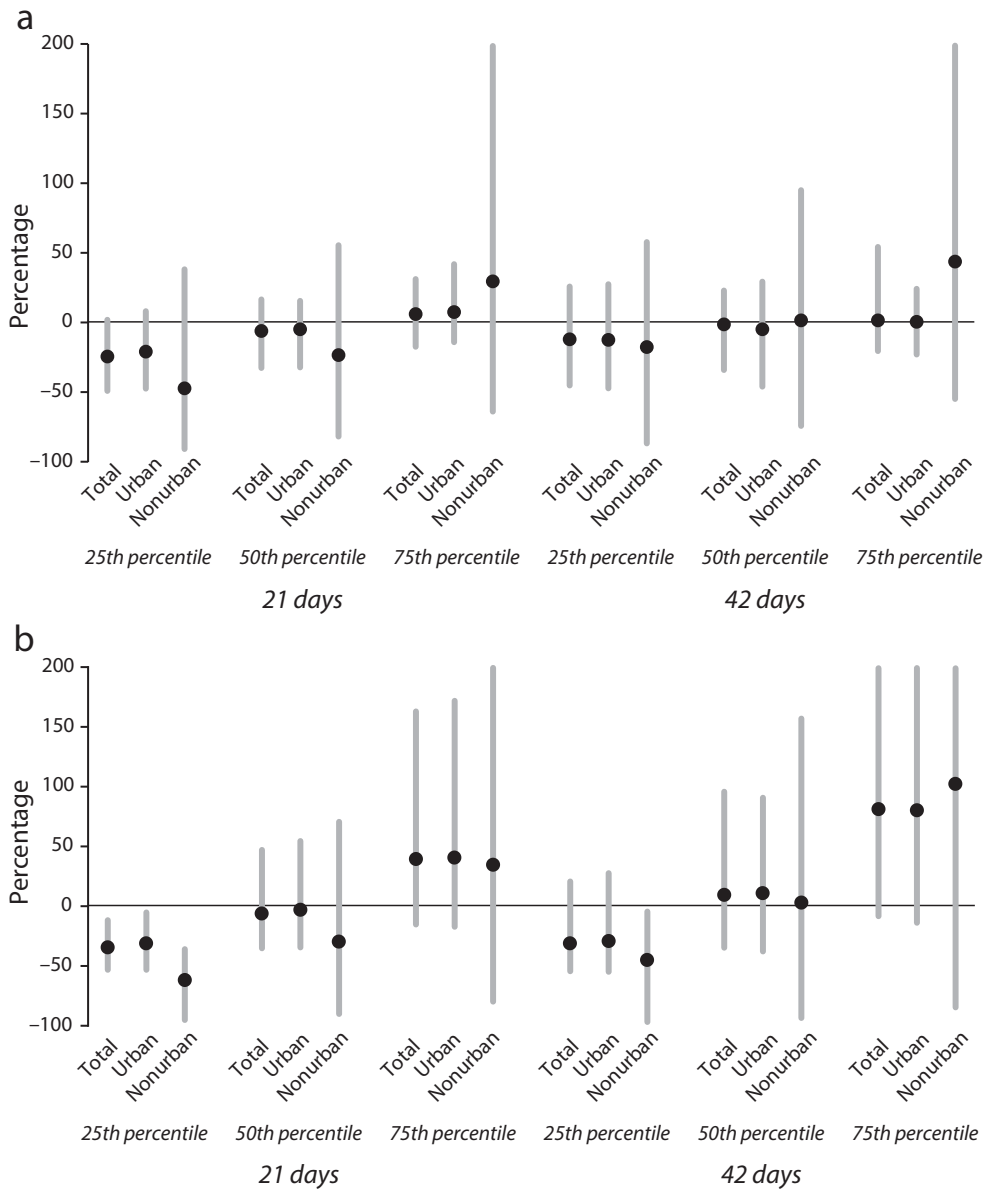

FIGURE 3— Percentage Errors of Projected Versus Actual Differentials in COVID-19 Cases Requiring Critical Care: United States, April 5, 2020–June 10, 2020

the importance of the reallocation of resources, including staff, across county lines in alleviating bottlenecks during times of high strain.[48,49]

Our models also did not account for heterogeneities arising from specific high-risk communities in different counties. For instance, places with large elderly populations or populations who have been historically and structurally marginalized and, as such, are beset with high levels of preexisting respiratory, cardiovascular, or immunocompromised conditions, may have even higher mortality rates than anticipated here.

Conclusions

This case study demonstrates the need for a robust, rapidly available supply and demand disaster response tool, like the one modeled here. Sustained investment in some semblance of a national hospital data system, perhaps even a national electronic medical record system with real-time data feeds, would be of great value to future efforts.[11,50] Early information on transmission, decompensation, and risk could also be used to better estimate demand in future adaptations. The disaster response tool shows the clear and primary importance of

nonpharmaceutical public health interventions in averting deaths during the first months of a viral pandemic. Those strategies coupled with innovative surge response by the medical system should be able to meet COVID-19 demand and minimize preventable deaths across most US counties. Ready-to-go spatiotemporal supply and demand data visualization and analytics tools should be advanced in rapidly supporting public health decisions for future preparedness and all-hazards disaster response.[51] AJPH

ABOUT THE AUTHORS

Alexis Zebrowski and Brendan G. Carr are with the Department of Emergency Medicine, Icahn School of Medicine at Mount Sinai, New York, NY. Andrew Rundle, Tonguc Yaman, Wan Yang, James W. Quinn, and Charles C. Branas are with the Department of Epidemiology, Mailman School of Public Health, Columbia University, New York. Sen Pei and Jeffrey Shaman are with the Department of Environmental Health Sciences, Mailman School of Public Health, Columbia University. Sarah Sims is with Patient Insight, Santa Monica, CA. Ronan Doorley is with Media Lab at the Massachusetts Institute of Technology, Cambridge. Neil Schluger is with the Division of Pulmonary, Allergy, and Critical Care Medicine, and Departments of Epidemiology and Environmental Health Sciences, Columbia University Irving Medical Center, Columbia University.

CORRESPONDENCE

Correspondence should be sent to Charles C. Branas, PhD, Gelman Professor of Epidemiology and Chair, Department of Epidemiology, Mailman School of Public Health, Columbia University, 722 West 168th St, Room 1508, New York, NY 10032 (e-mail: c.branas@columbia.edu). Reprints can be ordered at http://www.ajph.org by clicking the "Reprints" link.

PUBLICATION INFORMATION

Full Citation: Zebrowski A, Rundle A, Pei S, et al. A spatiotemporal tool to project hospital critical care capacity and mortality from COVID-19 in US counties. *Am J Public Health*. 2021;111(6): 1113–1122.

Acceptance Date: February 2, 2021.

DOI: https://doi.org/10.2105/AJPH.2021.306220

CONTRIBUTORS

The project was conceptualized by A. Zebrowski, A. Rundle, B. G. Carr, and C. C. Branas. Data were analyzed by S. Pei, T. Yaman, W. Yang, S. Sims, R. Doorley, J. Quinn, and J. Shaman. The article was initially drafted by A. Zebrowski and C. C. Branas. Critical review was performed by A. Rundle, S. Pei, N. Schluger, and J. Shaman. All authors helped to conceptualize ideas, interpret findings, and review drafts of the article.

CONFLICTS OF INTEREST

The authors have no conflicts of interest to report.

HUMAN PARTICIPANT PROTECTION

The work contained in this article was exempt from institutional review board approval because it did not contain human participants. All analyses were conducted using secondary data that were publicly available and collected for other purposes.

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The COVID-19 Pandemic: Effects on Civil Registration of Births and Deaths and on Availability and Utility of Vital Events Data

Carla AbouZahr, MSc, Martin W. Bratschi, PhD, Emily Cercone, MPH, Anushka Mangharam, MPH, Don de Savigny, PhD, Irina Dincu, MA, Anette Bayer Forsingdal, MA, Olga Joos, DrPH, MPH, RN, Montasser Kamal, PhD, Doris Ma Fat, MSc, Gloria Mathenge, MA, Fatima Marinho, PhD, Raj Gautam Mitra, MSc, Jeff Montgomery, MBA, William Muhwava, MA, Remy Mwamba, MSc, James Mwanza, MSc, Alvin Onaka, PhD, Tanja Brøndsted Sejersen, MSc, Maletela Tuoane-Nkhasi, PhD, Lynn Sferrazza, MSc, and Philip Setel, PhD

See also Copeland, p. 990.

The complex and evolving picture of COVID-19–related mortality highlights the need for data to guide the response. Yet many countries are struggling to maintain their data systems, including the civil registration system, which is the foundation for detailed and continuously available mortality statistics. We conducted a search of country and development agency Web sites and partner and media reports describing disruptions to the civil registration of births and deaths associated with COVID-19 related restrictions.

We found considerable intercountry variation and grouped countries according to the level of disruption to birth and particularly death registration. Only a minority of the 66 countries were able to maintain service continuity during the COVID-19 restrictions. In the majority, a combination of legal and operational challenges resulted in declines in birth and death registration. Few countries established business continuity plans or developed strategies to deal with the backlog when restrictions are lifted.

Civil registration systems and the vital statistics they generate must be strengthened as essential services during health emergencies and as core components of the response to COVID-19. (*Am J Public Health*. 2021;111:1123–1131. https://doi.org/10.2105/AJPH.2021.306203)

In March 2020, the COVID-19 outbreak was officially declared a global pandemic by the World Health Organization. In response, countries introduced public health and social measures aimed at slowing transmission of the virus including school and workplace closures, travel restrictions, and bans on public gatherings.[1] Public services not deemed "essential" were reduced or closed, placing the services they provide out of reach.

In some settings, this disruption also affected the civil registration and vital statistics (CRVS) system. Civil registration is the "continuous, permanent, compulsory, universal recording of the occurrence and characteristics of vital events pertaining to the population."[2(p65)] At the population level, civil registration is a source of vital statistics for national and subnational administrative areas. For individuals, civil registration provides legal recognition and documentation of life events (such as birth, death, marriage, and divorce), and is foundational for individual identity systems. Up-to-date information from CRVS systems are needed to manage population registers and national identification systems as well as sectoral databases such as electoral registers, tax, and social security, and health, educational, social, and banking services.

Despite its clear importance to individuals and governments, civil registration is far from universal. An estimated 29% of the world's children younger than 5 years have not had their births registered[3]; 55% of all deaths remain unregistered.[4] In this report, we examine the impact of the COVID-19 pandemic on CRVS systems and discuss the implications for decision-makers facing an acute need for timely and reliable data, particularly on mortality.

METHODS

We searched Google Scholar for articles on birth and death registration during the COVID-19 restrictions published between March and November 2020 using the following search terms: "civil/vital registration and vital statistics" + "COVID-19" + "low- and middle-income countries" + "death registration" + "death certificate" + "mortality." We reviewed Web sites and media articles to identify reports on civil registration during COVID-19 restrictions. We examined responses to the questionnaire issued by the United Nations Legal Identity Agenda (UN LIA) on the status of civil registration and vital statistics during the COVID-19 emergency.[5] We also drew upon experiences shared directly with the authors and on reports from countries collaborating with the Bloomberg Philanthropies Data for Health Initiative's CRVS systems improvement program. Our search was conducted primarily in English, French, Spanish, and Portuguese.

As of August 13, 2020, 61 countries responded to the UN LIA questionnaire, which was addressed to national civil registrars. The search of country Web sites generated usable information for several high-income settings. Additional information came through personal contacts in collaborating countries. As shown in Table 1, we found relevant information for a total of 66 countries comprising one third of all countries.

RESULTS

The core elements of the CRVS system are summarized in Table 2, which also provides an overview of disruptions experienced during COVID-19 restrictions. Many countries responding to the UN LIA questionnaire indicated that although civil registration is often considered essential, few governments have taken the necessary measures to ensure uninterrupted service provision. Table 3 groups countries into 4 categories according to the degree of disruption experienced.

Civil Registration Not "Essential"

Civil registration was not classified as an essential service in 11 countries (17%). For example, in India, where civil registration was not designated essential, registration of births and deaths has been severely disrupted.[6] Elsewhere, although civil registration was not designated as essential, certain registration services continued to function. In Bangladesh, some registration offices operated with distancing measures in place, and the online birth and death registration system received notifications from rural registration offices.[5] In Sri Lanka, mobile services were introduced for birth registration and procedural simplifications made to facilitate the granting of burial permits by local authorities, thus facilitating death registration.[5] In Uganda, health services stepped in to notify the civil registration authority of the occurrence of births. Health sector information technology staff ensured ongoing notification of births and deaths in the expectation that registration could take place and certificates could be issued after the lifting of pandemic restrictions.[7]

Civil Registration Limited to Certain Events

To cope with the anticipated service disruption and avert interruptions in the flow of mortality statistics, 5 countries (8%) limited registration to deaths and stillbirths only. In England and Wales, emergency COVID-19 legislation deprioritized birth registration and put registration of other vital events on hold.[8] Civil registration offices remained operational for the registration of stillbirths and deaths by telephone only; hospital-based birth and death registration facilities remained closed until COVID-19 restrictions were lifted.[9]

In Angola and Lesotho, limited availability of personal protective equipment led the Ministry of Home Affairs to limit services to registration of deaths.[5] In Armenia, birth and death registration remained possible but was suspended for all other vital events.[5] In Azerbaijan, in-person applications for registration continued to be possible for births, marriages, and deaths; all other registrations had to be done electronically.[5]

Services Facing Operational Constraints

Among the 34 countries (51%) classifying registration services as essential, service provision was hampered or scaled down because of travel restrictions and "stay-at-home" orders. Neither registration staff nor their clients were able to travel to the registration office for the in-person encounter needed to register a death and collect a copy of the certificate.

Only 3 of the countries in Central and South America that designated civil registration as an essential service (Chile, Ecuador, and Mexico) continued to operate normally; the remainder totally or partially suspended in-person services.[10] In Argentina, where shift work was arranged and appointments for in-person services could be scheduled, death registration continued, but birth registration ceased in some localities.[5] In Brazil, access to in-person registration services was partially suspended despite

TABLE 1— Regional Distribution of Countries With Information on Civil Registration and Vital Statistics (CRVS) Systems During the COVID-19 Pandemic

Region	Countries With Information on CRVS Services, No. (%)	Population of Countries With Information on CRVS Services, 1000s (% of Regional Population)
Africa	31 (56.4)	766 667 (57.2)
North and Central America	6 (15.0)	493 746 (78.8)
South America	5 (38.5)	345 397 (81.8)
Asia	15 (31.3)	2 157 508 (46.3)
Oceania	8 (57.1)	42 903 (75.7)
Total	65 (33.5)	3 727 847 (47.4)

Note. The sample size was 65 countries (excluding England and Wales).

ministerial commitments to service continuity.[11] In Colombia, civil registration services remained available only in the notaries' offices, not in the civil registration offices, reducing the number of registration outlets available to the public.[5] In Mexico, although death registration was considered an essential function and state governments were required to streamline registration procedures, decreases in the timely registration of births have been observed because of stay-at-home orders and measures to avoid overcrowding at registration offices and ensure the protection of registration officials.[5]

In Africa, disruptions to civil registration services were reported in Benin, Burkina Faso, Cameroon, Cabo Verde, Côte d'Ivoire, Ghana, Kenya, Mozambique, Senegal, and Sierra Leone despite the availability of civil registry staff on a rotational basis and the introduction of personal protective measures.[5] To mitigate disruption, Ghana developed a plan to roll out mobile registration at community level, working with local leaders and faith-based organizations.[5] In South Africa, the Department of Home Affairs continued with minimal staff and issued only death certificates, replacement identification cards, and birth certificates during the lockdown.[12]

Health institutions in several countries recorded information on births and deaths so that the civil registrar can be notified when restrictions are lifted. In Namibia, the government temporarily closed hospital-based registration

TABLE 2— Core Elements of the Civil Registration and Vital Statistics (CRVS) Process for Births and Deaths

Component	Definition	Nature of Service Disruption During COVID-19
Notification	The capture and onward transmission of minimum essential information on a vital event by a designated informant, using a CRVS authorized notification form (paper or electronic), with that transmission of information being sufficient to support civil registration and certification of the vital event.	Next of kin (or other informant) unable to travel to registration office to complete notification. Evidence of reductions in numbers of births and deaths occurring in health facilities, with corresponding reductions in health sector notifications, particularly where CRVS system at local level is paper-based and depends on in-person visit.
Registration	The act of registering a vital event at a civil registration office. At this point, details of the event are entered into the official civil registry by the civil registrar.	Civil registrars subject to workplace closures and travel restrictions. Lack of protective equipment at registration offices. Family members (or other informants) unable to travel to registration office to validate information and sign the register.
Certification	The issuance by the civil registrar of a legal document certifying a vital event.	As above. Families (or other informants) unable to travel to pick up a copy of the certificate. No mechanisms in place to permit digital transfer to the family of a copy of the certificate.
Vital statistics	Vital statistics are derived from the compilation and analysis of information on vital events and associated characteristics.	Missed and delayed registrations result in incomplete statistics and deprive decision-makers of timely and reliable data to guide decision-making. Compilation of statistics delayed because of workplace closures and staffing limitations, especially where paper-based systems are commonplace. During the pandemic, effective public health decision-making is reliant on timely and complete mortality statistics.

TABLE 3— Countries by Civil Registration System Status During the COVID-19 Pandemic

Status of Civil Registration System During the Pandemic	Countries
Civil registration services not considered essential and no continuity measures in place (n = 11)	Bangladesh, Eswatini, Guinea-Bissau, India, Malawi, Nigeria, Panama, Samoa, Solomon Islands, Sri Lanka, Uganda
Civil registration considered essential but limited to certain vital events (n = 5)	Angola, Armenia, Azerbaijan, England and Wales, Lesotho
Civil registration considered essential and services reorganized but facing operational constraints (n = 34)	Afghanistan, Argentina, Benin, Brazil, Burkina Faso, Cameroon, Colombia, Côte d'Ivoire, Democratic Republic of Congo, Djibouti, Ecuador, El Salvador, The Gambia, Ghana, Hong Kong, Indonesia, Kenya, Lao People's Democratic Republic, Madagascar, Mali, Marshall Islands, Mauritius, Mexico, Mozambique, Namibia, Panama, Philippines, Rwanda, Sao Tome and Principe, Senegal, Seychelles, Sierra Leone, Tanzania, Vanuatu
Civil registration considered essential and available without interruption (n = 16)	Australia, Bahrain, Cabo Verde, Chile, Comoros, Cook Islands, Costa Rica, Fiji, Georgia, Guatemala, Iran, Maldives, New Zealand, Republic of Korea, Tunisia, United States

Note. The sample size was 66 countries (England and Wales not included in regional totals).

offices, and births and deaths could be registered only at regional and subregional offices of the Ministry of Home Affairs, Immigration, Safety, and Security. However, the continuous e-birth and e-death notification systems through the health sector ensures that information about these events is available to the civil registrar once COVID-19 restrictions are lifted.[5]

In Rwanda, the local registration office is continuously notified of births and deaths in health facilities through an online portal in the expectation that official registration will be completed after the containment period.[5] In Tanzania, a decentralized model of registration through health facilities is in operation in 16 of the country's 26 regions to enable birth and death registration at health facilities. However, an overall decline in the number of registrations has been observed.[5]

In Afghanistan, COVID-19 restrictions and security concerns mean that services are provided only on an urgent and emergency basis.[5] In the Lao People's Democratic Republic, many vital events could not be registered because of COVID-19 travel restrictions, but the Ministry of Home Affairs has instructed local authorities to record vital events and report them to the Ministry of Home Affairs for registration following the lifting of restrictions.[5] In Tonga, staff worked in split teams to maintain services. However, registration points located in health facilities have been closed to free up resources for critical health needs.

Civil Registration Available Without Interruption

Fourteen countries (24%) reported no disruptions in registration services thanks to measures to facilitate access, including online registration. Costa Rica introduced an online notification system for births and deaths directly from hospitals, enabling appointments with the registrar to be scheduled, thus minimizing the risk of no-shows and delays.[5] In Guatemala, services identified as high priority include the issuance of identity documentation and the civil registration of deaths and other vital events. Arrangements were made to guarantee service continuity with provision for online issuance of certificates and measures to enable administrative staff to work from home and travel to the workplace only when on a shift.[5]

In Maldives, services have continued through a combination of online and in-office service provision. Most clients submit their requests electronically via the Web portal.[5] In New Zealand, civil registration continues uninterrupted; birth and death registration can be completed entirely online, with certificates being sent to families using contactless courier. In Fiji, registration services have continued as usual following the development of business continuity plans, adequately staffed and resourced registration points, and the introduction of measures to maintain physical distancing.[5]

Falling Demand for Birth and Death Certificates

Even when registration facilities continue to function, countries report reduced demand, particularly in settings where an in-person encounter with the civil registrar is required to complete the registration and certification process. In Ghana, although registration offices remained operational with health protection protocols in place, the population was reluctant to attend because of fear of becoming infected at the registration office or on public transport.[13] In response, the government is streamlining business processes and computer systems, developing an online service portal, and introducing an electronic notification system for deaths that

occur outside health facilities. It is also establishing information-sharing agreements with the heath sector, the police, and local cemetery registers, and considering using community-based volunteers to assist families in completing registration forms.

The requirement for a person-to-person service renders CRVS systems vulnerable to nonattendance. Decreased demand, coupled with limited service provision, will inevitably result in registration backlogs, delays, and reduced timeliness and completeness of birth and death statistics. Where problems existed before the pandemic, they would be exacerbated by the crisis. This matters for individuals who need legal documentation testifying to the occurrence of vital events and equally for decision-makers who need an ongoing stream of timely and reliable mortality statistics to understand the trajectory of the disease and the effectiveness of remedial interventions.

