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## SEARCH STRATEGY

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| S1 | American Journal of Public Health | Ebook Central, Public Health Database, Publicly Available Content Database | 595123* |

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# Reporting Conflicts of Interest

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## ABSTRACT (ENGLISH)

In their "Conflicts of Interest" statement, Wodak and Mendelsohn note that they are board members of the Australian Tobacco Harm Reduction Association (ATHRA), which they describe as "a health-promotion charity,"1 although it appears to have no membership beyond its three board members.2 They refer to funding from "small Australian vape businesses" but specify neither the businesses nor the amounts.1 They do not note that ATHRA has received funding from the UK-based Knowledge Action Change (KAC) organization, in whose events they have both participated. "4 The FSFW has also been criticized by the World Health Organization (WHO), which has referred to "a number of clear conflicts of interest involved with a tobacco company funding a purported health foundation"5 and has advised that "WHO will not partner with the Foundation. "9 We believe that Wodak and Mendelsohn should have declared a conflict of interest in relation to KAC as a tobacco industry-funded organization and that their comment should be amended to include this. /fIPH CORRESPONDENCE Correspondence should be sent to Emeritus Professor Mike Daube, PO Box 834, Western Australia 6904(e-mail: m.daube@curtin.edu.au).

## FULL TEXT

In their "Conflicts of Interest" statement, Wodak and Mendelsohn note that they are board members of the Australian Tobacco Harm Reduction Association (ATHRA), which they describe as "a health-promotion charity,"1 although it appears to have no membership beyond its three board members.2

They refer to funding from "small Australian vape businesses" but specify neither the businesses nor the amounts.1 They do not note that ATHRA has received funding from the UK-based Knowledge Action Change (KAC) organization, in whose events they have both participated. KAC has received substantial funding from the Foundation for a Smoke-Free World (FSFW). In response to a concern we have raised about a similar lack of acknowledgment of this funding in another journal, Mendelsohn responded only that, "Knowledge Action Change is a private organisation that made a one-off unconditional donation."3(p423)

KAC has received very substantial funding from the FSFW, which is solely funded by Philip Morris International and has been described as "essentially operating as a front group for Philip Morris International's (PMI) interests."4 The FSFW has also been criticized by the World Health Organization (WHO), which has referred to "a number of clear conflicts of interest involved with a tobacco company funding a purported health foundation"5 and has advised that "WHO will not partner with the Foundation. Governments should not partner with the Foundation and the public health community should follow this lead."5

Even a comment coauthored by Erkkila and Yach (both from the FSFW) in the same issue of AJPH notes that the FSFW receives $80 million annually from PMI.6 The FSFW's tax return for 2018 shows more than $1 million allocated to KAC.7 The return for 2019 shows more than $7 million allocated to KAC.8 The AJPH editorial policies are clear on the importance of full declaration of conflicts of interest, noting, "If there is doubt about whether a circumstance represents a conflict, it should be disclosed."9

We believe that Wodak and Mendelsohn should have declared a conflict of interest in relation to KAC as a tobacco industry-funded organization and that their comment should be amended to include this. /fIPH

CORRESPONDENCE

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CONTRIBUTORS

The authors contributed equally to this letter to the editor.

CONFLICTS OF INTEREST

The authors have no conflicts of interest to declare.

**References**

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# Individual Risk-Based Assessment for Blood Donation in the United States-Is It Time?

Bruhn, Roberta L, PhD, MS [1] [1] Epidemiology Core, Vitalant Research Institute, and the Department of Laboratory Medicine, University of California, San Francisco

ProQuest document link

## ABSTRACT (ENGLISH)

The COVID-19 pandemic has focused attention on two issues that have been of ongoing discussion and public health concern in the United States: continued declines in blood product utilization coupled with even larger declines in blood donation collection. These issues have resulted in a tenuous situation of a product with limited supply and limited shelf life. The pandemic has highlighted the effort required to maintain an already delicate balance of blood collection and supply and exacerbated the ramifications of such a limited supply by causing an additional, immediate, and significant reduction in the number of voluntary blood donations across the United States because planned blood drives following shelter-in-place orders were canceled. In April 2020, the US Food and Drug Administration (FDA) issued recommendations that included a reduction of the then deferral period for men who have sex with men (MSM) from 12 months to 3 months from last sexual contact with a man.1 These changes were long in the making and were issued following a dramatic decrease in blood product availability following the COVID19-related significant and abrupt drop in blood donation. Although the reduction in the MSM deferral period was not the only change made to donor deferral criteria, reductions in time-associated deferrals for travel-associated malaria, Creutzfeldt-Jakob disease, and variant Creutzfeldt-Jakob disease would not be expected to have similar import; removing the MSM time-based deferral is estimated to provide upward of a half million donations per year. Yet, following the issuance of this recommendation, a response to the call for blood donors who have recovered from COVID-19 (convalescent plasma) still resulted in some MSM being turned away from donation. Changes to the blood collection and testing infrastructure must be made timely and adopted uniformly to ensure that the safety of blood recipients remains the priority, while balancing the residual risk of any donated blood product with the availability of those products.

## FULL TEXT

The COVID-19 pandemic has focused attention on two issues that have been of ongoing discussion and public health concern in the United States: continued declines in blood product utilization coupled with even larger declines in blood donation collection. These issues have resulted in a tenuous situation of a product with limited supply and limited shelf life. The pandemic has highlighted the effort required to maintain an already delicate balance of blood collection and supply and exacerbated the ramifications of such a limited supply by causing an additional, immediate, and significant reduction in the number of voluntary blood donations across the United States because planned blood drives following shelterin-place orders were canceled.

In April 2020, the US Food and Drug Administration (FDA) issued recommendations that included a reduction of the then deferral period for men who have sex with men (MSM) from 12 months to 3 months from last sexual contact with a man.1 These changes were long in the making and were issued following a dramatic decrease in blood product availability following the COVID19-related significant and abrupt drop in blood donation. Although the reduction in the MSM deferral period was not the only change made to donor deferral criteria, reductions in time-associated deferrals for travel-associated malaria, Creutzfeldt-Jakob disease, and variant Creutzfeldt-Jakob disease would not be expected to have similar import; removing the MSM time-based deferral is estimated to provide upward of a half million donations per year. Yet, following the issuance of this recommendation, a response to the call for blood donors who have recovered from COVID-19 (convalescent plasma) still resulted in some MSM being turned away from donation. Changes to the blood collection and testing infrastructure must be made timely and adopted uniformly to ensure that the safety of blood recipients remains the priority, while balancing the residual risk of any donated blood product with the availability of those products.

In "Blood Donation and COVID-19: Reconsidering the 3-Month Deferral Policy for Gay, Bisexual, Transgender, and Other Men Who Have Sex With Men," Park et al. (p. 247) present their argument for eliminating time-based deferral and implementing risk-based deferral for blood donation in the United States to strengthen the resilience ofthe public health reliance on the voluntary blood donation system. The authors present the rationale that the reduction to three months deferral rather than elimination ofthe deferral entirely ignores scientifically rigorous studies indicating that the blood screening assays currently in use have a documented HIV-positive detection period of, most conservatively, 7 to 10 days, thereby reducing the risk of transfusiontransmitted HIV infection to the transfusion recipient to significantly less than that of more common, noninfectious disease complications from transfusion, such as those caused by circulatory overload.2 5

The authors' platform includes immediately implementing a universal, selfreported, risk-based deferral questionnaire that affords the opportunity for blood collection organizations to bring in new and subsequently return blood donors, alleviating some ofthe stress on the collection side by increasing the eligible blood donor population. Blood donation deferral should be based on individual risk assessment, regardless of gender identity or sexual orientation. Park et al. highlight that conflicting blood donation guidelines remain in place, as currently the donor health questionnaire permits a donor to self-identify gender and asks for their knowledge of sexual partner habits. They point to studies demonstrating donor lack of understanding ofthe donor health questionnaire, admission of not fully reading questions before answering them, and concealing behavior to donate blood, regardless of risk level. Where individual risk-based blood donor deferral programs have been established, studies have shown no increase in HIV incidence in blood donations. The authors put forward these studies as documented evidence of the effectiveness ofthe individual risk-based assessment.

However, to be effective, the riskbased assessment must be written in language that is not confusing to a donor and must be branched according to risk stratification to avoid undue donor time burden at the collection point. Perhaps donors at higher risk could be counseled and deferred for a specified period and low-risk donors would proceed to donation, but whatever the process would ultimately be, the donor health questionnaire in the United States is designed to be selfadministered, with a few additional probing questions for travel outside the United States and medication use, and there are potential issues with stigma and failure to disclose behaviors when donors are questioned face-to-face regarding behaviors.

How then can the donor health questionnaire and the subsequent interview process be streamlined so they lead to better disclosure and reduced risk for the transfusion recipient? The risk-based questionnaire with a branching design for risk stratification definitely has merit, and in fact a study sponsored by the FDA that has been designed to collect information to support the development of such a questionnaire is being piloted,6 but continued monitoring, rapid review of results, and open public discourse that includes all stakeholders is key. The authors present a rational argument that deserves thoughtful consideration and continued discussion.

CORRESPONDENCE

Correspondence should be sent to Roberta L. Bruhn, Epidemiology Core Codirector, Vitalant Research Institute, 270 Masonic Ave., San Francisco, CA (e-mail: rbruhn@vitalant.org). Reprints can be ordered at http://www.ajph.org by clicking the "Reprints" link.

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CONFLICTS OF INTEREST

The author has no conflicts of interest to declare.

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## DETAILS

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# Violent Victimization Among Lesbian, Gay, and Bisexual Populations in the United States: Findings From the National Crime Victimization Survey, 2017-2018

Bender, Annah K, PhD, MSW; Lauritsen, Janet L, PhD

ProQuest document link

## ABSTRACT (ENGLISH)

Objectives. To estimate US nonlethal violent victimization rates for lesbian, gay, and bisexual (LGB) males and females aged 16 years and older and to compare disparities among LGB and straight males and females, controlling for other correlates of victimization. Methods. We used data from the 2017 and 2018 National Crime Victimization Survey (NCVS) to provide nationally representative rates of various forms of violent victimization for self-identified LGB and straight persons. Multivariable models assessed the risk for violence associated with LGB status. Results. Total violence rates were 2 to 9 times higher among LGB persons compared with heterosexuals. For some forms of violence (e.g., rape and sexual assault, violence with serious injuries, and multiple offender violence) there were notably high disparities between bisexuals and heterosexuals. With adjustment for covariates, LGB orientation was associated with odds ratios nearly 2 to 4 times those of heterosexuals. Conclusions. This is one of the first known uses of NCVS data to estimate LGB victimization, revealing substantially higher rates of violence directed at LGB individuals. Public Health Implications. Sexual orientation and gender identity questions in federal surveys such as the NCVS enable monitoring of violent victimization rates and should continue. Collecting these data can help researchers understand victimization risk and guide appropriate resources toward victim services, especially important given the high violent crime levels experienced by LGB individuals. (AmJ Public Health. 2021;111:318-326. https://doi.org/10.2105/AJPH.2020.306017)

## FULL TEXT

### Headnote

Objectives. To estimate US nonlethal violent victimization rates for lesbian, gay, and bisexual (LGB) males and females aged 16 years and older and to compare disparities among LGB and straight males and females, controlling for other correlates of victimization.

Methods. We used data from the 2017 and 2018 National Crime Victimization Survey (NCVS) to provide nationally representative rates of various forms of violent victimization for self-identified LGB and straight persons. Multivariable models assessed the risk for violence associated with LGB status.

Results. Total violence rates were 2 to 9 times higher among LGB persons compared with heterosexuals. For some forms of violence (e.g., rape and sexual assault, violence with serious injuries, and multiple offender violence) there were notably high disparities between bisexuals and heterosexuals. With adjustment for covariates, LGB orientation was associated with odds ratios nearly 2 to 4 times those of heterosexuals.

Conclusions. This is one of the first known uses of NCVS data to estimate LGB victimization, revealing substantially higher rates of violence directed at LGB individuals.

Public Health Implications. Sexual orientation and gender identity questions in federal surveys such as the NCVS enable monitoring of violent victimization rates and should continue. Collecting these data can help researchers understand victimization risk and guide appropriate resources toward victim services, especially important given the high violent crime levels experienced by LGB individuals. (AmJ Public Health. 2021;111:318-326. https://doi.org/10.2105/AJPH.2020.306017)

In recent years, scholars have recognized violence and crime against sexual- and gender-minority groups as a major public health priority in the United States.1 These diverse groups, comprising varied sexual orientations (e.g., lesbian, gay, bi- or pansexual, and others) and gender identities (e.g., transgender, nonbinary, gender variant, queer, and others), represent as much as 5.4% and 0.3% of the US population, respectively.2,3 Unfortunately, both groups appear to be at high risk of violent victimization relative to the general population. Communitybased samples suggest that prevalence of sexual assault,4 intimate partner violence,5 property crime,6 and hate crimes6,7 among lesbian, gay, bisexual, and transgender (LGBT) individuals are nearly double those of heterosexuals. Within lesbian, gay, and bisexual (LGB) populations specifically, lesbian and bisexual women are more likely than gay and bisexual men to report lifetime sexual assault, including childhood and intimate partner sexual assault.8

For purposes of monitoring and improving our understanding of the victimization risk of LGBT persons, existing research faces several challenges. Many studies are based on community-based samples, or samples of youths or college students, leaving the generalizability of the findings to the US population uncertain. In addition, the focus of much past research is limited to certain forms of violence, such as sexual assault, intimate partner violence,9 and hate crimes,6,7 while less is known about how often other forms of violence are experienced by LGBT individuals. A notable exception involves a meta-analysis of 386 studies published between 1992 and 2009 that revealed high rates of many types of victimization among LGB persons versus heterosexuals, especially discrimination (effect size [ES]p = 0.41) and verbal harassment (ESp = 0.55).10 Yet many of the studies included were drawn from relatively small community-based samples, and, importantly, nationally representative data covering the years since the 2015 Supreme Court ruling extending marriage rights to LGBT couples in all 50 states are rare.

Recently, the National Crime Victimization Survey (NCVS), the nation's primary source of information on nonfatal violent victimization, began asking questions about respondents' sexual orientation and gender identity (SOGI),11 which were added to the survey in July 2016. Although other federal statistical surveys, such as the Behavioral Risk

Factor Surveillance System (BRFSS) and National Intimate Partner and Sexual Violence Survey (NISVS) also include SOGI questions, only the NCVS contains detailed measures of multiple types of violent victimization, enabling estimations of victimization rates among LGB persons aged 16 years and older and comparisons of their risks to those of heterosexuals. While the NCVS data collection also includes gender identity questions, the sample size for the transgender population is insufficient at this time for producing reliable victimization rates.

This article describes nonlethal violent victimization rates for LGB populations and compares them with the rates for "straight" populations, hereafter referred to as heterosexual. The NCVS data used here were collected in 2017 and 2018 and provide one of the first known uses of these data to report estimates of nonfatal crime victimization against the LGB population, stratified by sex (as reported by the household respondent before all interviews began) and sexual orientation.

## METHODS

The NCVS is an ongoing survey conducted by the Census Bureau for the Bureau of Justice Statistics, with a sample designed to be representative of persons aged 12 years and older living in households in the United States. The data enable estimation of the rate of different types of nonfatal violence over time. SOGI questions are administered to persons aged 16 years and older. NCVS data for 2017 and 2018 were made publically available in March 2020 through the National Archive of Criminal Justice Data.12

The NCVS collects self-report data about individuals' experiences with violence using a 6-month recall period designed to minimize errors associated with determining when an event occurred. Unlike many surveys of LGBT experiences, the data do not include lifetime estimates of victimization, instead focusing on recent occurrences. Therefore, the rates shown here reflect violence reported in 2017 and 2018. Our analysis was based on interviews with persons aged 16 years and older, resulting in a total unweighted sample size of 463 674 interviews. This large sample size is necessary for producing statistically reliable rates, particularly among smaller population subgroups and subcategories of violence. Response rates for the NCVS are high: in 2017, 76% of sampled NCVS households completed an interview, with a response rate among persons in these households of 84%.9 In 2018, the comparable household and person response rates were 73% and 82%, respectively.13

Victimization is measured through a series of cues and common-language questions, and numerous characteristics of incidents are used to code the event into crime types following the interview. Interviews are conducted in English and Spanish, as well as other languages under some circumstances. The NCVS data also include methodological information about each interview that previous research has shown affects survey reporting,14 such as the bounding of interviews with information from a previous interview, the type of interview (e.g., in-person, telephone), and the number of previous interviews. We took these conditions into account in our multivariable analysis.

Our definitions of violent crime paralleled those used by the Bureau of Justice Statistics in their annual reports on criminal victimization.13,14 Violent crime includes attempted or completed rape and sexual assault, robbery, aggravated assault, and simple assault. Aggravated assault includes attacks or attempted attacks with a weapon, and attacks without a weapon that result in serious bodily injury (e.g., broken bones, internal injuries, loss of consciousness). Simple assault includes attacks or attempted attacks without a weapon that result in minor injury (e.g., bruises) or no injury (e.g., attempts without physical contact). Serious violent crime rates include all violence other than simple assaults, and physically injurious violence is events resulting in physical injuries to the victim.

Victim-offender relationship information is also gathered for victimization events. Incidents in which the victim reported no previous relationship with the offender are coded as stranger violence, while those involving a spouse, ex-spouse, or current or former boyfriend or girlfriend are coded as intimate partner violence. Victimization involving other persons known to the victim (such as friends, acquaintances, and family members) are coded as violence involving other known persons. Rates of multiple offender victimization are also estimated. In incidents involving multiple offenders, the victim-offender relationship is coded according to the most familiar relationship to the victim.

Sexual orientation (and gender identity) items appear at the end of the base screening questionnaire (see Truman etal.,11 for further details). The item asks "Which of the following best represents how you think of yourself?" "[Lesbian or] gay," "Straight, that is, not [lesbian or] gay," "Bisexual," "Something else," or "I don't know the answer."

The phrase "lesbian or" is read to the respondent only if they are designated as female on the household roster. We coded persons as lesbian, gay, or bisexual if they responded accordingly, and as heterosexual if they respond "straight, that is, not [lesbian or] gay." Persons selecting other options or refusing to answer the question were excluded from the analysis. Such cases constituted 9.5% of the total weighted NCVS sample, with refusals constituting the majority of these responses (78.3%).

Victimization rates presented in this article were calculated by using the methodology followed by the Bureau of Justice Statistics.13,14 Rates represent the number of victimizations that occurred during the recall period among persons in each group, divided by the number of persons in each group and multiplied by 1000. Sample weights and design features were used to take into account the multistage complex sample design, which involves stratification (e.g., by location) and clustering (e.g., household and repeated interviews), as well as nonresponse. We generated the weighted sample-based rates by using SPSS version 26 (IBM, Somers, NY), and we estimated standard errors and confidence intervals by using generalized variance function parameters.15 Preliminary analysis determined that it was necessary to pool the NCVS 2017 and 2018 data to provide reliable estimates (with coefficients of variation less than 50%) of the different types of violent victimization among the subgroups.

To assess the extent to which differences in violent victimization between LGB and heterosexual males and females were associated with subgroup differences in sociodemographic characteristics known to be correlated with risk, we estimated survey-weighted logistic regression models in which the outcome consists of whether the respondent was violently victimized (1 =yes; 0 = no) during the recall period. These models included NCVS measures of the respondents' age, race, ethnicity, sex, and household income, as well as general information about their residential areas (i.e., metropolitan city, surrounding areas, and nonmetropolitan areas). Even with the large pooled sample size, it was necessary to limit the multivariable logistic regression analysis to assessments of total violent victimization, and the subcategory of serious violent victimization to minimize model fitting restrictions associated with sample and cell sizes. We estimated the survey-weighted logistic regression models with Stata version 15 (StataCorp LP, College Station, TX) and also took into account the complex survey design, clustered interviews, and sample weights.

## RESULTS

Descriptive statistics for respondents by sexual orientation are provided in Table 1. When the data were weighted and cases with unknown LGB status were excluded, estimates of the gay or lesbian, bisexual, and heterosexual populations were 1.4%, 0.7%, and 97.9%, respectively. The NCVS estimates of the gay or lesbian and bisexual populations were slightly lower than those found in the National Health Interview Survey (1.6% gay or lesbian, and 0.8% bisexual), and the proportion of adults who identified as bisexual were slightly higher in the National Survey on Drug Use and Health and in the National Survey of Family Growth.11 However, the differences in the estimates across these data sources were not large in magnitude and provide reasonable confidence in the external validity of the NCVS for purposes of estimating victimization rates.

The descriptive statistics revealed notable sociodemographic differences across the populations. Those who identified as bisexual were more likely to be younger, female, and in the lowest income category than were others. Persons who identified as gay or lesbian were more likely to report income in the $75 000 and above category than were bisexual and heterosexual persons. Heterosexuals were more likely to be aged 55 years and older, and less likely to live in the central cities of metropolitan areas than were others. We observed no significant differences in racial and ethnic composition across the 3 groups.

The 2017-2018 violent victimization rates for male and female LGB and heterosexual populations are shown In Table 2. Among males, total violent victimization rates were significantly higher among gay (38.6 per 1000; 95% confidence interval [CI] = 26.3, 50.9) and bisexual (76.7 per 1000; 95% CI = 43.6, 109.8) men compared with heterosexual men (19.4 per 1000; 95% CI = 17.4, 21.4). We also observed significant differences in the category of serious violent crime in which the rates among gay (19.2 per 1000; 95% CI = 10.9, 27.5) and bisexual (41.6 per 1000; 95% CI = 17.7, 65.5) males were higher than those of heterosexual males (6.8 per 1000; 95% CI = 5.8, 7.8). Although gay and bisexual males also exhibited higher rates of subcategories of violent victimization, only some of the differences in these rates were statistically significant because of the comparatively small sample sizes of the male and female LGB population and the lower frequency of the subcategories of violence. For example, rates of robbery among gay and bisexual males were between 2.8 and 5.6 times higher, respectively, than those of heterosexual males, yet these differences were not statistically significant at a P value of less than .05. The NCVS data revealed statistically significant differences in violence committed by other known persons (i.e., not strangers or intimate partners) in which the rates were higher among gay (17.9 per 1000; 95% CI = 9.9,25.8) and bisexual (40.3 per 1000; 95% CI = 16.8, 63.7) males compared with heterosexual males (5.7 per 1000; 95% CI = 4.8, 6.6). Comparisons of rates for lesbian, bisexual, and heterosexual females indicated that total violence rates were significantly higher among lesbians (78.4 per 1000; 95% CI = 57.9, 98.9) compared with heterosexual women (21.0 per 1000; 95% CI = 18.9, 23.1), and were notably the highest among bisexual females (189.1 per 1000; 95% CI = 155.0, 223.3). Bisexual females also experienced the highest rate of serious violent victimization (87.5 per 1000; 95% CI = 64.6, 110.4); however, differences in serious violence were not statistically significant between lesbian (9.6 per 1000; 95% CI = 3.3, 15.8) and heterosexual females (8.2 per 1000; 95% CI = 7.1, 9.3). Stranger violence rates were significantly higher among lesbian (48.9 per 1000; 95% CI = 33.2, 64.7) and bisexual females (87.5 per 1000; 95% CI = 64.6,110.4) compared with heterosexual females (5.5 per 1000; 95% CI = 4.7, 6.4). So, too, were violence rates involving multiple offenders, which was 1.9 per 1000 (95% CI = 1.5, 2.3) among heterosexual females, but 17.0 (95% CI = 8.3. 25.6) and 45.5 (95% CI = 29.6, 61.5) per 1000 among lesbian and bisexual females, respectively.