DISCUSSION

The major limitation of this study is the paucity of information on national CRVS system functioning during the pandemic. The initiative of the UN LIA is an important step, but only one third of the world's countries responded, with none from the region of Europe. We were unable to identify relevant civil registration information in countries with large populations, such as China, Egypt, Ethiopia, Pakistan, and Russia. Details of registration service restrictions are not always widely publicized, and, because services are locally administered, there can be significant in-country variation in service delivery. Media reporting fills some gaps—for example, on experiences of individuals and families in seeking to access registration services.[14] However, the impact of lockdowns and travel restrictions on numbers and timeliness of birth and death registration may well not be quantifiable for some time. Furthermore, although cause-of-death determination is an important component of death registration, this was not specifically addressed in the UN LIA survey.

Surging Data Needs

Demand for reliable and timely mortality data has surged in all countries during the pandemic, accompanied by a realization of the need to strengthen CRVS systems. Some countries have relied on hospital reporting of deaths among patients identified as being infected with COVID-19. However, these data are often incomplete because they do not include those who died outside hospitals—for example, at home or in a social care institution.[15,16] The CRVS system can generate more complete mortality data because it designed to capture all deaths, wherever they occur.

During a pandemic, decision-makers require timely data. Where death registration is compulsory within a specified (short) time frame, the individual records can rapidly be compiled to produce total mortality from all causes. By comparing these numbers with data on total deaths recorded in previous years over the same period, "excess mortality" can be calculated.[17] Provisional all-cause mortality data can be produced within 1 or 2 weeks of occurrence. By contrast, cause-of-death data take weeks or even months to statistically code, compile, and disseminate.[18] Weekly death counts therefore offer "the most objective and comparable way of assessing the scale of short-term mortality elevations across countries and time."[19]

Where timely CRVS data are not available or death registration is incomplete, rapid all-cause mortality surveillance systems can be established to accelerate CRVS reporting processes or leverage data from other facility- and community-based methods to measure the burden and spread of the epidemic.[20,21] Mortality surveillance could build upon existing health information or surveillance platforms—for example, those for severe acute respiratory illnesses and influenza-like illness—or the integrated disease surveillance and response system, although this potential has not yet been demonstrated in practice.[21] Such systems cannot substitute for a fully functional CRVS system, but they can potentially serve as an "on-ramp" to civil registration processes.[22]

Civil registration allows for granular data across administrative areas. Even where national data are lacking, mortality data can be produced for defined areas, such as cities, as shown by excess mortality in Istanbul (Turkey) and Jakarta (Indonesia).[23] Although these data cannot be generalized to the country as a whole, they nonetheless offer insights about local risks and behaviors that need to be addressed, such as congested public travel, high-density living arrangements, poverty, street living, and large gatherings.

Disaggregation of all-cause mortality is essential to identify relative risks by age,[24] sex,[25] ethnicity,[26] and social and economic status and, thus, introduce appropriate remedial interventions.[27] The United Nations recommends that death registration systems should routinely collect information on age, sex, place of occurrence, and place of usual residence. Additional information on education, occupation, citizenship, and ethnicity can be provided by informants

or family members of the decedent but may not always be available. Surges in COVID-19 infections among migrant laborers in Singapore and Germany highlight the importance of monitoring cases, deaths, and causes of death in particularly vulnerable populations.[28,29]

Mortality data can also be linked with records of confirmed COVID-19 cases to identify COVID-19–related deaths and calculate infection–fatality ratios and case–fatality ratios, indicators that are crucial inputs to decision-making about resource allocation and are used to guide policy decisions regarding the allocation of scarce medical resources.[30,31]

Added Value of Cause-Specific Mortality Data

While all-cause mortality data are important for near-real-time tracking of the trajectory of the COVID-19 pandemic, cause-specific data analyses provide insights to guide the response. Where the registration of death is accompanied by medical certification of cause of death, analysts have drawn attention to increased mortality attributable to both COVID-19 and non–COVID-19 causes.[32] Such trends can arise from changes in health-seeking behaviors because of fears of becoming infected, reluctance to add to the burden on health care services, or delays in the provision of care for non–COVID-19 conditions because of pressure on hospitals. They may also reflect shifts in the pattern of causes of mortality, such as increases in external causes of death such as suicide or domestic violence during extended periods of lockdown measures.

The World Health Organization and national health and statistics agencies have provided guidance on the medical certification and coding of causes of death in relation to COVID-19.[33,34] However, there is considerable variability in the implementation of these standards. In some settings, even if COVID-19 is mentioned on the medical certificate of cause of death, deaths are classified as COVID-19–related only if the decedent had tested positive for coronavirus before death, which may substantially underestimate mortality in places with limited access to testing. Variations in cause-of-death certification practices can be reflected in stark differences between statistics on COVID-19 deaths and all-cause mortality.[35]

Maintaining Civil Registration Operational Capabilities

The UN LIA has issued recommendations for civil registration authorities to ensure operational continuity during COVID-19 and allow for the continued production of comprehensive vital statistics.[36] These include contingency plans to meet postpandemic demand for registration services, working with the legislative branch to mitigate late registration penalties, interventions to deal with backlog, and formulating "business continuity plans" for the continuation of registration during disruptions. These should set out the requirements of minimum essential services, including how to protect the workforce. At the same time, it is important to provide support to health facilities, long-term-care homes, and funeral agencies that have key roles to play in the notification of deaths and in collecting information required for registration while facing high workloads and operational challenges during the pandemic.

Some national civil registration systems have experienced declines in revenues generated from services such as the issuance of identity cards and copies of certificates, which may hinder their ability to recover quickly from the effects of the lockdown.[5] There are fears of reduced support from international cooperation partners who may direct limited funds toward other health interventions. Governments, donors, and development partners should therefore work together to provide continuing support so that CRVS systems are better positioned to respond to the challenges of future emergencies.

Tracking the Impact on Vital Statistics

After the pandemic, national statistics offices will have an important responsibility to evaluate the impact of the crisis on the availability and quality of vital statistics derived from civil registration. Records of vital events among hard-to-reach and marginalized populations are typically poor in quality and completeness even under normal circumstances. In a pandemic, this could be exacerbated, especially in areas where the system is manual and requires personal interactions. Statistical methods should be used to identify gaps in registration completeness, especially in remote areas, among marginalized and vulnerable populations and those particularly hard-hit by the pandemic. National statistical offices will need to review their performance during and in the aftermath of the current pandemic and be well prepared to meet future challenges.[37]

An important lesson learned during the pandemic is that CRVS systems have the potential to be more responsive and dynamic to meet the data demands that accompany any health emergency. While producing national vital statistics reports with detailed geographic and socioeconomic disaggregation is

inevitably time consuming, especially in high-population countries, the potential of digital systems to accelerate the issuance of provisional or "predicted" statistics—for example, on all-cause or excess mortality—should be seized, thus increasing the policy relevance of CRVS.

Enhancing System Resilience

Looking to the future, countries and development partners must develop strategies for improving access to civil registration services and reducing vulnerability to shutdowns and service limitations during emergencies. Experience during this crisis has amply demonstrated that vulnerability is increased where registration is dependent on multiple in-person meetings between the civil registrar and family members to ensure that the information provided is accurate. While the need for in-person validation of information in registration records is important because these are legal documents that will be used on multiple occasions, it risks becoming a major barrier to registration. Validation by way of links across government databases could be explored as an alternative.

Strengthening Intersectoral Links

Some countries are establishing closer links between civil registration authorities and the health sector by officially designating health agents to notify civil registrars of births and deaths, thus reducing or eliminating the number of in-person visits required and alleviating the burden on families having to travel to civil registration offices. This "active" notification strategy can also improve the capture of events that are more likely to be missed by some civil registration systems, such as deaths in infancy and among females.

The health sector can also assist families and communities to catch up on missed registrations—for example, when birth registration services were temporarily deprioritized during the pandemic. This is critical because children whose births remain unregistered may be unable to access essential services. Should a child die before its birth has been registered, both the birth and the death will be missed in the national statistical system, resulting in incomplete statistics upon which to base policy decisions.

Advantages of Digital Systems

There is growing use of digital systems to speed up the production of mortality and cause-of-death statistics, reduce duplicate registrations, and share mortality data between jurisdictions to improve tracking of risks and outcomes. New Zealand is using the online death notification and medical certificate of cause of death to track daily deaths.[38] Provisional mortality information is available within hours of death rather than the 2 or more weeks it takes to receive the full death registration data. This allows the COVID-19 response team to monitor death rates and make real-time decisions on when to increase (or decrease) the government's response to the pandemic. In Hawaii, the electronic death registration system can link the causes of death listed on the medical certificate of cause of death to laboratory testing results, thus greatly improving the speed and accuracy of information on mortality related to COVID-19.[39]

Country experiences during the pandemic have shown that digitalization of CRVS systems could transform them from slow, passive, and reactive systems that depend on in-person attendance to systems that are resilient, proactive, and agile, without compromising quality standards, individual privacy, and confidentiality.

Conclusions

The COVID-19 pandemic has heightened the importance of country statistical systems for generating the data needed to monitor its dimensions and direction at local and national levels. Mortality data are critical not only from a health perspective but also from an economic one. As Glassman observes, "measuring deaths completely, accurately, and quickly is an essential prerequisite to better economic and public health policies during COVID-19 and beyond."[40] One-hundred-seventy years ago, the Shattuk Report's analysis of birth and death records laid the foundation for the development of health and social policies in the United States.[41] The COVID-19 pandemic has exposed the inadequacy of these basic systems in large parts of the world, especially in low-income countries. Addressing these shortcomings calls for political will and the ongoing support of local, regional, and global partners.

The Committee on the Rights of the Child and the United Nations have called on member states to protect the rights of children during the COVID-19 pandemic, including maintaining "the provision of basic services for children including healthcare, water, sanitation and birth registration."[42] Now, more than ever, people need access to legal documents as evidence of identity, civil status, and family relations. Civil registration systems and the vital statistics

they generate must be strengthened as core components of the response to COVID-19. Building resilience into CRVS systems will be essential to enable them to better function during future health shocks. Unless civil registration is recognized as essential, we stand to lose the gains in birth and death registration made in recent decades and the records of these vital events may be lost with serious implications for both individuals and governments. AJPH

ABOUT THE AUTHORS

Carla AbouZahr is with Vital Strategies/Bloomberg Philanthropies Data for Health Initiative, Geneva, Switzerland. Martin W. Bratschi, Anushka Mangharam, Fatima Marinho, Raj Gautam Mitra, James Mwanza, and Philip Setel are with Vital Strategies, New York, NY. Emily Cercone and Olga Joos are with the National Foundation for the Centers for Disease Control and Prevention, Inc, Atlanta, GA. Don de Savigny is with Swiss Tropical and Public Health Institute, Basel, Switzerland. Irina Dincu and Anette Bayer Forsingdal are with Centre of Excellence for Civil Registration and Vital Statistics Systems, International Development Research Centre, Ottawa, Ontario. Montasser Kamal is with the International Development Research Centre, Ottawa. Doris Ma Fat is with the World Health Organization, Geneva. Gloria Mathenge is with The Pacific Community, Noumea, New Caledonia. Jeff Montgomery is with New Zealand Department of Internal Affairs, Pacific Civil Registrars Network, Wellington, New Zealand. William Muhwava is with the African Centre for Statistics, Economic Commission for Africa, Addis Ababa, Ethiopia. Remy Mwamba is with UNICEF, New York, NY. Alvin Onaka is with State Registrar of Vital Statistics and Chief of the Office of Health Status Monitoring, Hawaii Department of Health, Honolulu, Hawaii. Tanja Brøndsted Sejersen is with United Nations Economic and Social Commission for Asia and the Pacific, Bangkok, Thailand. Maletela Tuoane-Nkhasi is with Global Financing Facility, The World Bank, Washington, DC. Lynn Sferrazza is with Global Health Advocacy Incubator, New York.

CORRESPONDENCE

Correspondence should be sent to Carla AbouZahr, 20B, chemin du Château, 1806 Saint-Légier, Switzerland (e-mail: abouzahr.carla@gmail.com). Reprints can be ordered at http://www.ajph.org by clicking the "Reprints" link.

PUBLICATION INFORMATION

Full Citation: AbouZahr C, Bratschi MW, Cercone E, et al. The COVID-19 pandemic: effects on civil registration of births and deaths and on availability and utility of vital events data. *Am J Public Health*. 2021;111(6):1123–1131.

Acceptance Date: January 19, 2021.

DOI: https://doi.org/10.2105/AJPH.2021.306203

CONTRIBUTORS

C. AbouZahr, M. W. Bratschi, and P. Setel conceptualized the idea for the article and developed the first draft with initial inputs from the rest of the group. All authors provided feedback and additional and new inputs and suggestions and reviewed the final article.

ACKNOWLEDGMENTS

Bloomberg Philanthropies supported the contribution of the authors employed by Vital Strategies.

Note. Bloomberg Philanthropies did not exert any role in relation to data collection, analysis, or interpretations.

CONFLICTS OF INTEREST

C. AbouZahr, M. W. Bratschi, A. Mangharam, F. Marinho, R. Mwamba, J. Mwanza, and P. Setel are employed by Vital Strategies.

HUMAN PARTICIPANT PROTECTION

This study was exempt from institutional board review because no human participants were involved.

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E-Cigarette Use Among Youths and Young Adults During the COVID-19 Pandemic: United States, 2020

Jennifer M. Kreslake, PhD, MPH, Bethany J. Simard, MPH, Katie M. O'Connor, MPH, Minal Patel, PhD, MPH, Donna M. Vallone, PhD, MPH, and Elizabeth C. Hair, PhD

Objectives. To determine whether the COVID-19 pandemic affected e-cigarette use among young people in the United States.

Methods. Data came from a weekly cross-sectional online survey of youths and young adults (aged 15–24 years). Logistic regression analyses measured odds of past-30-day e-cigarette use (n = 5752) following widespread stay-at-home directives (March 14–June 29, 2020), compared with the pre–COVID-19 period (January 1–March 13, 2020). Logistic regression among a subsample of current e-cigarette users (n = 779) examined factors associated with reduced use following stay-at-home orders.

Results. Odds of current e-cigarette use were significantly lower during the COVID-19 pandemic compared with the pre–COVID-19 period among youths aged 15 to 17 years (odds ratio [OR] = 0.72; 95% confidence interval [CI] = 0.54, 0.96) and young adults aged 18 to 20 years (OR = 0.65; 95% CI = 0.52, 0.81). E-cigarette users with reduced access to retail environments had higher odds of reporting reduced e-cigarette use (OR = 1.51; 95% CI = 1.07, 2.14).

Conclusions. COVID-19 stay-at-home directives present barriers to e-cigarette access and are associated with a decline in e-cigarette use among young people.

Public Health Implications. Findings support the urgent implementation of interventions that reduce underage access to e-cigarettes to accelerate a downward trajectory of youth and young adult e-cigarette use. (*Am J Public Health*. 2021;111:1132–1140. https://doi.org/10.2105/AJPH.2021.306210)

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COVID-19, caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), was declared a pandemic on March 11, 2020.[1] As of January 2021, there have been more than 22.4 million cases and 375 000 deaths from COVID-19 in the United States.[2] Public health interventions to prevent community transmission of the virus have included the temporary closure of nonessential businesses, a shift to online learning for schools, and telework for offices.[3,4] The burden of COVID-19 is substantial,[5] and the public health effects associated with the social and economic changes resulting from the pandemic are evolving as jurisdictions respond to emerging evidence.

Before COVID-19, e-cigarettes had replaced combustible cigarettes as the most commonly used tobacco product among youths and young adults. In 2018, current e-cigarette use among high school–aged youths reached 20.8%, a 78% increase from 2017.[6] In 2019, usage continued to increase, with 25% of 12th-grade students reporting e-cigarette use in the past 30 days.[7] Young adults (aged 18–25 years) exhibited a 46.2% increase in current e-cigarette use between 2017 and 2018 (5.2% to 7.6%), paralleling increases in younger populations. Public health authorities were responding to the rapid increase in e-cigarette use with interventions designed to reduce exposure and access to e-cigarettes among youths and young adults. These approaches included school-based policy and educational interventions, as well as local and federal policy interventions aimed at restricting sales of flavored e-cigarette

pods, supporting state- and local-level e-cigarette tobacco retail licensing, and promoting an increase in the minimum purchase age for tobacco products to 21 years.[8–14]

It is unknown whether public health responses to the COVID-19 pandemic have the potential to interrupt, at least temporarily, youth and young adult access to e-cigarettes. Certain types of retailers (e.g., gas stations, convenience stores, grocery stores, and drug stores) were deemed essential businesses and permitted to remain open during stay-at-home orders. While retailers are commonly reported as sources of tobacco products by youths, these retail outlets are less frequently reported as sources by youths purchasing e-cigarettes compared with other tobacco products.[15] Youths also report obtaining e-cigarettes at vape shops—a type of retail establishment that would be deemed nonessential and subject to closures during the COVID-19 pandemic.[15] Comparable data on purchase locations among young adults are scarce, but a small 2018–2019 survey suggested that more than 50% report purchasing from vape shops, tobacco specialty shops, or e-cigarette brand retailers on the Internet.[16]

As recently as 2018, social sources were the most common way that youths (74%) obtained e-cigarettes.[15] Approximately one quarter of young adults aged younger than 21 years have reported receiving their e-cigarette device from someone else.[16] Most e-cigarette users, including those who own their devices, report sharing e-cigarettes in social settings.[17,18] During the COVID-19 pandemic, access to social sources may be constrained by school closures and other social distancing practices.

The purpose of this study was to examine whether the COVID-19 pandemic is associated with changes in the prevalence of e-cigarette use among youths and young adults and determine the extent to which COVID-19–related changes in retail and social environments affected e-cigarette use. A recent study by Gaiha et al. found that more than half (56.4%) of ever e-cigarette users (aged 13–24 years) surveyed in May 2020 reported that they had modified their e-cigarette use behaviors since the COVID-19 pandemic began.[19] A limitation of this study is that it relied exclusively on respondents' retrospective, subjective assessments of changes in their e-cigarette use. Recent estimates from the 2020 National Youth Tobacco Survey indicates that the prevalence of e-cigarette use has declined significantly among high-school students, from 27.5% in 2019 to 19.5% in 2020.[20] However, the fielding period for the 2020 survey (January 16–March 16, 2020) preceded the arrival of COVID-19 in the United States. Although e-cigarette use is highest among those aged 18 to 20 years,[21] similar data on recent changes in past-30-day prevalence among young adults are scarce.

METHODS

Data were drawn from a continuous cross-sectional survey of youths (aged 15–17 years) and young adults (aged 18–24 years) using the national Dynata (formerly Research Now) opt-in online panel (https://www.dynata.com). Approximately 222 unique respondents were sampled per week using sampling quotas to yield approximately equal proportions by age group and gender. The survey included measures of tobacco-related attitudes, beliefs, behaviors, and product use. On March 25, 2020, we added a COVID-19 module to the survey, which stayed for the remainder of the fielding period. Respondents were screened to exclude those who had participated in any tobacco-related surveys within the past 6 months. During the study period (January 1, 2020–June 29, 2020), a total of 5752 respondents completed the survey. Data were weighted according to US Census demographic benchmarks to be nationally representative.

Phase 1. Prevalence of E-Cigarette Use

First, we sought to determine whether the likelihood of past-30-day e-cigarette use differed among youths and young adults following the onset of stay-at-home directives throughout the United States by using logistic regression models, either age-adjusted or stratified by age group. To confirm that observed changes were not solely attributable to the federal restriction on flavored cartridge-based e-cigarettes implemented in February 2020, a secondary analysis was limited to past-30-day use of non-JUUL products (i.e., excluding JUUL-only users). Non-JUUL products are increasingly popular among young people and largely unaffected by the federal flavor restriction and would not be expected to decline significantly in the absence of any other intervention (e.g., COVID-19).[22] To identify whether switching to combustible cigarettes explained any observed differences in e-cigarette use before and during the COVID-19 pandemic, we repeated the analysis using past-30-day cigarette smoking as the outcome.

Analytic sample. We analyzed the responses from participants (n = 5164) who completed the survey between January 1, 2020, and June 29, 2020. We classified respondents according to

whether they were surveyed before or during the COVID-19 pandemic. The "pre-COVID-19" survey period was defined as January 1, 2020, to March 13, 2020 (n = 2344). This period occurred before the onset of nationwide stay-at-home efforts. We used a comprehensive review of health department Web sites of 50 states and the District of Columbia to determine the timing and scope of the first official stay-at-home or shelter-in-place guidance. By March 14, 2020, nearly all states had made an emergency declaration about the pandemic, and most implemented some form of stay-at-home or shelter-in-place orders within the subsequent 2 weeks. The respondents who were surveyed from March 14 through June 29, 2020, were classified as being in the "during COVID-19" survey period (n = 3408). We selected June 29, 2020, as the study end date because it preceded many state efforts to relax some stay-at-home directives.

Measures. The main predictor was the time period during which respondents completed the survey (0 = before COVID-19; 1 = during COVID-19). Current e-cigarette use was the primary outcome of interest, defined as use on at least 1 day in the past 30 days. To test whether the observed effect is attributable to flavor restrictions primarily affecting JUUL products, we conducted a secondary analysis to exclude JUUL-only use from the e-cigarette use outcome, now defined as use of any e-cigarette product other than JUUL on at least 1 day in the past 30 days. A third outcome was past-30-day use of combustible cigarettes.