For each type of violence shown here, bisexual women were found to have significantly higher rates of victimization than heterosexual females, and also higher rates than lesbian females for all crime types except simple assault. Because the bisexual population is significantly younger and of lower income than the other populations, it is necessary to determine the extent to which these differences persist when such correlates are taken into account.16

The multivariable model predicting total violent victimization showed that the differences between heterosexual and LGB persons were statistically significant after we controlled for age, race/ ethnicity, household income, residential area type, interview conditions, and missing data on the SOGI questions (Table 3). Compared with heterosexual females, odds of experiencing a violent victimization in 2017 or 2018 were 2.0 times higher among lesbian females (95% CI = 1.34, 2.99) and 3.61 times higher among bisexual females (95% CI = 2.78,4.68). The patterns in the odds ratios (ORs) among males were generally similar to those among females. Odds of violent victimization were 1.9 times higher among gay males (95% CI = 1.34, 2.69) and 2.66 times higher among bisexual males (95% CI = 1.65, 4.30), with heterosexual males and females exhibiting similar odds of a violent victimization. Although the ORs for violent victimization were higher among the LGB population, the 95% CIs show that differences among bisexual, gay, and lesbian persons were not statistically significant when these additional factors were taken into account. The likelihood ratio (LR) test showed that inclusion of the male and female sexual orientation in the analysis significantly improved model fit (LR test statistic = 75.5; P <.001).

Odds of serious violent victimization were 4.64 times higher for bisexual females (95% CI = 3.32, 6.51) compared with heterosexual females, and the difference between lesbian and heterosexual females was not statistically significant once the correlates were included. Odds of serious violence were 2.41 times higher among gay males (95% CI = 1.58, 3.65) and 3.84 times higher among bisexual males (95% CI = 2.10, 7.03), with heterosexual males and females exhibiting similar likelihoods of serious violence. Similar to total violence, ORs for bisexual, gay, and lesbian persons did not differ significantly from one another in the analysis of serious violence, and model fit was significantly improved when sexual orientation was included (LR test statistic = 63.7; P<.001).

We conducted supplementary analyses to consider interactions between race/ethnicity and sexual orientation, but the results were found to be statistically unreliable given the further sample restrictions.

## DISCUSSION

Our results indicate that males and females identifying as LGB experienced violent victimization in 2017 to 2018 at significantly higher rates than heterosexual males and females. Rates of serious violence were significantly higher against gay and bisexual males versus heterosexual males, and higher for bisexual females compared with heterosexual females. The multivariable analysis showed that differences in total violence between LGB and heterosexual males and females remained significant when sociodemographic correlates of victimization were taken into account. Similar patterns emerged when we restricted the outcome to serious violence; however, in this analysis, the OR for lesbian females was not significantly different from that of heterosexual females.

Many of these findings beg further inquiry. For example, some of our findings concerning specific forms of violence, such as stranger violence, showed large differences between heterosexual females compared with lesbian and bisexual females whose rates were more than 8 and 15 times higher, respectively. Generally speaking, stranger violence risk is hypothesized to be associated with residential proximity to violent crime areas and variations in routine activities (e.g., work, leisure) that increase exposure to potential offenders.17 The NCVS data do not provide detailed items that would permit assessment of the role of each of these factors. However, it is reasonable to hypothesize that some of the differences in stranger violence that we found would persist even if such factors were taken into account because of the high levels of heterosexist violence (e.g., verbal harassment, being followed) found in previous studies of LGB individuals.10 As future years of NCVS data become available, it will be possible to assess additional features of stranger violence to learn more about the contexts of such incidents.

Furthermore, community and convenience samples of LGB victimization have consistently revealed higher reported rates of violence across the life course, including bullying18 and dating violence19 in adolescence, sexual assault5 and intimate partnerviolence in adulthood,4,9 sexual orientation bias or hate crimes,6,7,20 and the potential for increased risk of elder abuse.21 Additional years of data will enable a determination ofwhetherthese patterns hold true in a diverse, nationally representative population. More data can illuminate how LGB persons may be differentially impacted by violent victimization in different phases of the life span, as early life adversities, reported at consistently higher rates among LGB individuals compared with heterosexuals,22 are associated with increased risk for various types of victimization in adulthood.23

## Limitations

Our study represents the first report, to our knowledge, of LGB victimization for years 2017 to 2018 using NCVS data; however, it is not without limitations. One restraint was the limited statistical power to estimate victimization rates for transgender individuals even with a large pooled sample. Although the NCVS includes gender identity questions, we made the decision to focus on sexual orientation only rather than conflating sexual orientation with gender identity, in keeping with expert recommendations by scholars of sexual and gender minority populations.24 The sample size of LGB groups would not permit examination of potential intersectional differences according to race, ethnicity, and sexual orientation. Because the NCVS relies on a household-based sample, interviews were not conducted with persons who were homeless and those in institutional settings such as prisons or jails or nursing homes, and it is unknown how the exclusion of these persons might affect victimization estimates for either LGB or straight persons.

Although the NCVS data permit nationally representative estimates of subgroup rates for many types of violent victimization and do so using a consistent methodology over time, these data are subject to concerns that affect all survey data, such as recall error and underreporting. Potential sources of error in the NCVS have been studied extensively25; however, we are unaware of any research that has examined whether survey reporting error in victimization data varies across LGB and heterosexual male and female samples. Others have noted that the NCVS produces estimates of rape, sexual assault, and intimate partner violence that are lower than those found in other surveys that use different methodological approaches.26 How this might influence the disparities that we reported for these types of victimization is unknown. To our knowledge, the possibility that underreporting of these forms of violence may vary across male and female LGB and heterosexual groups has not been assessed in the NCVS.

## Conclusions

In contrast with other probability-based surveys such as the BRFSS and the NISVS, the NCVS permits the examination of multiple forms of violent victimization with detailed measures that more fully estimate the burden of violence among the LGB population. Our findings reveal that LGB persons in the United States experienced significantly higher rates of total violence than heterosexuals in 2017 to 2018, and that, within the LGB population, bisexual women experienced violence at the highest rates. In multivariable models, greater odds of violent victimization were associated with LGB identity, younger age, lower household income, and metropolitan area city residence. While additional research is indicated, what our findings most underscore is the urgent need for multisector violence prevention programs; victim services that are affirming, inclusive, and culturally tailored to various LGB groups; and widespread social norms changes to eliminate discrimination, prejudice, and violence on the basis of sexual orientation.

Public Health Implications

Nationally representative surveys with sufficient sample sizes to estimate risk among SOGI populations are necessary to further investigate and continue monitoring the burden of violent victimization and need for victim support among these groups. As of this writing, the future of SOGI questions among those aged 16 and 17 years is in doubt, and multiple researchers have submitted a petition to the Bureau of Justice Statistics advocating continued inclusion of questions to ascertain sexual orientation and gender identity for youths27- an age group, which, among LGB individuals, reports high rates of violent victimization, including assaults and school bullying,28 compared with heterosexual youths. Our findings emphasize the ongoing need for SOGI questions in the NCVS to estimate victimization risk in all LGB populations, including those younger than 18 years. Â1PU

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A. K. Bender conceptualized the study.J. L. Lauritsen analyzed the data. Both authors wrote the article.

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# Optimizing Access to Preventive Reproductive Health Care: Meeting Patients Where They Are At

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## ABSTRACT (ENGLISH)

Today, we hear ourselves repeating this wise attending's words while working in our hospital's family planning clinic in response to a question we sometimes hear from learners: "Why do you think she waited so long to have her abortion?" Patients seeking abortion care and those pursuing preventive reproductive health care describe many of the same psychosocial, interpersonal, and structural barriers to obtaining care.1,2 Notable psychosocial challenges to obtaining care include medical mistrust and not prioritizing one's personal health amid competing demands; interpersonal barriers include parenting and caregiving for adult family members; and structural barriers include instability around insurance, transportation, and childcare.1 Although many barriers to seeking abortion and preventive reproductive health care coincide, those seeking abortion care face additional challenges, including stigma and antiabortion legal restrictions. The Turnaway Study was a landmark five-year longitudinal study that followed individuals who presented for abortion just before or after the gestational age limits at 30 abortion clinics across the United States.2 Participants who presented after the clinics' gestational age limits and were unable to obtain a desired abortion were more likely to experience economic hardship and report being in fair or poor health years later, compared with those who presented in time to obtain their desired abortion.2,3 Furthermore, what is often called the "wellwoman visit," which we refer to as the "preventive reproductive health visit" in recognition that not all individuals assigned female at birth identify as women, is an important opportunity to provide health screening, counseling, immunizations, contraception, and preconception care to help address individual and population-level reproductive health disparities.

## FULL TEXT

How can someone show up two hours late for an appointment? Should I still see this patient?" I (J.C.) vividly remember asking this of my continuity clinic preceptor early in my intern year about a patient presenting for her annual gynecological visit. My preceptor was an experienced and skilled obstetrician-gynecologist who had worked in this public hospital on the West Side of Chicago, Illinois, for many years. "Julie," she said, "just think about all that it took for her to get here. She likely had to take a bus, a train, and then a bus again. Think of all the ways that could have gone wrong. All to get here today. This may be her only interaction with a provider for a while and an important opportunity to address her reproductive health needs. We have to meet her where she's at." Of the many lessons I learned in four years of obstetrics-gynecology residency, this was one of my most salient learning points, and I was grateful to have received it early in my career. Her comments helped mesnapoutofmynaiveté and appreciate my position of privilege compared with many of the patients I have the good fortune to care for.

### PREVENTIVE REPRODUCTIVE HEALTH CARE BARRIERS

Today, we hear ourselves repeating this wise attending's words while working in our hospital's family planning clinic in response to a question we sometimes hear from learners: "Why do you think she waited so long to have her abortion?" Patients seeking abortion care and those pursuing preventive reproductive health care describe many of the same psychosocial, interpersonal, and structural barriers to obtaining care.1,2 Notable psychosocial challenges to obtaining care include medical mistrust and not prioritizing one's personal health amid competing demands; interpersonal barriers include parenting and caregiving for adult family members; and structural barriers include instability around insurance, transportation, and childcare.1 Although many barriers to seeking abortion and preventive reproductive health care coincide, those seeking abortion care face additional challenges, including stigma and antiabortion legal restrictions.

Delays in accessing reproductive health care can have significant and devastating effects. The Turnaway Study was a landmark five-year longitudinal study that followed individuals who presented for abortion just before or after the gestational age limits at 30 abortion clinics across the United States.2 Participants who presented after the clinics' gestational age limits and were unable to obtain a desired abortion were more likely to experience economic hardship and report being in fair or poor health years later, compared with those who presented in time to obtain their desired abortion.2,3 Furthermore, what is often called the "wellwoman visit," which we refer to as the "preventive reproductive health visit" in recognition that not all individuals assigned female at birth identify as women, is an important opportunity to provide health screening, counseling, immunizations, contraception, and preconception care to help address individual and population-level reproductive health disparities.1

### INNOVATIVE APPROACHES TO OVERCOMING BARRIERS

Given the myriad interacting barriers individuals face in obtaining reproductive health care, innovative strategies to engage people in reproductive health care must prioritize meeting people where they are, figuratively and sometimes literally, to help them overcome their own context-specific barriers. One important component in these strategies is identifying and leveraging clinical opportunities for those who face substantial challenges when they interface with the health care system. A prime example of such a clinical opportunity is pregnancy because the vast majority of pregnant women seek medical care at some point in their pregnancy. Yee et al.4 identified prenatal visits and postpartum hospitalizations as encounters to implement a program to help low-income, largely minority women overcome barriers to engaging in follow-up postpartum care. These encounters were used as opportunities to address preventive health needs such as contraception, maternal health, mood, and transitions in care.4 The abortion visit also has been identified as a clinical point of contact with a substantial number of individuals who may lack a regular health care provider with whom to obtain routine preventive reproductive health care. Two studies found that people presenting for induced abortion had a lower prevalence of having a regular provider compared with the general reproductive-aged population.5,6 Other pregnancy-related encounters, such as emergency department visits for management of miscarriage or ectopic pregnancy, represent additional opportunities to connect with individuals who are otherwise disconnected from preventive reproductive health care.

In addition to identifying clinical opportunities to reach individuals who do not routinely engage in preventive reproductive health care, approaches are needed to improve access to and use of care. Patient navigation is a model historically used to link individuals from low-resource settings to cancer screening and follow-up care. Patient navigators are lay health workers without formal medical training who come from a local community and serve as a bridge between members of that community and health care services. More recently, patient navigation has been used in obstetric and abortion settings to support low-income and minority individuals in their pursuit of preventive reproductive health care.4,7 Yee et al.4 adapted the patient navigation model to the postpartum context, working with a patient navigator experienced in facilitating cancer screenings and treatments to translate these skills to assist patients in the postpartum period. To help patients overcome barriers to obtaining postpartum care, this patient navigator scheduled appointments, sent appointment reminders, provided psychosocial support, facilitated logistical and social work needs, and helped identify primary care medical homes for patients beyond the postpartum period. An evaluation of this postpartum patient navigation program found that patients in the program were significantly more likely to obtain care in the postpartum period compared with those who had not participated in the program.4 A similar model of patient navigation has been described linking individuals seeking abortion care to preventive reproductive and contraceptive care after the abortion visit.7

Beyond helping individuals overcome barriers to accessing preventive reproductive health care, innovative strategies have been developed to bring preventive reproductive health care to the individual. Haider et al.8 recognized that attendance was low at postpartum visits during which contraceptive counseling often occurs, but attendance by postpartum patients at well-baby visits was high. Accordingly, they implemented a program offering colocation of contraceptive services to mothers presenting for their young infants' well-baby visits. Although uptake of a colocated visit was slightly less than 20%, study participants viewed this concept positively, and those who attended a colocated visit were more likely to be using highly effective contraception at five months compared with control participants.8 Optimizing system-level interventions, such as offering colocated services, is one promising strategy to improving access to care. In addition, even though telemedicine is not entirely novel, recent practice changes in response to the coronavirus disease 2019 pandemic have brought this modality of care to the forefront. The expansion of telemedicine during the current pandemic has allowed many to access preventive reproductive health care, including contraceptive counseling, reproductive life planning, and pregnancy options counseling, in the convenience and privacy of their own phones.

Although these myriad opportunities and evidence-based interventions help individuals overcome barriers to engaging in preventive reproductive health care, limitations and persistent challenges must be acknowledged and addressed. Importantly, preventive reproductive health care offers many potential health benefits but remains a downstream intervention that cannot fully mitigate long-standing, underlying structural and environmental factors that negatively affect individuals' reproductive health and contribute to population-level reproductive health disparities. For example, innovative telemedicine interventions cannot reach those who are unable to afford regular phone service or who live in geographic areas that lack efficient high-speed Internet. Ultimately, state and federal policies and public health efforts must address these underlying structural barriers. Professional organizations must advocate for these essential changes, and health care professionals and researchers should continue to innovate solutions that address unmet reproductive health care needs. ,4jPH

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# Racial Disparities in Access to and Utilization of Jail- and Community-Based Mental Health Treatment in 8

# US Midwestern Jails in 2017

Hedden, Bethany Joy, MSW; Comartin, Erin, PhD, MSW; Hambrick, Nanci, MSW; Kubiak, Sheryl, PhD, MSW

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## ABSTRACT (ENGLISH)

Objectives. To examine the dual disproportionality that individuals with serious mental illness and people of color (P°C) occupy in the criminal-legal system. Methods. This study follows a cohort of 623 individuals who screened positive for mental health issues at booking in 8 Midwestern jails in 2017. We followed individuals through the jails' practices of jail-based mental health treatment, and we used Medicaid billing data to assess community-based behavioral health treatment engagement in the postyear period after jail release. The aim was to examine if an individual's race/ethnicity was associated with their access to jail- and community-based mental health treatment. Results. We did not find any racial disparities in jail-based treatment, although 3 community-based outcomes significantly differed. Compared with P°C, White people had 1.9 times greater odds of receiving community-based mental health and substance use treatment and 4.5 times greater odds of receiving co-occurring disorder treatment. Conclusions. Barriers that individuals released from jail face adversely affect P°C, resulting in reduced access to treatment. Critical race theory can expose the assumptions and functions of systems of care and the possible reproduction of implicit bias in potential solutions. (Am J Public Health. 2021;111:277-285. https://doi.org/10.2105/AJPH.2020.305992)

## FULL TEXT

### Headnote

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Conclusions. Barriers that individuals released from jail face adversely affect P°C, resulting in reduced access to treatment. Critical race theory can expose the assumptions and functions of systems of care and the possible reproduction of implicit bias in potential solutions. (Am J Public Health. 2021;111:277-285. https://doi.org/10.2105/AJPH.2020.305992)

By the end of 2016, approximately 6.6 million individuals were under community supervision or incarcerated in the United States; of this population, about 745 200 were incarcerated in jails.[1,2] Jail racial compositions have changed over the last 10 years, with the percentage of (non-Hispanic) White people increasing and the percentage of (non-Hispanic) Black people ing.[2] However, people are disproportionally overrepresented in jails, making up about one third (33.6%) of those incarcerated and yet composing around 13% of the general population.[2,3] Those with serious mental illness (SMI) are also disproportionality represented in jails, with 1 in 4 likely to have an SMI (measured by a validated nonspecific psychological distress scale, the Kessler-6), which is 5 times greater than the rates for SMI (defined as serious functional impairment) among the adult general population.[4,5] Individuals with a substance use disorder (SUD) are also overrepresented in jails, with two thirds (63%) of individuals incarcerated in jails (IIJ) having an SUD, compared with 5% of adults in the general population.6 Individuals with SMI or SUD, as well as people of color (P°C), occupy a space of dual disproportionality in the criminal-legal system.

Prior studies have sought to examine racialized differences in SMI prevalence and treatment engagement for IIJ while inside the carceral setting. A consistent finding in the literature is a higher prevalence of SMI using both objective screening tools (Kessler-6) and selfreport measures (diagnoses) among White people incarcerated in jail (31% and 57%, respectively) compared with P°C incarcerated in jail (22% and 31%, respectively).4 Mental health (MH) treatment access while inside jail differed by race as well. Among IIJ with a prior MH history (i.e., self-reported mental or emotional condition or prior mental hospitalization), 44.7% of White people received some type of treatment compared with 34.2% to 40.6% of P°C.7 A more recent study, which operationalized SMI as a diagnosis of schizophrenia or bipolar disorder, found that compared with White Americans, African Americans were 5% less likely and Asian Americans were 10% less likely to receive jail-based treatment.8 In another study, among IIJ who were considered in need of treatment based on the Personality Assessment Inventory, no racialized differences were found in request or enrollment in MH treatment during incarceration.9

Racial disparities in community-based MH treatment during the preincarceration period are also present. Among IIJ who demonstrated MH treatment need based on the Personality Assessment Inventory, White people self-reported higher rates of community-based MH treatment prior to the current jail stay than P°C.9 Specifically, 13.6% of White people reported prior psychiatric hospitalizations, 21.3% prior outpatient treatment, 27.3% prior mood medications, and 15.2% use of current mood medications, compared with Black people, who had lower utilization on each category (7.4% prior hospitalizations, 7.5% prior outpatient treatment, 10.7% prior mood medications, and 4.0% current mood medication).9 These findings are consistent with a study of 18421 IIJ across 10 metropolitan jail sites in which racial disparities existed among those who reported prior MH, SUD, and co-occurring disorder (COD) treatment engagement, with White people more likely than P°C to utilize treatment.10

To date, no study has assessed racial disparities in community-based behavioral health treatment of IIJ with SMI in the postincarceration period. Earlier studies reported communitybased MH treatment prior to the target jail stay, and most have assessed these practices in 1 jail setting.810 Other studies assessed the role that SMI plays in recidivism but did not describe racial differences among these rates.11,12 This exploratory study adds to the existing body of knowledge by following individuals into the community after the target jail stay to uncover how race/ ethnicity is associated with engagement in both jail- and community-based MH treatment 1 year after release from 8 Midwestern jail facilities. It aimed to examine whether an individual's race/ ethnicity is associated with their access to jail- and community-based MH treatment. On the basis of prior researchers' work, and the contributions of critical race scholars, we hypothesized that racial disparities would exist for both jail- and community-based MH treatment engagement.710

## METHODS

This analysis is part of a larger study that began in 2014 when the research team was hired to evaluate 8 Midwestern county jail diversion pilot programs funded by a unit of state government. At that time, individuals admitted to these diversion programs were tracked for treatment engagement and recidivism outcomes in the year following the receipt of jail diversion services. In 2017, these same counties expanded their services into other areas of the criminallegal system, switching the focus from a program-level outcomes evaluation to a systems evaluation. Jail staff screened and followed individuals for 3 months inside the jail. State-wide Medicaid claims data tracked behavioral health treatment engagement in the 14 months after leaving jail. The primary focus of the systems evaluation was to assess each jail's "process-as-usual" in the identification of SMI, and its referral to and engagement in jail-based MH treatment.

### Study Population

We merged 3 data sources at the individual level: (1) an instrument administered to individuals at jail booking; (2) administrative data from each jail regarding MH processes, as well as legal history and recidivism; and (3) Medicaid encounter data from the state's Department of Health and Human Services. The variables used from these sources are described in the next section; additional details on how the variables were categorized are reported elsewhere.13 MH identification varied across jails, with each having its own practice as usual. One jail used the Kessler-6 as its identification practice, whereas 6 jails used a combination of questions related to prior MH treatment.14 In 1 jail, the identification was asking if the individual was suicidal. In the overall sample (n = 2856), the jails identified 623 individuals (21.8%) as having an SMI by the jails' process as usual. Individuals who were identified as having an SMI (n = 623) became the sample for the current study. Although a second SMI screening and identification did not occur at the time of jail release, the study sample had an average length of stay in jail of just over a month (35.93 days; Table 1). It is therefore reasonable to assume that individuals will likely need services upon community reentry, especially given the mental health impact of incarceration.

Independent Variables

A screening instrument administered by the jails to individuals during booking captured all demographic characteristics. The key variable of interest in this study is race/ethnicity. Respondents- or, in some cases within 1 jail, staff- completed the race/ethnicity variable on the screening instrument, which included the following possible responses: White, Black, Latino, Native American, or Other. These responses were collapsed into "White" and "P°C." We wanted a more nuanced analysis of race/ethnicity, but small sample sizes of Latino, Native American, and Other races (4.9% total) did not allow for statistical analyses. Finally, although it was the priority of the research team to have individuals selfidentify their race/ethnicity on the screening instrument, some jails' booking practices were solely electronic. Officers entered information into the database while conducting the standard booking procedures. The remaining demographic variables included gender (male or female), age (calculated by date of birth and jail booking date), housing insecurity, and county size (coded based on US Department of Agriculture population sizes).

Behavioral health history included 4 variables: Kessler-6 (K6) score, prior MH treatment or medications, substance misuse, and whether the individual was a community MH (CMH) client prior to jail booking. The K6 is a validated selfreport screening tool. A K6 score of 9 or higher is correlated with SMI in jailbased populations.15 The score for each individual was blind tojail staff, and thus the process-as-usual hinged only on the jails' identification practice. We gathered prior MH treatment or medication, as well as 2 validated measures that screen for substance misuse in primary care settings, from the screening instrument.16 CMH client was provided in the Medicaid encounter data and dichotomously coded if the individual had received 1 or more MH services from a CMH provider in the year prior to their jail stay.

We included 3 variables in legal history: past year jail, target jail stay felony charge, and length of stay in jail. We gathered past year jail, dichotomously coded, from the screening instrument, whereas felony charge, operationalized as the most severe charge for the target jail stay, and length of stay, measured in days, were provided by each jail.

Dependent Variables

The key outcomes analyzed in this study include the MH treatment that individuals received during their target jail stay and treatment they received once they transitioned to the community.

Jail-based mental health treatment The American Psychiatric Association's 2016 guidelines for jail MH practices note that these institutions should have processes for identifying SMI, referral to MH treatment, and assessments and treatment received in jail.17 In addition to these guidelines, this study assessed who received diversion services that were offered during the program evaluation phase of the study.

Using the process discussed in the "Study Population" section, we collected from the jail staff at each institution data on referral to, and engagement in, MH treatment of the sample identified as having an SMI. Prior to any data collection, the research team established data extraction procedures for these variables based on each jail's processes (through review of electronic medical records or a tracking spreadsheet). Once the screening instruments were collected, a list of identifiers were returned to each jail, and staff were asked to note ifan individual received either referral to or treatment by MH clinicians for a 3-month period after taking the screening instrument. MH staff operating diversion services in the jail were also provided with the sample identifiers and asked if the individual participated in diversion services in the same period.

Community-based mental health treatment. We used Medicaid encounter data to determine MH, SUD, and COD treatment of individuals 14 months after they left jail. Current Procedural Terminology codes and dates of treatment were provided for every treatment related to an MH or SUD diagnosis code. When an individual received the same type of treatment on the same date, by the same provider, we counted it as 1 COD treatment. All others were counted as MH or SUD.

## Statistical Analyses

We used bivariate analyses (x2 test of independence and independent samples t tests) to assess for differences between White people and P°C by demographic, behavioral health, and legal histories, as well as the jail- and community-based treatment outcomes. To assess the impact race had on jailand community-based MH treatment, we used logistic regression models for 6 outcomes that differed by race at the bivariate level: within-the-jail (1) referral, (2) treatment, and (3) diversion, and within-the-community (4) MH, (5) SUD, and (6) COD treatment engagement. Although they are significant at the bivariate level, we did not perform logistic regression models on diversion, as these can be considered rare events.18 For analysis regarding communitybased outcomes, we reduced the sample from 623 cases to 434 cases after removing individuals who went directly to prison from the target jail stay (n = 35) and those who were not found in the Medicaid encounter data (n = 154). These 189 individuals were not significantly different by race, gender, or age compared with the follow-up sample. All independent variables that significantly differed by race at the bivariate level were included as control variables in the logistic regression models.

## RESULTS

There were total of 623 individuals in this study: 39.8% (n = 248) were P°C and 60.2% (n = 375) were White people. We found no racial differences when comparing the jail identification practices by race: P°C (21.8%, n = 248) were as likely as White people (21.9%, n = 375) to be identified as having an SMI (t(1, n = 623) = 0.000; P>.05). Bivariate analyses regarding outcome variables found that White people were more likely to have received a jail-based referral (95.2%, n = 357; x2(1) = 7.347; P <.01) and diversion services (12.3%, n = 46; x2(1) = 5.633; P<.05) compared with P°C (89.5%, n = 222; 6.5%, n = 16, respectively). P°C were more likely to have received jail-based MH treatment (71.0%, n = 176; x2(1) = 8.575; P<.01) than were White people (59.5%, n = 223). For community-based behavioral health treatment engagement, White people engaged in MH treatment (51.7%, n = 134; x2(1)= 14.638; P<.001), SUD treatment (47.1%, n = 122; x2(1) = 12.276; P<.001), and COD treatment (23.3%, n = 60; x2(3) = 18.487; P <.001) at greater proportions than P°C (33.1%, n = 58; 30.3%, n = 53; 7.4%, n = 13, respectively; Table 1).

We performed 5 logistic regression models to assess the correlates of MH outcomes, with race being the variable of concern. After we controlled for significant factors that differed by race at the bivariate level, race was not significantly associated with the 2 jail-based models (Table 2). Race was significantly associated with community-based MH treatment engagement (x2(1) = 5.505; P< .05). The model was able to successfully predict 76.3% of cases and explain 43.4% of the model variance. White people had 1.9 times greater odds of engaging in community-based MH treatment (adjusted odds ratio [AOR] = 1.937; P <.05; 95% confidence interval [CI] = 1.111, 3.376) compared with P°C (Table 3). Race was also significantly associated with SUD treatment engagement (x2(1) = 5.240; P<.05), successfully predicting 74.6% of cases and explaining 37.0% of the model variance. White people had 1.9 times greater odds of engaging in SUD treatment (AOR = 1.865; P<.05; 95% CI = 1.090, 3.190) compared with P°C (Table 3). Lastly, race was also significantly associated with COD treatment engagement (x2(1) = 17.152; P<.001), successfully predicting 83.7% of cases; the variance explained was 29.9%. White people had 4.5 times greater odds of receiving communitybased COD treatment (AOR = 4.472; P<.001; 95% CI = 2.082, 9.605) compared with P°C (Table 3).

## DISCUSSION

This exploratory, multisite study's analysis of racial disparities in jail- and community-based MH treatment engagement found no differences in racial disparities in jail-based MH treatment, after controlling for other key factors. This finding is similar to the findings of some prior research and contrary to those of others.7 9 Racial disparities in community-based treatment engagement indicated that White people had a greater chance of engaging in treatment of MH, SUD, and COD compared with P°C upon release from jail.

Although race/ethnicity and behavioral health do not predict involvement in the criminal-legal system outright, institutional violence-state-sanctioned inequalities that cause (inter)personal violence-greatly affects P°C and individuals with SMI.19,20 Literature that discusses jail- and community-based treatment engagement for IIJ commonly separates barriers to treatment along 2 lines: (1)the individual's intrapersonal attitudes (such as internalized stigma) toward treatment, as influenced and reaffirmed by dominant discourse; and (2) structural barriers to treatment (such as cost and availability), as constructed by inequalities resulting from systematic oppression.9 It is worth considering that the lack of racial disparities found in jails may be the unintended consequences of P°C being overdiagnosed, which may contribute to the individual's attitudes toward treatment.21 However, among studies in which racial disparities in SMI prevalence and jail-based treatment were present, it is plausible that the inverse is true, the bias here being an underdiagnosis among P°C through the racial biases of MH screens.22

Regarding the individual's intrapersonal attitudes, trust in institutions was found to be a barrier for individuals with COD (and SUD). It is possible that IIJ are coerced into MH treatment inside of jails because of the power differential between those incarcerated and those incarcerating. Upon release, an individual may disengage from treatment through distrust of CMH.23 Perceiving attrition between jail- and communitybased treatment as "self-determination" obscures the impact of our racist reality, one in which P°C may not feel safe engaging in services. The perception of "choice" is further complicated, as not all those affected by incarceration rank health as a top priority, with housing, employment assistance, education, and assistance in getting benefits outranking physical and behavioral health.24 Furthermore, time-a social determinant of health-is racialized, with P°C being disproportionately harmed because they have lost time through incarceration and thus have less time to secure these community resources.25 This may create difficultly for providers if individuals who need treatment are less likely to solicit or engage these types of supports. Trauma may also create barriers to behavioral health treatment. Traumatic experiences are particularly high for IIJ.26 Compared with IIJ without SMI, IIJ with SMI are more likely to be unhoused in the year before arrest, have higher rates of physical and sexual abuse, and have familial histories of SUD or intergenerational incarceration, experiences that can traumatize individuals and communities.7,27

## Limitations

Although the findings of this multisite study contribute to the literature on racial differences in community-based behavioral health treatment, limitations exist. First, there were some inconsistencies in collection of the race variable: it was usually the incarcerated individual who reported race/ethnicity, but at 1 jail, staff reported it. In addition, there are more categories within race/ethnicity than were offered to the IIJ or jail staff. Increased specificity on race/ethnicity within jails and carceral settings is necessary for future studies.28 Second, MH identification practices varied across the 8jails, and concern exists regardingtheir accuracy in assessing SMI. There may be cases in which IIJ were misidentified as having a MH need, whereas others may have been missed who needed services. Future studies should include jails with reliable identification practices.

Third, the nature of administrative data does not allow for researcher input into data points for collection, and thus limits analyses. Fourth, the jail-based MH services collection is limited by the 3month data collection allowed in the jails. Individuals who stayed in jail longer than 3 months (12.2%, n = 76) may have received such services after the study period. Fifth, we assessed our community-based behavioral health treatment engagement using Medicaid encounter data. Although a substantial proportion of the sample was found (n = 434, 72.6%), individuals covered by private health insurance and Veterans Affairs were missed (n = 154, 27.4%). Sixth, the operationalization of COD treatment engagement was highly conservative; therefore, it is possible that COD treatment engagement is higher in reality than was calculated for use in this study.

Seventh, the best approach to analyzing the nested nature of this data is multilevel modeling; however, the current number of jails did not provide enough level-2 power for this type of analysis. Eighth, although our regression models had high Nagelkerke R2 proportions (29.9% to 43.4%), other factors could contribute to the receipt of these treatments. For example, behavioral health treatment engagement has been associated with specific substances, as individuals who use more severe substances are more likely to receive treatment.10 Probation conditions may also influence who is receiving treatment. Discriminatory practices such as classism, ableism, and mentalismsanism may also contribute to the unexplained variance. Finally, CMH agencies face multiple challenges in providing treatment, such as long wait lists, limited or restricted funding, and local transportation issues.9 Future work should consider the impact of such factors on treatment engagement after jail release.

## Public Health Implications

Successfully addressing structural barriers to treatment of individuals with SMI affected by the criminal-legal system is often described as engineering "easy access" to community-based MH treatment and other necessary resources such as seeking and maintaining affordable housing.29 However, others take a more radical approach, calling for a redesign of the entire US health care system.30 A suggestion of the latter entails sophisticated case management programs and systems-organizations partnerships between corrections and local CMHs.30 Other suggestions for addressing the overrepresentation of individuals with SMI in the criminal-legal system include providing traumaspecific interventions, providing integrated COD treatment, connecting individuals to supported employment and housing providers, and, as appropriate, utilizing evidence-based practices.12,31 Furthermore, since the rapid connection to treatment after jail is critically important because of risks of suicide and overdose, the timing of such potential solutions must be considered in redesigning health care service delivery in the United States.32

Regardless of the specific barrier to behavioral health treatment, this study's findings and the presence of such barriers are indicative of the legacy of mentalism, racism, and discrimination against those who have been incarcerated. Racial disparities are not surprising when operating from a perspective informed by critical race theory, which can assist in illuminating how current systems reproduce discourse informed by the "aftermath of slavery, labor exploitation, and racial discrimination."33 Critical race theory articulates several principles that form its foundation:

1 Racism is ordinary (meaning that it is pervasive, ever-present, and continuously shaping the world).

2 White people often have little selfinterest in dismantling racist structures because racism, in some ways, benefits them-termed the "interest-convergence hypothesis" or material determinism.

3 Race is a social-not biological- construct.

4 US dominant discourse has narrativized non-White groups differently over time while steadfastly remaining anti-Black-termed differential racialization.

5 The unique voices of P°C are important and should be centered.34

By applying a critical race theory lens to CMH and criminal-legal policies and practices, administrators and staff are better equipped to discern how efforts to dismantle structural racism may be stalled by implicit bias and are entangled in other forms of violence, such as classism and sexism. Efforts should include authentic leadership and engagement from P°C and culturally responsive mental health interventions, which can be up to 4 times more effective than nonculturally responsive engagement strategies and interventions.35 A measured approach to racism's pervasiveness must become the operating framework for systems reform and intersystem coordination so that increasing MH engagement for P°C is but 1 viable contribution in realizing our shared commitment for racial justice. .4JPU

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CONTRIBUTORS

B.J. Hedden analyzed the data and drafted the article. E. Comartin oversaw study design and data collection, mentored and supervised B.J. Hedden, and wrote and edited the article. N. Hambrick informed development of the study and edited the article. S. Kubiak designed the study and edited the article.

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CONFLICTS OF INTEREST

The authors declare no conflicts of interest.

HUMAN PARTICIPANT PROTECTION

The Wayne State University institutional review board reviewed both the program and systems evaluations and found the study to be nonhuman participation research because of its evaluative nature.

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## DETAILS

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# Postpartum Medicaid Extension to Address Racial Inequity in Maternal Mortality

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## ABSTRACT (ENGLISH)

The United States has one of the highest maternal mortality rates among high-income countries, with deeply troubling disparities that demonstrate long-standing inequity rooted in racism in our health care system. The US pregnancy-related mortality ratio, defined as the number of deaths of women while pregnant or up to one year after delivery from any cause related to or aggravated by the pregnancy or its management, has increased from 14.5 pregnancy-related deaths per 100 000 live births in 2007 to 16.9 per 100 000 in 2016.1 Nearly a quarter of pregnancyrelated deaths occur between 43 days and one-year postpartum, with cardiovascular conditions being the leading cause of death. State-level data show that substance use disorder and poor perinatal mental health are among the leading causes of postpartum mortality. Two of three pregnancy-related deaths may be preventable. The racial disparities in pregnancy-related mortality in the United States are deeply troubling. Between 2007 and 2016, there were 40.8 pregnancy-related deaths per 100 000 live births among non-Hispanic Black mothers and 29.7 pregnancy-related deaths per 100 000 live births among non-Hispanic American Indian/Alaska Native mothers compared with 12.7 pregnancy-related deaths per 100 000 live births among non-Hispanic White mothers. Recent events have drawn public attention to structural racism, or "the totality of ways in which societies foster racial discrimination through mutually reinforcing systems.. . [that] in turn reinforce discriminatory beliefs, values, and distribution of resources."3(p1453)

Biases embedded in algorithms, clinicians' screening tools and predictive models, and underrepresentation of minorities in the provider workforce demonstrate that structural racism is embedded in every aspect of our health care system, which leads to unacceptable health outcomes. The ongoing COVID-19 pandemic has highlighted and exacerbated these issues: Black Americans have more than twice the odds of hospital admission, and Native Americans are infected at up to four times the rate of their White counterparts. Bias and systemic racism in health care must be addressed, given the differences in maternal mortality that Black women experience after accounting for other sociodemographic risk factors.

## FULL TEXT

The United States has one of the highest maternal mortality rates among high-income countries, with deeply troubling disparities that demonstrate long-standing inequity rooted in racism in our health care system. The US pregnancy-related mortality ratio, defined as the number of deaths of women while pregnant or up to one year after delivery from any cause related to or aggravated by the pregnancy or its management, has increased from 14.5 pregnancy-related deaths per 100 000 live births in 2007 to 16.9 per 100 000 in 2016.1 Nearly a quarter of pregnancyrelated deaths occur between 43 days and one-year postpartum, with cardiovascular conditions being the leading cause of death. State-level data show that substance use disorder and poor perinatal mental health are among the leading causes of postpartum mortality. Two of three pregnancy-related deaths may be preventable.2

The racial disparities in pregnancyrelated mortality in the United States are deeply troubling. Between 2007 and 2016, there were 40.8 pregnancyrelated deaths per 100 000 live births among non-Hispanic Black mothers and 29.7 pregnancy-related deaths per 100 000 live births among non-Hispanic American Indian/Alaska Native mothers compared with 12.7 pregnancy-related deaths per 100 000 live births among non-Hispanic White mothers. Recent events have drawn public attention to structural racism, or "the totality of ways in which societies foster racial discrimination through mutually reinforcing systems.. . [that] in turn reinforce discriminatory beliefs, values, and distribution of resources."3(p1453)

Biases embedded in algorithms, clinicians' screening tools and predictive models, and underrepresentation of minorities in the provider workforce demonstrate that structural racism is embedded in every aspect of our health care system, which leads to unacceptable health outcomes. The ongoing COVID-19 pandemic has highlighted and exacerbated these issues: Black Americans have more than twice the odds of hospital admission,4 and Native Americans are infected at up to four times the rate of their White counterparts.5 Bias and systemic racism in health care must be addressed, given the differences in maternal mortality that Black women experience after accounting for other sociodemographic risk factors.

Although it is not a panacea for addressing all facets of structural racism, extending Medicaid coverage from 6 weeks to 12 months postpartum may reduce inequities in care. Currently, the federal mandate for pregnancy-related Medicaid provides coverage to women living at 138% of the federal poverty line (FPL) up to 60 days postpartum. Women of color are disproportionately enrolled in Medicaid during the perinatal period. Half of women who have Medicaid-funded births are uninsured before pregnancy, and 55% of Medicaid-insured women will experience a gap in insurance coverage by six months postpartum. The improvement in coverage that postpartum Medicaid extension provides may be as beneficial as Medicaid expansion through the Affordable Care Act (ACA), which reduced income eligibility for nonpregnant adults to 138% FPL.

Expansion states decreased the uninsured rate among women who gave birth in the past year, increased preconception Medicaid enrollment among low-income women, reduced racial disparities in preterm birth and low birth weight,6 and decreased infant mortality. Support from professional societies such as the American College of Obstetricians and Gynecologists and the American Medical Association has led to the passage of legislation extending Medicaid postpartum in several states since 2018, including Missouri, which was a nonexpansion state at that time. Legislation extending Medicaid postpartum has also been introduced in the nonexpansion states Texas, Georgia, Wisconsin, and South Carolina. Although the passage of legislation is promising, other changes are necessary to facilitate implementation and to collect data supporting adoption of this policy elsewhere.

Reimbursement is a critical aspect of implementation of postpartum Medicaid extension. Most states pay for maternity care through Medicaid by using a bundled payment for the perinatal period, which includes prenatal care, labor and delivery, and postpartum care. Episode payments, particularly with the incorporation of carefully selected quality metrics, could lead to efficient value-based care and waste reduction via gain sharing, whereby providers and institutions can convert savings from efficient care provision to increased service provision in areas that are not covered by insurers. However, the global payment structure needs to be adjusted to account for more visits for postpartum or well-woman care in the first year postpartum. Two options are increasing the value ofthe global fee and unbundling the payment structure for postpartum care. Without appropriate reimbursement, passing policies extending postpartum Medicaid coverage may not result in increased access to postpartum care.

Innovative health care delivery mechanisms, such as telemedicine and mobile application-supported care, may also allow increased postpartum care delivery. There has been significant development of health care infrastructure and workforce capacity to support these innovative delivery mechanisms during the COVID-19 pandemic. There are limited data showing that perinatal telemedicine can provide health outcomes comparable with those of traditional methods of health care delivery for diabetes, hypertension, and perinatal depression. Preliminary data also show that telemedicine has the potential to be cost saving when utilized on an appropriate scale. Although the feasibility of telemedicine services can be limited by factors such as access to appropriate technology and the availability of appropriate childcare support, mobile applications have been shown to reduce racial disparities in postpartum blood pressure management. At the state level, Illinois Medicaid recently agreed to provide home blood pressure cuffs to support telemedicine efforts during the COVID-19 pandemic.

Research examining differences in maternal and perinatal outcomes after the implementation of postpartum Medicaid extension as well as the impact of innovative health care delivery mechanisms on inequities in postpartum care will provide critical data that can guide the state-level adoption and implementation of postpartum Medicaid extension. As previously discussed, data from states that opted into the ACA's Medicaid expansion show promising effects on health outcomes. Research specifically examining populations benefiting from postpartum Medicaid extension and the impact of innovative health care delivery mechanisms in the perinatal period could support the adoption of policy changes and new models for postpartum care delivery nationally.

Reductions in racial disparities in maternal mortality will ultimately require transforming care across the perinatal continuum, of which postpartum care improvement is a significant component. Other proposed solutions-including improved maternal death reporting, sustainable support for perinatal quality collaboratives and maternal mortality review committees, increased pregnancy and postpartum support (e.g., doulas, patient navigators, breastfeeding peer counselors, home visits, and case management), pregnancy-centered medical homes, and implicit bias training-have been well characterized in the literature.7 Increased access to postpartum health care via Medicaid extension could allow safer birth spacing via improved access to contraception, increased provision of mental health care, improved access to medication-assisted treatment and recovery services, and longer follow-up for medical complications that occur during pregnancy as well as chronic diseases.

As we face the stark racial and ethnic disparities of COVID-19 and nationwide civil unrest in response to structural racism, it is critical that we build on the momentum created by increased public awareness of racism's detrimental consequences on health outcomes, the recent consensus of professional societies, and the passage of legislation in several states to advocate effective implementation of postpartum Medicaid extension. Efforts focused on implementation may include changes to reimbursement in the postpartum period, support for innovative health care delivery mechanisms, and research examining resulting health outcomes. We have an opportunity not only to promote equity and improve access to postpartum care but also to take needed action to address racial disparities in maternal and perinatal outcomes in the postpartum period.

CORRESPONDENCE

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CONFLICTS OF INTEREST

M.A. Simon Is a member of the US Preventive Services Task Force (USPSTF), and her views and those of the USPSTF do not necessarily represent the views expressed in this editorial.