In all models, we included respondents' state of residence as a covariate to control for variation in state-level tobacco control policies that may affect youth access to tobacco products. To further control for variation in COVID-19 interventions by geographic region, we assigned each respondent a score that estimated the strength of their state's COVID-19 response from the beginning of the pandemic. We derived the score from 2 sources: the CoronaNet COVID-19 Government Response Event Dataset and a database of school closure policies in the United States.[23–25] We used CoronaNet to determine the number of COVID-19–related measures states and the District of Columbia had taken by March 14, 2020—specifically, declaration of emergency, curfew, lockdown, quarantine requirements, restrictions on mass gatherings, social distancing recommendations, and mandatory closures of nonessential businesses. The total possible range was from 0 to 7; state scores on March 14, 2020, ranged from 0 to 5. The plurality of states (43.1%) had 1 measure in place by this date, one quarter (25.5%) had 2 measures, and slightly less than one third (30.9%) had implemented 3 to 5 measures. Less than 2% had no COVID-19 measures on March 14, 2020. Because of the age range of the study population, a measure of school closure guidance affecting the remaining school year was also included (0 = no official closure guidance or expired closure policy; 1 = recommended or locally determined closures; 2 = state-mandated closures). Most states (82.4%) had mandated school closures. A small proportion of states (13.7%) provided recommendations, but school closure policies and processes were determined on a local level; few (3.9%) had no guidance on school closures. The number of COVID-19–related measures and school closure variables were added together to create the state COVID-19 response score.

Additional covariates included age category (15–17, 18–20, or 21–24 years), race/ethnicity (non-Hispanic White, non-Hispanic Black or African American, Hispanic), a subjective measure of socioeconomic status (perception that financial circumstances do not meet basic expenses, just meet basic expenses with nothing left over, meet needs with a little left over, or live comfortably),[26] and binary gender.

Phase 2. Determinants of Reduced E-Cigarette Use

In the second phase of the study, we conducted a multivariable logistic regression analysis to determine whether respondents' self-reported reduced access to retail environments and sharing e-cigarettes with friends were associated with self-reported changes in their level of e-cigarette use.

Analytic sample. The analysis was restricted to a subsample of current e-cigarette users surveyed during the COVID-19 period (March 14, 2020–June 29, 2020; n = 779).

Measures. The outcome of interest was self-reported change in the amount of e-cigarette use reported by current vape users during the COVID-19 pandemic, measured using the following item: "How much do you vape each day compared to how much you vaped before the public health crisis resulting from coronavirus (COVID-19)?" (1 = more than before; 2 = less than before; 3 = about the same as before). The variable was recoded to be dichotomous (1 = less than before; 0 = more than or about the same as before) based on descriptive analyses that indicated the greatest proportion of current users reported reduced use of e-cigarettes.

TABLE 1— Survey Respondent Characteristics: United States, January 1– June 29, 2020

	Full Sample (n = 5752), No. (Weighted %) or Mean ±SE	Surveyed Before COVID-19[a] (n = 2344), No. (Weighted %) or Mean ±SE	Surveyed During COVID-19[a] (n = 3408), No. (Weighted %) or Mean ±SE
Age, y			
15–17	1562 (27.0)	618 (26.2)	944 (27.5)
18–20	1866 (32.1)	806 (33.8)	1060 (30.8)
21–24	2324 (41.0)	920 (40.0)	1404 (41.6)
Gender			
Male	2939 (51.2)	1163 (50.1)	1776 (52.0)
Female	2813 (48.8)	1181 (49.9)	1632 (48.0)
Race/ethnicity			
Non-Hispanic White	3208 (66.7)	1323 (67.0)	1885 (66.4)
Non-Hispanic Black	675 (10.6)	275 (10.4)	400 (10.7)
Hispanic	1281 (17.5)	529 (17.5)	752 (17.4)
Non-Hispanic other	272 (5.2)	108 (5.0)	164 (5.4)
Perceived financial circumstances[b]			
Low	2298 (39.3)	970 (40.9)	1328 (38.2)
High	3454 (60.7)	1374 (59.1)	2080 (61.8)*
Self-reported change in retail environments	NA	NA	1807 (58.7)
Store hours changed			1187 (38.9)
Consumer goods harder to find in stores			1241 (40.8)
Difficulty affording consumer goods because of job or income loss			524 (16.8)
Past 30-d combustible cigarette use	1343 (23.2)	584 (25.0)	759 (22.0)*
E-cigarette use in past mo, among current users, days[c]	11.8 ±0.34	12.3 ±0.46	11.0 ±0.39*
Self-reported change in e-cigarette use[d]	NA	NA	
More than before			199 (25.6)
Less than before			383 (48.6)
About the same as before			192 (25.8)
Self-reported change in e-cigarette sharing[d]	NA	NA	
More than before			98 (12.7)
Less than before			355 (45.7)
About the same as before			185 (23.8)
Never shared an e-cigarette			136 (17.8)

Note. NA = not applicable.

[a]Respondents surveyed January 1–March 13, 2020, were classified as in the "before COVID-19 pandemic" category, and those surveyed March 14–June 29, 2020, were classified as in the "during COVID-19 pandemic" category.
[b]Lower perceived financial circumstances do not meet basic needs or just meet needs with nothing left over. Higher perceived financial circumstances meet basic needs with a little left over or allow the respondent to live comfortably.
[c]Range = 1–30.
[d]Among current (past-30-d) e-cigarette users (n = 779).
*$P < .05$.

The following item was used as an indicator of change in e-cigarette access at retail point of sale: "During the past few weeks, which of the following changes to your daily life have you experienced because of the public health crisis resulting from coronavirus (COVID-19)?" Respondents were coded "1" if they selected any of the following response

options: store hours have changed where I usually shop; products in stores are harder to find where I usually shop; or I am having trouble affording products when I shop because of job or income loss; and "0" if they reported none of these experiences. Because sharing e-cigarettes may influence access (for self or others), we included self-reported changes in sharing behaviors as a second predictor in the model. Change in sharing behaviors was measured by asking all current e-cigarette users, "Compared to before the public health crisis resulting from coronavirus (COVID-19), how often are you sharing an e-cigarette/vape device with other people?" Categorical response options were 0 = about the same as before; 1 = less than before; 2 = more than before; 3 = have never shared e-cigarettes/vapes. Other controls included age category, number of days using e-cigarettes in past 30 days (range: 1–30), state of residence, strength of state-level COVID-19 response, race/ethnicity, perceived financial circumstances, and gender.

RESULTS

More than half (59.3%) of the total sample (n = 5752) were surveyed during the COVID-19 pandemic, while the remainder of those surveyed (40.7%) served as the comparison for e-cigarette use from the pre–COVID-19 period (Table 1). Approximately one quarter (27.0%) of respondents were aged 15 to 17 years, one third (32.1%) were aged between 18 and 20 years, and the remainder (41.0%) were aged 21 to 24 years. The sample was evenly divided by gender (48.8% female, 51.2% male). The majority of the sample was non-Hispanic White (66.7%), with smaller proportions identifying as non-Hispanic Black (10.6%) or another race (5.2%). Less than one quarter (17.5%) reported Hispanic or Latino ethnicity. The majority felt that their financial circumstances allowed them to live comfortably or meet needs with a little left over (60.7%). The pre– and during–COVID-19 samples did not differ significantly by age group, race/ethnicity, or gender (Table 1). A significantly greater proportion of respondents surveyed during the COVID-19 pandemic had high perceived financial circumstances compared with respondents surveyed previously, but the magnitude of this difference was small (59.1% vs 61.8%; $P = .045$).

Patterns of E-Cigarette Use

In descriptive analyses, a decline in monthly prevalence of e-cigarette use could be observed among young adults (aged 18–20 years) and, to a lesser extent, among youths (aged 15–17 years) starting in March 2020 (Figure 1 and Table A, available as a supplement to the online version of this article at http://www.ajph.org).

Among current e-cigarette users surveyed during the COVID-19 period, the average number of days used in the past month was significantly lower (mean = 11.0; SE = 0.39) compared with current users surveyed before COVID-19 (mean = 12.3; SE = 0.46; $P < .05$). Nearly one half (48.6%) of current e-cigarette users reported vaping less than before the COVID-19 pandemic, while about one quarter (25.6%) reported vaping more (Table 1).

More than one third of respondents reported encountering changes in store hours (38.9%) or that products were harder to find in stores (40.8%) because of the COVID-19 pandemic (Table 1). Slightly less than one fifth (16.8%) of respondents said they were having difficulty affording consumer goods because of job or income loss attributable to the pandemic. These experiences were similar within the subsample of current e-cigarette users (37.3%

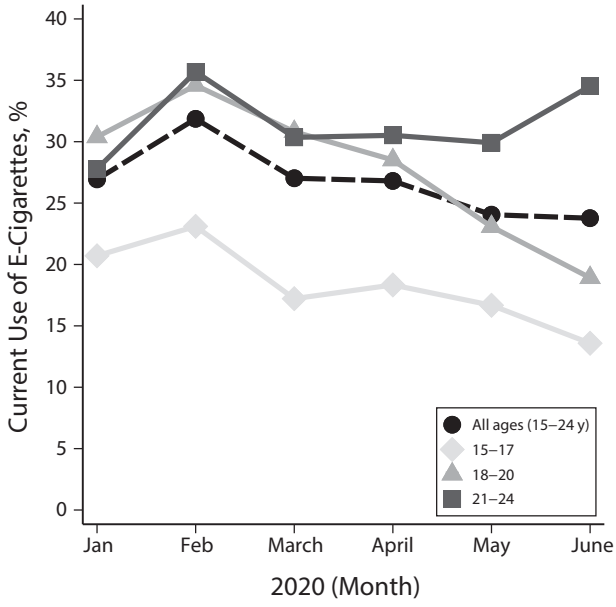

FIGURE 1— Estimated Monthly Prevalence of Past-30-Day E-Cigarette Use Among Youths and Young Adults Before and During the COVID-19 Pandemic, by Age Group (n = 5164): United States, January 1–June 29, 2020

reported changing store hours, 37.7% felt products were more difficult to find, and 22.9% were having difficulty affording products because of job or income loss).

The plurality (45.7%) of current e-cigarette users reported sharing e-cigarettes less than before the COVID-19 pandemic, a small proportion (12.7%) reported sharing more than before, and slightly less than one quarter (23.8%) reported sharing e-cigarettes about the same amount as before (Table 1). Less than one fifth of current users (17.5%) said that they had never shared e-cigarettes with other people.

Phase 1. Prevalence of E-Cigarette Use

In the age-adjusted model, the odds of current e-cigarette use were significantly lower during the COVID-19 pandemic (March 14–June 29, 2020) compared with the pre–COVID-19 period (January 1–March 13, 2020; odds ratio [OR] = 0.83; 95% confidence interval [CI] = 0.73, 0.94; Table 2). Non-Hispanic Black respondents had significantly lower odds of using e-cigarettes compared with non-Hispanic White respondents (OR = 0.60; 95% CI = 0.48, 0.73). Respondents with lower perceived financial circumstances had 1.42 times the odds (95% CI = 1.24, 1.61) of using e-cigarettes during the COVID-19 pandemic compared with those with greater perceived financial resources, and male respondents had 1.22 times higher odds (95% CI = 1.07, 1.38) compared with female respondents. In models stratified by age, the odds of e-cigarette use were significantly lower during the COVID-19 pandemic compared with the pre–COVID-19 period among respondents aged 15 to 17 years (OR = 0.72; 95% CI = 0.54, 0.96) and 18 to 20 years (OR = 0.65; 95% CI = 0.52, 0.81). No significant differences in e-cigarette use prevalence were observed among respondents aged 21 years and older.

As with the models presented in Table 2, the analysis of current non-JUUL e-cigarette use found significantly lower odds of use during the COVID-19 pandemic compared with the previous period (OR = 0.82; 95% CI = 0.71, 0.94; Table B, available as a supplement to the online version of this article at http://www.ajph.org). In models stratified by age, we observed significantly lower odds of non-JUUL e-cigarette use for respondents aged 15 to 17 years (OR = 0.71; 95% CI = 0.52, 0.97) and 18 to 20 years (OR = 0.66; 95% CI = 0.51, 0.84), with no significant difference among young adults aged 21 years and older.

While the odds of combustible cigarette use were also lower during the COVID-19 period in the age-adjusted model (OR = 0.81; 95% CI = 0.71, 0.93), older respondents (aged 21–24 years) were the only age group in stratified models in which a pre–post difference was evident (OR = 0.82; 95% CI = 0.68, 0.99; Table C, available as a supplement to the online version of this article at http://www.ajph.org). Cigarette smoking was the only outcome for which the strength of state-level COVID-19 response was a weak but significant predictor; we observed a negative relationship both in the age-adjusted model (OR = 0.94; 95% CI = 0.89, 1.00) and for the stratified model for young adults aged 18 to 20 years (OR = 0.90; 95% CI = 0.82, 1.00).

Phase 2. Determinants of Reduced E-Cigarette Use

Current e-cigarette users who reported facing reduced access to the retail environment because of the pandemic were significantly more likely to report that they were using e-cigarettes less than before the COVID-19 pandemic (OR = 1.51; 95% CI = 1.07, 2.14) compared with those who did not report experiencing reduced retail access (Table 3). Those who reported sharing e-cigarettes less during the COVID-19 pandemic had nearly twice the odds of reporting a reduction in e-cigarette use frequency (OR = 1.95; 95% CI = 1.27, 3.00), compared with those who reported no change in e-cigarette sharing. Conversely, respondents who increased their sharing of e-cigarettes during the COVID-19 pandemic had lower odds of reducing their use (OR = 0.50; 95% CI = 0.27, 0.92).

DISCUSSION

This study is the first, to our knowledge, to present evidence that declines in the prevalence of e-cigarette use among young people (aged 15–20 years) are associated with the COVID-19 pandemic. The declines during the study period could not be attributed solely to other policy interventions, such as the federal flavor restrictions on cartridge-based e-cigarettes (e.g., JUUL) implemented in February 2020; similar declines were observed in use of non-JUUL products (e.g., disposable flavored e-cigarettes), which were largely unaffected by the restriction. While significant declines in e-cigarette use were not observed among young adults aged 21 to 24 years, this age group did exhibit decreases in combustible cigarette use during the COVID-19 pandemic. No evidence was found of increases in combustible cigarette use associated with the COVID-19 pandemic among any age group.

The retail environment appeared to affect youth and young adult e-cigarette use during the COVID-19 pandemic.

TABLE 2— Odds of Past-30-Day E-Cigarette Use During the COVID-19 Pandemic (March 14–June 29, 2020) Compared With Before the Pandemic (January 1–March 13, 2020) Among Youths and Young Adults, Age-Adjusted or Stratified by Age Group: United States

	All Ages (n = 5164), OR (95% CI)	Aged 15–17 Years (n = 1396), OR (95% CI)	Aged 18–20 Years (n = 1653), OR (95% CI)	Aged 21–24 Years (n = 2115), OR (95% CI)
Survey period[a]				
Before COVID-19 pandemic	1 (Ref)	1 (Ref)	1 (Ref)	1 (Ref)
During COVID-19 pandemic	0.83 (0.73, 0.94)	0.72 (0.54, 0.96)	0.65 (0.52, 0.81)	1.06 (0.87, 1.28)
Age, y				
15–17	0.50 (0.42, 0.59)			
18–20	0.86 (0.75, 1.00)			
21–24	1 (Ref)			
Race/ethnicity				
Non-Hispanic White or other	1 (Ref)	1 (Ref)	1 (Ref)	1 (Ref)
Non-Hispanic Black	0.60 (0.48, 0.73)	0.45 (0.26, 0.78)	0.47 (0.32, 0.68)	0.78 (0.58, 1.04)
Hispanic	0.97 (0.83, 1.12)	0.86 (0.62, 1.20)	0.75 (0.58, 0.98)	1.22 (0.98, 1.51)
Perceived financial circumstances[b]				
Low	1.42 (1.24, 1.61)	1.44 (1.06, 1.96)	1.59 (1.27, 1.99)	1.32 (1.09, 1.59)
High	1 (Ref)	1 (Ref)	1 (Ref)	1 (Ref)
Strength of state-level COVID-19 response	0.99 (0.94, 1.04)	0.97 (0.86, 1.09)	0.99 (0.90, 1.08)	1.00 (0.93, 1.08)
State of residence	1.00 (0.99, 1.00)	0.99 (0.98, 1.00)	1.00 (1.00, 1.01)	1.00 (0.99, 1.01)
Gender				
Male	1.22 (1.07, 1.38)	0.85 (0.64, 1.13)	1.11 (0.89, 1.38)	1.52 (1.26, 1.84)
Female	1 (Ref)	1 (Ref)	1 (Ref)	1 (Ref)

Note. CI = confidence interval; OR = odds ratio.

[a]Respondents surveyed January 1–March 13, 2020, were classified in the "before COVID-19 pandemic" category, and those surveyed March 14–June 29, 2020, were classified in the "during COVID-19 pandemic" category.

[b]Lower perceived financial circumstances do not meet basic needs or just meet needs with nothing left over. Higher perceived financial circumstances meet basic needs with a little left over or allow the respondent to live comfortably.

E-cigarette users who reported barriers in access to consumer goods, including variation in store hours, product availability, or product affordability were more likely to report reductions in their e-cigarette use. These results suggest that retail point of sale remains an important location for intervention efforts to reduce youth and young adult e-cigarette use.

Results also suggest that changes in the social environments of youths and young adults during the COVID-19 pandemic may play a role in reducing e-cigarette use. The positive association between reported reductions in sharing e-cigarettes and reductions in e-cigarette use observed during the pandemic is consistent with the literature that finds that peers and social interactions are an important source of e-cigarettes for individuals aged younger than 21 years.[15]

The strengths of this study include the weekly survey data collection, which allows specificity in terms of defining a pre– and during–COVID-19 sample and precision in estimating the prevalence of tobacco use behaviors over time. Despite its strengths, the study is subject to limitations. First, the phase 2 analysis used self-reported assessments of COVID-related impacts (i.e., pre– vs during–COVID-19 level of e-cigarette use and sharing, changes in the retail environment), which are subject to recall and social desirability bias. Despite this limitation, the analysis provides useful insight into the possible mechanisms by which COVID-19 may be influencing declines in e-cigarette use. Second, beyond controlling for state of residence, this study did not control specifically for the variation in state or local Tobacco 21 policies, which restrict e-cigarette

TABLE 3— Multivariable Logistic Regression of Predictors of Self-Reported Reductions in E-Cigarette Use Among Youth and Young Adult (Aged 15–24 Years) Current E-Cigarette Users During the COVID-19 Pandemic: United States, March 14–June 29, 2020

	OR (95% CI)
Experienced reduced access to retail environments	1.51 (1.07, 2.14)
E-cigarette–sharing practices during pandemic	
More than before	0.50 (0.27, 0.92)
Less than before	1.95 (1.27, 3.00)
Have never shared e-cigarettes with others	0.92 (0.55, 1.52)
About the same as before	1 (Ref)
No. of d used e-cigarettes in past mo	0.94 (0.92, 0.96)
State of residence	0.99 (0.98, 1.01)
Strength of state-level COVID-19 response	1.04 (0.92, 1.19)
Age, y	
15–17	1.00 (0.64, 1.55)
18–20	1.26 (0.85, 1.87)
21–24	1 (Ref)
Race/ethnicity	
Non-Hispanic White or other	1 (Ref)
Non-Hispanic Black	1.72 (0.96, 3.08)
Hispanic	1.28 (0.88, 1.85)
Perceived financial circumstances	0.97 (0.69, 1.37)
Gender	
Male	0.84 (0.60, 1.17)
Female	1 (Ref)

Note. CI = confidence interval; OR = odds ratio. The sample size was n = 764.

sales to individuals aged younger than 21 years. However, the federal law limiting tobacco sales, including e-cigarette sales, to individuals aged 21 years and older went into effect before the start of the study period (December 2019).[27]

As the COVID-19 pandemic has persisted, it remains uncertain whether young people are developing adaptive behaviors to access e-cigarettes as stay-at-home orders, remote work and distance education, and the closures of nonessential businesses continue throughout the United States. It cannot be assumed that the observed reductions in the prevalence of e-cigarette use among youths and young adults will continue when the pandemic subsides and societal activities resume. As schools resume in-person classes, it will be important to have school-based policies and proper training to empower staff to intervene in e-cigarette use and sharing among youths in school settings.[8] Remarkably, less than 18% of e-cigarette users in our study reported that they have never shared an e-cigarette with anyone. Behavior change interventions (e.g., mass media campaigns) are recommended to further discourage sharing of e-cigarettes, particularly in the context of heightened concern about transmission of COVID-19 and other illnesses such as influenza.

Findings support an urgency in implementing interventions designed to reduce underage access to e-cigarettes to help accelerate the downward trajectory of e-cigarette use among youths. Despite observed declines, e-cigarette use among young people remains at concerning levels, and population-based interventions including tax policies, clean-indoor-air laws, public education campaigns, and restrictions on flavored products are needed. These macro-policy solutions must be implemented in conjunction with one another to have the greatest potential in driving further reductions in e-cigarette use among young people. AJPH

ABOUT THE AUTHORS

All authors are with the Schroeder Institute at Truth Initiative, Washington, DC.

CORRESPONDENCE

Correspondence should be sent to Jennifer Kreslake, PhD, MPH, Schroeder Institute at Truth Initiative, 900 G St NW, Washington, DC 20001 (e-mail: jkreslake@truthinitiative.org). Reprints can be ordered at http://www.ajph.org by clicking the "Reprints" link.

PUBLICATION INFORMATION

Full Citation: Kreslake JM, Simard BJ, O'Connor KM, Patel M, Vallone DM, Hair EC. E-cigarette use among youths and young adults during the COVID-19 pandemic: United States, 2020. *Am J Public Health*. 2021;111(6):1132–1140.

Acceptance Date: January 25, 2021.