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## DETAILS

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# E-Cigarette Use and Adult Cigarette Smoking Cessation: A Meta-Analysis

Wang, Richard J, MD; Bhadriraju, Sudhamayi, MD; Glantz, Stanton A, PhD

ProQuest document link

## ABSTRACT (ENGLISH)

Objectives. To determine the association between e-cigarette use and smoking cessation. Methods. We searched PubMed, Web of Science Core Collection, and EMBASE and computed the association of e-cigarette use with quitting cigarettes using random effects meta-analyses. Results. We identified 64 papers (55 observational studies and 9 randomized clinical trials [RCTs]). In observational studies of all adult smokers (odds ratio [OR] = 0.947; 95% confidence interval [CI] = 0.772, 1.160) and smokers motivated to quit smoking (OR = 0.851; 95% CI = 0.684,1.057), e-cigarette consumer product use was not associated with quitting. Daily e-cigarette use was associated with more quitting (OR= 1.529; 95% CI = 1.158, 2.019) and less-than-daily use was associated with less quitting (OR = 0.514; 95% CI = 0.402,0.665). The RCTs that compared quitting among smokers who were provided e-cigarettes to smokers with conventional therapy found e-cigarette use was associated with more quitting (relative risk= 1.555; 95% CI = 1.173, 2.061). Conclusions. As consumer products, in observational studies, e-cigarettes were not associated with increased smoking cessation in the adult population. In RCTs, provision of free e-cigarettes as a therapeutic intervention was associated with increased smoking cessation.

## FULL TEXT

### Headnote

Objectives. To determine the association between e-cigarette use and smoking cessation.

Methods. We searched PubMed, Web of Science Core Collection, and EMBASE and computed the association of e-cigarette use with quitting cigarettes using random effects meta-analyses.

Results. We identified 64 papers (55 observational studies and 9 randomized clinical trials [RCTs]). In observational studies of all adult smokers (odds ratio [OR] = 0.947; 95% confidence interval [CI] = 0.772, 1.160) and smokers motivated to quit smoking (OR = 0.851; 95% CI = 0.684,1.057), e-cigarette consumer product use was not associated with quitting. Daily e-cigarette use was associated with more quitting (OR= 1.529; 95% CI = 1.158, 2.019) and less-than-daily use was associated with less quitting (OR = 0.514; 95% CI = 0.402,0.665). The RCTs that compared quitting among smokers who were provided e-cigarettes to smokers with conventional therapy found e-cigarette use was associated with more quitting (relative risk= 1.555; 95% CI = 1.173, 2.061).

Conclusions. As consumer products, in observational studies, e-cigarettes were not associated with increased smoking cessation in the adult population. In RCTs, provision of free e-cigarettes as a therapeutic intervention was associated with increased smoking cessation.

Electronic cigarettes (e-cigarettes) deliver an aerosol of nicotine by heating a solution typically consisting of nicotine, propylene glycol, glycerin, and flavorings.1 In the United States, e-cigarettes are mass-marketed consumer products that, according to the 2009 Family Smoking Prevention and Tobacco Control Act (TCA), fall underthe jurisdiction of the Food and Drug Administration (FDA) CenterforTobacco Products (CTP). In particular, TCA 910 requires manufacturers to demonstrate to CTP that marketing a new tobacco product (including e-cigarettes) would be "appropriate for the protection of the public health."2

E-cigarettes have been promoted for smoking cessation3,4 even though, as of November 2020, no e-cigarette has been approved as a smoking cessation medication by the FDA Center for Drug Evaluation and Research (CDER). The standards that CTP and CDER apply to approve e-cigarettes as consumer products or therapeutic devices are fundamentally different. When considering whether e-cigarettes are "appropriate for the protection of public health," CTP must assess population as well asindividual impactsforthe products as actually used. Observational studies of the effects of e-cigarettes as they are actually used in the general population (which we refer to as "consumer product" use) are relevant to CTP's decisionmaking. By contrast, when considering whether e-cigarettes warrant approval as a therapy, CDER only considers the efficacy (and risks) of a proposed therapy administered to a specific class of individuals at specified doses under medical supervision. Therefore, randomized clinical trials (RCTs) in which e-cigarettes are provided to selected patient populations as part of a smoking cessation program under medical supervision are relevant to CDER's decision-making.

The question of how e-cigarettes as consumer products have an impact on public health gained urgency when, in 2019, a federal court5 required ecigarette companies to submit premarket tobacco product applications to the FDA by September 2020 to continue to sell e-c¡garettes as consumer products. When considering whether allowing the sale of a particular e-cigarette is "appropriate for the protection ofthe public health,"2 CTP must consider, among other things, how e-cigarettes as consumer products lead people who smoke to "transition away from combustible tobacco products."6 The requirement to submit a premarket tobacco product application may also motivate some e-cigarette companies to apply to CDER for approval of their product as a therapeutic smoking cessation device. Therefore, it is important to assess the evidence on the effects of e-cigarettes as consumer products on cigarette smoking cessation as well as, separately, a prescription smoking cessation therapy.

Only 2 previous meta-analyses ofthe effect of e-cigarette use on smoking cessation included at least 10 studies. One in 2016 included 20 studies (2 RCTs and 18 observational studies) and concluded that the "odds of quitting cigarettes were 28% lower in those who used e-cigarettes compared with those who did not use e-cigarettes (odds ratio [OR] 0.72, 95% CI 0.57-0.91)."7(p116) Another meta-analysis in 2017 that included 10 studies (2 RCTs and 8 observational studies) found that "there is very limited evidence regarding the impact of [electronic nicotine delivery systems] . . . on tobacco smoking cessation.... Data from [RCTs] are of low certainty and [data from] observational studies of very low certainty."8(p1)

Since 2017, the number of studies reporting on the association between ecigarette use and smoking behavior has continued to accumulate, and they have provided greater understanding of population- and individual-level effects of e-cigarette use on smoking cessation. Increasingly, observational studies are reporting more nuanced findings, with exposure categorized by frequency or intensity of e-cigarette use, or with samples restricted to people motivated to quit cigarette smoking, all of which have been hypothesized to have an impact on the effects of e-cigarette use on smoking cessation. The number and quality ofthe RCTs evaluating the effects of e-cigarettes on smoking cessation have also increased. The richness of these data prompted this meta-analysis, in which we summarize the state ofthe current scientific knowledge on the effect of e-cigarette use on cigarette smoking cessation. We conducted 4 analyses, examining (1) the effect of e-cigarette consumer product use among people who smoke, regardless of motivation to quit smoking; (2) the effect of e-cigarette consumer product use among people who smoke who are motivated to quit smoking; (3) the effect of daily and less-than-daily e-cigarette consumer product use among people who smoke; and (4) the effect of being provided with free e-cigarettes as a therapeutic intervention in RCTs compared with conventional therapy.

## METHODS

We followed the statements on the Preferred Reporting Items for Systematic Reviews and Meta-Analyses and the

Meta-Analysis of Observational Studies in Epidemiology.9,10 The meta-analysis was registered with PROSPERO on April 9, 2019, (CRD42019128465) and subsequently updated to reflect refinements in the specific questions asked (detailed in the Statistical Analysis section), to clarify what "conventional therapy" among the RCTs meant, and to add another investigator and associated funding. Further updates were made to add use ofthe Grading of Recommendations Assessment, Development, and Evaluation11 (GRADE) guidelines for assessing the quality of evidence from RCTs and adjustment of study standard errors and 95% confidence intervals (CIs) for multiple use of some data (usually the reference group). These refinements are detailed in the updated PROSPERO registrations.

Data Sources and Searches

An academic librarian developed the search strategy and searched PubMed, Web of Science Core Collection, and EMBASE databases on January 14, 2020. Search terms included "vaping," "electronic cigarette," "stop," "quit," "smoking cessation," and "abstain" (search strategy in the Appendix, available as a supplement to the online version of this article at http://www.ajph.org). Search results were not limited by language, publication dates, or for being an abstract only.

Eligibility Criteria

We considered studies eligible if (1) the target population was adults aged 18 years or older; (2) the exposure was e-cigarette use, however this was defined by study authors (definitions included ever use, current use, and daily use, among others); and (3) the outcome was smoking cessation, however this was defined by study authors (definitions included point prevalence of abstinence, continuous abstinence, selfreported abstinence, and biochemically verified abstinence, among others). Both observational studies and RCTs were eligible. For RCTs, we limited the definition of e-cigarette use to nicotine e-cigarettes; we excluded studies that compared nicotine e-cigarettes with nonnicotine e-cigarettes.

Study Selection and Data Extraction

We conducted study selection and data extraction by using the Covidence Webbased software platform (Veritas Health Innovation, Melbourne, Australia). The second author screened abstracts for inclusion into the full-text review. The first 2 authors performed full-text review of 36 randomly chosen studies and established a concordance rate of 81% ($\kappa = 0.57$; $P < .001$). The third investigator resolved uncertainty on the discordant studies. The remaining full-text review and data extraction was split evenly between the first 2 authors. The third author reviewed and confirmed every study that was excluded. Although we did not exclude abstracts from our search, all studies that met criteria for inclusion in this meta-analysis were full peer-reviewed journal publications.

Data extraction was completed by the first 2 authors, including study design (longitudinal observational study, crosssectional observational study, or RCT), study population, period of time over which data were collected, whether sampling was restricted by motivation to quit smoking, definition of smoking cessation, the definition or definitions of e-cigarette use, whether e-cigarette exposure was categorized by frequency of use, how the unexposed group was defined, which variables were adjusted for, and reported OR for the association between e-cigarette use and smoking cessation. A study was considered examining motivation to quit smoking if evidence of this motivation was part of inclusion or exclusion criteria for the study or for the analysis. For example, a study that excluded potential participants because they had not made at least 1 quit attempt during the year before enrollment was considered to have restricted their sampling to participants motivated to quit smoking. Studies that categorized e-cigarette use by frequency of use almost universally used 2 (daily vs less-than-daily e-cigarette use) or 3 (daily vs less-than-daily vs experimental or prior e-cigarette use) levels.

When unadjusted and adjusted ORs were presented, we used the adjusted ORs. When an aggregate OR was presented in addition to ORs categorized by frequency of e-cigarette use, we used both aggregate and frequency-specific ORs in separate analyses; when only frequency-specific ORs were presented in the absence of an aggregate OR, we extracted and used the frequencyspecific ORs. When an aggregate OR was presented in addition to ORs stratified by a variable other than frequency of use, we only used the aggregate OR. When only stratified ORs were presented in the absence of an aggregate OR, we used the stratified ORs. When no OR was presented but could be calculated from the absolute numbers presented in the study, we calculated the OR.

For 4 observational studies, measures of association other than ORs were presented.1215 For these 4 studies, we contacted the study authors for further information. For one study, the authors provided an OR, which we included in the meta-analysis.12 For 2 other studies, the authors did not provide an OR, but the journal article reported a prevalence ratio or risk ratio, which we included in the meta-analysis.13,14 For the fourth study, the authors did not provide an OR and the journal article reported a prevalence difference, so we excluded this study.15

For RCTs, we extracted relative risk (RR) and absolute risk differences as the measures of association. For one RCT with multiple comparison groups,16 we used the comparison with free cessation aid; the groups provided with financial incentives in addition to free cessation aids were not considered a meaningful comparison with the exposure group, which was provided with free e-cigarettes.

Three RCTs included study arms in which participants were provided with nonnicotine e-cigarettes as a control condition.1719 Participants randomized to these study arms were excluded from analysis because the goal of the analysis was to compare smoking cessation in people who smoke who used ecigarettes with those who do not, not to assess the importance of the nicotine in the e-cigarettes.

We assessed risk of bias by using a modification of the ACROBAT-NRSI tool20 for observational studies and the Cochrane Risk of Bias Tool21 for RCTs by the first author in consultation with the third author (details in Appendix). We applied the GRADE11 approach to assess the quality of evidence for the RCTs. We did not use the GRADE approach to assess the observational studies because GRADE is designed to assess the quality of evidence for therapeutic interventions, not behavioral effects associated with consumer products.

Statistical Analysis

The observational studies and RCTs addressed fundamentally different questions (the behavioral effects of e-cigarettes as consumer products vs e-cigarettes as a smoking cessation therapy), and there was substantial heterogeneity in study design among the observational studies of e-cigarettes as consumer products, including differences in sampling methodologies (with or without restriction on motivation to quit smoking) and approach to analyses (whether e-cigarette use was or was not categorized by frequency of use). Given this variability, combining all studies in a single meta-analysis would result in a measure of association that would be difficult to interpret. In addition, many of the studies reported several different ORs, such as ORs for different exposure groups (daily e-cigarette use vs less-than-daily e-cigarette use) or different cigarette smoking characteristics (daily smoking vs less-than-daily smoking). To use as much of the available information as possible and to enhance interpretability, we posed 4 separate questions:

1 What is the effect of e-cigarette consumer product use on smoking cessation among all people who smoke, regardless of their intention to quit? Forthis analysis, we included observational studies for which inclusion and exclusion criteria were not predicated on motivation to quit smoking.

2 What is the effect of e-cigarette consumer product use on smoking cessation among people who smoke who express some motivation to quit smoking? Forthis analysis, we included observational studies that restricted participant eligibility to those who expressed some motivation to quit smoking.

3 Among people who smoke, what is the effect of intense e-cigarette consumer product use, defined as use of e-cigarettes at least daily, on smoking cessation, and is the effect different from that of less-than-daily use of e-cigarettes? Forthis analysis, we included observational studies that categorized exposure by frequency of e-cigarette use or restricted participant eligibility to those who met a specified threshold for frequency of use.

4What is the effect of the provision of free e-cigarettes as a smoking cessation therapeutic intervention? For this analysis, we included only RCTs.

Different ORs from the same study were sometimes used to answer different questions. There were 2 situations in which we used multiple estimates from a single study.

The first situation was when a study reported different estimates of effect that could be used to answer different questions. An example of this is a study by Subialka Nowariak et al22 In this study, the authors presented an OR for the effect of e-cigarette use as a binary variable on smoking cessation for all participants in the study (0.63; 95% CI = 0.48,0.82). They also presented ORs for the effect of e-cigarette use on smoking cessation categorized by frequency of e-cigarette use compared with no e-cigarette use. For daily use, the OR was 1.16; for intermediate use, the OR was 0.50; and for infrequent use compared with no use, the OR was 0.35. In this case, we used the aggregate OR when answering question 2 and we used frequency-specific ORs when answering question 3. There were 7 studies that reported multiple ORs that were used to answer different questions.

The second situation in which we used multiple estimates was when a study only reported multiple estimates of effect without reporting aggregate estimates of effect. An example of this is Biener and Hargraves.23 In this study, the authors presented an OR for smoking cessation comparing daily e-cigarette users to never e-cigarette users and an OR comparing less-thandaily e-cigarette users to never ecigarette users. No aggregate OR was presented. In this case, we included both ORs for our analysis in question 1. There were 11 studies for which multiple ORs were included for this reason.

Among the studies that contributed multiple ORs to the meta-analyses, different exposure groups were compared with the same reference group except for 1 study (in which the same ecigarette users were compared with 2 different control groups, no cessation aid, or nicotine replacement therapy24). Reusing some data to compute several ORs resulted in a correlation between the estimated intervention effects. We adjusted for these correlated comparisons by adjusting the reported standard errors and 95% CIs using Bonferroni corrections. Because Bonferroni can be overly conservative, we also did a sensitivity analysis in which we used the reported standard errors and 95% CIs without Bonferroni corrections.

We performed random effects metaanalysis with Stata version 15.0 (StataCorp LP, College Station, TX) metan command. We assessed statistical heterogeneity by using the I2 statistic. Using the metareg command, we tested the effect of study characteristics (study type [cross-sectional vs longitudinal], whether controlled for nicotine dependence, quit definition [7 vs >30 days], and e-cigarette use [ever vs current]), and when the studies were conducted on our findings for the observational studies used to answer questions 1 through 3. (For question 4, there were only 9 RCTs, which was not enough studies to do such analysis.) Except for when the study was conducted, the study characteristics were coded as dummy variables (0 or 1), so the coefficient and P value associated with each variable assessed the impact of that characteristic on the reported ORs across observational studies. Using the metabias command, we conducted Egger's test for the presence of publication bias. The Stata do file used to conduct the analysis, including applying the Bonferroni corrections to the standard errors and 95% CIs, is in the Appendix. All the data for the analysis appears in Table A (available as a supplement to the online version of this article at http://www.ajph.org).

## RESULTS

The systematic search of articles before January 15, 2020, identified 6575 records, of which 64 studies were included in this systematic review and metaanalysis (Figure A and Table A, available as supplements to the online version of this article at http://www.ajph.org). Fifty-five of these were observational studies,12 14,22 72 and 9 were RCTs.16 19,73 77 We extracted 95 ORs.

We grouped the studies according to which of the 4 questions they could help answer (Table B, available as a supplementto the online version of this article at http://www.ajph.org). A given study could be included in the analysis for 1 or more questions.

### Study Characteristics

Of the 55 observational studies, 41 were cohort studies and 14 were crosssectional studies. Most (36) of the observational studies were from the United States. The others were from Great Britain (5), France (3), Italy (3), Canada, the European Union, Germany, Greece, Hong Kong, Japan, or Switzerland (1 each); 1 observational study included participants from the United States, Great Britain, Canada, and Australia (Table 1 and Table A). Two of the studies had high risk for selection bias, 3 for bias in exposure measurement, 12 for bias in outcome measurement, 5for bias from confounding, and 6 for bias from missing data (Table 1 and Table C, available as a supplement to the online version of this article at http:// www.ajph.org). None had unknown risk of selection bias, 27 had unknown risk of exposure measurement, 37 had unknown risk of outcome measurement, 14 had unknown risk of confounding, and 24 had unknown risk of missing data.

Of the 9 RCTs, 3 were from the United States, 2 from Great Britain, 2 from New Zealand, and 1 each from Italy and Korea (Table A). One had high risk for performance bias, 3 had high risk for attrition bias, and 1 had high risk of reporting bias (Table 1 and Table D, available as a supplement to the online version of this article at http://www.ajph.org). In 7 ofthe 9 RCTs,16,17,19,73,74,76,77 the comparison group was directly provided with nicotine replacement therapy or with the means to obtain such aid freely; in the other 2 RCTs, participants randomized to the comparison group were provided only with smoking cessation counseling.18,75

When we applied the GRADE approach to assess the quality of evidence in the RTCs, we judged there to be no serious limitations with regard to risk of bias, inconsistency, imprecision, or publication bias (Table 2). However, there was substantial concern for indirectness of evidence that derives from the limited number of e-cigarette products that have been studied in RCTs compared with the very large number of e-cigarette products available for sale to the public. Seven e-cigarette products were tested in the 9 RCTs (Elusion, One Kit, Vuse, Vype, eGO-C, and eVOD were used in 1 clinical trial each; NJOY was used in 2; the product was not named in 1 clinical trial). Whether the results from these clinical trials can be universally applied to the thousands of e-cigarette products available in the global market is unknown. It is possible that differences in e-cigarette product, nicotine concentration of e-liquid, nicotine formulation (salt vs free-base), flavoring agents, distribution strategy (free e-liquid refills vs limited e-liquid refills; e-liquids with a consistent nicotine concentration vs e-liquids with a declining nicotine concentration), and cointerventions would reduce the external validity of these studies as applied outside ofthe clinical trial setting. As such, the overall quality of evidence from the RCTs was judged to be moderate.

Answers to the 4 Questions

1.Among all people who smoke, ecigarette consumer product use was not significantly associated with smoking cessation. To evaluate the effect of e-cigarette consumer product use on smoking cessation among all adults who smoke, we used observational studies that did not restrict sampling by motivation to quit smoking. The total sample for this analysis comprised 44 ORs from 35 studies 13,14,23,25,26,28,31,33,34,36,40,42,43, 45,47,50,52,54,56,58,59,62,64,67,70,72,79 In this population, the point estimate for the effect of e-cigarettes on smoking cessation was close to the null, with a 95% CI that spanned the possibility of a small negative to a small positive effect on smoking cessation (OR = 0.947; 95% CI = 0.772, 1.160; P =.293; Figure 1 and Table 3). There was no significant difference between longitudinal and cross-sectional studies (P =.09).

Among the 24 ORs of all people who smoke in which a range of study characteristics were reported, these characteristics (cross-sectional vs longitudinal study design, whether e-cigarette exposure was defined as either current use or ever use, the duration of abstinence that defined smoking cessation [7 days vs >30 days], whether nicotine dependence was adjusted for in the analysis, when the data were collected or the risk of bias in individual studies) did not significantly affect the OR estimate (Table E, available as a supplement to the online version of this article at http:// www.ajph.org).

2.Among people who smoke who express some motivation to quit smoking, ecigarette consumer product use was not significantly associated with smoking cessation. To evaluate the effect of e-cigarette consumer product use on smoking cessation among people who smoke who were motivated to quit smoking, analysis was limited to observational studies that restricted participant eligibility to those who expressed some motivation to quit smoking. The total sample for this analysis comprised 24 ORs from 20 studies 12,22,24,27,29,30,35,41,44,46,51,53,57,60,61, 65,66,68,69,71 In this population, the point estimate for the effect of e-cigarettes on smoking cessation was below the null, but the 95% CI did not exclude the possibility of a very small positive effect on smoking cessation (OR = 0.851; 95% CI = 0.684, 1.057; P =.143; Figure 2 and Table 3). In addition, there was a significant reduction in quitting among the longitudinal studies (OR = 0.751; 95% CI =0.591, 0.954). There was no significant difference between longitudinal and cross-sectional studies (P =.11). Studies that defined quitting using 7day point prevalence shows significantly less quitting than studies using 30-day or longer point prevalence; other study characteristics did not significantly affect the estimated OR (Table F, available as a supplement to the online version of this article at http:// www.ajph.org).

3.Among people who smoke, daily e-cigarette consumer product use was associated with significantly increased smoking cessation, while less-than-daily e-cigarette use was associated with significantly less smoking cessation. To evaluate the effect of different intensities of e-cigarette consumer product use on smoking cessation, analysis was limited to studies that reported ORs stratified by frequency of e-cigarette use or that restricted participant eligibility to those who met a specified threshold for frequency of use-for example, at least 50 puffs per week for at least the past 6 months.55 The total sample for this analysis comprised 31 ORs from 15 studies 13,14'22-23,28,32,38,39,45,49,52,55,56,64,67 Compared with no e-cigarette use, daily e-cigarette use was associated with significantly higher odds of smoking cessation (OR =1.529; 95% CI = 1.158, 2.019; P =.005; Figure 3 and Table 3). Compared with no e-cigarette use, less-than-daily e-cigarette use was associated with significantly lower odds of smoking cessation (OR = 0.508; 95% CI = 0.400, 0.645; P <.001). The effect of daily e-cigarette use was significantly different from the effect of less-than-daily e-cigarette use (P<.001). Study characteristics did not significantly affect the estimated OR (Table G, available as a supplement to the online version of this article at http:// www.ajph.org).