DOI: https://doi.org/10.2105/AJPH.2021.306210

CONTRIBUTORS

J. M. Kreslake conceptualized and designed the study and drafted the article, with significant written contributions by K. M. O'Connor, M. Patel, and D. M. Vallone. B. J. Simard conducted statistical analyses. E. C. Hair advised on statistical analyses and provided critical review of the article.

ACKNOWLEDGMENTS

This study was funded by Truth Initiative.

CONFLICTS OF INTEREST

The authors have no potential or actual conflicts of interest to disclose.

HUMAN PARTICIPANT PROTECTION

This study was approved by Advarra institutional review board.

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Variation in Reporting of the Race and Ethnicity of COVID-19 Cases and Deaths Across US States: April 12, 2020, and November 9, 2020

Megan D. Douglas, JD, Ebony Respress, MSPH, Anne H. Gaglioti, MD, MS, Chaohua Li, MPH, Mitchell A. Blount, MPH, Jammie Hopkins, DrPH, MS, Peter T. Baltrus, PhD, Robina Josiah Willock, PhD, MPH, Lee S. Caplan, MD, PhD, MPH, Daniel E. Dawes, JD, and Dominic Mack, MD, MBA

See also Noppert and Zalla, p. 1004.

Despite growing evidence that COVID-19 is disproportionately affecting communities of color, state-reported racial/ethnic data are insufficient to measure the true impact.

We found that between April 12, 2020, and November 9, 2020, the number of US states reporting COVID-19 confirmed cases by race and ethnicity increased from 25 to 50 and 15 to 46, respectively. However, the percentage of confirmed cases reported with missing race remained high at both time points (29% on April 12; 23% on November 9). Our analysis demonstrates improvements in reporting race/ethnicity related to COVID-19 cases and deaths and highlights significant problems with the quality and contextualization of the data being reported.

We discuss challenges for improving race/ethnicity data collection and reporting, along with opportunities to advance health equity through more robust data collection and contextualization. To mitigate the impact of COVID-19 on racial/ethnic minorities, accurate and high-quality demographic data are needed and should be analyzed in the context of the social and political determinants of health. (*Am J Public Health*. 2021;111:1141–1148. https://doi.org/10.2105/AJPH.2021.306167)

COVID-19 has infected more than 114 million people worldwide, killing more than 2.5 million.[1] Every US state has COVID-19 infections, with more than 28.6 million cases and more than 513 000 deaths in the United States.[2] In early April 2020, data from several large US cities showed that COVID-19 was disproportionately affecting racial/ethnic minority populations.[3–5] The magnitude of the reported disproportionate COVID-19 impact on communities of color was and continues to be staggering. Many studies have confirmed that Black, Hispanic, Native American, Native Hawaiian, and Pacific Islander Americans are more likely to contract, be hospitalized for, and die from COVID-19 than are White Americans.[6–11] Several studies and reports have highlighted the large number of cases and deaths being reported with unknown race/ethnicity, suggesting that the observed disparities are larger than reported and demonstrating an urgent need to improve the completeness and consistency of COVID-19 race/ethnicity data.[12]

Our goal in this study was to describe the evolution, granularity, and quality of COVID-19 data reported by race/ethnicity at the state level. We analyzed changes in state reporting of COVID-19 data between April 12 and November 9, 2020, highlighting observed gaps in available data that preclude a true accounting of the COVID-19 impact on racial/ethnic minority communities. Based on these gaps, we discuss interventions to improve data quality, recognize challenges to improvement, and propose strategies to mitigate the impact of COVID-19 on racial/ethnic minorities.

RACE/ETHNICITY DATA

Problems related to the quality and availability of race/ethnicity data have been a pervasive problem in public health surveillance for decades.[13] Public

health surveillance assesses the effects of disease on populations and is instrumental in public health responses to disease outbreaks such as the COVID-19 pandemic.[14] Surveillance data, including on race/ethnicity, are used in mathematical modeling to assess the trajectory of illness among populations and to inform subsequent distribution of resources to affected communities. The Office of Management and Budget (OMB) defines minimum standards for collecting and reporting race/ethnicity across federal agencies.[15] The OMB standards provide a baseline of 5 race categories and 2 ethnicity categories, collected as 2 separate fields, which can be supplemented by more finely detailed categories and tailored for local relevance.

Despite its utility, surveillance data have challenges, including timeliness, comprehensiveness, ethical implications, and lack of consistency in reporting across jurisdictions. Traditional strategies for dealing with missing data in public health surveillance, such as excluding cases with incomplete data, are problematic for race/ethnicity data because these data are unlikely to be missing completely at random. Imputation methods have evolved to predict race/ethnicity using data from US Census and other administrative data sources.[16] However, self-reported race/ethnicity provides the most accurate and comprehensive source for assessing racial/ethnic disparities.

REPORTING OUTCOMES BY RACE/ETHNICITY

Racial/ethnic disparities in COVID-19 outcomes are prominent and associated with historical inequities and systemic racism.[17] Two key factors amplifying the impact of COVID-19 on communities of color are (1) disproportion of minorities serving in "essential," high-exposure positions[18,19]; and (2) systemic inequities in access to wealth, quality health care, education, transportation, and healthy food (i.e., the social and political determinants of health),[20] resulting in disproportionate prevalence of chronic illnesses and underlying conditions associated with increased COVID-19 susceptibility and worse disease outcomes.[21,22] Both of these factors are compounded by residential segregation, lending bias, and current day redlining, policies that sustain health inequities in communities of color by targeting resources and investments elsewhere.[23]

Despite growing evidence that COVID-19 disproportionately affects communities of color, racial/ethnic data are incomplete and inconsistent and obscure the true magnitude of COVID-19 racial/ethnic disparities. High-quality individual-level data should include granular and consistent race/ethnicity categories, which are needed to understand the effect on populations historically vulnerable to disparities in health outcomes, and should be contextualized using neighborhood sociodemographic characteristics to identify emerging outbreaks, prioritize communities with the most need, and allocate resources. Data are also needed to hold policymakers and public health officials accountable for addressing the observed health inequities related to COVID-19. Without accurate data, policies and interventions to mitigate racial/ethnic disparities cannot be implemented and progress toward equity cannot be measured.

STANDARDIZING RACE/ETHNICITY COVID-19 DATA

Early in the pandemic, the Centers for Disease Control and Prevention (CDC) released a COVID-19 case report form that collects key information on persons under investigation for COVID-19 infection.[24] In theory, this form would standardize information collected using the OMB race/ethnicity categories. However, state and local authorities were not required to use this form, and, in turn, health care professionals and laboratories in many jurisdictions opted not to collect or report patient race/ethnicity with testing results. Without federally mandated standards providing uniformity of racial/ethnic data collection and reporting, states had broad discretion on what to report, when to report it, and even whether to report it at all. The resulting patchwork of available data undermines efforts to advance health equity in the wake of COVID-19. Recognizing the issue of incomplete and inconsistent data, the CDC issued additional guidance requiring all laboratories to collect and report patient race/ethnicity for all COVID-19 tests completed.[25]

STATE VARIATION IN DATA REPORTING

The COVID Tracking Project at the *Atlantic* reports COVID-19 case, death, hospitalization, and testing data for all 50 states, Washington, DC, and the US territories.[26] These data are publicly available through a creative commons license (CC-BY-NC-4.0). The COVID-19 Racial Data Tracker gathers data from every state on the race/ethnicity data fields reported for COVID-19 cases and deaths.[27] Data from the COVID-19 Racial Data Tracker shed light on the variation in state-level reporting of COVID-19 by race/ethnicity and trends in data reporting over time. We compared the number of states and Washington, DC, reporting COVID-19 confirmed cases

and deaths by race/ethnicity on April 12 and November 9, 2020. We analyzed 2 indicators of the data quality: combined reporting of race/ethnicity and percentage of cases and deaths with unknown race/ethnicity.

Table 1 compares states reporting COVID-19 confirmed cases and deaths by race/ethnicity at the 2 time points. On April 12, 2020, 25 states reported confirmed cases by race and 15 reported confirmed cases by ethnicity. On November 9, 2020, 49 states and Washington, DC, reported confirmed cases by race and 46 reported confirmed cases by ethnicity. On April 12, 2020, 21 states reported COVID-related deaths by race and 11 reported deaths by ethnicity. On November 9, 2020, all 50 states and Washington, DC (100%) reported deaths by race and 47 (92%) reported deaths by ethnicity. By contrast with the OMB standard of separate race and ethnicity categories, 20 states (39%) combined reported race and ethnicity for confirmed cases into a single category and 19 (37%) combined reported race and ethnicity for deaths into a single category.

Whether states opt to report race/ethnicity cannot be conflated with the quality of the data. As we will describe in more detail, COVID-19 data quality problems are complex and pervasive. For this reason, we analyzed one of the more consistently reported data quality indicators: reported percentage of cases and deaths with unknown race/ethnicity. Figure 1 demonstrates the reported cases and deaths with unknown race/ethnicity on November 11, 2020. We display the percentage of cases reported with unknown race in 4 quartiles (0.0%–10.0%, 10.1%–20.0%, 20.1%–40.0%, and 40.1%–100.0%) and indicate states with more than 50% of cases and deaths reported with unknown ethnicity.

Appendix A (available as a supplement to the online version of this article at http://www.ajph.org) compares the percentage of cases and deaths reported with unknown race/ethnicity on April 12 to that reported on November 9, 2020. Across all states, the average of the percentage of reported cases with unknown race or ethnicity was 29% and 39%, respectively, on April 12 and decreased to 23% and 29%, respectively, on November 9, 2020. The average of the percentage of reported deaths with unknown race/ethnicity was 15% and 29%, respectively, on April 12 and decreased to 7% and 9%, respectively, on November 9, 2020. Over this time, the percentage of cases reported with unknown race decreased in 18 states, increased in 6, and remained the same in 1. The percentage of cases reported with unknown ethnicity decreased in 11 states and increased in 3. The percentage of deaths reported with unknown race decreased in 12 states, increased in 8, and remained the same in 1. The percentage of deaths reported with unknown ethnicity decreased in 7 states and increased in 3.

REMAINING GAPS AND INCONSISTENCIES

Our team has been actively monitoring changes to individual states' COVID-19 tracking and reporting Web sites. In addition to the percentage of cases and deaths reported with missing race/ethnicity, several other factors affect the quality of the data, including the methods of collection and reporting. We observed several other persistent inadequacies in data uniformity and quality not captured by this analysis.

The methods used to collect racial/ethnic data are unclear. Race/ethnicity data should be self-reported, allowing individuals to self-identify.[28] Misclassification of race/ethnicity occurs when individuals are precluded from self-identification.[29] It is unknown whether and to what extent clinics, hospitals, and laboratories are reporting self-reported race/ethnicity data. When race/ethnicity is missing, we do not know whether the individual declined to answer or the data are missing for some other reason.

The fields and definitions used to report racial/ethnic data are inconsistent and often do not align with accepted public health standards. As noted, many states combine reporting of race and ethnicity into a single category. Aggregating race and ethnicity data in this way obscures important distinctions between and among groups. Hispanic Black people and non-Hispanic Black people are not a monolithic group; they often have distinct cultural and historical backgrounds. Additionally, states selectively report on proportionally smaller minority groups, such as American Indian/Alaska Native and Native Hawaiian/Pacific Islander. Because of their smaller proportion of the population, some states elect to combine these distinct groups into 1 category—"other"—which diminishes our ability to evaluate the impact of COVID-19 and other extant risk factors on their communities. States such as California, Washington, and Colorado, which have larger populations of these minority groups, have recognized that these groups experience COVID-19 at disproportionate rates.[30] However, data for these groups are systematically missing or inaccurate in many places, despite the known elevated risk of contracting COVID-19 owing to higher rates of preexisting and comorbid conditions.[31]

We also note that few states report the presence of comorbid conditions or socioeconomic factors. Nor do they

TABLE 1— Comparing Reporting of Race/Ethnicity for COVID-19 Confirmed Cases and Deaths: United States, April 12, 2020, and November 9, 2020

	April 12, 2020				November 9, 2020			
US State	Reporting Cases by Race	Reporting Cases by Ethnicity	Reporting Deaths by Race	Reporting Deaths by Ethnicity	Reporting Cases by Race	Reporting Cases by Ethnicity	Reporting Deaths by Race	Reporting Deaths by Ethnicity
AK					•	•	•	•
AL	•	•			•	•	•	•
AR	•				•	•	•	•
AZ	•		•		•[a]	•[a]	•[a]	•[a]
CA	•		•		•[a]	•[a]	•[a]	•[a]
CO					•[a]	•[a]	•[a]	•[a]
CT	•	•	•		•[a]	•[a]	•[a]	•[a]
DC	•	•	•		•	•	•[a]	•[a]
DE			•		•[a]	•[a]	•[a]	•[a]
FL					•	•	•	•
GA	•	•			•[a]	•[a]	•[a]	•[a]
HI					•		•	
IA					•	•	•	•
ID					•	•	•	•
IL	•		•		•[a]	•[a]	•[a]	•[a]
IN	•	•	•	•	•	•	•	•
KS					•	•	•	•
KY	•		•		•	•	•	•
LA					•		•	•
MA	•	•	•	•	•[a]	•[a]	•[a]	•[a]
MD	•		•		•[a]	•[a]	•[a]	•[a]
ME					•	•	•	•
MI	•	•	•	•	•	•	•	•
MN	•	•	•	•	•	•	•	•
MO	•	•	•	•	•	•	•	•
MS	•		•		•[a]	•[a]	•[a]	•[a]
MT	•				•	•	•	
NC	•	•	•	•	•	•	•	•
ND					•		•	
NE					•	•	•	•
NH					•[a]	•[a]	•[a]	•[a]
NJ			•	•	•[a]	•[a]	•[a]	•[a]
NM					•[a]	•[a]	•[a]	•[a]
NV					•[a]	•[a]	•[a]	•[a]
NY			•	•			•[a]	•[a]
OH	•	•	•	•	•	•	•	•
OK					•	•	•	•
OR					•	•	•	•
PA					•	•	•	•
RI					•[a]	•[a]	•[a]	•[a]

Continued

TABLE 1— Continued

	April 12, 2020				November 9, 2020			
US State	Reporting Cases by Race	Reporting Cases by Ethnicity	Reporting Deaths by Race	Reporting Deaths by Ethnicity	Reporting Cases by Race	Reporting Cases by Ethnicity	Reporting Deaths by Race	Reporting Deaths by Ethnicity
SC	•	•	•		•	•	•	•
SD					•[a]	•[a]	•	•
TN	•	•			•	•	•	•
TX	•				•[a]	•[a]	•[a]	•[a]
UT					•[a]	•[a]	•	•
VA	•				•[a]	•[a]	•	•
VT					•	•	•	•
WA	•	•	•	•	•[a]	•[a]	•[a]	•[a]
WI	•	•	•	•	•	•	•	•
WV					•		•	
WY					•	•	•	•
Average	25	15	21	11	50	46	51	47

[a]Reports race/ethnicity as a single category.

provide county- or zip code–level COVID-19 data by race/ethnicity. Data related to housing, workplace exposure, insurance status, and access to health care are nearly universally absent from state reporting. Even fewer states report race/ethnicity associated with testing rates, hospitalizations, ventilator use, and other metrics needed to assess the severity of illness and COVID-19 complications among minority patients. Other important categories of individual-level data are also missing completely from state reporting. People with disabilities; people who are lesbian, gay, bisexual, transgender, or queer; and people with behavioral health conditions have historically had significant health disparities and are also being disproportionately affected by COVID-19.[32,33] As states continue to fight surging infection numbers of new cases and attempt to implement vaccination distribution programs, the need for culturally and linguistically appropriate mitigation strategies that are informed by communities is even more critical.[34]

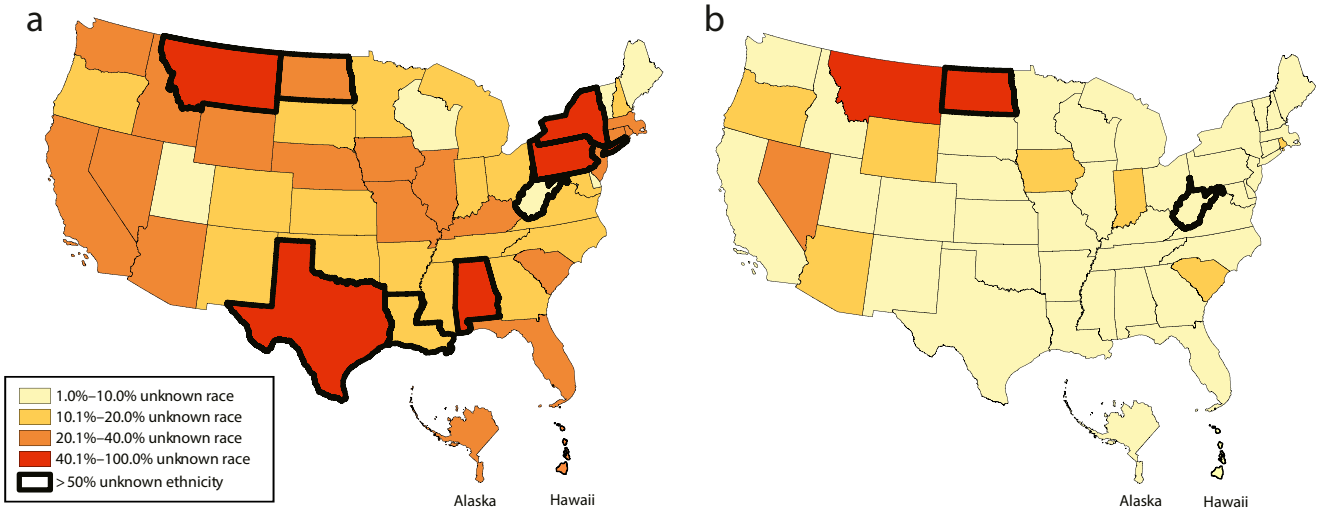

FIGURE 1— Percentage of COVID-19 Confirmed (a) Cases and (b) Deaths With Unknown Race/Ethnicity: United States, November 9, 2020

Comprehensive and consistent fields of demographic data are needed to contextualize COVID-19 burden on minority, rural, and other vulnerable communities.

CHALLENGES FOR IMPROVING DATA REPORTING

The reasons for these problems are multifactorial, ranging from technical to ethical, which also makes them difficult to solve. For example, race/ethnicity fields may not be consistently recorded across states, may be self-reported or ascribed, and may be reported as missing when an individual reports "do not wish to answer." Complicating the ability to report uniform and complete race/ethnicity data is the fact that state and local public health authorities receive COVID-19 testing data from several sources, including health care professionals, hospitals, and public and commercial laboratories. Many states use an electronic lab reporting system to collect COVID-19 case data, which introduces problems with data standardization and access to needed technology, especially in rural and other underserved settings.[35] To overcome challenges with missing race/ethnicity data, several strategies are being employed, including imputation methods such as the Bayesian improved surname geocoding methodology.[36] However, the extent to which these practices are used and their effectiveness are unknown.

Historical misuse of race/ethnicity data poses another challenge to gathering data needed to fully understand COVID-19 racial/ethnic disparities. Redlining intentionally weaponized racial/ethnic data collected in financial lending applications to prevent people of color from owning homes and building generational wealth, with long-term effects on health.[37] Racially biased algorithms are a current example of data misuse, resulting in less access to health care resources among racial/ethnic minorities.[38] Many studies have reinforced the problematic narrative that race and ethnicity are risk factors for disease, despite being social, not biological constructs.[39] It is imperative that racism, not race, be recognized as the root cause of historical and COVID-19 health inequities. Mistrust in health care and governmental systems discourages individuals from disclosing their race/ethnicity. Transparency and accountability for how data are used to allocate resources and reduce the existing racial/ethnic disparities are necessary for improving both trust and disclosure. Furthermore, actively engaging communities in efforts to tailor data collection and to mitigate the impact of COVID-19, including recruitment of community health workers, may improve trust and, in turn, the data being reported.

Finally, public health and health system capacity constrain the ability of individual states to implement robust, evidence-based public health interventions to mitigate the effects of COVID-19 on racial/ethnic minority and other vulnerable populations. Disinvestment and budget constraints for state and local health departments are often the most severe in places with high concentrations of racial/ethnic minority populations.[40] Thus, the very places with the most need for high-quality race/ethnicity data also have the most limited resources to implement these practices. This disinvestment by policymakers compounds the barriers to uncovering the full impacts of COVID-19 on communities of color.

OPPORTUNITIES TO ADVANCE HEALTH EQUITY

To improve the uniformity of racial/ethnic COVID-19 data, all states should require the reporting of racial/ethnic data using the OMB Race and Ethnic Standards for Federal Statistics.[28] Robust reporting across population health measures, including positive cases, hospitalizations, deaths, underlying conditions, and testing rates, is optimal. It will also be important to monitor and publicly report vaccinations by race/ethnicity. States and local public health authorities should analyze demographic data in the context of social determinants of health, including housing, employment status and setting, health insurance status, and access to health care. They should also conduct ecologic analyses to identify the social, geographic, cultural, ecologic, and policy factors associated with COVID-19 burden and spread.

State and local authorities should apply a health equity lens when making COVID-19 decisions, such as when and where to reopen, how to define the "essential workforce," and how to designate publicly available testing and vaccination sites. This entails inclusion and engagement of communities, who should be leading and actively informing these efforts. With limited federal intervention, local governments and public health departments will need the authority to make decisions based on the best public health data, which includes comprehensive, finely detailed, and high-quality racial/ethnic data. State governors should provide this authority and support local officials and community leaders in interventions that seek to mitigate COVID-19 disparities. State and local health officials should increase

efforts to overcome deep mistrust by investing in culturally tailored information and training and linguistically appropriate interventions and by building a representative public health workforce, including community health workers, that includes members of disproportionately affected communities.

CONCLUSIONS

This study highlights significant improvements and deficiencies in reporting race/ethnicity data related to COVID-19. Although trends in race/ethnicity data reporting for COVID-19 have improved over time, we noted variation across all measures of race/ethnicity data reporting, including the measures being reported (testing, cases, and deaths), categories of race/ethnicity reported, and geographic granularity of data. In this analysis, we identified persistent data quality issues that are amenable to data standardization and process improvements. The nonuniformity of race/ethnicity COVID-19 data, and other notifiable disease data, continues to impede public health and policy leaders' ability to assess the national landscape of COVID-19 racial/ethnic health disparities, and thus impedes efforts to advance health equity. AJPH

ABOUT THE AUTHORS

Megan D. Douglas, Anne H. Gaglioti, Chaohua Li, Mitchell A. Blount, Peter T. Baltrus, and Dominic Mack are with the National Center for Primary Care, Morehouse School of Medicine, Atlanta, GA. Ebony Respress, Jammie Hopkins, and Daniel E. Dawes are with the Satcher Health Leadership Institute, Morehouse School of Medicine. Robina Josiah Willock and Lee S. Caplan are with the Department of Community Health and Preventive Medicine, Morehouse School of Medicine.

CORRESPONDENCE

Correspondence should be sent to Megan D. Douglas, JD, 720 Westview Dr, NCPC Building, Suite 300, Atlanta, GA 30310 (e-mail: mdouglas@msm.edu). Reprints can be ordered at http://www.ajph.org by clicking the "Reprints" link.

PUBLICATION INFORMATION

Full Citation: Douglas MD, Respress E, Gaglioti AH, et al. Variation in reporting of the race and ethnicity of COVID-19 cases and deaths across US states: April 12, 2020, and November 9, 2020. *Am J Public Health*. 2021;111(6):1141–1148.

Acceptance Date: January 11, 2021.

DOI: https://doi.org/10.2105/AJPH.2021.306167

CONTRIBUTORS

M. D. Douglas, E. Respress, A. H. Gaglioti, M. A. Blount, J. Hopkins, P. T. Baltrus, D. E. Dawes, and D. Mack conceptualized the study and selected data sets and methods used in the data analysis and interpretation. M. D. Douglas, E. Respress, A. H. Gaglioti, M. A. Blount, J. Hopkins, P. T. Baltrus, R. Josiah Willock, L. S. Caplan, and D. Mack wrote the article. C. Li developed the tables, figures, and maps. All authors approved the final version to be published.

ACKNOWLEDGMENTS

This work was supported in part by a $40 million award from the US Department of Health and Human Services Office of Minority Health's National Infrastructure for Mitigating the Impact of COVID-19 Within Racial and Ethnic Minority Communities through a cooperative agreement to create the National COVID-19 Resiliency Network (award 1CPIMP201187-01-00). Support for the work was made possible through funding from Google.org Charitable Giving (grants TF2005-091260 and TF2010-094862).

CONFLICTS OF INTEREST

The authors have no conflicts of interest to declare.

HUMAN PARTICIPANT PROTECTION

No protocol approval was necessary because no human participants were involved in this study.

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Stay-at-Home Orders, Mobility Patterns, and Spread of COVID-19

Tim Murray, PhD

See also Baker, p. 999.

Objectives. To understand how stay-at-home orders changed mobility patterns and influenced the spread of COVID-19.

Methods. I merged 2020 data from the Virginia Department of Health, Google Mobility Reports, and the US Census to estimate a series of 2-way fixed-effect event-study regression models.

Results. A stay-at-home order caused people to increase the amount of time spent at home by 12 percentage points and decrease the time the spent at work by 30 percentage points, retail and recreation venues by 40 percentage points, and grocery stores and pharmacies by 10 percentage points. People did not sustain changes in mobility and gradually returned to prepandemic levels before the stay-at-home order was lifted. In areas where people spent the most time at indoor locations, there was a large increase in COVID-19.

Conclusions. A more robust and stricter policy response coordinated at the national level combined with a strong economic response from policymakers could have increased the effectiveness of the stay-at-home order. (*Am J Public Health*. 2021;111:1149–1156. https://doi.org/10.2105/AJPH.2021.306209)

The United States did not have a uniform policy response to the COVID-19 pandemic, resulting in each state developing its own policy response. These policies largely consisted of nonpharmaceutical interventions (NPIs), or stay-at-home orders, limiting large gatherings, and promoting social distancing. These kinds of NPIs have been shown to be effective at reducing the spread of COVID-19.[1,2] Compliance with NPIs partially falls on individual businesses to enforce the specific mandates from the state, and it partially falls on individual people to comply and alter their behavior. If both business and people do not fully comply, the effectiveness of the NPI decreases.

The NPIs implemented by Virginia are similar to those of many states. On March 12, 2020, the governor of Virginia declared a state of emergency and, on March 25, 2020, issued a stay-at-home order that closed all nonessential businesses, limited gatherings to 10 people, and closed all public schools for the remainder of the academic year. The stay-at-home order would remain in effect until May 15, 2020, when Virginia began a 3-phase reopening. What makes Virginia unique is that the spread of COVID-19 was not uniform across the state. When splitting up Virginia into its 3 major metropolitan statistical areas (MSAs)—Hampton Roads, Richmond, and Northern Virginia (shown in Figure 1)—Northern Virginia and Richmond saw an increase in new cases at the start of the pandemic peaking in early June, whereas Hampton Roads did not start to see a significant increase in cases until late June and peaked in late August, which can be seen in Figure 2. It is possible that some of these differences could be attributable to differences in testing. Hampton Roads and Northern Virginia administered about the same number of tests per capita, and Richmond administered more tests per capita throughout the study period. However, all 3 MSAs saw testing increase at the same growth rate with parallel trends, so testing likely did not contribute to the changing dynamics over the study period or between the MSAs. These differing trends make Virginia a good candidate to study how people's mobility patterns may have influenced the spread of COVID-19 differently across the MSAs. In addition, data from the US Census[3] in Table A (available as a supplement to the online version of this article at http://www.ajph.org) show that

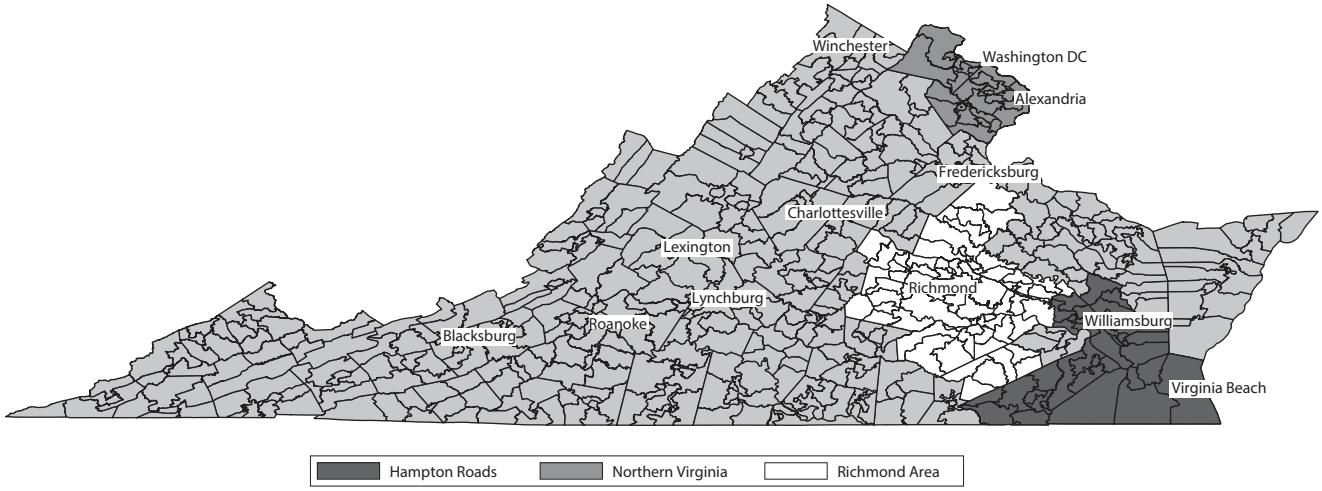

FIGURE 1— Map of Virginia With Major Metropolitan Statistical Areas

Source. Author's calculations using shapefile data from the US Census Bureau.

Virginia is relatively representative of the United States.

While ultimately mass testing, contact tracing, and the development of a vaccine are the best ways to combat a pandemic, these can take time to develop and produce. In the event of a future pandemic, immediate government response can have large downstream effects on public health and mitigation.[4] The United States was slow to respond to the COVID-19 pandemic. Rice[5] notes that even waiting a week to implement policies can have large consequences in the number of cases and death. This article provides some insights into the effectiveness of the policies implemented in Virginia and how people's behavior changed in response in hopes that in a future pandemic these results might be useful to public health officials and policymakers to make quicker and more informed decisions to help slow the spread of disease.

METHODS

The data used in this study came from multiple sources and covered the period of February 15 through August 28, 2020. Since the start of the pandemic, Google has made cellphone location data publicly available to study COVID-19. The Google Community Mobility Reports[6] provide de-identified data aggregated up to the county level that track mobility patterns for smartphone users who have Google location history turned on (see Aktay et al.[7] for more information on this process). Average daily mobility patterns for each county are reported as a percent change from a baseline period before the start of the pandemic between January 3 and February 6, 2020. Data on COVID-19 cases came from the Virginia Department of Health.[8] County population estimates for 2020 in Virginia came from the University of Virginia Weldon Cooper Center for Public Service.[9] Location and shapefile data were used to generate the map in Figure 1, and population density came from the US Census Bureau.[10] Weather data came from the National Oceanic and Atmospheric Administration.[11]

To study the impact of Virginia's stay-at-home order and phased reopening on COVID-19 cases and mobility patterns, I estimated a series of 2-way fixed-effect event-study specifications in which the regressions took the following form:

$$(1)\qquad Y_{i,t} = \beta_0 + \sum_{j \neq 3/25} \beta_j D_{i,t} + \gamma R_{i,t-1} + \theta X_{i,t} + d_t + \varphi_i + \varepsilon_{i,t}$$

where $D_{i,t}$ is a set of daily event time dummy variables that take a 1 on a particular day, t, at location i and 0 for all other days not t. I omitted the dummy variable for February 20, 2020. Thus, the coefficients for β_j measure the impact of the stay-at-home order at time j relative to 35 days before it was implemented on March 25, 2020. I included binned dummy variables for the first and last 5 days of the sample, but did not report them. The interpretation of these event time dummy variables is the change relative to February 20, 2020. The event time dummy variables are presented graphically with 95% confidence intervals clustered at the county level.

$R_{i,t-1}$ is the inverse hyperbolic sine (IHS) of total cases in location i at time $t-1$. The IHS has similar properties to the log transformation but allows for zero-value observations, which is necessary when counting COVID-19 cases near the beginning of the pandemic for

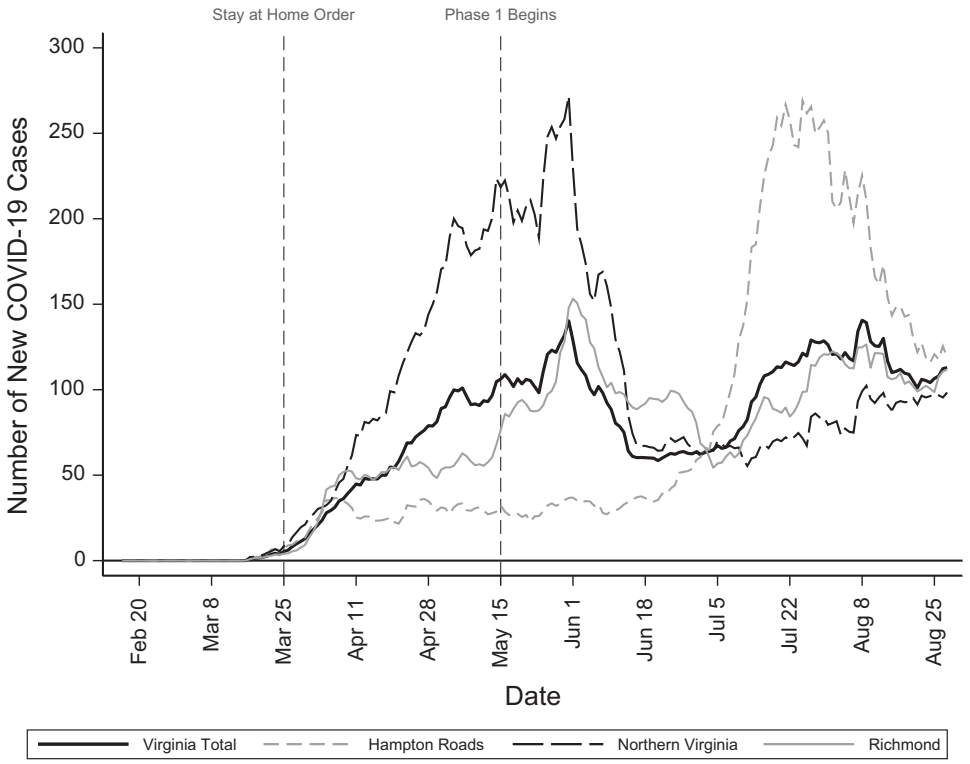

FIGURE 2— Daily New Cases of COVID-19 per 1000 People in Virginia

Source. Author's calculations using data from the Virginia Department of Health.
Note. Graph shows a 7-d moving average of COVID-19 cases in Virginia per 1000 people.

some counties.[12–14] $X_{i,t}$ is a set of county-specific variables controlling for differences in weather that include a dummy variable for if it rains, a dummy variable for hot days when the temperature is above 32.2°C (90°F), and a dummy variable for cold days when the temperature is below 0°C (32°F). d_t denotes a month fixed effect and φ_i denotes a county fixed effect. The fixed effects are of particular importance to this specification because of the short time period of this study. They will capture differences in population density and urban status as those will not change during the study period and daily media announcements that may affect individual mobility patterns. The majority of people get their news from the same sources,[15] and, because the coverage of the pandemic likely did not change much during the study period, media coverage is likely covered in the fixed effects, although imperfectly. The fixed effects will also likely capture other unmeasured omitted variables because of the short period covered in this study, though it cannot be said with certainty that there is not some omitted-variable bias.

This study presents a series of event-studies with different independent variables ($Y_{i,t}$). First, a set of event-studies is presented separately for the 7-day moving average of the mobility patterns in the following venues: for time spent at home, a location of work, at retail and recreation venues (including restaurants and bars), and grocery stores and pharmacies. Second, a separate event-study was conducted in which the IHS of daily COVID-19 cases per 1000 people was the variable of interest ($Y_{i,t}$).

For the regression in which the IHS of daily COVID-19 cases per 1000 people is the variable of interest, the interpretation of the regression coefficients for β_j can be interpreted as semi-elasticities (or percent change) by applying the transformation of $\exp(b_j) - 1$ as proposed by Bellemare and Wichman.[16] Results report both the IHS coefficients and the semielasticities. All regressions were estimated separately for the entire state of Virginia and the 3 major metropolitan areas of Hampton Roads, Richmond, and Northern Virginia. I conducted all data analyses using the statistical software Stata version 16.1 (StataCorp LLC, College Station, TX).

RESULTS

In this section, I discuss the results from how the stay-at-home order in Virginia affected both mobility patterns and new

cases of COVID-19 using the event-study methodology laid out in the Methods section.

Mobility Patterns

Figure A (available as a supplement to the online version of this article at http://www.ajph.org) shows the results graphically of the event-study regressions for all of Virginia (the full regression output for all regressions can be found in Tables B through F, available as supplements to the online version of this article at http://www.ajph.org). Figure A, Panel A, shows that, following the stay-at-home order, people decreased the amount of time they spent at their place of work by more than 30 percentage points. People started to spend less time at work several weeks before the stay-at-home order was declared, likely an anticipation effect as the governor of Virginia declared a state of emergency on March 12, 2020. After around April 15, 2020, people started to increase the amount of time at their place of work. After Virginia began its phased reopening on May 15, 2020, people have been spending around 15 percentage points less time at their place of work. Correspondingly, Figure A, Panel B, shows the opposite trend for time spent at home. After the stay-at-home order was declared, people were spending around 12 percentage points more time at home than they were before the pandemic; however, this was short-lived as there was a gradual trend downward that started immediately. By mid-June, people were spending the same amount of time at home as they were before the start of the pandemic.

Figure A, Panel C, shows that people had a significant decrease of more than 40 percentage points at retail and recreation venues, which include restaurants and bars, just after the stay-at-home order was issued. However, almost immediately, people started to gradually increase the amount of time they spent at these primarily indoor locations and returned to their pre-pandemic level by early June.

Figure A, Panel D, shows that there was a large increase in the amount of time spent at grocery stores in the weeks just before the stay-at-home order was declared, which was followed by a decrease to around of 10 percentage points less time relative to before the pandemic. This pattern is likely in response to the demand-shock that typically occurs at the beginning of a pandemic or natural disaster as people were preparing for the possibility of being stuck at home for an extended period of time and the possibility of a future supply shock to goods they need.[17,18]

Figure 3 shows the results graphically of the event-study regressions separated by MSA. All 3 MSAs generally show the same trend as the entire state, but with different magnitudes. People living in Northern Virginia had a greater response to the stay-at-home order compared with people in Hampton Roads and Richmond. They spent a greater amount of time at home, and significantly less time at their place of work, at retail and recreation venues, and at grocery stores and pharmacies.

People in Hampton Roads and Richmond did not change their mobility patterns to the extent of people in Northern Virginia. The most notable difference in mobility patterns was for time spent at retail and recreation venues, which are primarily indoor locations that include restaurants, bars, and shopping centers. Figure 3, Panel C, shows that people in Richmond were spending the same amount of time at these locations as before the start of the pandemic, but people in Hampton Roads were spending more time at these locations than before the start of the pandemic.

New COVID-19 Cases

Figure B shows the results of the event-study regressions for new daily COVID-19 cases in Virginia in total separated by MSA, and Figure C shows the transformation of those results to semielasticities. The regression results conceptually show the same pattern as Figure 2, while introducing controls for cross-county differences and local concentration of COVID-19 cases, but with large 95% confidence intervals. All of the figures show that Northern Virginia and Richmond had an increase in cases between March and late May, whereas Hampton Roads saw a relatively flat number of cases until mid-June when there was a large increase peaking in late August. It is important to also understand how new COVID-19 cases and changes in mobility are related.

It is important to also understand how new COVID-19 cases and changes in mobility are related. Figure 4 shows the correlation between changes in mobility patterns and the percent change in daily COVID-19 cases 11 days later in a similar fashion to Li et al.[19] Figure 4 shows that there is a negative correlation in more than 60% of the counties in Virginia between time spent at home and COVID-19 cases 11 days later, indicating that an increase in time spent at home led to a decrease in new COVID-19 cases. Figure 4 also shows that there is a positive correlation in more than 60% of the counties in Virginia for time spent at work, retail and recreation, and grocery and pharmacy, indicating that an

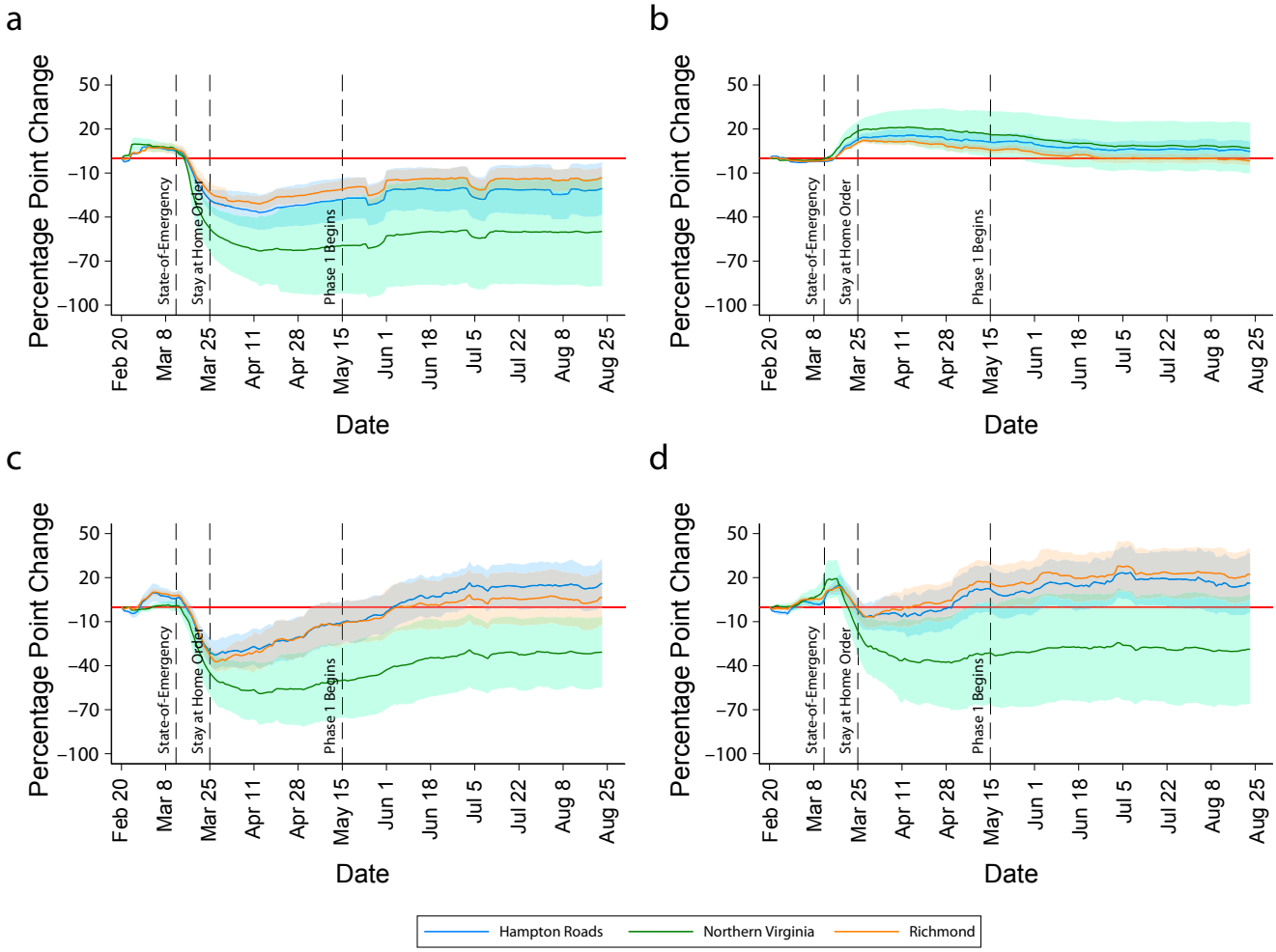

FIGURE 3— Two-Way Fixed Effect Event-Study Results for Mobility Patterns in Virginia by Metropolitan Statistical Area for (a) Places of Work, (b) Home, (c) Retail and Recreation, and (d) Grocery and Pharmacy: February 2020–August 2020

Note. Each line in each graph represents the results of a separate 2-way fixed-effect event-study regression of the specified mobility pattern. The solid line represents the point estimates of D_{it} from equation 1. The base date of comparison is February 20, 2020. Controls included in the regressions are the lagged inverse hyperbolic sine of total cases, population density, urban status, a month fixed effect, and a county fixed effect. The shaded area represents a 95% confidence interval of the point estimate clustered at the county level.

increase in time spent at these locations led to an increase in new COVID-19 cases.