4.Provision of free e-cigarettes was associated with significantly increased smoking cessation in randomized clinical trials of e-cigarettes as smoking cessation therapy. Nine RCTs16 19,73 77 were included for analysis. In 7 of the 9 RCTs, the control group was provided free cessation aids16,17,19,73,74,76,77; 2 RCTs provided the control group with smoking cessation counseling only.18,75 In RCTs, provision of free e-cigarettes was associated with higher smoking cessation compared with conventional therapies (RR = 1.555; 95% CI = 1.173, 2.061; P = .002; Figure 4 and Tables 2 and 3). The absolute cessation rate for the conventional therapy was 0.086 (95% CI = 0.043, 0.129); e-cigarette use increased the absolute cessation rate by 0.040 (95% CI = 0.008, 0.073; P =.014; Figure 4 and Table 2).

There was no evidence of significant publication bias based on the available published studies used to answer any of the 4 questions (Table 3). There was significant study heterogeneity among the published studies used to answer questions 1 through 3, but not the RCTs used to answer question 4 (Table 3).

The sensitivity analysis in which we did not adjust for multiple comparisons in several of the studies produced similar results to the main analysis (Tables H-K, available as supplements to the online version of this article at http://www.ajph. org).

## DISCUSSION

E-cigarette companies3 and e-cigarette advocates4 have promoted e-cigarettes as effective cigarette smoking cessation tools. In this meta-analysis, we found that, in observational studies of adults who smoke cigarettes, e-cigarette consumer product use was not significantly associated with cigarette smoking cessation. In observational studies of adults who smoke cigarettes and express some motivation to quit smoking, ecigarette consumer product use was not significantly associated with cigarette smoking cessation. Among observational studies that categorized ecigarette consumer product use by frequency of use, daily use of e-cigarettes was associated with increased smoking cessation, while less-than-daily e-cigarette use was associated with decreased smoking cessation. In the United States, most e-cigarette users use e-cigarettes less than daily (United States: 66% in 201 1-2012,23 79% in 2013-2014,64 and 66% in 2014-201513). In the European Union the percentage of less-than-daily smokers was 48% in 2014.52 In contrast to the results from observational studies of e-cigarettes as consumer products, provision of free e-cigarettes as a smoking cessation therapy in the context of RCTs was significantly associated with increased smoking cessation.

### Study Heterogeneity

As with many meta-analyses, there was substantial heterogeneity (Table 3) among the observational studies of ecigarettes as consumer products, which were designed to answer different questions and which adjusted for different covariates and potential confounders. While most of the observational studies were conducted in the United States, about one third of studies were from outside of the United States (Table A), which may also have contributed to the heterogeneity because of the availability of different e-cigarette products and differences in regulatory environments. We partially addressed this problem by subdividing the observational studies according to major differences in the definition of the target population and of the exposure. In addition, a sensitivity analysis did not find any statistically significant effects that resulted from differences in key characteristics of observational study design, when the studies were conducted, or assessment of bias in individual studies (Table E).

Substantial heterogeneity is a major challenge to interpreting results, but reflects the nature of e-cigarettes as a broad class of diverse consumer products currently available for sale and consumption across global markets. E-cigarette devices differ in their design and their component materials. They differ in nicotine formulation, nicotine concentration, flavoring agents, and other additives. E-cigarette products differ in branding, marketing, and appeal to population subsegments. Local regulation of e-cigarettes varies across national and subnational jurisdictions, affecting patterns and topologies of use.

Amid these challenging circumstances, the FDA and other regulators must decide whether the sale of e-cigarettes as consumer tobacco products (as opposed to specific therapeutic interventions administered to specified classes of patients under clinical supervision) would be "appropriate for protection of public health," the standard in the law. Making a quantitative determination about the effects of e-cigarettes as consumer products on smoking behavior is an important element of the regulatory impact analysis that the CTP is required to do. Thus, the heterogeneity observed in the studies reflects variability ofuse ofe-cigarettesasconsumer products makes the observational studies more relevant and useful to CTP in developing and implementing regulation of e-cigarettes as consumer products.

The RCTs were conducted in 5 countries (Table A), but did not exhibit significant heterogeneity (Tables 2 and 3), perhaps because of the more tightly controlled environment in terms of participant selection and intervention than exists in real-world observational studies.

## Implications for FDA Regulation of E-Cigarettes

The observational studies have substantial implications for FDA regulation of e-cigarettes as tobacco (consumer) products. When determining whether a new tobacco product is appropriate for the protection of the public health, TCA 910(c)(4) requires FDA to consider

the risks and benefits to the population as a whole including users and nonusers of the tobacco product, and taking into account (A) the increased or decreased likelihood that existing users of tobacco products will stop using such products; and (B) the increased or decreased likelihood that those who do not use tobacco products will start using such products.

Moreover, TCA 911(g)(1) provides that a Modified Risk Tobacco Product order (which would allow a company to sell their e-cigarette with claims that the product is less harmful than other tobacco products on the market or exposes the consumer to reduced exposure to substances found in other tobacco products) can be issued only if FDA determines that the applicant has demonstrated that the product

as it is actually used by consumers, will (A) significantly reduce harm and the risk oftobacco-related disease to individual tobacco users; and (B) benefit the health of the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products.

If e-cigarette consumer product use is not associated with more smoking cessation, there is no population-level health benefit for allowing them to be marketed to adults who smoke, regardless of the relative harm of e-cigarettes compared with conventional cigarettes. Moreover, to the extent that people who smoke simply add e-cigarettes to their cigarette smoking (becoming so-called dual users), their risk of heart disease,80 83 lung disease,84,85 and cancer86 could increase compared with smoking alone.

The other 2 questions CTP is mandated to consider-the direct toxicity of e-cigarettes and the potential that e-cigarette availability increases smoking rates among the youths-are also important and not included in our metaanalysis. The fact that e-cigarettes have attracted millions of youths to nicotine,87,88 many of whom would have been unlikely to initiate nicotine use with conventional cigarettes,89 91 further undermines the idea that allowing the marketing of e-cigarettes would be "appropriate for the protection of public health." Evidence of toxicity of e-cigarettes is also growing, including myocardial infarction and other heart disease,80 83,92 lung disease,84,85,93,94 and cancer.86,95,96

By contrast, the RCTs suggest that specific e-cigarettes may meet the CDER standard as therapeutic interventions to be delivered to specific classes of patients at specified doses under medical supervision. Among the 9 RCTs in this meta-analysis, provision of free e-cigarettes significantly increased smoking cessation compared with conventional therapies, including nicotine replacement therapy. The overall quality of evidence was judged "moderate" (Table 2), however, because whether the results from these clinical trials can be extrapolated to the thousands of products available on the global market is unknown. It is possible that differences in e-cigarette product, nicotine concentration of e-liquid, nicotine formulation (salt vs free-base), flavoring agents, distribution strategy (free e-liquid refills vs limited e-liquid refills; e-liquids with a consistent nicotine concentration vs e-liquids with a declining nicotine concentration), and cointerventions would reduce the external validity of these findings when extrapolated to different e-cigarette products or when extrapolated outside of the clinical trial setting.

Even with these problems, the RCTs suggest that a specific e-cigarette might be able to pass the "efficacy" test for approval as a smoking cessation therapy administered under medical supervision as part of a cessation program. Approval of e-cigarettes as a cessation therapy, however, also requires that they be "safe," meaning that the benefit-to-risk ratio must be favorable. As noted previously, recent evidence links e-cigarette use to heart disease,80 83,92 lung disease,84,85,93,94 and cancer86,95,96; this evidence raises questions about whether the benefit-to-risk ratio would be favorable enough for approval as a medication. The fact that 80% of people who smoked in the e-cigarette arm of 1 of the RCTs were still using e-cigarettes a year later compared with 9% of nicotine replacement therapy users reinforces this concern.73 In addition, while outperforming nicotine replacement therapy, the efficacy of e-cigarettes was similarto or below that of FDA-approved therapies including bupropion and varenicline.97 If approved as a medication, e-cigarettes should be only available under prescription because of their high abuse potential, similar to prescriptiononly nicotine inhalers that have been approved as cessation medications.98

## Limitations

Publication bias is always a potential concern. While we did not find evidence of publication bias based on our analysis of the published studies (Table 2), Egger's test suffers from low power when the number of studies is small. In addition, our assessment of publication bias is based on the published studies (i.e., we did not do a search of http://clincaltrials.gov for registered but unpublished RCTs), and there is a chance that other RCTs of e-cigarettes as smoking cessation therapy that yielded null results were never published.99 Thus, it is possible that we are over-estimating the efficacy of e-cigarettes as therapeutic interventions for smoking cessation.

"Motivation to quit" is defined broadly in this review, following the design of the observational studies. There were studies that restricted sampling to participants who expressed some intent or motivation to quit smoking (as determined by the study investigators), and there were studies that did not restrict sampling to participants who expressed any intent or motivation to quit.

While all RCTs included some form of biochemical verification of smoking status, only 3 of the observational studies did.1229,35 (Few population studies ever include biochemical verification.) Self-report is, however, the established standard for population observational studies. The 2020 Surgeon General report Smoking Cessation: A Report of the Surgeon General observed that "self-reported data have been found to adequately reflect patterns of cigarette smoking among adults, including whether a respondent who has smoked in the past is currently not smoking, using scientifically validated biomarkers and other approaches."100(p37)

There is always the possibility that unspecified confounding variables could be affecting results. The wide range of potential confounders considered in the observational studies reduces the likelihood that this is the case.

## CONCLUSIONS

E-cigarette use as a consumer product is not significantly associated with cigarette smoking cessation in the general adult population. E-cigarettes may warrant consideration as a prescription drug to be used as part of a clinically supervised smoking cessation intervention, provided that the associated risks are commensurate with the benefit.

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CONTRIBUTORS

R.J. Wang and S. Bhadriraju, the co-first authors, collected the data and wrote the first draft. S.A. Glantz reviewed the data collection and resolved differences. R.J. Wang and S.A. Glantz did the statistical analysis and most of the additional analysis required to respond to the reviewers. All authors approved the final draft.

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CONFLICTS OF INTEREST

The authors have no conflicts of interest to disclose.

HUMAN PARTICIPANT PROTECTION

This study did not involve human participants.

## Sidebar

Public Health Implications. E-cigarettes should not be approved as consumer products but may warrant consideration as a prescription therapy. (AmJ Public Health. 2021;111:230-246. https://doi.org/10.2105/AJPH.2020.305999)

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## DETAILS

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|---|---|
| **Subject:** | Clinical trials; Smoking cessation; Smoking; Motivation; Confidence intervals; FDA approval; Nicotine; Consumer products; Public health; Drug addiction; Tobacco; Cigarette smoking; Electronic cigarettes; Meta-analysis; Intervention; Vaping; Systematic review; Random effects; Observational studies; Abstinence |
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# Reporting Certainty of Evidence on E-Cigarette Use for Adult Smoking Cessation

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ProQuest document link

## ABSTRACT (ENGLISH)

The National Academy of Medicine recommends evaluating the quality of the body of evidence for each outcome in a systematic review.1 Endorsed by more than 100 organizations internationally, Grading of Recommendations Assessment, Development, and Evaluation (GRADE) provides an explicit, systematic, and transparent approach to this assessment of the quality of evidence (or "certainty of evidence").2 It is designed for evaluating the certainty of evidence from randomized clinical trials (RCTs) on therapeutic interventions to inform clinical decision making as well as observational studies on exposures to inform public health decision making.3 Consequently, GRADE can be used to assess certainty of evidence in the two distinct bodies of evidence that Wang et al. discuss in their article (this issue of AJPH, p. 230) on e-cigarette use for adult smoking cessation: RCTs of e-cigarettes as a prescription therapy and observational studies of e-cigarettes as consumer products.

Wang et al. used the GRADE approach to assess certainty of RCT evidence on e-cigarettes as a prescription therapy. They specified their interest in the effect of providing free nicotine e-cigarettes (compared with counseling alone or combined with pharmacological support) on smoking cessation among adult populations who smoke cigarettes at any duration and frequency. In addition to specifying the review question, GRADE emphasizes the need to specify the definition of "certainty of evidence" as well. GRADE currently recommends "the certainty that a true effect lies on one side of a specified threshold or within a chosen range,"4(p4) with review teams choosing the most appropriate threshold or range for the intended decision-making context. As Wang et al. do not define certainty in the PROSPERO registration or article, an explicit definition is needed to ensure a coherent conceptual basis for their certainty ratings and appropriate reader interpretation of findings.

## FULL TEXT

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Wang et al. used the GRADE approach to assess certainty of RCT evidence on e-cigarettes as a prescription therapy. They specified their interest in the effect of providing free nicotine e-cigarettes (compared with counseling alone or combined with pharmacological support) on smoking cessation among adult populations who smoke cigarettes at any duration and frequency. In addition to specifying the review question, GRADE emphasizes the need to specify the definition of "certainty of evidence" as well. GRADE currently recommends "the certainty that a true effect lies on one side of a specified threshold or within a chosen range,"4(p4) with review teams choosing the most appropriate threshold or range for the intended decision-making context. As Wang et al. do not define certainty in the PROSPERO registration or article, an explicit definition is needed to ensure a coherent conceptual basis for their certainty ratings and appropriate reader interpretation of findings.4,5

In their review of RCTs on e-cigarettes as a prescription therapy, Wang et al. generally met the criteria set by the GRADE Working Group for determining whether the GRADE approach was used appropriately.2 GRADE classifies certainty of evidence into one of four levels: "high,""moderate,""low," and "very low." Following GRADE guidance for bodies of evidence consisting only of RCTs, the authors started at "high" certainty and then assessed this body of evidence for potential downgrading across five domains: study limitations (risk of bias), inconsistency of results, indirectness of evidence, imprecision, and publication bias. They ultimately rated certainty of evidence as "moderate," downgrading one level for indirectness because ofthe limited number of e-cigarette products evaluated in the included RCTs. Users of this review might be interested in whether the authors have sufficient confidence in the applicability ofthe available evidence to a subset of e-cigarette products for which their certainty would be higher (i.e., by not downgrading because of indirectness). This subset could be based on the factors the authors mention in their analysis of indirectness, such as nicotine concentration of e-liquid, nicotine formulation, flavoring agents, and distribution strategy.

Additional information is needed to appraise the decisions not to downgrade for inconsistency, publication bias, and study limitations. First, the authors provide a strong justification for no serious inconsistency in their assessment of the relative risk of e-cigarettes. However, they do not discuss the substantial heterogeneity in the synthesis of risk difference estimates (absolute risk reductions).6 The authors should report whether they have identified patient characteristics that permit them to confidently classify patients into subpopulations at appreciably different risk and, subsequently, warrant differences in recommendations across these subpopulations.2

Second, as Wang et al. note, their statistical assessment of publication bias is underpowered because of the small number of RCTs in their evidence base, and they did not use trial registries, gray literature, or expert contacts to attempt to identify unpublished studies. They also did not use additional methods to detect publication bias (e.g., contourenhanced funnel plots, qualitative signals to raise suspicion of additional missing results).6 These limitations of the review methods hinder the already difficult task of judging whether to downgrade certainty for publication bias.2

Lastly, given modifications Wang et al. made to the Cochrane Risk of Bias tool and a lack of justifications for ratings,6 it is unclear whether the assessments of study limitations meet the criteria GRADE requires.2 For example, the authors do not report whether low-risk participants randomized to e-cigarette use means that included RCTs used a random component in the sequence generation process (e.g., a computer random number generator) and an adequate method to conceal allocation (e.g., central allocation).2,6 Further information from the authors on these considerations (e.g., in online supplements or materials archived in a repository) would address questions about the final certainty rating provided forthis body of evidence. To ensure that this information is available to readers, AJPH should consider requiring sufficient detail to appraise GRADE certainty of evidence ratings in systematic reviews submitted to the journal.

By contrast to their synthesis of RCTs, Wang et al. did not use GRADE to assess certainty of evidence in their syntheses of observational studies. In addition to evidence from RCTs on e-cigarettes as a prescription therapy, GRADE is also designed for the type of observational evidence on e-cigarettes as consumer products included in this review.2 Consequently, GRADE certainty ratings for this body of evidence are needed to facilitate appropriate interpretation of review findings when used to inform public health recommendations.3 For example, using an odds ratio of 1.0 as the threshold, Wang et al. could evaluate the certainty of evidence on the presence of a (causal) association between e-cigarette use as a consumer product and adult smoking cessation.4

With an observational body of evidence, Wang et al. have the option of starting at "low" certainty and assessing three additional domains for upgrading (magnitude of effect, dose-response gradient, and effect of plausible residual confounding), if there are no major limitations in the body of evidence. Alternatively, they have the option to start at "high" certainty when using a risk of bias tool that mitigates the concerns about confounding and selection bias in observational studies that otherwise lead to an observational body of evidence starting at "low." Currently, GRADE has approved one tool for this latter option, the Risk of Bias in Nonrandomized Studies of Interventions (ROBINS-I) tool, given its underlying logic and nuanced assessment of confounding and selection bias.7

As ROBINS-I is the successor to the Cochrane Risk of Bias Assessment Tool: for Non-Randomized Studies of Interventions (ACROBAT-NRSI), which is used in the current review (and the developers of ACROBAT-NRSI now recommend using ROBINS-I instead), Wang et al. should consider the option of starting at "high" certainty and update their risk of bias assessments using (all domains in) ROBINS-I. Additionally, the authors should attend particularly to inconsistency in their certainty of evidence assessment, as this body of observational evidence has considerable (and currently unexplained) heterogeneity in the reported metaanalyses.2,6

For future dissemination, Wang et al. should consider user-tested templates for formulating informative narrative statements and creating summary of findings tables that effectively communicate certainty of evidence ratings.5 Using these templates can help to ensure that the best available research evidence about the effects of ecigarettes on adult smoking cessation is appropriately considered (along with information about other important factors, such as equity, acceptability, feasibility, and resource use) when making clinical, health system, and public health decisions.3

CORRESPONDENCE

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CONFLICTS OF INTEREST

S. Grant is a member of the Grading of Recommendations Assessment, Development and Evaluation Working Group.

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## DETAILS

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|---|---|
| **Subject:** | Clinical trials; Smoking cessation; Smoking; Public health; Cigarettes; Heterogeneity; Drug addiction; Working groups; Decision making; Electronic cigarettes; Evaluation; Bias; Therapeutic applications; Handbooks; Quality assessment; Ratings; Nicotine; Consumer products; Cigarette smoking; Ratings &rankings; Reviews; Clinical decision making; Vaping; Systematic review; Observational studies |
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# Impact of Differential Privacy and Census Tract Data Source (Decennial Census Versus American Community Survey) for Monitoring Health Inequities

Krieger, Nancy, PhD; Nethery, Rachel C, PhD; Chen, Jarvis T, ScD; Waterman, Pamela D, MPH; Wright, Emily, BA; Rushovich, Tamara, MPH; Coull, Brent A, PhD

ProQuest document link

## ABSTRACT (ENGLISH)

Objectives. To investigate how census tract (CT) estimates of mortality rates and inequities are affected by (1) differential privacy (DP), whereby the public decennial census (DC) data are injected with statistical "noise" to protect individual privacy, and (2) uncertainty arising from the small number of different persons surveyed each year in a given CT for the American Community Survey (ACS). Methods. We compared estimates of the 2008-2012 average annual premature mortality rate (death before age 65 years) in Massachusetts using CT data from the 2010 DC, 2010 DC with DP, and 2008-2012 ACS 5-year estimate data. Results. For these 3 denominator sources, the age-standardized premature mortality rates (per 100 000) for the total population respectively equaled 166.4 (95% confidence interval [CI] = 162.2, 170.6), 166.4 (95% CI = 162.2, 170.6), and 166.3 (95% CI = 162.1, 170.5), and inequities in the range from best to worst quintile for CT racialized economic segregation were from 103.4 to 260.1, 102.9 to 258.7, and 102.8 to 262.4. Similarity of results across CT denominator sources held for analyses stratified bygenderand race/ ethnicity. Conclusions. Estimates of health inequities at the CT level may not be affected by use of 2020 DP data and uncertainty in the ACS data. (Am J Public Health. 2021;111:265-268. https://doi.org/10.2105/AJPH.2020.305989)

## FULL TEXT

### Headnote

Objectives. To investigate how census tract (CT) estimates of mortality rates and inequities are affected by (1) differential privacy (DP), whereby the public decennial census (DC) data are injected with statistical "noise" to protect individual privacy, and (2) uncertainty arising from the small number of different persons surveyed each year in a given CT for the American Community Survey (ACS).

Methods. We compared estimates of the 2008-2012 average annual premature mortality rate (death before age 65 years) in Massachusetts using CT data from the 2010 DC, 2010 DC with DP, and 2008-2012 ACS 5-year estimate data.

Results. For these 3 denominator sources, the age-standardized premature mortality rates (per 100 000) for the total population respectively equaled 166.4 (95% confidence interval [CI] = 162.2, 170.6), 166.4 (95% CI = 162.2, 170.6), and 166.3 (95% CI = 162.1, 170.5), and inequities in the range from best to worst quintile for CT racialized economic segregation were from 103.4 to 260.1, 102.9 to 258.7, and 102.8 to 262.4. Similarity of results across CT denominator sources held for analyses stratified bygenderand race/ ethnicity.

Conclusions. Estimates of health inequities at the CT level may not be affected by use of 2020 DP data and uncertainty in the ACS data. (Am J Public Health. 2021;111:265-268. https://doi.org/10.2105/ AJPH.2020.305989)

Despite the importance of accurate census data for public health-for denominators, for characterizing areas, and for allocating political representation and resources1-little is known about how census tract (CT) estimates of health rates and inequities-critical for local health monitoring and analysis2,3-will be affected by the new use of differential privacy (DP) with the 2020 decennial census (DC).4 In brief, DP refers to a procedure whereby statistical "noise" is injected into the publicly released DC data to protect individual privacy.4 New research has raised concerns that DP combined with census postprocessing of these data may bias substate population counts (e.g., counties, CTs), deflating population counts in urban and American Indian areas and inflating them in other areas, and thus affecting computation of rates.5

Also still poorly understood are impacts of the 2008 federal shift from collecting detailed social and economic data in the DC long form to the annually conducted American Community Survey (ACS).6 Of particular concern is the uncertainty arising from the small number of different persons surveyed each year in a given CT, producing wide margins of error for population counts.7

To our knowledge, no research has assessed the potential impact of DP on population health estimates computed from CT data or compared this impact with that of sampling-related error in the ACS. In November 2019, the US Census Bureau released its first-ever DP demonstration product, comprising the 2010 DC data with DP applied, enabling research to address this issue.4 We empirically evaluated the impact of using CT population counts from the 2010 DC, 2010 DC with DP, and 2008-2012 ACS on estimating inequities in premature mortality in Massachusetts.