DISCUSSION

The COVID-19 pandemic forced many people make changes to their daily lives—working from home, not going to the gym, not going out to eat—to slow the spread of COVID-19. Many of these changes were in response to NPIs (or stay-at-home orders) implemented by state and local governments. For the NPIs to work, this requires enforcement by businesses and cooperation by individuals. It is important to understand how people responded to the stay-at-home order to gauge the effectiveness of these measures in combating the spread of COVID-19. Virginia presents a unique opportunity to do so by comparing how people changed their mobility patterns as there was not a uniform pattern in COVID-19 cases across the state. There are 2 noteworthy trends in mobility patterns. First, people initially responded to the stay-at-home order with a large change in mobility patterns, but, almost immediately, they gradually began to trend back to prepandemic levels. Second, people in Hampton Roads started spending a greater amount of time at indoor locations compared with the other MSAs and prepandemic levels while at the same time seeing an increase in COVID-19 cases.

Declaring a stay-at-home order was successful at getting people to increase

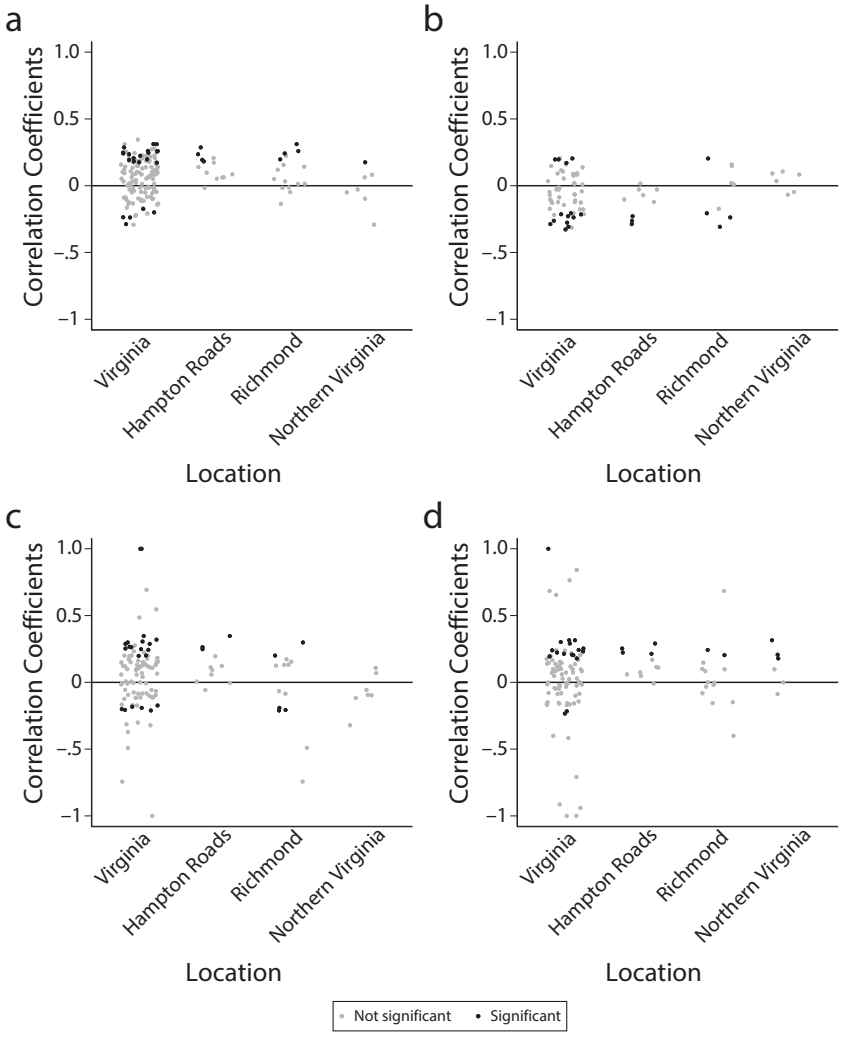

FIGURE 4— Correlation Between Changes in Mobility and Change in COVID-19 Cases in Virginia for (a) Places of Work, (b) Home, (c) Retail and Recreation, and (d) Grocery and Pharmacy: February 2020–August 2020

Source. Author's calculations using Google Mobility Reports and data from the Virginia Department of Health.
Note. Each panel shows the correlation between changes in mobility patterns for that venue and percentage change in new COVID-19 cases 11 d later. Significance is $P < .05$.

the amount of time they spent at home and decrease the amount of time they spent at work and other indoor locations such as retail and recreation venues, grocery stores, and pharmacies. Given the correlations seen in Figure 4, these changes in mobility patterns likely led to decreases in new cases of COVID-19 cases. People mostly stayed away from their location of work, as they were shut down by the NPI. However, almost immediately, people started to decrease the amount of time they were spending at home and increase the amount of time they spent at retail and recreation venues. There are several likely causes of this. During a pandemic, people faced a trade-off between income and health[20] and being under a stay-at-home order increases anxiety about health, worrying about financial security, and loneliness.[21] While the United States provided a relief package that issued a one-time $1200 stimulus check and increased unemployment benefits by $600 per week, those benefits expired at the end of July. Political deadlock prevented further stimulus. With only 25% of the US population able to work from home,[22] some people needed to return to work who otherwise would have stayed at home had there been a stronger relief and stimulus package. In addition, the NPIs issued by individual states in response to COVID-19 became politicized and criticized by President Trump and some Republican members of Congress.[23] This could have created uncertainty as to the effectiveness and need for NPIs causing some people to resume normal activities.

As seen in Figure 1, Northern Virginia experienced a much higher volume of COVID-19 cases at the beginning of the pandemic. This may have caused people living there to be more vigilant, which led to the larger change in mobility patterns compared with the other MSAs. This, in turn, may have led to the lower volume of COVID-19 cases in Northern Virginia after the state began its phased reopening.

After Northern Virginia and Richmond saw a large decrease in daily COVID-19 cases, Hampton Roads saw a large increase in cases. In the weeks leading up to this increase in cases, people in Hampton Roads increased the amount of time they spent at primarily indoor locations—such as restaurants, bars, shopping centers, and recreation venues—that Figure 4 shows are correlated with increases in new COVID-19 cases. People in Hampton Roads were spending more time at these locations starting in early June than they were before the start of the pandemic, and

people from Richmond and Northern Virginia were either at or below prepandemic levels. This increase in time spent at primarily indoor locations could be the reason for the increase and the high volume of COVID-19 cases in Hampton Roads in July and August that corresponds with an increase in time spent at retail and recreation venues. Spending a prolonged period of time at indoor locations increases the risk of COVID-19 transmission.[24,25] This risk is 18.7% higher compared with outdoor locations.[26] It is likely that the amount of time people in Hampton Roads were spending at retail and recreation venues relative to prepandemic levels after the phased reopening began was a large factor in the high number of COVID-19 cases in that MSA.

As this study was not able to draw a causal estimate between mobility and COVID-19 cases, it is important to note that there are other possible causes of the increased rates of COVID-19 cases in Hampton Roads in July and August—most notably, tourism. Hampton Roads is a tourist destination, primarily in Virginia Beach. Smith Travel Research[27] reports that, in late August, hotel occupancy was less than 50% nationwide; however, the only major market to have hotel occupancy above 60% was Virginia Beach and Norfolk, Virginia, indicating an increase in tourist travel to the region. However, the Virginia Department of Health does not believe tourism is responsible for the increase in COVID-19 cases in Hampton Roads.[28]

Limitations

There are several limitations to this study. First, the Google Community Mobility Reports only show data for users who have opted into location tracking. It is possible that there are differences in users who opt-in versus those who do not and that they do not display the same mobility changes. Second, data used in this study were aggregated by county and not individual-level data, and, therefore, the trends cannot be analyzed by demographics and other characteristics. Third, as noted in Liu,[29] there are possibly unobserved factors yet to be measured and fully understood that could potentially affect people's behavior in response to the NPIs attributable to how recent the study period is. Last, the results of this study can likely be extended to the United States as a whole and to individual states with similar social, economic, and political environments. However, it is possible that states that differ significantly socially, economically, and politically may have experienced different patterns and the results of this study may not be generalized to them.

Public Health Implications

Understanding the degree to which NPIs, such as stay-at-home orders, were effective in getting people to alter their behavior to stop the spread of COVID-19 will be valuable to public health officials and policymakers in the event of a future pandemic. Not only will a fast and strict public policy response mitigate the spread of disease, but it also can lead to a faster economic recovery.[30–32] This study helps identify how people changed their mobility patterns because of a stay-at-home order. I show that an NPI, such as the stay-at-home order declared in Virginia, was successful in getting people to spend more time at home, less time at their place of work, and less time at other indoor locations. However, people did not exhibit a sustained change in their mobility patterns, likely attributable to a combination of inconsistent messaging from policymakers, income-related issues, and social needs. I also show that in areas where people had the largest increase in time spent at primarily indoor locations after the beginning of a phased reopening, there was a corresponding increase in new COVID-19 cases.

Public health officials and policymakers can learn from these patterns to improve NPIs in the event of a future pandemic. A clear and consistent public relations campaign coordinated nationally will likely have a stronger and more effective response to NPI measures. Furthermore, ensuring that people do not have to weigh the tradeoff between income and health can make it easier for people to comply with a stay-at-home order. Policymakers should consider more robust stimuli to ensure that people are able to maintain their income during a pandemic if they are unable to work from home. Lastly, public health officials and policymakers should consider additional or stricter NPIs to see a sustained change in mobility patterns. When beginning a phased reopening, stricter rules on indoor activities may be warranted as this study shows that an increased time spent at these locations may be a strong contributing factor to an increase in the spread of disease. Stronger and stricter NPIs that are coordinated at the national level may help slow the spread of a future pandemic, which, in turn, would improve the welfare of many people in the country. Future studies should seek to continue to learn more about how individual people responded and specific different demographic groups responded to NPIs to help inform public health officials and policymakers of additional ways public policy can help

stop the spread of disease during a pandemic. AJPH

ABOUT THE AUTHOR

Tim Murray is with the Department of Economics and Business, Virginia Military Institute, Lexington, VA.

CORRESPONDENCE

Correspondence should be sent to Tim Murray, Department of Economics and Business, Virginia Military Institute, 345 Scott Shipp Hall, Lexington, VA 24450 (e-mail: murrayt@vmi.edu). Reprints can be ordered at http://www.ajph.org by clicking the "Reprints" link.

PUBLICATION INFORMATION

Full Citation: Murray T. Stay-at-home orders, mobility patterns, and spread of COVID-19. *Am J Public Health*. 2021;111(6):1149–1156.

Acceptance Date: January 19, 2021.

DOI: https://doi.org/10.2105/AJPH.2021.306209

ACKNOWLEDGMENTS

The author gratefully thanks Joseph Lucibello for his assistance collecting data on the weather and Gabrielle E. W. Giersch, PhD, for her helpful thoughts and comments.

CONFLICTS OF INTEREST

The author has no conflicts of interest to declare.

HUMAN PARTICIPANT PROTECTION

No human participant protection was required for this study as all data analysis was conducted using de-identified data that were collected by third parties.

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Cumulative Rates of Child Protection Involvement and Terminations of Parental Rights in a California Birth Cohort, 1999–2017

Emily Putnam-Hornstein, PhD, Eunhye Ahn, MSW, John Prindle, PhD, Joseph Magruder, PhD, Daniel Webster, PhD, and Christopher Wildeman, PhD

See also Font, p. 993.

Objectives. To document the cumulative childhood risk of different levels of involvement with the child protection system (CPS), including terminations of parental rights (TPRs).

Methods. We linked vital records for California's 1999 birth cohort (n = 519 248) to CPS records from 1999 to 2017. We used sociodemographic information captured at birth to estimate differences in the cumulative percentage of children investigated, substantiated, placed in foster care, and with a TPR.

Results. Overall, 26.3% of children were investigated for maltreatment, 10.5% were substantiated, 4.3% were placed in foster care, and 1.1% experienced a TPR. Roughly 1 in 2 Black and Native American children were investigated during childhood. Children receiving public insurance experienced CPS involvement at more than twice the rate of children with private insurance.

Conclusions. Findings provide a lower-bound estimate of CPS involvement and extend previous research by documenting demographic differences, including in TPRs.

Public Health Implications. Conservatively, CPS investigates more than a quarter of children born in California for abuse or neglect. These data reinforce policy questions about the current scope and reach of our modern CPS. (*Am J Public Health*. 2021;111:1157–1163. https://doi.org/10.2105/AJPH.2021.306214)

AJPH June 2021, Vol 111, No. 6

As of 2018 in the United States, approximately 28.6% of children in foster care were awaiting adoption; half of these children had a pending or completed legal termination of parental rights (TPR).[1] Under the Adoption and Safe Families Act of 1997 (Pub L No. 105–89), states are required to file a petition seeking a TPR when children have been in foster care for 15 of the most recent 22 months and cannot safely return to the legal and physical custody of their parents. For children born to parents who have previously had their rights terminated or have committed egregious acts, such as the murder or severe and intentional injury of another child, reasonable family reunification efforts and these minimum time-in-care restrictions can be bypassed. Likewise, exemptions to TPR time frames can be obtained when a child has been removed from his or her biological parents but placed with other family members in a guardianship arrangement.[2]

Despite the significance of a state policy that legally severs the most fundamental of relationships—that of a child and their parents—there is relatively little research concerning the number or characteristics of children who experience a TPR arising from abuse or neglect. Studies have found that parental characteristics, such as substance abuse,[3–5] economic status,[4] disabilities,[6] and mental health,[6] along with a child's age and race/ethnicity,[7] are all correlated with the likelihood of a TPR, but each is also a risk factor for maltreatment and child protection system (CPS) involvement generally.[8–10] The only cumulative lifetime estimate of the number of children who experience a TPR can be found in the form of a recent

study that used synthetic cohort life tables to estimate the risk of experiencing this event at the national and state levels.[11] Findings indicate that roughly 1 in 100 US children will have their relationship with their biological parents involuntarily terminated between birth and aged 18 years.[11] In describing the phenomenon as a form of "state-induced parental loss," Wildeman et al. noted, "The risk of parental rights termination is sufficiently high, variable across states, and racially disparate to merit significantly more attention."[11(p39)]

We used linked birth and child protection data from California[12,13] to reproduce and extend national estimates of TPRs[11] in addition to other encounters with CPS (i.e., investigations, substantiations, foster care placements) produced by Kim et al.,[14,15] Wildeman et al.,[11,16,17] and Yi et al.[18] These earlier studies relied on synthetic cohort life table methodologies to generate national cumulative rates of CPS events, an approach that aggregates counts of the age-specific incidence to estimate a cumulative rate of that event, conditional on the event having not yet occurred as of a specific age interval. Synthetic cohort estimates generally show minimal bias, but because children's identification numbers are unique at the state level but not the national level, this method will overestimate the cumulative incidence of each event. Additionally, national studies have been limited to estimating group differences by race/ethnicity and gender.

We used a method that underestimates the cumulative number of children who experience involvement with CPS, providing a "floor" that can be contrasted with the "ceiling" generated through upwardly biased national synthetic cohort studies. Specifically, we linked vital birth records reflecting all children born in California in 1999 to longitudinal statewide CPS records from 1999 to 2017. We then documented the cumulative rate at which children experienced (1) an investigation of alleged maltreatment, (2) a substantiation for maltreatment, (3) a removal and placement in foster care, and (4) a TPR—all in California and conditional on a successful match between a birth and child protection record. For each level of CPS involvement, we additionally calculated cumulative rates and bivariate risk ratios (RRs) by sociodemographic characteristics universally measured at birth, generating the first estimates of group differences throughout childhood by maternal age and education, birth payment method, and paternity.

We had 3 objectives. First, we sought to provide a lower-bound estimate of different levels of CPS involvement using longitudinal data for a state-specific birth cohort, permitting important comparisons to a synthetic cohort life table methodology. Second, we wanted to extend the current cumulative risk literature through sociodemographic estimates that have not yet appeared in peer-reviewed publications. Third, given the limited attention it has received in academic studies, we wanted to produce data that would contribute to an understanding of TPRs.

METHODS

We used 2 population-based sources of records for this study: vital birth records and CPS records. Vital records for all live births registered in California in 1999 (n = 519 448) allowed us to draw on retrospective data to construct a cohort of children we could prospectively follow from birth through aged 18 years. Using a combination of unique (e.g., maternal Social Security numbers) and nonunique (e.g., child first, middle, and last name; child date of birth; residential address) personal identifiers available for both the focal child and their parents, we used an open-source algorithm to probabilistically link vital birth records to CPS records to capture each child's interactions with the system occurring between 1999 and 2017.

We developed the linkage algorithm using machine-learning methods and trained it on a range of administrative data sources from California.[13] We obtained vital birth records from the California Department of Public Health. CPS records fell under the authority of the California Department of Social Services, and we accessed them under a data-sharing agreement. We established record matches at the child level using a probabilistic algorithm developed using machine-learning methods and clerically reviewed training data. After the linkage process was complete, we stripped records of all direct identifiers and created a restricted analytic data set. We additionally dropped 240 birth records from the overall cohort because of missing state and local IDs, leaving us with a total cohort of 519 248 births. In the CPS data, we constructed a file that reflected records for all children reported for abuse or neglect between 1998 and 2017 (n = 5 379 814). In the CPS file, there were 216 679 children with a birth year recorded as 1999. This included children subsequently identified as duplicates and children born out of state.

Variables

We coded the sociodemographic characteristics of each child in our cohort based on fields universally recorded at birth. In addition to child sex (female,

male), we constructed several variables from maternal fields, including race and ethnicity (Black, Latina or Hispanic, Asian or Pacific Islander, Native American, White); age at time of birth (< 20 years, 20–24 years, ≥ 25 years); and education (less than high school, high school diploma, or more). We derived birth payment method from health insurance type (private insurance, public insurance). We inferred paternity establishment from the presence of a named father at the time of delivery (established, missing). Rates of missingness were low (e.g., 0.53% for maternal race and ethnicity, 1.45% for maternal education).

We longitudinally configured CPS records to document first-ever events that occurred for each child between birth and aged 18 years: (1) investigated for alleged maltreatment, (2) substantiated as a victim of maltreatment, (3) removed and placed in foster care, and (4) experienced a TPR. We defined an investigation as a referral of alleged maltreatment that was screened-in and had an accompanying disposition. We classified a child as substantiated if at least 1 allegation was substantiated during childhood. Likewise, we coded a child as having been placed in foster care if he or she was removed and placed in a kin or nonkin placement under the supervision of the child welfare system. We recorded a child as having had a TPR if any identified parent connected to that child had a date of termination documented in the administrative records.

Analysis

Using our linked records, we calculated the cumulative percentage of children in our 1999 California birth cohort who experienced various levels of CPS involvement before aged 18 years. We then developed stratified estimates by child sex; maternal race and ethnicity, age, and education level; birth payment method; and paternity establishment. We calculated bivariate RRs and accompanying 99% confidence intervals (CIs) using a generalized linear model with a log link, Poisson distribution, and robust SEs.[19] Finally, we computed the cumulative percentage of children who had experienced various levels of CPS involvement by year of life. We conducted all analyses using Stata version 16.0 (StataCorp LP, College Station, TX).

RESULTS

We present sociodemographic characteristics of the birth cohort by levels of CPS involvement in Table 1. In Figure 1, we present the cumulative percentage of children who had experienced an investigation, substantiation, foster care placement, or TPR by year of life. In California, 519 248 children were born in 1999 and defined as the cohort we followed prospectively for our analysis. Mirroring the secondary sex ratio nationally, the cohort was defined by slightly more male than female births. Consistent with California demographics, a plurality was born to Latina or Hispanic mothers. Slightly more than 1 in 10 children were born to adolescent mothers, and approximately 30% of children were born to mothers with less than a high school diploma. Overall, 92.8% of children had paternity established at birth. Cumulatively, 26.3% of children in the cohort were investigated for alleged maltreatment, and 10.5% were substantiated as victims of abuse or neglect. Between birth and aged 18 years, 4.3% of children were removed and placed in foster care at least once; 1.1% experienced a legal TPR.

Although the magnitude of group differences varied somewhat across levels of CPS involvement, sociodemographic patterns were directionally consistent. The cumulative percentage of Black and Native American children who had CPS encounters was significantly higher than that of other children. In the cohort overall, approximately half of Black (46.8%) and Native American (50.2%) children were investigated for alleged maltreatment before aged 18 years; both groups experienced all levels of CPS involvement at more than twice the rate of White children in the cohort. The likelihood of CPS involvement exhibited an inverse relationship to both maternal age at birth and maternal education levels. The rate of TPR was twice as high for children born to adolescent mothers as children born to mothers aged 25 years or older (RR = 2.52; 99% CI = 2.31, 2.75). Likewise, children born to mothers with less than a high school diploma experienced a TPR at twice the rate of those with mothers who had completed high school (RR = 2.60; 99% CI = 2.42, 2.78).

Receipt of public health insurance and missing paternity were also strongly related to all levels of CPS involvement. Children whose births were covered by public insurance were twice as likely to experience an investigation during childhood (RR = 2.11; 99% CI = 2.08, 2.13). Meanwhile, the rate at which children receiving public insurance had a legal TPR was 6 times that of children in the cohort covered by private insurance (RR = 6.13; 99% CI = 5.61, 6.70). Although only 1 in 14 children in California was born without established paternity at birth (n = 37 513), nearly 50% were investigated and parental rights were terminated for nearly 6% (n = 2153) of those children.

DISCUSSION

We used a birth cohort methodology to document the cumulative percentage of

TABLE 1— Sociodemographic Characteristics and the Cumulative Percentage of Children With Different Levels of Involvement With the Child Protection System: California's 1999 Birth Cohort

		Investigated		Substantiated		Placed in Foster Care		TPR	
Variable	1999 Birth Cohort, No. (%)	Cumulative %	RR (99% CI)	Cumulative %	RR (99% CI)	Cumulative %	RR (99% CI)	Cumulative %	RR (99% CI)
Total	519 248 (100.0)	26.3	. . .	10.5	. . .	4.3	. . .	1.1	. . .
Child sex									
Female	253 734 (48.9)	26.7	1.03 (1.02, 1.05)	10.8	1.05 (1.03, 1.08)	4.4	1.01 (0.98, 1.05)	1.1	1.06 (0.99, 1.14)
Male	265 511 (51.1)	25.9	1 (Ref)	10.2	1 (Ref)	4.3	1 (Ref)	1.1	1 (Ref)
Maternal race/ethnicity									
Black	34 156 (6.6)	46.8	2.10 (2.06, 2.14)	21.8	2.28 (2.21, 2.36)	12.3	2.97 (2.83, 3.11)	3.2	2.46 (2.24, 2.70)
Native American	2 532 (0.5)	50.2	2.25 (2.14, 2.38)	27.4	2.87 (2.63, 3.13)	14.4	3.49 (3.07, 3.97)	3.8	2.95 (2.27, 3.83)
Latina/Hispanic	252 691 (48.7)	29.0	1.30 (1.28, 1.32)	10.8	1.14 (1.11, 1.16)	4.0	0.96 (0.92, 1.00)	0.8	0.65 (0.60, 0.70)
Asian/Pacific Islander	57 087 (11.0)	13.2	0.59 (0.58, 0.61)	4.3	0.46 (0.43, 0.48)	1.3	0.32 (0.29, 0.35)	0.3	0.22 (0.18, 0.27)
White	172 188 (33.2)	22.3	1 (Ref)	9.5	1 (Ref)	4.1	1 (Ref)	1.3	1 (Ref)
Maternal age at birth, y									
< 20	57 693 (11.1)	45.7	2.25 (2.21, 2.28)	20.4	2.69 (2.62, 2.76)	9.1	2.99 (2.87, 3.12)	2.1	2.52 (2.31, 2.75)
20–24	120 519 (23.2)	33.8	1.66 (1.64, 1.68)	13.9	1.82 (1.78, 1.87)	5.7	1.86 (1.78, 1.93)	1.3	1.57 (1.45, 1.70)
≥ 25	341 036 (65.7)	20.4	1 (Ref)	7.6	1 (Ref)	3.0	1 (Ref)	0.8	1 (Ref)
Maternal education									
Less than high school	155 364 (29.9)	36.2	1.65 (1.63, 1.67)	15.8	1.94 (1.90, 1.98)	7.1	2.31 (2.23, 2.38)	1.9	2.60 (2.42, 2.78)
High school diploma	356 358 (68.6)	21.9	1 (Ref)	8.1	1 (Ref)	3.1	1 (Ref)	0.7	1 (Ref)
Birth payment method									
Public	218 643 (42.1)	37.7	2.11 (2,08, 2.13)	16.7	2.82 (2.76, 2.89)	7.6	4.12 (3.69, 4.29)	2.1	6.13 (5.61, 6.70)
Private	298 178 (57.4)	17.9	1 (Ref)	5.9	1 (Ref)	1.9	1 (Ref)	0.3	1 (Ref)
Paternity established									
Missing	37 513 (7.2)	48.9	1.99 (1.96, 2.02)	26.2	2.82 (2.76, 2.90)	15.6	4.53 (4.37, 4.70)	5.7	7.76 (7.24, 8.31)
Established	481 735 (92.8)	24.5	1 (Ref)	9.3	1 (Ref)	3.4	1 (Ref)	0.7	1 (Ref)

Note. CI = confidence interval; RR = risk ratio; TPR = termination of Parental rights. Missing values: child sex = 3 (0.00%), maternal age = 62 (0.01%), maternal race/ethnicity = 2756 (0.53%), birth payment method = 1220 (0.23%), and maternal education = 7526 (1.45%).

children born in California in 1999 who experienced a TPR and other levels of CPS involvement. Our findings directionally align with national estimates produced using synthetic cohort life table estimates[11,15–18] and extend earlier published findings by documenting group differences by several new sociodemographic stratifications,

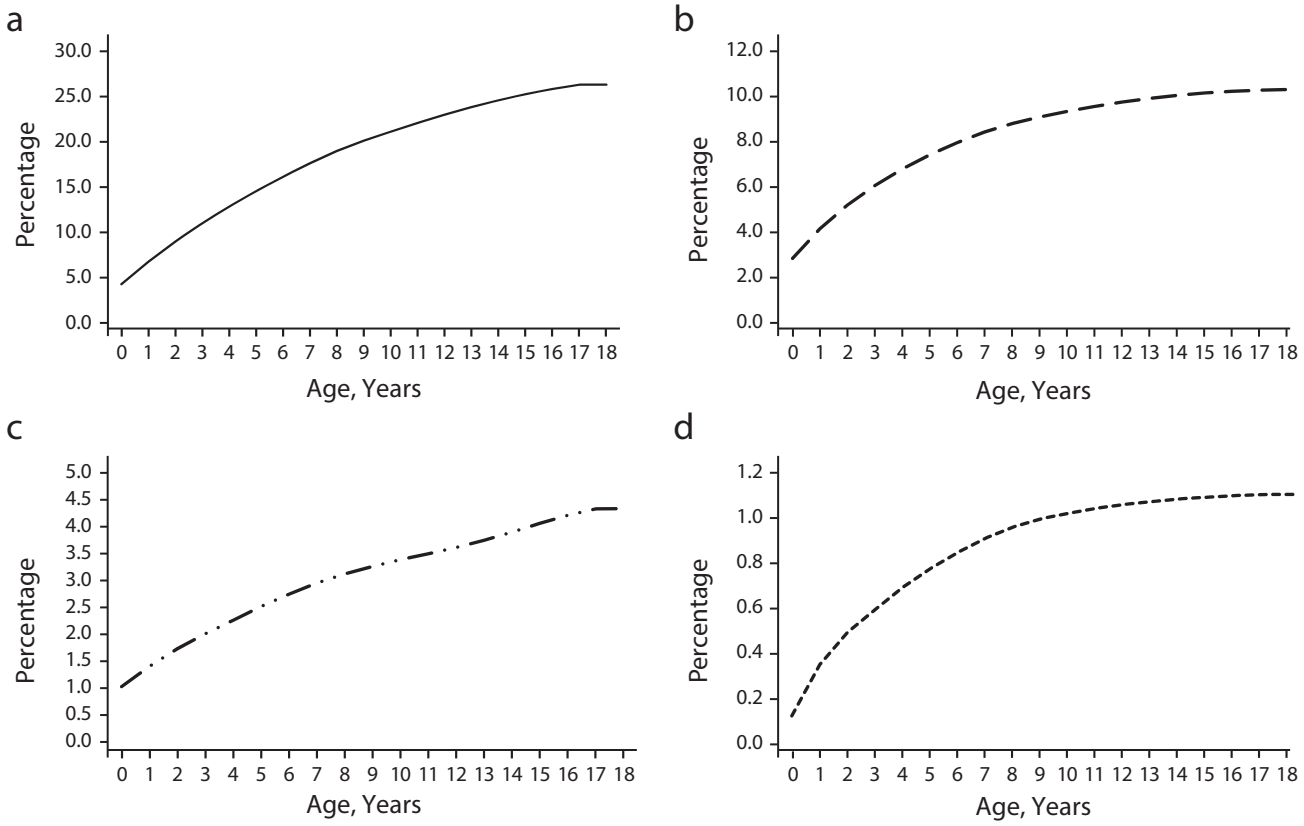

FIGURE 1— Cumulative Percentage, by Age, of Children Born in California Experiencing First (a) Investigation, (b) Substantiation, (c) Foster Care Placement, and (d) Termination of Parental Rights: 1999 birth cohort

including maternal age, maternal education, and public versus private health insurance. Importantly, our findings also underscore the reach of our modern CPSs (conservatively, more than one quarter of children were investigated), even though a relatively small percentage of all children experienced a temporary (i.e., foster care [4.3%]) or permanent (i.e., a TPR [1.1%]) separation from their birth parents.

Despite using different methodological approaches, our estimates of children born in California who had CPS involvement during childhood are largely consistent with those generated nationally using synthetic cohort life tables.[11,15–18] Specifically, Kim et al.,[15] estimated that 37.4% of US children experience an investigation for alleged maltreatment; we documented that approximately 26.3% of children in our state birth cohort were investigated for abuse or neglect. Meanwhile, Wildeman et al.[17] estimated that 12.5% and Yi et al.[18] estimated that 11.7% of children are substantiated as victims nationally between birth and aged 18 years. We confirmed that among children born in California, a cumulative 10.3% were substantiated. Likewise, national estimates suggest that 5.3% to 5.9% of children experience a removal and placement in foster care[16,18]; our findings suggest that 4.3% of children in our California birth cohort spent time in foster care. Finally, a TPR will occur to an estimated 1.0% of US children (and 1.1% of children in California), which aligns with 1.1% of children in our birth cohort.[11]

The general consistency of the numbers, despite different estimation methodologies, time frames, and geographies, underscores several things. First, our findings reinforce the use of synthetic cohort life table methodologies for producing cumulative estimates from federal data files when truly longitudinal data are not available (i.e., National Child Abuse and Neglect Data System and the Adoption and Foster Care Analysis and Reporting System). Life table methodologies constructed from state data files provide an upwardly biased estimate of CPS involvement because the identification of children experiencing their first event is unique in but not between states. Consistent with the magnitude of differences between the estimates we produced versus those in the published

literature, bias in the synthetic cohort estimates is almost certain to be highest for investigations and then progressively lower for substantiation, placement, and TPR (with likely very close to no bias for TPR because the probability of parental rights being terminated in 2 states seems exceptionally low).

Meanwhile, state-specific birth cohort estimation techniques will be downwardly biased because CPS events for children born in 1 state who then move outside that state cannot be observed. Likewise, the estimates we presented are conditioned on our success in accurately linking children from birth records to CPS records. Our methodology means that any children we were unable to match will be counted as having not had CPS involvement, depressing our numerator. The alignment between findings produced in our analysis and those published earlier suggests that either of these 2 methods can be used to produce estimates that approximate the true cumulative rates of CPS involvement. Although additional state-specific validations should be generated, findings from this study also positively point to the general quality of underlying state data submissions to the US Children's Bureau.

Finally, our findings also highlight known socioeconomic disparities that emerge not only in the cumulative risk of investigations during childhood but across all levels of CPS involvement through TPRs. These disparities undoubtedly reflect root causes associated with higher rates of childhood adversities. However, an exclusive focus on poverty and associated risk factors ignores the extent to which official child protection records reflect a system designed—through regulations, statutes, and policies—to do exactly what the numbers reflect: surveil and investigate large numbers of children and families even though only a small number will ultimately receive services. Unfortunately, the limited specificity with which CPS surveillance operates is disproportionately borne by low-income families and families of color.

Limitations

The estimates we derived must be understood in the context of several limitations. First, as described earlier, our cumulative rates underreport the number of children who had CPS involvement, as we only observe contacts occurring in the state. Second, the extent to which the magnitude of differences between estimates generated through a California birth cohort versus a national synthetic cohort generalize to other states remains unknown. Finally, our ability to accurately ascertain whether a child experienced a TPR was made difficult by the limited availability of data. Approximately 6% of children we defined as having had a TPR had a record for only a single parent. We cannot rule out the possibility that the child remained in the custody of another biological parent. Nevertheless, because 99.7% of children who had a TPR in our data also had an identified foster care record, it seemed reasonable to assume that the child had been removed from the custody of both parents.

Public Health Implications

Our findings underscore the extent to which child protection systems in the United States (and Australia,[20] New Zealand,[21] and across the globe[22,23]) have involvement with children and their families. Although the fraction of children who are separated from their parents during childhood because of abuse and neglect is relatively small, the cumulative number of children who are investigated by CPS during childhood is substantial. Roughly half of Black and Native American children in California are investigated for maltreatment during childhood. These childhood numbers, both overall and by race and ethnicity, should be taken seriously by federal and state policymakers—and have received too little attention to date. AJPH

ABOUT THE AUTHORS

Emily Putnam-Hornstein is with the School of Social Work, University of North Carolina at Chapel Hill. Eunhye Ahn and John Prindle are with the Suzanne Dworak-Peck School of Social Work, University of Southern California, Los Angeles. Joseph Magruder and Daniel Webster are with the School of Social Welfare, University of California, Berkeley. Christopher Wildeman is with the Department of Sociology, Duke University, Durham, NC.

CORRESPONDENCE

Correspondence should be sent to Emily Putnam-Hornstein, School of Social Work, Tate-Turner-Kuralt Building, 325 Pittsboro St, CB #3550, Chapel Hill, NC 27599-3550 (e-mail: eph@unc.edu). Reprints can be ordered at http://www.ajph.org by clicking the "Reprints" link.

PUBLICATION INFORMATION

Full Citation: Putnam-Hornstein E, Ahn E, Prindle J, Magruder J, Webster D, Wildeman C. Cumulative rates of child protection involvement and terminations of parental rights in a California birth cohort, 1999–2017. *Am J Public Health*. 2021;111(6):1157–1163.

Acceptance Date: January 27, 2021.

DOI: https://doi.org/10.2105/AJPH.2021.306214

CONTRIBUTORS

E. Putnam-Hornstein conceptualized the study, led the writing, obtained funding, and supervised the project. E. Ahn performed statistical analyses. J. Prindle supervised the statistical analyses. J. Magruder, D. Webster, and C. Wildeman helped conceptualize the study. All authors contributed to the writing of the article, interpretation of data, and the final article as submitted.

ACKNOWLEDGMENTS

This analysis was funded by the US Department of Health and Human Services, Administration for Children and Families (project officer: Jenessa Malin), Office of Planning, Research, and Evaluation (contract HHSP233201500035I/75P00119F37041 to Mathematica Policy Research, Inc.). This analysis would not have been possible without critical data infrastructure support funding provided to the Children's Data Network from First 5 LA, the Conrad N. Hilton Foundation, and the Heising-Simons Foundation.

The authors would like to acknowledge the contributions of colleagues at the Children's Data Network and the California Child Welfare Indicators Project. This project would not have been possible without the support and partnership of the California Department of Social Services, whose commitment to generating new knowledge is a model for all public agencies.

Note. The results and conclusions derived from this study are solely those of the authors and do not reflect the opinion of any government agencies or departments.

CONFLICTS OF INTEREST

The authors have no conflicts of interest to report.

HUMAN PARTICIPANT PROTECTION

All record linkages and analyses were reviewed and approved by California's Committee for the Protection of Human Subjects. Access to child protection records fell under a data-sharing agreement with the California Department of Social Services; vital birth records were obtained from the California Department of Public Health following review and approval by the Vital Statistics Advisory Committee.

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SARS-CoV-2 Infection Among Correctional Staff in the Federal Bureau of Prisons

Robin L. Toblin, PhD, MPH, Sylvie I. Cohen, MD, MPH, and Liesl M. Hagan, MPH

Objectives. To examine SARS-CoV-2 (severe acute respiratory syndrome coronavirus 2) epidemiology and risk factors among Federal Bureau of Prisons (BOP) staff in the United States.

Methods. We calculated the SARS-CoV-2 case rate among 37 640 BOP staff from March 12 to June 17, 2020, using payroll and COVID-19–specific data. We compared occupational factors among staff with and without known SARS-CoV-2 using multiple logistic regression, controlling for demographic characteristics. We calculated relative risk among staff in stand-alone institutions versus complexes (> 1 institution).

Results. SARS-CoV-2 was reported by 665 staff across 59.8% of institutions, a case rate of 1766.6 per 100 000. Working in dorm-style housing and in detention centers were strong risk factors, whereas cell-based housing was protective; these effects were erased in complexes. Occupational category was not associated with SARS-CoV-2.

Conclusions. SARS-CoV-2 infection was more likely among staff working in institutions where physical distancing and limiting exposure to a consistent set of staff and inmates are challenging.

Public Health Implications. Mitigation strategies—including augmented staff testing, entry and exit testing among inmates, limiting staff interactions across complexes, and increasing physical distancing by reducing occupancy in dorm-style housing—may prevent SARS-CoV-2 infections among correctional staff. (*Am J Public Health*. 2021;111:1164–1167. https://doi.org/10.2105/AJPH.2021.306237)

AJPH June 2021, Vol 111, No. 6

COVID-19, which is caused by SARS-CoV-2 (severe acute respiratory syndrome coronavirus 2), disproportionately affects residents and staff in congregate living environments.[1–4] However, little is known about SARS-CoV-2 risk among correctional staff. This report examines SARS-CoV-2 epidemiology and risk factors among Federal Bureau of Prisons (BOP) staff.

METHODS

We used National Finance Center payroll data to ascertain assigned institution type (Table A, available as a supplement to the online version of this article at http://www.ajph.org), occupational category (online Table B), age, gender, and race/ethnicity of staff employed between March 1 and May 23, 2020. Among institution types, security level is a proxy for inmate housing type, with low security characterized by dorm-style housing and medium and high security characterized by cell-based housing. Complexes comprise 2 or more adjacent institutions that often share staff. We grouped occupational categories by function.

We used BOP COVID-19 databases to ascertain reported staff cases, inmate cases, and institution type within complexes from March 12 to June 17, 2020. Staff obtained testing voluntarily, largely outside of the BOP, and were required to report positive results to the BOP's occupational health branch.

We calculated the SARS-CoV-2 case rate among BOP staff. We used multiple logistic regression to identify occupational risk factors for SARS-CoV-2 among staff overall. To account for the potential impact of community transmission, we ran a second model that included only staff working in institutions with an outbreak. We defined an outbreak as 4 or more cases among staff and inmates combined, at least one of which involved

staff, occurring within 14 days of one another. Both models controlled for age, gender, and race/ethnicity. We excluded 7 infected staff without payroll data. Payroll data did not include institution type within complexes; thus, we calculated relative risks among staff with SARS-CoV-2 to compare staff working in stand-alone institutions (i.e., in low-, medium-, or high-security institutions, or in institutional medical centers) with staff in analogous institution types within a complex. Analyses used SAS Enterprise Guide 7.1 (SAS Institute, Cary, NC).

RESULTS

From March 12 to June 17, 2020, 37 640 staff worked in 122 BOP institutions, including 35 institutions within 15 complexes, and 11 administrative sites. Staff were predominantly male (71.5%), aged 35 to 54 years (68.9%), and non-Hispanic White (63.1%). The largest occupational category was correctional services (49.0%); 30.8% of staff worked in a complex.

SARS-CoV-2 was reported by 665 staff across 73 institutions (59.8%), a case rate of 1766.7 per 100 000; the inmate case rate was 4813.2 per 100 000, a ratio of 2.7 inmate to staff cases. The median number of staff cases per institution was 3 (range = 1–61); the median number of combined cases (staff + inmates) was 4 (range = 1–1011). In the 50 institutions (68.5%) with both staff and inmate cases, the median number of staff cases was 7 (range = 1–61) and of combined cases was 24.5 (range = 1–1011). The median number of staff cases in the 23 institutions (31.5%) without inmate cases was 1 (range = 1–5); 7 of these institutions (30.4%) had 2 or more temporally related staff cases. Outbreaks occurred in 42 institutions (57.5%), with 620 staff cases and 6180 inmate cases, accounting for 92.5% of staff cases and a staff case rate of 4286.2 per 100 000.

Risk factors for SARS-CoV-2 infection included working in a stand-alone low-security institution, correctional complex, or detention center, and Black race; working in stand-alone high-security institutions was protective (Table 1). Gender, age, and occupational category were not associated with infection. This pattern of findings was generally consistent when we examined institutions with outbreaks separately (online Table C).