## METHODS

Our 3 CT population sources were (1) the most recent DC file with DP, produced by the US Census Bureau in November 2019 forthe 2010 DC4,810; (2) the original 2010 DC; and (3) the 20082012 5-year estimates from the ACS.6

### Mortality Data

We obtained individual-level mortality data for 2008 to 2012 for all premature deaths (younger than 65 years; n = 55 836 deaths) from the Massachusetts Department of Public Health11 (Table A, available as a supplement to the online version of this article at http:// www.ajph.org). We geocoded the residential address at death to the corresponding CT2; only 0.4% of deaths could not be geocoded with this level of precision, yielding an analytic data set with 55 560 deaths. We focused on premature mortality because this outcome is a widely used population health indicator that manifests strong social gradients and is not affected by misclassification of cause of death.2,3

### Metric for Health Inequities

We used the index of concentration at the extremes (ICE) for racialized economic segregation, which we developed in 2014, building on Massey's initial use of the ICE for solely economic measures,12 with our measure shown in numerous studies to be more sensitive to health inequities than metrics employing solely economic or racial data (Table B, available as a supplement to the online version of this article at http:// www.ajph.org). The ICE delineates people's concentration, in an area, in the extremes of the selected measure and ranges from -1 (all in the deprived group) to 1 (all in the most privileged group).12 Its formula is

(1) ...

where A,, P,, and T¡ correspond, respectively, to the number of persons in the ith geographic area categorized as belonging to the most privileged extreme, the most deprived extreme, and the total population whose privilege level was measured.12 For our analyses, we set these extremes as (1) high-income White (alone) population versus (2) low-income Black (alone) population12 (see Table Bfor the census variables used). Missing data precluded computing the ICE for 19 (1.3%) of the Massachusetts CTs.

## Statistical Methods

We computed, for the total population and also stratified by race/ethnicity and gender, the 2008-2012 average annual age-standardized premature mortality rate (death before age 65 years per 100 000 persons, standardized to the year 2000 standard million2) and associated 95% confidence interval (CI) in Massachusetts using CT population counts from the 2010 DC, 2010 DC with DP, and 2008-2012 ACS 5-year estimate data. We then categorized the CT in quintiles of the ICE for racialized economic segregation, aggregated the mortality and population count data across tracts within each quintile (without taking into account spatial correlations), and computed premature mortality rates by ICE quintile, overall and by race/ ethnicity and gender. We then plotted and compared the point estimates and their 95% CIs for each source of population count data. We also conducted sensitivity analyses using the percentage of persons below poverty (Table B).

## RESULTS

In 2010, the population of Massachusetts included 5 644905 persons younger than 65 years (based on the 2010 DC) and 1478 CTs. The age-standardized premature mortality rates (per 100 000) for the total population were highly similar across the 3 denominator sources (DC, DP, and ACS) and respectively equaled 166.4 (95% CI = 162.2, 170.6), 166.3 (95% CI = 162.2, 170.5), and 166.4 (95% CI = 162.1, 170.6; Figure 1). Also similar across denominator sources was the range from best to worst quintile for CT racialized economic segregation (103.4-260.1, 102.9-258.7, and 102.8262.4; Table C, available as a supplement to the online version of this article at http ://www.ajph.org).

Robustness across CT denominator sources held for analyses stratified by race/ethnicity and by gender (Table C), with results for the non-Hispanic White population closely paralleling those for the total population (reflecting that they constituted 74.0% of the 2010 Massachusetts population younger than 65 years). Among the Black population (7.1 % of the total population aged younger than 65 years), these rates respectively equaled 230.5 (95% CI = 210.5, 250.6), 229.8 (95% CI = 209.8, 249.8), and 226.4 (95% CI = 206.4, 245.8)-and the range across the ICE quintiles was 173.0 to 258.6.161.3 to 260.4, and 177.5 to 249.6 (Table C). These rates for women were identical across the 3 CT denominator sources (118.6; 95% CI = 107.6, 129.6) and virtually identical for men (214.2 [95% CI = 199.0, 229.4]; 214.2 [95% CI = 198.9, 229.4]; and 214.0 [95% CI = 198.8, 229.3]); for both groups, the range in rates across the ICE quintiles was likewise similar across the 3 denominator sources (Table C). Sensitivity analyses of inequities by the CT poverty level yielded similar results across the 3 denominator sources (Table C).

## DISCUSSION

Our study, the first, to our knowledge, to compare estimates of premature mortality rates and inequities in this outcome using CT denominators obtained from the 2010 DC, the 2010 DC with DP, and the 2008-2012 5-year estimate ACS data, provides novel evidence that these estimates-at least in the state of Massachusetts-are robust to the source of denominator data employed. This finding held when we aggregated across the total population, and also when we stratified by race/ethnicity, and by gender.

One key limitation of our study concerns generalizability. Additional research should investigate whether similar results are obtained for other states, for other small geographic units (especially those not nested within counties;

e.g., American Indian areas), and different health outcomes (e.g., morbidity, health practices, and cause-specific mortality) as expressed across the life course (e.g., from infancy to among the elderly). An additional limitation is that our study did not statistically account for spatial correlation among CTs or the available margins of error for ACS estimates7; this is a focus of our ongoing work.

In summary, our results provide initial evidence that monitoring of population health and health inequities using aggregated CT-level population denominators may not be adversely affected by the impending shift to use of differentially private census data, starting with the 2020 decennial census. >4jPH

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CONTRIBUTORS

N. Krieger conceptualized the study and led the drafting of the article. N. Krieger, R. C. Nethery, J.T. Chen, and B.A. Coull designed the statistical analyses. P. D. Waterman assembled the data. R. C. Nethery and J.T. Chen led conduct of the analyses. E. Wright and T. Rushovich assisted with analyses. All authors contributed to the article's content and approved the final version for submission.

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CONFLICTS OF INTEREST

None of the authors have any conflicts of interest to declare.

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## DETAILS

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| **Subject:** | Population; Minority &ethnic groups; Censuses; Public health; Mortality; Gender; Census; Health disparities; Age; Ethnicity; Privacy; Mortality rates; Confidence intervals; Statistical analysis; Uncertainty; Economic indicators; Segregation; Data; Estimates; Polls &surveys |
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Document 10 of 38

# Lethal Means Counseling, Distribution of Cable Locks, and Safe Firearm Storage Practices Among the Mississippi National Guard: A Factorial Randomized Controlled Trial, 2018-2020

Anestis, Michael D, PhD; Bryan, Craig J, PsyD; Capron, Daniel W, PhD; Bryan, Annabelle O, MS

ProQuest document link

## ABSTRACT (ENGLISH)

Objectives. To examine whether lethal means counseling and provision of cable locks prompt safe firearm storage relative to control among firearm-owning members of the Mississippi National Guard. Methods. This randomized controlled trial utilized a 2 x 2 factorial design (lethal means counseling vs control, provision of cable locks vs no cable locks). Follow-up assessments took place at 3 and 6 months after baseline. Data were collected (n = 232; 87.5% male; mean age = 35.01 years; 77.2% White) from February 2018 through July 2020. Results. Relative to control, lethal means counseling and provision of cable locks resulted in greater adoption of several safe storage methods overtime. Lethal means counseling outperformed control (3 months: 55.0% vs 39.0%; odds ratio [OR] =

1.91). Cable locks outperformed control at 3 and 6 months on number of storage methods (1.41 vs 1.11; d = 0.29 and 1.34 vs 1.16; d = 0.15, respectively) and locking devices (59.8% vs 29.9%; OR = 3.49 and 58.4% vs 35.8%; OR = 2.52, respectively) Conclusions. Lethal means counseling and cable locks can result in sustained changes in firearm storage. Public Health Implications. The military may benefit from lethal means counseling, perhaps administering at point of entry. Trial Registration. Clinical Trials.gov identifier: NCT03375099. (Am J Public Health. 2021;111:309-317. https://doi.org/10.2105/AJPH.2020.306019)

## FULL TEXT

### Headnote

Objectives. To examine whether lethal means counseling and provision of cable locks prompt safe firearm storage relative to control among firearm-owning members of the Mississippi National Guard.

Methods. This randomized controlled trial utilized a 2 x 2 factorial design (lethal means counseling vs control, provision of cable locks vs no cable locks). Follow-up assessments took place at 3 and 6 months after baseline. Data were collected (n = 232; 87.5% male; mean age = 35.01 years; 77.2% White) from February 2018 through July 2020.

Results. Relative to control, lethal means counseling and provision of cable locks resulted in greater adoption of several safe storage methods overtime. Lethal means counseling outperformed control (3 months: 55.0% vs 39.0%; odds ratio [OR] = 1.91). Cable locks outperformed control at 3 and 6 months on number of storage methods (1.41 vs 1.11; d = 0.29 and 1.34 vs 1.16; d = 0.15, respectively) and locking devices (59.8% vs 29.9%; OR = 3.49 and 58.4% vs 35.8%; OR = 2.52, respectively)

Conclusions. Lethal means counseling and cable locks can result in sustained changes in firearm storage.

Public Health Implications. The military may benefit from lethal means counseling, perhaps administering at point of entry.

Trial Registration. Clinical Trials.gov identifier: NCT03375099. (Am J Public Health. 2021;111:309-317. https://doi.org/10.2105/AJPH.2020.306019)

Firearms account for the majority of US suicides1 and more than 60% of military suicides.2 Suicide mortality is higher in homes with a firearm,3 and statewide firearm ownership rates are correlated with suicide rates even after controlling for other risk factors.4 9 Suicide risk associated with firearm availability may be reduced when firearms are stored safely, however.10,11 Safe firearm storage may be promoted with lethal means counseling, which involves discussing ways to limit an individual's access to specific methods for suicide. Although lethal means counseling is a recommended best practice for suicide prevention,12 research on its acceptability and effectiveness is limited.13 Preliminary evidence suggests lethal means counseling delivered in an emergency department increases the likelihood that parents of suicidal adolescents will restrict access to suicide methods.14,15 Because 90% of suicide attempts with firearms are fatal,16 lethal means counseling cannot only be offered after a suicidal crisis has emerged, as this would result in many high-risk individuals not being exposed to the intervention. Supporting this perspective is research suggesting that the benefits of safe firearm storage may be most pronounced among individuals without a known mental illness and with low suicidal intent.10

Within the military, a preventive approach may be especially important because military personnel are more likely to own firearms17 but the majority do not use safe storage methods.18 20 Military personnel are also more likely to use firearms when attempting suicide.21,22 Acutely suicidal military personnel are prone to unsafely storing firearms,19 underreporting suicidal thoughts to military or civilian sources,23,24 and failing to disclose access to a firearm.25 Encouraging safe storage among all firearm-owning military personnel, regardless of acute suicide risk level, is therefore critical. The effectiveness of lethal means counseling and related strategies (e.g., distributing cable locks) as a preventive strategy among military personnel remains unknown. The primary aims of the present study were to examine if lethal means counseling and distribution of cable locks increase the use of safe storage practices in a community sample of firearm-owning military personnel. Using a 2 x 2 factorial design, we randomized firearm-owning US National Guard service members to receive lethal means counseling, cable locks, or both. We assessed firearm storage practices 3 and 6 months after baseline. We anticipated that participants who received lethal means counseling or cable locks would exhibit increased safe storage behaviors during follow-up.

## METHODS

Participants were 232 firearm-owning members of the Mississippi National Guard. Service members were recruited via online advertising and in person at military-sponsored and community events. To minimize selection bias, the study-titled "Project Safe Guard"-was advertised as a "health and home safety" study. Service members filled out a screening questionnaire to assess eligibility. Those reporting current membership in the Mississippi National Guard and ownership of at least 1 firearm were scheduled for a baseline appointment at the University of Southern Mississippi to complete informed consent procedures. Service members consenting to participate completed a series of structured interviews and selfreport questionnaires, after which they were randomized to 1 of 4 groups: (1) lethal means counseling, (2) lethal means counseling plus cable locks, (3) health and stress counseling (HSC), or (4) HSC plus cable locks. Immediately after the intervention, participants completed a second series of self-report questionnaires. Participants were contacted at 3 and 6 months after baseline to complete structured interviews and self-report questionnaires. Participants received $50 for completing the baseline appointment and $75 for each follow-up assessment.

The present study used a 2 x 2 factorial design with randomization stratified by gender and lifetime history of suicidal thoughts. Randomization was achieved by using a computerized algorithm via Qualtrics to minimize bias or human error. Follow-up assessments were conducted at 3 and 6 months after baseline.

### Interventions

All interventions were delivered by clinical psychology doctoral students, each of whom completed a standardized 2daytrainingworkshop conducted by 2 of the investigators (A. O. B. and C.J. B.) that included didactics, demonstrations, and role plays with supervision and feedback. After the training, clinicians completed practice sessions that were audio recorded and reviewed by the trainers for fidelity monitoring. At least 2 practice sessions with a minimum 85% fidelity score was required for clinicians to begin administering the interventions to participants. All study interventions were audio recorded and rated by 1 of the trainers with a published fidelity rating scale.26 Supervision and feedback were provided to study clinicians. At the conclusion of the 6-month session, participants were offered all interventions they were not randomized to receive at baseline free of charge.

Lethal means counseling. Lethal means counseling was administered by using a motivational interviewing-based protocol.26 28 In this protocol, the clinician used a guiding approach to identify methods for safe firearm storage and reflected the participant's reasons for and against safe firearm storage, with a particular focus on the service member's verbalized reasons for wanting to adopt or use the identified storage methods. Once a plan for safe firearm storage was identified and agreed upon by the participant and clinician, it was written down and a copy given to the participant. On average, lethal means counseling required approximately 10 to 15 minutes.

Health and stress counseling. HSC was used as an active attention control. In the HSC condition, the clinician used a guiding approach to identify potential methods for enhancing stress management, sleep quality, diet, or exercise; the specific topic discussed was chosen by the participant. Once a plan was identified and agreed upon, it was written down and a copy was given to the participant. On average, HSC required 10 to 15 minutes.

Cable locks. In the cable lock groups, participants were given cable locks for each of their personal firearms (up to a maximum of 10) after they had completed their assigned counseling intervention. All service members were given instructions on how to utilize the cable locks if they indicated that they did not know how to use them or if they believed they were incompatible with their personal firearms. Cable locks were provided by the Defense Suicide Prevention Office.

### Measures

Firearm storage practices. Service members were asked if they used each of the following firearm storage practices: (1) storing firearms in a gun safe, (2) using a locking device when the firearm is not in use, and (3) storing firearms unloaded. Response options were "yes" or "no." Participants were directed to answer in a manner that reflected the practice used for their least-secured firearm (e.g., if at least 1 firearm was not stored in a safe, the participant was directed to answer "no" in response to that question). Participants were asked to report their current firearm storage practices at baseline (before the intervention), and 3 months and 6 months after baseline.

Intervention acceptability. Service members were asked immediately after treatment if they would recommend the intervention to a peer. Responses were coded dichotomously as yes (1) or no (0).

Statistical Analysis

We evaluated the study hypotheses by using intent-to-treat analyses that included all participants enrolled and randomized to each intervention. Missing data during follow-up were low (7.8% at 3 months and 9.9% at 6 months after baseline) and random (Little's test: X2(3) = 3.9; P =.269). For all analyses, we used generalized linear mixed modeling (GLMM) with a random intercept, nesting of repeated assessments within participants, and a sandwich variance estimator. Independent variables included counseling group (lethal means counseling vs HSC), cable lock group (given vs not), time (baseline, 3 months, 6 months), all 2-way interactions, and the 3-way interaction. We used a Satterthwaite approximation because simulation studies show the method minimizes type I error rates.29 The primary outcome was firearm storage practices and was modeled as a count variable computed as the sum total of 3 firearm storage practices (i.e., gun safe, locking device, and firearm unloaded) that conformed to a Poisson distribution.

We next constructed a series of GLMMs to examine treatment effects on each firearm storage practice and intervention acceptability as separate binary outcomes. We also conducted a series of sensitivity analyses that repeated these GLMMs in the subset of participants denying the use of each safe storage practice at baseline, thereby enabling us to assess intervention effects and acceptability among those participants who did not use various safe storage practices. We conducted all analyses with SPSS version 25 software (IBM, Somers, NY).

We calculated a priori power and sample size estimates for the primary outcome by using previously reported rates of between-group differences in rates of restricting access to potential suicide methods (Kruesi et al.14; McManus et al.15), which suggested a large effect of lethal means counseling on means restriction behaviors (odds ratios [ORs] >4). We chose to estimate a more conservative effect (i.e., OR = 2.0-2.5), however, because these studies were conducted with high-risk adolescents receiving treatment in an emergency department after a suicide attempt, and the lethal means counseling was provided to the adolescent's parents. The present study, by contrast, was conducted in a community sample of adult firearm owners. Assuming a 2-tailed a = 0.05, a total sample of 200 participants (100 per factor level, or 50 per intervention group) was needed to detect a minimum OR of 2 with 80% power. To account for expected attrition, we recruited an additional 8 participants per condition for a total sample of 232.

RESULTS

Demographic characteristics of the sample are summarized in Table 1. Flow of participants through the study is summarized in Figure 1. Dropout rates across the 4 intervention groups did not significantly differ (%2[3] = 6.2; P =.104): lethal means counseling only (6.8%), lethal means counseling plus cable lock (18.2%), HSC only (5.4%), and HSC plus cable lock (9.7%).

Cable Lock Distribution and Storage Practices

In the cable lock group, the mean number of firearm storage methods used (F[2643] = 9.1; P<.001) and rate of locking device use (F[2643] = 15.9; P<.001) significantly increased over time. In the control group, the rate of locking devices significantly increased over time (F[2643] = 4.4; P = .013). These increases were larger in the cable lock group (Table 2). At 3 months, participants in the cable lock group reported a slightly higher mean number of firearm storage methods on average (mean = 1.41 [SE = 0.10] vs mean = 1.11 [SE = 0.10]; d = 0.29; 95% confidence interval [CI] = 0.09, 0.49) and were more than twice as likely to use locking devices (59.8% [SE = 6.0%] vs 29.9% [SE = 5.2%]; OR = 3.49; 95% CI = 1.98, 6.14). At 6 months, the difference in mean firearm storage methods used was negligible between groups (mean = 1.34 [SE = 0.10] vs mean = 1.16 [SE = 0.10]; d = 0.15; 95% CI = -0.06, 0.35). The rate of locking device use reduced slightly but was still approximately 1.5 times higher in the cable lock group (58.4% [SE = 6.1%] vs 35.8% [SE = 5.8%]; OR = 2.52; 95% CI = 1.44, 4.40).

Results of our sensitivity analyses yielded statistically significant betweengroup differences for locking device use

(Table 3). Using a gun safe was less common in the cable lock group at 3 months (0.0% [SE = 0.0%] vs 15.3% [SE = 0.0%]) but rates of use were comparable across groups at 6 months (15.3% [SE = 4.4%] vs 13.4% [SE = 4.4%]; OR = 1.17; 95% CI = 046, 2.98). In the cable lock group, the rate of locking device use was approximately 3 times more common at 3 months (42.6% [SE = 6.7%] vs 15.3% [SE = 3.9%]; OR = 4.11; 95% CI = 1.93, 8.74) and 1.9 times more common at 6 months (22.9% [SE = 5.0%] vs 42.8% [SE = 6.8%]; OR = 2.52; 95% CI = 1.26, 5.05).

## Lethal Means Counseling and Storage Practices

In the lethal means counseling group, the mean number of storage methods used (F[2643] = 11.3; P<.001), rate of gun safe use (F[2643] = 3.9; P = .020), and rate of locking device use (F[2643] = 17.7; P<.001) significantly increased over time. In the control group, there was no change in any outcome variable. The observed increases were only slightly larger in the lethal means counseling group (Table 2). At 6 months, the participants in the lethal means counseling group were approximately 30% more likely to use a locking device (55.0% [SE = 6.3%] vs 39.0% [SE = 5.9%]; OR = 1.91; 95% CI = 1.10, 3.32).

Results of our sensitivity analyses yielded a statistically significant between-group difference only for locking device use (Table 3). Using a gun safe was more common in the lethal means counseling group at 3 months (22.8% [SE = 5.0%] vs 0.0% [SE = 0.0%]) but rates of use were comparable across groups at 6 months (18.7% [SE = 4.6%] vs 10.9% [SE = 3.6%]; OR =1.88; 95% CI = 0.72, 4.88). In the lethal means counseling group, locking device use was comparable at 3 months (25.9% [SE = 5.7%] vs 27.7% [SE = 5.6%]; OR = 0.91; 95% CI = 0.45, 1.85) and 1.6 times higher at 6 months (40.4% [SE = 6.5%] vs 24.7% [SE = 5.4%]; OR = 2.07; 95% CI = 1.04, 4.11).

## DISCUSSION

In the present study, we examined the effectiveness of a single session of lethal means counseling and the distribution of cable locks for prompting safe storage practices in a community sample of US National Guard personnel using a primary prevention framework wherein participants were recruited on the basis of firearm ownership ratherthan suicide risk. Several results were consistent with expectations. First, service members who received lethal means counseling reported a larger increase in the number of safe storage practices used over time, specifically the use of gun safes and locking devices, relative to those randomized to HSC. Second, service members who received 1 or more cable locks were more likely to use locking devices over time as compared with those who received no cable locks. Our results did not support the superiority of lethal means counseling and gun locks in combination beyond the effects of either intervention alone.

These results are promising when we consider that our method for assessing use of firearm storage practices utilized a conservative criterion wherein all firearms in the household had to be stored with a given practice to be considered present. If any firearm within the home was unlocked, for example, the criterion for safe storage was not met. In this sense, these results could underestimate the impact of lethal means counseling and cable lock distribution by disregarding incremental behavior changes wherein some, but not all, firearms were more safely stored after intervention.

The appropriateness of each intervention likely differs by setting. Distributing cable locks, for instance, may be more scalable but may increase only 1 storage method. Lethal means counseling, by contrast, may increase a wider range of storage options but is less scalable. In our sensitivity analyses, individuals who did not use gun safes and received a cable lock were less likely than those who did not receive a gun lock to store all of their firearms in a gun safe. It is possible, for instance, that the distribution of locking devices reduces the perceived utility or value of gun safes.

The speed with which participants adopted various storage practices was notable. Among those who did not use locking devices, 42.6% of those who received a cable lock versus 15.3% of those who did not reported using locking devices on all firearms within 3 months. Lethal means counseling, by contrast, showed a slower adoption rate for locking devices (approximately 26% by 3 months and 40% by 6 months after baseline), but a faster adoption rate for gun safes. The speed with which a particular storage method is adopted may vary within lethal means counseling in part because this particular intervention is not focused on a single method and also because this protocol involves working within the values and motivations of individuals rather than prescribing a particular set of actions.