Compared with staff working in their stand-alone counterparts, staff in complex-based low-security institutions had a lower relative risk (RR) of SARS-CoV-2 (0.6; 95% confidence interval [CI] = 0.5, 0.7), but risk was higher for staff in complex-based medium-security institutions (RR = 1.6; 95% CI = 1.2, 2.1) and high-security institutions (RR = 8.1; 95% CI = 3.1, 20.8; online Table D).

DISCUSSION

The SARS-CoV-2 case rate among BOP staff from March 12 to June 17, 2020 was 1766.7 per 100 000 among the total BOP population (crude case rate) and 4286.2 per 100 000 in institutions with outbreaks, higher than among cruise ship staff[2] and lower than among staff in homeless shelters reported during a similar time period.[3] Transmission source is difficult to ascertain and likely varies. Institutions with inmate cases had more staff cases, consistent with transmission between staff and residents in other congregate settings.[2,3] Some institutions with staff cases had no inmate cases, consistent with studies suggesting SARS-CoV-2 introduction by staff,[5] as well as potential staff-to-staff transmission. Notably, occupational category was not associated with SARS-CoV-2 infection, reflecting the interconnected operations within correctional environments and underscoring the need to universally maximize physical distancing, use of personal protective equipment (PPE), and vaccine distribution to protect staff and inmates. Although the BOP has implemented swift contact tracing, augmented voluntary staff testing could further control transmission[1–3]; staff uptake would be critical.[6]

Institution type had the strongest association with SARS-CoV-2 infection. Compared with working in stand-alone medium-security institutions, working in stand-alone low-security institutions was a strong risk factor, whereas working in stand-alone high-security institutions was protective. These differences may be due to higher risk of infection in dorm-style housing (low-security facilities) relative to cell-based housing (medium- and high-security facilities), consistent with previous studies examining infection among inmates.[5,7] This finding supports the BOP's strategy to reduce population size and relocate some inmates from dorm-based to cell-based institutions. The BOP could consider retrofitting dorm-based housing to further distance inmates.

The influence of institution type (i.e., dorm-style as a risk, cell-based as protective) was erased in correctional complexes. This dynamic could be explained by cross-complex interactions among staff, including commuting in vanpools, eating together, and working across institutions to support operational efficiencies. Maintaining staff assignments to a single institution, eating separately, and using alternate commuting arrangements could prevent transmission.

Working in a detention center was also strongly associated with infection.

TABLE 1— Association of Occupational Factors With SARS-CoV-2 Infection Among 37 640 Federal Correctional Staff: United States, March 12–June 17, 2020

Characteristic	SARS-CoV-2+ No. (%)[a]	Not SARS-CoV-2+ No. (%)	Unadjusted OR (95% CI)	Adjusted OR[b] (95% CI)
Age (continuous)	NA	NA	1.0 (1.0, 1.0)	1.0 (1.0, 1.0)
Gender				
Female	192 (28.9)	10 549 (28.5)	1.0 (0.9, 1.2)	1.0 (0.8, 1.2)
Male	473 (71.1)	26 426 (71.5)	1 (Ref)	1 (Ref)
Race/ethnicity				
White	344 (52.4)	23 035 (63.3)	1 (Ref)	1 (Ref)
Native American	9 (1.4)	342 (0.9)	1.8 (0.9, 3.5)	1.6 (0.8, 3.2)
Asian	16 (2.4)	684 (1.9)	1.6 (0.9, 2.6)	1.1 (0.7, 1.9)
Black	184 (28.0)	7 718 (21.2)	1.6 (1.3, 1.9)	1.3 (1.1, 1.6)
Hispanic or Latino	104 (15.8)	4 625 (12.7)	1.5 (1.2, 1.9)	1.1 (0.8, 1.3)
Institution type				
Staff location	10 (1.5)	2 208 (6.0)	0.6 (0.3, 1.1)	0.5 (0.3, 1.1)
Stand-alone low security[c]	214 (32.2)	6 161 (16.7)	4.3 (3.3, 5.6)	4.3 (3.3, 5.6)
Stand-alone medium security	75 (11.3)	9 226 (25.0)	1 (Ref)	1 (Ref)
Stand-alone high security	5 (0.8)	2 392 (6.5)	0.3 (0.1, 0.6)	0.3 (0.1, 0.7)
Correctional complex	200 (30.1)	11 379 (30.8)	2.2 (1.7, 2.8)	2.1 (1.6, 2.8)
Detention center	138 (20.8)	2 853 (7.7)	6.0 (4.5, 7.9)	5.7 (4.3, 7.7)
Stand-alone medical center	23 (3.5)	2 756 (7.5)	1.0 (0.6, 1.6)	1.1 (0.7, 1.7)
Occupational category				
Administrative	48 (7.3)	3 092 (8.5)	1 (Ref)	1 (Ref)
Case management	56 (8.5)	3 155 (8.7)	1.1 (0.8, 1.7)	1.1 (0.8, 1.7)
Correctional services	338 (51.5)	18 147 (49.9)	1.2 (0.9, 1.6)	1.1 (0.8, 1.5)
Facilities/safety	57 (8.7)	2 681 (7.4)	1.4 (0.9, 2.0)	1.3 (0.9, 2.0)
Food/commissary	40 (6.1)	2 214 (6.1)	1.2 (0.8, 1.8)	1.1 (0.7, 1.7)
Health care	55 (8.4)	3 165 (8.7)	1.1 (0.8, 1.7)	1.2 (0.8, 1.8)
Industry	6 (0.9)	467 (1.3)	0.8 (0.4, 1.9)	1.2 (0.5, 2.9)
Recreation/education	34 (5.2)	1 781 (4.9)	1.2 (0.8, 1.9)	1.2 (0.8, 1.9)
Well-being	22 (3.4)	1 670 (4.6)	0.9 (0.5, 1.4)	0.9 (0.5, 1.4)
Missing[d]	9 (1.5)	603 (1.6)	1.0 (0.5, 2.0)	1.5 (0.7, 3.1)

Note. CI = confidence interval; NA = not available; OR = odds ratio; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2. Staff are excluded who began employment between May 24 and June 17, 2020.

[a]Staff testing occurred on a voluntary basis, largely outside of the Federal Bureau of Prisons (BOP). This column represents staff who reported infection to the BOP.
[b]OR was adjusted for gender, age, race/ethnicity, institution type, and job category.
[c]Includes stand-alone minimum-security prison camps.
[d]There were 612 staff without occupational title available in payroll data. To ensure these data were not missing systematically, they were included as a category.

Because detention centers are in urban population centers and hold inmates coming directly from the community or other jurisdictions during trial, they have especially high population turnover, likely contributing to transmission.[8] The BOP has implemented testing and quarantine at admission, consistent with Centers for Disease Control and Prevention guidance,[9] to reduce staff exposure to cases among new intakes and transfers.

This analysis has several limitations. First, data were unavailable on the source of infection (i.e., coworkers, inmates, community), community transmission levels, underlying medical conditions, or individual behaviors including physical distancing and PPE use, limiting our ability to attribute infection to occupational factors alone. However, even when the model included only

outbreak facilities, the pattern of findings remained consistent. Second, misclassification may have occurred among (1) infected staff who were not tested or did not report their results (although the BOP mandates reporting known cases and offers COVID-19–specific sick leave); (2) staff potentially infected while performing temporary duty at another institution, but whose infection was attributed to their home duty station; and (3) the 5% of staff who, because of underlying health conditions, were assigned alternate duties, but whose infection was attributed to their original occupational category. Third, institution type within complexes was only available for infected staff, restricting the regression models. Fourth, payroll data used for analyses did not include staff who began employment between May 24 and June 17. Finally, risk factors may have changed since this analysis.

PUBLIC HEALTH IMPLICATIONS

SARS-CoV-2 infection was more likely among correctional staff working in settings where it is challenging to practice physical distancing or limit interactions to a consistent set of staff and inmates: correctional complexes, detention centers, and institutions with dorm-style housing. Augmented voluntary staff testing, measures to increase physical distancing (i.e., retrofitting and reducing populations in dorm-style housing), limited staff interactions between institutions within a complex, and continued testing and quarantining of new and transferring inmates could help prevent or contain future outbreaks. AJPH

ABOUT THE AUTHORS

Robin L. Toblin, Sylvie I. Cohen, and Liesl M. Hagan are with the Health Services Division, Federal Bureau of Prisons, Washington, DC. Robin L. Toblin and Sylvie I. Cohen are with the Commissioned Corps of the United States Public Health Service, Rockville, MD.

CORRESPONDENCE

Correspondence should be sent to Robin L. Toblin, 11785 Beltsville Dr, Rm 6304, Beltsville, MD 20705 (e-mail: robin.toblin@fda.hhs.gov). Reprints can be ordered at http://www.ajph.org by clicking the "Reprints" link.

PUBLICATION INFORMATION

Full Citation: Toblin RL, Cohen SI, Hagan LM. SARS-CoV-2 infection among correctional staff in the Federal Bureau of Prisons. *Am J Public Health*. 2021;111(6):1164–1167.

Acceptance Date: February 14, 2021.

DOI: https://doi.org/10.2105/AJPH.2021.306237

CONTRIBUTORS

R. L. Toblin conceptualized the study, curated data, conducted the formal analysis, performed the methodology, wrote the original draft, and reviewed and edited the article. S. I. Cohen conceptualized the study, curated data, collected resources, and reviewed and edited the article. L. M. Hagan performed the methodology and reviewed and edited the article.

ACKNOWLEDGMENTS

This work was completed using government (Federal Bureau of Prisons [BOP]) resources and staff time. R. L. Toblin and L. M. Hagan were detailed to the BOP from the Food and Drug Administration and the Centers for Disease Control and Prevention, respectively, to help with the COVID-19 response.

We are grateful for the contributions of Neal Langan, Jason Gwinn, Jennifer Batchelder, Erik Faust, and Kyle Shea of the BOP Office of Research and Evaluation and Jeanne Ocampo and Charles Dusseau of the BOP Health Services Division for data analytic and statistical support; the staff of the BOP Emergency Operations Center for maintaining the staff COVID database; and Michael Long, Christopher Bina, Jeffrey Allen, Te Cora Ballom, and Jeffrey Burkett from the BOP Health Services Division for helpful suggestions in previous versions of this article.

CONFLICTS OF INTEREST

The authors have no potential or actual conflicts of interest to report.

HUMAN PARTICIPANT PROTECTION

This study was examined by the BOP institutional review board and was determined to be used for operational purposes, and therefore categorized as exempt research.

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2020 in *AJPH*: A Review and Thank You to Our Authors

Alfredo Morabia, MD, PhD

ABOUT THE AUTHOR

Alfredo Morabia is the editor-in-chief of AJPH*, Washington, DC.*

What a year! The publication frenzy created by the COVID-19 crisis has, of course, impacted *AJPH*. And we have kept you informed about journal policy throughout the crisis.[1,2] Now that full statistics for 2020 are available, I review them here and illustrate what our editorial policy has been by citing some notable papers we published in 2020. This is also our way of thanking authors and peer reviewers for their contributions to the journal. (See the full article with a list of reviewers at https://www.ajph.org.)

STATISTICS

We received 5310 submissions in 2020, about 15 per day; 1800 of them had the pandemic as their main topic. This was about 2000 more total submissions than in 2019. We read them all and accepted 5.2% of the research and analysis papers and 48.8% of opinion pieces, some of them commissioned. When a submission was not a good match for *AJPH*, we proposed alternative journals in our decision letters, as we have been doing for the past five years. Even though the flow of submissions is expected to remain much larger than before the crisis (5000 projected for 2021), we have now redesigned the journal[3] and our instructions for authors.

Interest in the journal grew in 2020. Readers downloaded 5.3 million full-text papers from the *AJPH* Web site, up from 4.6 million in 2019. News coverage of our articles in 2020 reached 5861 media hits and 7.5 billion audience impressions, which are visits to pages in which there were articles citing *AJPH*.

Finally, despite the large influx of papers, our peer reviewers managed to keep pace and render 2105 decision recommendations to our editors, most within 12 days of accepting the invitation to review. Peer reviewers volunteer their time and expertise to assist in advancing the field of public health. We are ever grateful to them for their dedication and responsiveness.

WHILE COVID-19 RAGED . . .

The first paper we published on the topic of COVID-19, by Smith and Fraser, warned that COVID-19 would strain the public health system, especially because it would be concomitant with natural disasters that have become the new normal in some areas of the country.[4] Indeed, at the end of 2020, the National Centers for Environmental Information reported that "2020 was a historic year of extremes" (https://bit.ly/3rQjaJV). There were 22 separate tropical cyclones and severe storms, mostly in central and southern states; there was a drought in Plains states; and wildfires ravaged the western United States. These were six more than in 2017 and 2011, which beat the previous annual record of disasters, creating more than $16 billion in damages.

In the spring of 2020, we received numerous submissions comparing the incidence and mortality of COVID-19 across populations. These papers used the convenience sample data generated by public authorities in the United States and other countries. We declined to publish articles relying on these COVID-19–specific data unless the authors took additional steps to assess potential selection and misclassification biases. Pearce et al. explained why these comparisons were flawed in the absence of population-based information.[5]

From its onset, the pandemic exposed the consequences of the structural racism that pervades our health care system and is a major obstacle to making public health interventions a common good. Bowleg wrote, "We're not all in this together."[6] Auerbach and Miller declared that COVID-19 "exposed the cracks" in already fragile public health and mental health systems.[7] It was also obvious that many nonrelocatable and, therefore, high-risk jobs were held by people with low incomes who lived in disadvantaged communities.[8] Similarly, prisons were "amplifiers of the COVID-19 pandemic hiding in plain sight."[9] Articles in the journal also echoed the uproar against racism and assertions of White supremacy articulated in the massive demonstrations that followed the murder of George Floyd.[10,11]

From the beginning of the pandemic, our editorial strategy has been to focus

on post–COVID-19 reconstruction. Because it takes three to four months from submission to publication of a research paper or analytic essay in *AJPH*, we could not publish time-sensitive results about the evolution of the pandemic. But our schedule enabled us to publish in November an article on "Reimagining public health in the aftermath of a pandemic"[12] and, in December, an assessment of the huge amounts of money that will be required to build strong foundations for public health—some of which could be obtained by eliminating wasteful spending for medical care.[13]

Throughout the crisis, public health practitioners have contended with disinformation, often generated by right-wing extremist groups (https://abcn.ws/3sgzd4e) and sometimes fed by high-ranking members of the previous administration (https://on.wsj.com/3dvmk1N). In collaboration with the National Cancer Institute, we published a supplement, "Health Misinformation on Social Media."[14] In addition, Broniatowski et al. revisited the case of the "Disneyland" measles outbreak to emphasize that misinformation on social media was feeding disastrous vaccine hesitancy.[15] Another article, based on a follow-up of the April 7, 2020, Wisconsin election, reported that in-person voting during which voters and election officials respected masking and personal distance rules had been safe.[16]

. . . THE OTHER PUBLIC HEALTH ISSUES DID NOT STAND STILL

The COVID-19 pandemic may have diverted attention from other, still acute public health issues.

The opioid and HIV epidemics exemplify such issues. Alpren et al. described the control of an outbreak of HIV infection among people who inject drugs during 2015 to 2018 in two cities in northeastern Massachusetts, which resulted in a significant decline in new HIV diagnoses, but also observed that opioid use was fueling HIV transmission in Massachusetts and likely in other urban settings.[17] Cicero et al. also reported that polysubstance use needed to be taken into consideration to effectively meet the treatment, prevention, and policymaking challenges of the opioid epidemic.[18]

Another significant area of public health in which the pandemic exacerbated problems is workplace health and safety. The 50th anniversary of the passing of the Occupational Safety and Health Act coincided with the refusal of the Trump administration to issue ready-to-be-implemented standards for prevention of infectious diseases in the workplace (https://am.ajph.link/POD_May2020). Two of our authors argued that to eliminate work injuries and illnesses, we must remake and modernize the Occupational Safety and Health Administration and restructure the relationships of employers and workers with the agency and each other.[19]

Last year, an article in the journal proposed that there can be a "public health of pleasure."[20] One article proposed the use of pornography to discuss sexuality with adolescents.[21]

Although how the epidemic of vaping has been affected by COVID-19 is not yet clear, the US Food and Drug Administration (FDA) released guidance in 2020 that would regulate the industry. We invited comments from industry- and non–industry-related researchers about an article from the director of the FDA Center for Tobacco Products, Mitch Zeller.[22] The set of articles illuminated how the FDA had developed a strategy to navigate between fueling the epidemic of nicotine addiction in youths and denying a potentially effective means of risk reduction to cigarette smokers. A meta-analysis by Wang et al., showing that e-cigarettes used as consumer products are not associated with increased smoking cessation but that free e-cigarettes provided as a clinical intervention are, contributes support to the FDA strategy.[23]

Finally, Norris et al. described the evolution of abortion access in Ohio between 2010 and 2018,[24] an issue that has been exacerbated by the imperviousness of the previous administration to the anxiety of pregnant women infected by COVID-19.

WHAT'S COMING

Articles in future issues will include work we have commissioned or spontaneously received about strategies for constructing just foundations for public health. The subjects of these articles will include, for example, vaccine hesitancy and roll out, the needs of disadvantaged and marginalized communities, environmental justice, and infrastructure. In addition, we recently invited articles describing the damage that the "fascist threat" has already caused to health in recent years and the damage that it could potentially cause.[25] Check out the calls for papers.

It is probably accurate to predict (and to hope) that substantial changes will occur in public health financing, policy, and practice in the next several years. AJPH

CORRESPONDENCE

Correspondence should be sent to Alfredo Morabia, MD, PhD, Barry Commoner Center for Health and the Environment, Queens College, CUNY, 65-30 Kissena Blvd, Flushing, NY 11367 (e-mail: amorabia@qc.cuny.edu). Reprints can be ordered at http://www.ajph.org by clicking the "Reprints" link.

PUBLICATION INFORMATION

Full Citation: Morabia A. 2020 in *AJPH*: a review and thank you to our authors. *Am J Public Health*. 2021;111(6):e1–e14.

Acceptance Date: March 18, 2021.

DOI: https://doi.org/10.2105/AJPH.2021.306298

CONFLICTS OF INTEREST

The author has no conflicts of interest.

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Appropriate Use of the Asian American Demographic Category in Health Disparities Research

Alice Guan, MPH, and Arnab Mukherjea, DrPH, MPH

ABOUT THE AUTHORS

Alice Guan is a PhD student with the Department of Epidemiology & Biostatistics, University of California, San Francisco. Arnab Mukherjea is an Associate Professor and Incoming Chair of the Department of Public Health, California State University, East Bay.

Yi recently advocated for disaggregating data among Asian Americans and provided actionable recommendations researchers should take to equitably improve the health of this population.[1] Specifically, Yi suggested that researchers conduct subgroup analyses and provide a context for Asian American samples in their methods. In 2000, *AJPH* led initial calls for data disaggregation among Asian Americans and Pacific Islanders,[2] which have been echoed continuously by scholars and practitioners for the past two decades.[3–5] Such practices are standard in the United Kingdom, although calls for additional granularity have been put forth.[6]

Following recommendations for subgroup representation and concomitant action steps for accurate depictions of populations studied, we sought to assess the extent to which the existing body of scientific literature focusing on Asian Americans adequately captures disparities at the subgroup level. We conducted a search of PubMed for articles that included the term "Asian American" (or referenced Asians in the United States) in the title up to October 2020. We reviewed these articles and coded them with respect to whether data were aggregated or specific subgroups were delineated.

Our search yielded 1117 articles; 312 were excluded because they were not empirical studies, they were duplicates, or they were not peer reviewed (e.g., conference proceedings). Overall, 22.7% of the articles aggregated data, and the remainder delineated at least one subgroup. Of 619 articles that articulated specific subgroups, 4.5% did not include any of the largest three populations (Chinese, Asian Indian or South Asian, Filipino); 27.2%, 32.9%, and 35.4% of the articles included one, two, and three of those groups, respectively.

The landscape of literature on Asian American health provides convincing evidence for the relevance of Yi's article. Currently, there is no conventional standard for use of the term Asian American. As Yi and others have documented, this may mask inequalities experienced by Asian American subgroups. Especially in light of understanding inequities related to COVID-19,[7] an accurate characterization of Asian American disparities is desperately needed. Specifically, research focused on a singular community should include the featured racial (e.g., "Chinese") or regional (e.g., "South Asian") subgroup in the title or abstract. In investigations of multiple subgroups, the term Asian American (or a similarly broad identifier) should be used only when the study populations comprise the majority of Asian Americans in the focal geography; otherwise, titles should explicate the specific subgroups investigated.

In summary, we call for health researchers, practitioners, and policymakers to not overgeneralize the study of Asian American health issues but,

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rather, to be precise when investigating health indicators among this population's diverse communities. AJPH

CORRESPONDENCE

Correspondence should be sent to Arnab Mukherjea, Department of Health Sciences, California State University, East Bay, Student & Faculty Support Center 502, 25800 Carlos Bee Blvd, Hayward, CA 94542 (e-mail: arnab.mukherjea@csueastbay.edu). Reprints can be ordered at http://www.ajph.org by clicking the "Reprints" link.

PUBLICATION INFORMATION

Full Citation: Guan A, Mukherjea A. Appropriate use of the Asian American demographic category in health disparities research. *Am J Public Health*. 2021;111(6):e15–e16.

Acceptance Date: March 1, 2021.

DOI: https://doi.org/10.2105/AJPH.2021.306266

CONTRIBUTORS

The authors contributed equally to study conceptualization, research design, data collection and analysis, and interpretation and contextualization of findings.

ACKNOWLEDGMENTS

We acknowledge the Asian American Research Center on Health for supporting networking and mentorship efforts within a broader pipeline strategy of increasing Asian American representation in public health research and practice.

CONFLICTS OF INTEREST

The authors have no conflicts of interest to declare.

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EDITOR'S NOTE

No response from Yi is forthcoming.