In addition to examining the efficacy of the intervention, we also examined acceptability. Our decision to conduct this trial using a politically conservative sample of individuals in a high-firearm-ownership state represents a strength. High rates of acceptability would thus serve as a sign that productive conversations on this topic are possible even in difficult circumstances. We considered acceptability by using 2 variables: attrition rate and selfreported likelihood of recommending the intervention to peers. Retention rates for the study were high, with 90.9% of the baseline sample completing the entire protocol. Furthermore, attrition rates did not differ across conditions. In addition, across the entire protocol, only 1 participant indicated that he or she would not recommend the intervention, and that individual was randomized to the HSC-only condition, meaning that all individuals who received lethal means counseling or a cable lock indicated that they would recommend their intervention.

## Limitations

A limitation of our study involved variability across treatment groups on baseline firearm storage practices. Although not statistically significant, participants randomized to the HSC plus cable lock group were approximately twice as likely to use gun safes as participants randomized to the lethal means counseling plus cable lock group (39% vs 19%). To assess the potential impact of this variability on our results, we conducted sensitivity analyses wherein we repeated our analyses in the subset of participants who did not endorse this storage practice at baseline. The results of these analyses did not differ from our primary analyses, however, suggesting that this limitation did not adversely affect our results. Stratifying by storage practices at baseline is recommended for future studies. Another limitation is our use of self-report to assess firearm storage practices, although there is no reason to think that accurate self-disclosure would be nonrandomly distributed across intervention groups. The generalizability of our results beyond members of the Mississippi National Guard may also be limited. Our use of doctoral students- albeit with limited clinical experience- to conduct lethal means counseling may limit our understanding of the potential broader reach of lethal means counseling when provided by health care professionals, commanders, and other community members.

## Conclusions

Despite these limitations, these results highlight that lethal means counseling and the provision of cable locks can facilitate meaningful and sustained changes in firearm storage practices. It is difficult to estimate the number of lives that would be saved if these protocols were broadly implemented, as data demonstrating that adoption of safe storage prevents otherwise likely suicide deaths are lacking. Given the frequency with which firearms are used in military suicides, promoting safe firearm storage may represent an invaluable tool for military suicide prevention. These results suggest that lethal means counseling and cable lock distribution could positively address this issue, even among firearm-owning service members not seeking out either intervention. Pending replication, broader implementation of lethal means counseling and cable lock distribution within the US military may represent an important step toward lowering the military suicide rate. >4JPU

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CONTRIBUTORS

M.D. Anestis led the conceptualization and implementation ofthe study, wrote approximately 60% of the initialdraft ofthe article, and led the effort at revisions. C.J. Bryan contributed to the conceptualization ofthe study, co-led the training of study clinicians, ran the analyses, wrote approximately 20% ofthe initialdraft ofthe article, and contributed to the revision process. D. W. Capron helped lead the conceptualization and implementation ofthe study, wrote approximately 10% of the article, and contributed to the revision process. A. O. Bryan helped co-lead the training of study clinicians, led the fidelity monitoring and clinicalsupervision of study clinicians, wrote approximately 10% ofthe article, and contributed to the revision process.

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CONFLICTS OF INTEREST

M.D. Anestis receives personal income from book royalties related to firearms and suicide as well as speaking and consulting fees on these topics. C.J. Bryan receives personal income from trainings on lethalmeans counseling.

HUMAN PARTICIPANT PROTECTION

Approvalwas received and annually renewed from the University of Southern Mississippi institutional review board and the US Army MedicalResearch and MaterielCommand Human Research Protection Office.

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## DETAILS

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# Is Good Enough Good Enough? E-Cigarettes, Evidence, and Policy

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## ABSTRACT (ENGLISH)

In 2017, under the leadership of Scott Gottlieb, the US Food and Drug Administration (FDA) opened the door to considering e-cigarettes as a harm-reduction product. In January 2020, the agency signaled its intention to continue to chart that path, writing, [T]he potential for [electronic nicotine delivery systems] to act as a substitute for cigarettes, thereby encouraging smokers to seek to switch completely away from combustible cigarettes, may be dependent, in part, upon the product having acceptability and abuse liability more comparable to a cigarette. Yet what has always remained unclear is what evidentiary standard the FDA will apply as it reviews products and evaluates public health benefit.

## FULL TEXT

In 2017, under the leadership of Scott Gottlieb, the US Food and Drug Administration (FDA) opened the door to considering e-cigarettes as a harmreduction product. In January 2020, the agency signaled its intention to continue to chart that path, writing,

[T]he potential for [electronic nicotine delivery systems] to act as a substitute for cigarettes, thereby encouraging smokers to seek to switch completely away from combustible cigarettes, may be dependent, in part, upon the product having acceptability and abuse liability more comparable to a cigarette.1(p20)

Yet what has always remained unclear is what evidentiary standard the FDA will apply as it reviews products and evaluates public health benefit.

EVALUATING EVIDENCE

Systematic reviews and meta-analyses are intended to give clarity by looking across studies, aggregating findings from the strongest, weeding out the weakest. Nonetheless, how different nations and organizations have evaluated this question of what counts as appropriate evidence has depended heavily on the context and the primary concerns of review bodies.

In 2018, for instance, back-to-back systematic reviews from National Academics of Science, Engineering, and

Medicine (NASEM) and Public Health England (PHE) took a very different view of what observational studies and randomized controlled trials offered. For NASEM, randomized controlled trials were the most conclusive evidence that could speak to pressing policy questions. Observational studies, whether cohort or cross-sectional, suffered from the messiness of real life. For PHE, although randomized controlled trials were important, observational studies were invaluable precisely because they captured the lived experience.2

Two years later, we have two more contributions that seek to draw policy conclusions from an even broader literature with great variation in quality.

In this issue of the journal, Wang et al. (p. 230) make a contribution with a meta-analysis that leans heavily toward observational studies (55 out of 64 studies). The observational studies, they concluded, were not associated with cessation. In contrast, they found that randomized controlled trials that provided free e-cigarettes were "significantly associated" with quitting compared with conventional therapy.

A 2020 Cochrane review, updated from 2016, which leaned more heavily toward randomized controlled trials (26 out of 50 studies), was cautiously optimistic. Its authors concluded,

There is moderate-certainty evidence that ECs [e-cigarettes] with nicotine increase quit rates compared to ECs without nicotine and compared to [nicotine replacement therapy]. Evidence comparing nicotine EC with usual care/no treatment also suggests benefit, but is less certain.3(p2)

There have been important contextual shifts between 2018 and 2020. We have seen the rise and fall of panic over EVALI (acute e-cigarette or vaping product use-associated lung injury). After an alarming rise between 2017 and 2019, the 2020 National Youth Tobacco Survey found that the proportion of high schoolers who report vaping in the past 30 days has dropped considerably. But we have also seen an all-out assault on ecigarettes, which sets the stage for how we evaluate the accumulating evidence.

What stands out in the 2020 landscape of systematic evidentiary reviews is that despite ongoing debate around a number of issues-youth uptake, the implications of dual use, the collateral harms from vaping-is that we have modest evidence from both observational studies and randomized controlled trials that e-cigarettes do contribute to smoking cessation.

But if the landscape and the evidence are shifting, consistent with the past is that we are unlikely to see a change in the debate over what counts as evidence when it comes to meta-analysis and systematic review. In 2018, Villanti et al. argued that no systematic reviews to date have addressed the most pressing use issues that contribute to variations in findings. Likewise, they underscore the Cochrane Handbook for Systematic Reviews cautions that metaanalyses can compound the confusion when they combine studies reliant on "different study designs."4(p399)

Observational studies can measure very different things, making it challenging to identify studies that can be analyzed as a coherent whole. Metaanalysis is a technique meant to draw broad conclusions from studies that are similar in design. For example, it can be problematic to compare studies that solicited volunteers to studies that observe individuals who began using e-cigarettes on their own.

The chief difference between this latest review and the Cochrane review involves the studies included. The Cochrane reviews were concerned about the selection bias in longitudinal studies, which generally do not capture smokers who successfully quit using e-cigarettes. Rather, they focus on current smokers, with different levels of motivation to quit, who are trying e-cigarettes to stop. As the authors explained in 2016, exclusion of treatment successes "is likely to show a low treatment effect, even for treatments that are highly effective."5(p19) As a result, they concluded, "In future versions of this review, we will no longer include this group of studies."5(p19)

Wang et al. describe the observational studies they selected as exhibiting "substantial heterogeneity." The authors also underscore that the evaluation of ecigarettes is made more complex by variations in quality, design, nicotine formulation and concentration, flavoring, and a complex patchwork of local, national, and global regulation. We would expect some differences in study selection based on the specific questions driving the analysis. Although each review asks a spectrum of questions-Wang et al. were concerned about the effect of daily e-cigarette use on cessation and the impact of free ecigarettes while the Cochrane review also asked about unwanted side effects-at the heart of both was the same fundamental question: do ecigarettes help people to stop smoking?

The main difference, then, is that Wang et al. included many of those studies and aimed to control for confounding with a sensitivity analysis. One author has underscored the value ofthis kind of analysis in response to previous critiques of selection bias (see https:// bit.ly/2J8xBrF and Kalkhoran and Glantz6). The Cochrane reviews excluded observational studies that did not include smokers who had successfully quit using e-cigarettes.

For those primarily concerned about potential unintended consequences of vaping to those who do not currently use e-cigarettes, precaution warrants setting the evidentiary bar low. For those primarily concerned about reducing the immediate harms to smokers while minimizing unintended consequences, moderate evidence is good enough. For some, then, this most recent analysis will not meet even a low evidentiary bar. For others, it will exceed that bar. Still others will call the evidence from the updated 2020 Cochrane review into question. In other words, debates about quality of the evidence should not mask competing values about the risks of inadvertent harms of e-cigarettes, whether to smokers themselves or to nonsmoking or nonvaping bystanders. Evidence and value judgments about which harms are most concerning and what represents an acceptable trade continue to intersect.

## SO WHERE DOES THIS LEAVE US?

The key question from a policy perspective is not only "Do e-cigarettes contribute to smoking cessation?" but also "What level of evidence is good enough to accept e-cigarette harm reduction?" As we debate this, it is important to remember that, as powerful as systematic reviews and meta-analyses can be, any evidentiary evaluation and summation is only as good as the data that go in. And even when the strictest standards are applied, the strong effects found in well-designed studies will be diluted.

A new study by Mendez and Warner considers 360 best- and worst-case scenarios related to vaping, smoking, and health. In only three oftheir models did the harms marginally outweigh the benefits. Nonetheless, they conclude, "e-cigarettes represent a meaningful if thus far modest public health contribution and could represent a more substantial one [emphasis added]."7(p6) An effect need not be robust to produce consequential population health contributions.

We cannot, as a result, think of evidence apart from the policy that can amplify or minimize potential impact. Wang et al. argue that we do not have enough evidence to support e-cigarettes as a consumer product. Rather, based on their findings that cost and daily use are associated with quitting, they suggest that e-cigarettes may have a role as prescription therapy for smokers.

Both the specific conclusions ofthis study and the broader landscape of moderately strong and, from a population Impact perspective, goodenough evidence suggest we should be thinking bigger in terms of public health policy. Smart policies consistent with the FDA's Comprehensive Plan for Tobacco and Nicotine Regulation can widen, rather than restrict, access to those who desperately need an alternative to deadly, combustible tobacco products while still restricting access to nonsmoking youths, in particular. ,4jPH

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## CONFLICTS OF INTEREST

The author has no conflicts of interest to disclose.

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## DETAILS

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# RiskScape: A Data Visualization and Aggregation Platform for Public Health Surveillance Using Routine Electronic Health Record Data

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## ABSTRACT (ENGLISH)

Automated analysis of electronic health record (EHR) data is a complementary tool for public health surveillance. Analyzing and presenting these data, however, demands new methods of data communication optimized to the detail, flexibility, and timeliness of EHR data. RiskScape is an open-source, interactive, Web-based, user-friendly data aggregation and visualization platform for public health surveillance using EHR data. RiskScape displays near-real-time surveillance data and enables clinical practices and health departments to review, analyze, map, and trend aggregate data on chronic conditions and infectious diseases. Data presentations include heat maps of prevalence by zip code, time series with statistics fortrends, and care cascades for conditions such as HIV and HCV. The platform's flexibility enables it to be modified to incorporate new conditions quickly-such as COVID-19. The Massachusetts Department of Public Health (MDPH) uses RiskScape to monitor conditions of interest using data that are updated monthly from clinical practice groups that cover approximately 20% of the state population. RiskScape serves an essential role in demonstrating need and burden for MDPH's applications for funding, particularly through the identification of inequitably burdened populations. (Am J Public Health. 2021; 111:269-276. https://doi.org/10.2105/AJPH.2020.305963)

## FULL TEXT

### Headnote

Automated analysis of electronic health record (EHR) data ¡s a complementary tool for public health surveillance. Analyzing and presenting these data, however, demands new methods of data communication optimized to the detail, flexibility, and timeliness of EHR data.

RiskScape is an open-source, interactive, Web-based, user-friendly data aggregation and visualization platform for public health surveillance using EHR data. RiskScape displays near-real-time surveillance data and enables clinical practices and health departments to review, analyze, map, and trend aggregate data on chronic conditions and infectious diseases. Data presentations include heat maps of prevalence by zip code, time series with statistics fortrends, and care cascades for conditions such as HIV and HCV. The platform's flexibility enables it to be modified to incorporate new conditions quickly-such as COVID-19.

The Massachusetts Department of Public Health (MDPH) uses RiskScape to monitor conditions of interest using data that are updated monthly from clinical practice groups that cover approximately 20% of the state population. RiskScape serves an essential role in demonstrating need and burden for MDPH's applications for funding, particularly through the identification of inequitably burdened populations. (Am J Public Health. 2021; 111:269-276. https://doi.org/10.2105/AJPH.2020.305963)

State and local health departments are responsible for monitoring the magnitude, trends, and patterns of infectious diseases, chronic conditions, and health behaviors over time and within various populations. The efficiency and timeliness of data available to public health agencies and processes for managing and interpreting these data, however, are variable. While notifiable diseases are often infectious and reported rapidly and electronically to health departments, data on nonnotifiable conditions such as asthma, obesity, and hypertension are more limited.

Public health agencies use systems such as the Behavioral Risk Factor Surveillance System (BRFSS), the National Health and Nutrition Examination Survey (NHANES), all-payer claims databases, hospital-based data sources, and electronic laboratory reporting for data on chronic disease and health behaviors. The BRFSS is a self-reported, telephone-based survey that provides important public health data but has relatively small sample sizes and delays of about 1 to 2 years between data collection and publication. The NHANES combines self-reported data with physical examinations, including laboratory testing, but the sample size is also relatively small, so it does not provide state or local level results; it also involves a wait of 2 or more years before results are disseminated. Moreover, none of these major public health surveillance systems include user-friendly, interactive visualization tools as part of the system. By contrast, continual, automated analysis of electronic health record (EHR) data is emerging as a complementary tool for public health surveillance of infectious diseases, chronic conditions, and health behaviors. Novel and emerging infections-such as COVID-19-require new, timely sources of data.

EHR-based surveillance has the promise of providing health departments with rich, timely, and clinically detailed data from large populations. Examples include New York City's Macroscope System1 and the Colorado Health Observation Regional Data Service network.2 EHR-based surveillance can serve as the source for data visualization systems that allow public health practitioners to monitor and explore health indicators at the aggregate level. We describe in this article the Massachusetts Department of Public Health's (MDPH's) RiskScape platform, a Web-based interactive data portal for displaying and analyzing near-realtime surveillance data from EHR systems.

### DEVELOPMENT AND EVOLUTION OF RISKSCAPE

In 2006, the Department of Population Medicine at Harvard Medical School and Harvard Pilgrim Health Care Institute obtained funding from the Centers for Disease Control and Prevention, via their Centers of Excellence in Public Health Informatics Program, to develop an automated reporting platform for notifiable diseases using EHR data. Working closely with MDPH, we developed the Electronic medical record Support for Public health (ESP; http://esphealth.org) surveillance platform. ESP is an opensource software suite that clinical practices can populate with EHR data by using a common data model (i.e., a standard data structure with data elements to which all sites map their underlying data); ESP analyzes these data for notifiable diseases and chronic conditions, generating individual case reports for notifiable disease and aggregate summaries of nonnotifiable conditions to the state health department.3,4 Selected Massachusetts practice groups use ESP for automated notifiable disease reporting. We have since added further functionality to ESP to enable MDPH to query ESP data for aggregate counts of notifiable and nonnotifiable conditions via a Web-based user interface, in a secure, transparent, and controlled fashion using a system called MDPHnet.5,6 MDPHnet data are also aggregated and deidentified to support the RiskScape data visualization platform.

RiskScape is a Web-based interactive data aggregation and visualization tool that allows users to generate timely, tailored, high-level summaries of specific health measures and conditions of interest on an in-care population. It enhances public health surveillance by enabling policymakers and public health managers to easily review data on numerous conditions of interest, both notifiable (e.g., chlamydia, HCV infection) and nonnotifiable (e.g., asthma, obesity, hypertension).

Because RiskScape draws on EHR data, it can provide data on denominators (i.e., patients in care during a specified period of time), care patterns, case counts, and estimates of various conditions' prevalence. Denominators are important because they allow one to calculate and compare rates of disease and care patterns rather than just counts. Users interested in chlamydia, for example, can evaluate testing and coinfection rates as well as disease prevalence, while users interested in hypertension can examine diagnosed hypertension and controlled hypertension in addition to total hypertension counts and prevalence rates. Users have the option to select among multiple outcomes; filter down to populations of interest; stratify by demographics, comorbidities, and certain treatments; and compare conditions between locations or across time. By providing public health officials the capacity to rapidly and easily work with surveillance data, RiskScape makes it possible for users to explore their evolving hypotheses about disease distribution, disparities, and the impact of public health interventions in near real time.

## RISKSCAPE IN MASSACHUSETTS

In Massachusetts, RiskScape currently draws upon EHR data from 3 clinical practice groups. Atrius Health serves a population of about 720 000 individuals in eastern Massachusetts, the majority of whom have health insurance. Cambridge Health Alliance serves about 140 000 individuals and is a safety net provider for vulnerable populations in eastern Massachusetts including Cambridge and greater Boston. The Massachusetts League of Community Health Centers data include approximately 400 000 people at federally qualified community health centers throughout the state. Taken together, these clinical practice groups represent approximately 20% of the state population and include people ofall age groups, races, and ethnicities. Participation by additional sites that provide care, particularly in the central and western parts of the state, is currently being considered. Of note, patients who seek care at multiple sites in the network are not currently linked or de-duplicated.

Because the data in RiskScape are from patients in care at participating sites, they are not a random sample and do not necessarily reflect the general population, though Massachusetts has a very high percentage of the population with health insurance, likely meaning generalizability is less of a concern compared with a state with low insurance coverage. However, we do not have geographic coverage across the state. (This issue and other important considerations are discussed in the Limitations section later.)

We have previously compared estimates of various chronic conditions from the RiskScape source data to those from the Massachusetts BRFSS data and observed comparable estimates of disease prevalence, particularly at the state level; for small-area estimates we observed correlations by condition and locale after adjustment for MDPHnet versus census demographics but with some variability and outliers.6 Although comparing these 2 distinct systems has limitations, this analysis suggested that we have reasonable capacity to estimate some conditions on the local level but need to devote more attention to areas where coverage is currently lacking (i.e., the central and western parts of the state).

RiskScape utilizes an individual-level, deidentified data set that is automatically generated monthly by each participating site's ESP installation. The extract transmitted to RiskScape includes 1 row per patient in the practice and includes dichotomous (e.g., gender, type 2 diabetes status, influenza vaccination), categorical (e.g., age group, race, ethnicity, smoking status, body mass index grouping), and continuous (e.g., number of medical encounters in the last year, blood pressure, hemoglobin A1C) variables. Geographical data are based on each patient's most recent zip code of residence. The underlying data at each site are assessed approximately quarterly for data quality and consistency. We review patterns in patient visits, prescriptions, immunizations, and other measures to identify anomalies for detailed investigation and rectification. In addition, all of MDPHnet's key users, including MPDH epidemiologists, participating site representatives, and those implementing and maintaining the system, meet regularly to share and discuss forthcoming updates to the system (and potential new sites).

Participating sites populate their ESP systems using standardized daily extracts from their EHRs that include structured data on all patient encounters from the preceding 24 hours. The extracts include demographics, diagnosis codes, prescriptions, laboratory tests (all are included in the extract, but we only map and clean the subset pertinent to the conditions we assess), vaccinations, and social history (e.g., tobacco use). ESP analyzes these data nightly to detect chronic conditions and notifiable diseases using custom algorithms designed to maximize sensitivity, positive predictive value, or both depending upon the condition.3,4,6 9 The algorithms integrate vital signs, laboratory tests, prescriptions, and diagnosis codes from both current and previous encounters to detect conditions of public health interest. For example, the prevalent hypertension algorithm evaluates diagnosis codes, blood pressure measures, and medication prescriptions to assess whether a person meets our definition of hypertension (2 or more elevated blood pressure readings within a year, diagnosis codes for hypertension, or normal blood pressure readings but prescribed an antihypertensive). Note that users with programming expertise can adapt ESP's existing algorithms or develop new algorithms to redefine existing conditions in new ways or identify different conditions to meet their specific needs.

ESP system data are stored on dedicated servers managed within sites' data centers per local policy and procedure. Access to the ESP servers is managed by site. All communication between ESP and RiskScape, and between RiskScape and users, is encrypted in transit. RiskScape does not maintain personal health information data, but the application and data are maintained on a dedicated server. The RiskScape database is configured for access from the application only. All remote accesstothe server and the RiskScape application is via whitelisted and authorized permission. Further information about ESP is available at http://esphealth.org, including technical details and links to download the algorithms used in Massachusetts.

## USING RISKSCAPE

Authorized users log into the RiskScape Web site to review estimates of disease and conditions. There are 4 ways of examining the data: heat maps of disease prevalence by zip code, bar graphs and pie charts to evaluate demographic and clinical characteristics, time series to evaluate changes over time, and continuum-of-care tabular reports to evaluate care cascades. The dashboard (Figure 1) allows the user to review and select a condition, specify the population of interest, and designate the favored analysis (e.g., heat map, demographic description). These capabilities are further described herein and shown in Figures A through C (available as supplements to the online version of this article at http://www.ajph.org).

To generate prevalence estimates, users first select a condition of interest. The conditions in RiskScape are defined by algorithms that have been developed and validated within the system: type 1 diabetes, type 2 diabetes, prediabetes, gestational diabetes, categories of body mass index, hypertension, smoking status, asthma, treated depression, influenza-like illness, Lyme disease, vaccination status for several vaccines (influenza, Tdap), chlamydia, gonorrhea, opioid prescription, benzodiazepine prescription, and cardiovascular risk score. Users can then select among various denominator options; in our RiskScape instance, these are predominantly outpatient or ambulatory encounters. The default option is "patients with >1 encounter in the past two years." Users have the option, however, to select the denominators' minimum encounter count (> 1 encounter or >2 encounters), look-back period (past 1 year or past 2 years), and minimum number of lifetime encounters within the participating site. Clinical encounter counts for the purpose of estimating denominators (i.e., persons at risk) are defined broadly and include any interaction in the EHR with at least 1 vital sign (i.e., blood pressure, height, weight, or temperature), diagnosis code, prescription, laboratory test, or immunization; multiple encounters on the same day are treated as a single encounter. The rationale for these different denominator options and their impact on disease prevalence estimates has been previously described.10

In the heat map capability (Figure A), we can review, for example, the relative prevalence of pediatric asthma, with each outlined area representing a zip code. The taupe zip codes are those with inadequate or no data included in the system (RiskScape will only provide data on disease prevalence in a zip code if there are data on at least 100 residents in the zip code). A user can click on a zip code and a pop-up window with the following information will display: the prevalence of the outcome in that zip code, the number of patients in the numerator and denominator, and RiskScape's coverage rate for the chosen zip code (i.e., number of people with the user's selected demographic characteristics in that zip code within RiskScape vs the count of people with those demographic characteristics in the zip code per the 2010 US Census [any zip codebased population estimates can be used]).

The bar charts and pie graphs that RiskScape can generate allow users to explore the demographic and clinical characteristics of patients with a chosen outcome. The bar graph in Figure B depicts the prevalence of obesity (defined as a body mass of >30 kg/m2) among adults aged 20 years or older while the pie chart shows the age distribution of people with obesity. Users can specify target towns and neighborhoods for analysis, compare 2 locations side by side, or compare disease prevalence in the chosen location to the state as a whole. Neighborhoods are currently only available for the City of Boston.

RiskScape can also generate time series and regression statistics to help users assess trends and changes over time. The denominator is calculated each month based on the number of patients who meet the user's chosen denominator criteria (e.g., those with at least 1 encounter in the last 1 year; this automatically adjusts for temporal changes in the population of patients in care). Figure C shows the prevalence of hypertension among adults from January 2012 through July 2020, stratified by race. Users can select a "trend line summary" to receive statistics on a trend for a particular group based on generalized least squares regression. Users can specify an inflection point to assess for changes in disease prevalence and trends before versus after a specific point in time. This feature can be used to obtain a rapid sense of the impact of new programs or policy changes on processes of care (such as hemoglobin A1C testing or gonorrhea screening) or prevalence (such as gonorrhea cases).

An additional capability within RiskScape is a set of "continuum of care" summary reports for HIV, HIV risk, HCV, diabetes, and cardiovascular risk score. For these reports, users can select the clinical site of interest, the time period, age groups, gender, race, and ethnicity for the analysis. These reports provide users with data on the fraction of patients with key diagnoses who are retained in care, receive recommended processes of care, and success rates for disease control.

For HCV infection, RiskScape reports the number and percentage of individuals tested for HCV, the number among them who test positive, the number with an HCV viral load test, and whether the latest test had detectable virus. The number of individuals who have acute HCV are reported separately from those who have chronic HCV, as defined by internally validated algorithms. The report provides the number of HCV cases who have been treated, their recent viral load results, and the number of patients with HCV who spontaneously cleared their infection without treatment.

For individuals with HIV, the care cascade starts with the number of patients with HIV and then reports the number and percentage of those with the following: an encounter after diagnosis, a prescription for HIV medications, being retained in care, a measured viral load, viral suppression, and diagnosis with an opportunistic infection. That same cascade is reported separately for those who are newly diagnosed with HIV during a specified time period.

There is also a care cascade designed to track uptake of HIV preexposure prophylaxis. ESP calculates an estimated risk of HIV acquisition in the forthcoming year for every person in the system using a validated EHR-based prediction rule.11,12 It then stratifies the population into high-, medium-, and low-risk categories and summarizes HIV testing rates, preexposure prophylaxis prescribing, and HIV acquisition perstrata.

The diabetes continuum-of-care reportstarts with individuals with at least 1 clinical encounter in the specified year(s) of interest and then provides the number and percentage of those patients with a hemoglobin A1C test, those with diabetes, the number on treatment, and patients' outcomes by hemoglobin A1C strata.

Finally, we recently created a report to provide information on risk factors and preventive care for patients at risk for cardiovascular disease using the American College of Cardiology's Atherosclerotic Cardiovascular Disease risk score algorithm.13 This score is calculated for every member of the population aged 20 to 60 years, divides the population into strata of risk (low, medium, high, established cardiovascular disease), and then for each strata characterizes the fraction of the population screened and treated for hypertension, diabetes, hypercholesterolemia, and smoking. This analysis provides a unique populationlevel perspective on risk for cardiovascular disease and where opportunities to improve preventive practices might lie.

## WHO CAN USE RISKSCAPE?

RiskScape in Massachusetts is accessible only to authorized members of MDPH and participating sites via logins and passwords. However, RiskScape source code is open source and freely available to developers under a 3-clause Berkeley Source Distribution license. Source code is available from http:// esphealth.org.

In Massachusetts, clinical practice groups' participation in RiskScape and the underlying MDPHnet system is voluntary. Staff from each of the participating sites are informed of new capabilities added to the system and weigh in on prioritization and development of the platform. Stakeholders from MDPH, participating sites, the informatics developer (Commonwealth Informatics Inc), and the coordinating center (Harvard Pilgrim Health Care Institute) have biweekly conference calls to discuss updates, address any technical issues, and confer on plans. Within Massachusetts, users are trained and provided with background information on RiskScape and the underlying ESP system. Documentation is embedded in the platform, including algorithm definitions and major data interpretation issues. Data that can be queried via MDPHnet could be made available to external researchers, with permission and appropriate institutional review board oversight, but this has not occurred. To date, any research conducted using data from the underlying system has been limited to MDPHnet collaborators.

## LIMITATIONS

Data from EHR systems must be interpreted appropriately, with understanding ofthe limitations inherentto the data type. The population is people in care and may not be representative of the general population, and diagnoses may be recorded that are differential or suspect only. The prevalence estimates generated by RiskScape must be interpreted with the same caution as with any data leveraged from clinical databases developed for clinical care or billing rather than for public health surveillance. The accuracy and completeness of EHR data vary, and disease detection frequency of a system like RiskScape is only as complete as the underlying source EHR data. Variations in the frequency of patients seeking care; differences between clinicians and practices in testing, diagnosing, and treatment practices; variations and changes in the completeness and accuracy of coding; and the total amount of time an individual has been affiliated with a given site are challenges inherent to the use of EHR data for surveillance. The data in RiskScape may be incomplete for individuals who divide their care between clinical sites contributing to RiskScape and other health care institutions outside ofthe system. Patients who seek care at multiple sites in the network are not currently de-duplicated, potentially leading to inflation of numerators, denominators, or both depending on the query. The major limitations of the system are documented within RiskScape and are actively discussed with MDPH users to facilitate their interpretation of data drawn from the platform.

It is technically feasible to link data from MDPHnet with data from other sources such as vital statistics, disease registries, claims databases, and other EHR repositories and then enable RiskScape to display data integrated across multiple sources, but such work has not yet been undertaken. Governance issues as well as the technical and logistical aspects ofthat work have been discussed with MDPH and linkage with other sources may be pursued at some later time.

While RiskScape does not currently provide an option to generate prevalence adjusted by age or other demographics that could account for differences between clinical sites' patient populations and the Massachusetts census data, we have found that crude disease prevalences tend to be very similar to those adjusted for age, race/ethnicity, and gender, particularly at the state level. This is presumably a reflection of the size of the RiskScape population as well as the diversity ofthe contributing practices in Massachusetts.6

## IMPLICATIONS

RiskScape enables epidemiologists, other public health professionals, and site staff focused on population health to quickly examine patterns and trends in various conditions or measures of interest. The ability to generate estimates of chronic disease and other nonnotifiable conditions or measures on a monthly basis, stratified by site, allows users to follow trends in disease prevalence and care patterns, with increased frequency and timeliness relative to most existing public health surveillance systems for chronic conditions.

At this time, sites can review their own data individually and compare their data with data from other sites, enablingthem, for example, to develop community needs assessments as well as to better understand health status, needs, and opportunities ofthe populations in their catchment areas. The demographic and geographic stratifications provide insight into the epidemiology of conditions and measures that are hard to obtain elsewhere. For example, patterns ortrends in health disparities are difficult to find elsewhere because of lack of data or incomplete data on race/ethnicity in other systems. While race and ethnicity data are not complete in RiskScape, they are more complete than in other data sources routinely used for public health surveillance (e.g., notifiable disease case report forms or electronic laboratory data), and the system is larger and more timely than other routine surveillance systems (e.g., BRFSS).

The aggregate nature of the system means we can examine data on measures not otherwise available to MDPH. For example, MDPH does not have access to data on the number of people tested for HIV outside of sites that they fund. RiskScape's continuum-of-care reports allow MDPH to see patterns of care and prevention for a general patient population across numerous types of clinical sites. In addition, it can be readily adapted for new conditions, making otherwise inaccessible or hardto-access data available to public health agencies. For example, we have developed pilot definitions for COVID-19 laboratory-based and syndromic surveillance criteria via ESP.

Over time, RiskScape has become an increasingly important tool in MDPH's planning and evaluation of chronic disease efforts. Examples of its use include identifying local hot spots of chronic disease and affected populations for targeted intervention, exploring population-level prevalence of risk factors for chronic disease to inform program design, and evaluating program impact, especially for statewide infrastructure grants. In addition, RiskScape serves an essential role in demonstrating need and burden for MDPH's applications for funding, particularly through the identification of inequitably burdened populations. As such, RiskScape has become an indispensable tool to support data-driven public health practice. That being said, there are numerous considerations for a jurisdiction or entity to plan for when preparing to implement a system like RiskScape. Governance, initial and ongoing funding, maintenance (e.g., monitoring of data quality), and expansion (e.g., creation and incorporation of new conditions) of the system are some of the major issues. It is also imperative for each stakeholder to fully understand what their participation includes. RiskScape is currently being adapted and implemented by multiple jurisdictions outside of Massachusetts under the umbrella of the National Association of Chronic Disease Directors' Multistate EHR-based Network for Disease Surveillance (http://chronicdisease. org/page/MENDSinfo).

In conclusion, RiskScape quickly and easily enables users to identify novel patterns and trends, get a rapid sense of the impact of new interventions, inform the design of program evaluations, provide data for new funding applications, generate hypotheses, and help plan for future analyses.

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CONTRIBUTORS

N. M. Cocoros, C. Kirby, B. Zambarano, K. Eberhardt, C. Rocchio,J.T. Menchaca, and M. Klompas designed the system described. M.Josephson, D. Erani, E. Hafer, M. Weiss, B. Herrick, M. Callahan, and T. Isaac contributed data and information to the system. N. M. Cocoros and M. Klompas initiated the article. N. M. Cocoros drafted, wrote, and revised the article. All authors reviewed and provided feedback on the article.

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Institutionalreview board (IRB) review has not been required for the installation and implementation of RiskScape for the Massachusetts Department of Public Health given that the system is used for public health surveillance using aggregated data along with small cellsuppression rules. Work on the system conducted by the Harvard Pilgrim Health Care Institute as the coordinating center, however, has been reviewed and approved by the Harvard Pilgrim Health Care IRB, per Harvard Pilgrim's internal policies. Practices participate on behalf of their patients;patient consent is not required.

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## DETAILS

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# Violent Victimization of Sexual Minorities: A Clearer Lens on a Wicked Problem, but Solutions Remain Obscured

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ProQuest document link

## ABSTRACT (ENGLISH)

In this issue of AJPH, Bender and Lauritsen (p. 318) use the National Crime Victimization Survey (NCVS) since it began including sexual orientation and gender identity data in 2017 to detail sobering findings about violence endured by sexual minorities in the United States. For example, compared with heterosexual women, gay and bisexual men and lesbian and bisexual women all had greater odds-ranging from 90% to 261% increased odds-of reporting violent victimization in the last six months, including serious crimes like sexual and physical assault. Such a clear, nationally representative picture of how the wicked problem of violence disproportionately burdens sexual minority communities has, heretofore, been largely elusive, although the study results are not entirely surprising.

## FULL TEXT

In this issue of AJPH, Bender and Lauritsen (p. 318) use the National Crime Victimization Survey (NCVS) since it began including sexual orientation and gender identity data in 2017 to detail sobering findings about violence endured by sexual minorities in the United States. For example, compared with heterosexual women, gay and bisexual men and lesbian and bisexual women all had greater odds-ranging from 90% to 261% increased odds-of reporting violent victimization in the last six months, including serious crimes like sexual and physical assault. Such a clear, nationally representative picture of how the wicked problem of violence disproportionately burdens sexual minority communities has, heretofore, been largely elusive, although the study results are not entirely surprising.

WHERE WE HAVE BEEN

For many health equity researchers, community advocates, and policymakers concerned about the health and wellbeing of sexual minority individuals, the findings are both a long-sought stanza and an expected chorus in a recitation of violence. The findings are long sought because, as the authors note, sexual orientation measures on federal surveys are not standard elements, and for many federal surveys, including NCVS, they are only recent additions. That sexual minorities can only now quantify victimization from the NCVS hearkens Sell and Holliday's indictment of public health malpractice1; sexual minorities are a segment of the populace that funds federal surveys yet do not benefit from representation in said surveys. The results were expected because researchers for several decades have documented high rates of violent victimization among sexual minorities. In 1980, Miller and Humphreys2(p182) lamented in their article about gay men's victimization that, "In lieu of a major study that will permit representative sampling ... we are thrown back on availability samples and limited data." The ensuing work over the next four decades relied on mostly convenience-based sampling,3 and the warnings of disparities were perhaps drowned out by louder warnings about biased sampling and limited generalizability. The siren now rings clear.

The ways that public health meets the challenge of addressing these disparities in violent victimization, however, are less clear. Of course, there has been social progress for sexual minorities. In the last decade, the United States saw the end of the US Department of Defense policy of "Don't Ask, Don't Tell" that barred sexual minorities from openly serving in the military (although a separate ban on transgender persons is currently in effect), the legal recognition of same-sex marriage, and the protection from employment discrimination. Yet the NCVS data clearly show the seemingly ever unfinished business of equity in America. Sexual minority respondents to the NCVS who indicated surviving serious violent crime did so in the six months prior to the survey-in this era of increasing equality.

AREAS WE MUST FORGE

Mobilizing to conquer these disparities requires a deeper reckoning about the insidious architecture ofviolence against sexual minorities in the United States: the cunning ways that sexual minorities are made lesser and "other," the entitlement of the perpetrators and the cultural and sociopolitical structures that embolden them, and the data and service systems inadequately designed for the hard work of equity.

The "othering" of sexual minorities happens overtly, and it quintessentially facilitates dehumanization that allows violence from an entitled majority. Sexual minorities can legally be refused housing in 23 states, and 11 states permit refusal of child welfare services to same-sex couples and their children.4 Devaluation also happens covertly when discrimination is wrapped in the facade of religious freedom, and denial of service is dismissed as a reality of capitalism. The mere act of deciding whether sexual minorities should have the right to marry or serve in the military-opportunities taken for granted by the majority but debated for a minority-is pageantry of oppression initiated by the question, "Is the minority worthy?" Arbitration of personhood is an effective dog whistle. Operationalizing these codified injustices and colloquial aggressions is an unfolding science mostly focused on sexual minorities, themselves, to understand the implications on their health. However, the lenses of science and prevention must expand to understand whether and how legislated discrimination may drive perpetration of violence and, if so, hold the blowers of the dog whistles accountable.

Perpetrators of violence against sexual minorities are largely unstudied in violence prevention. Violence prevention in the United States has uncanny penchants for recentering the responsibility on victims. For example, sexual assault prevention for women usually includes strategies about how strategically a woman should drink alcohol, how closely she should watch for date rape drugs, how she should dress, and how cautiously she should walk at night. Where are the widespread sexual assault prevention strategies that confront the irrational masculinity fueling men to think they are entitled to women's bodies? In terms of sexual minorities, where are the prevention strategies that confront homophobic and heterosexist hegemonies casting sexual minorities as targets? At best, perpetrators' actions are bemoaned as unpredictable, and at worst, they are viewed as justified; such dismissals sanction violence. Resources should be invested in understanding mutable characteristics of perpetrators to inform violence prevention. Simultaneous investments are necessary for public health researchers, social workers, and policymakers to develop community-based strategies to dismantle contextual factors that embolden perpetrators.

Finally, data systems and public services must meet the challenges of violence prevention and when prevention fails, honestly account the tolls of violence and serve the survivors. For example, the Federal Bureau of Investigation tracks hate crimes based on sexual orientation, indicating recent increases in sexual orientation-related hate crimes, particularly after 2016 (Figure 1).5 Yet the Federal Bureau of Investigation's data system for hate crimes is voluntary and thus largely underestimates violence against sexual minorities. Although the NCVS data are a step toward finally achieving nationally representative estimates of violent crime victimization of sexual minorities, they alone are not enough. If sexual minorities are more likely to be victims of serious violent crime than are heterosexual persons, then a reasonable hypothesis is that death by violence is also more prevalent. Yet mortality data inclusive of sexual orientation barely exist. The NCVS results add a new layer of urgency to determine whether there are corresponding sexual orientation-related disparities in preventable deaths, which requires inclusion of data about sexual orientation in US mortality surveillance systems.6

The NCVS results also challenge researchers, advocates, and policymakers to understand what happens when sexual minorities who are victimized then interface with legal and judicial systems; that is, if they decide to report their victimization. Limited research suggests that sexual minorities interpret police as biased,7 which could jeopardize reporting victimization, especially if that victimization was related to the victim's sexual orientation. Even for crimes unrelated to the victim's sexual orientation, disclosure of minority sexual orientation may emerge in official reporting or statements from spouses or partners, forcing disclosure. Again, Miller and Humphreys' research about victimization among gay men observed that, "In being attacked, they [gay men] did not so much come out of the closet as have the closet involuntarily ripped from around them."2(p178)The availability, acceptability, and preparedness of the postvictimization legal and social services fields for sexual minorities are vastly understudied in terms of their effectiveness for justice and healing.

Bender and Lauritsen provide America both with its clearest picture yet about violence suffered by sexual minorities and with a clarion call for public health research and practice, social work, law, and public policy to unite with communities for systemic efforts to reduce sexual orientationrelated disparities in violence.

CORRESPONDENCE

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## DETAILS

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# The Public Health Penalty of Attending to the Proximal

Galea, Sandro, MD, DrPH [1] ; Vaughan, Roger, DRPH, MS [2] [1] is with the School of Public Health, Boston University, Boston, MA [2] is with The Rockefeller University, New York, NY

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## ABSTRACT (ENGLISH)

Four years ago, we stated in this same column that we were "on the cusp of a new administration in the United States," and we predicted, "In the coming four years, our social divides and health divides both will deepen, unfortunately reinforcing each other."1(p203) That has sadly been the case. Today, we are again on the cusp of a new presidential administration with the hope that we can begin the work of healing those divides and resulting inequities. In this context, the work of public health has never been more important. We are in the middle of a global pandemic, and public health is at the heart of the national conversation as perhaps never before. This moment has taught the world that our collective health is fragile and that we are vulnerable unless we build the structures that create a healthier world. As we aspire to do so, we have an unprecedented opportunity to illuminate the core concepts that inform how we do what we do and why we, and the world, should approach the task of public health in a particular way. In last month's perspective,2 we discussed the role of prevention and how a critical way forward will be to embed the ethos of prevention into all that we do and to move beyond an approach that is reactive to one that aims to anticipate and mitigate adverse health. Considering prevention, then, to be why we should act, we now focus on how we should act. If we consider maintaining good health and preventing sickness important core values for public health, how do we best achieve that?

## FULL TEXT

Four years ago, we stated in this same column that we were "on the cusp of a new administration in the United States," and we predicted, "In the coming four years, our social divides and health divides both will deepen, unfortunately reinforcing each other."1(p203) That has sadly been the case. Today, we are again on the cusp of a new presidential administration with the hope that we can begin the work of healing those divides and resulting inequities. In this context, the work of public health has never been more important. We are in the middle of a global pandemic, and public health is at the heart of the national conversation as perhaps never before. This moment has taught the world that our collective health is fragile and that we are vulnerable unless we build the structures that create a healthier world.

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### ATTENDING TO THE DISTAL OR THE PROXIMAL

This brings us to a critical tension in public health today, one that should inform our global reckoning with the work of public health going forward: Is poor health best prevented by working at distal levers of influence, on the structures and policies that shape the world around us-and hence health- or should we focus on the particular, more proximal forces that we interact with on a daily basis, those that are tangibly linked to the production of health?

The reader will recognize that the answer to such a question is neither straightforward nor simple. But some insight emerges by way of illustration from the work of Hedden et al. in this issue of AJPH (p. 277), which centers on a significant challenge for population health: the US system of mass incarceration.

It is amply documented that serious mental illness is a substantial concern in the US system of mass incarceration. There is little question that the prevalence of mental illness among persons in US jails or prisons is substantially higher than it is in the general population,3 making incarceration a de facto system of addressing mental illness across the country. That, in and of itself, should be sufficient cause for deep concern for public health; clearly the use of a punitive approach to deal with a prevalent form of illness runs in direct contravention to notions of health as a human right,4 and perhaps with simpler notions of human decency. Clearly, a distal approach to this challenge would be to dismantle a system of incarceration that also doubles as a system of housing people with mental illness and to replace that with a compassionate approach that considers how we tackle the influences that might drive mental illness and how we create systems that can provide support and care for persons with mental illness rather than consign them to a carceral system that, at best, does not tend to their core mental health problems and, at worst, exacerbates them.5

The challenge for public health is that we have a large, and seemingly intractable, system of incarceration as a clear and present reality, and thinking only about undoing such a system exposes us to reasonable charges of unhelpful idealism. To that end, it is not unreasonable to consider ways to work more proximally, to introduce systems of care for persons with mental illness that can offset some of the experiences of incarceration. Hedden et al. study such systems with the aim of finding whether race/ethnicity is associated with access to jail- and community-based mental health treatment. They found that although there were no racial/ethnic differences in jail-based treatment, White people had 1.9 times greater odds of receiving community-based mental health and substance use treatment and 4.5 times greater odds of receiving cooccurring disorder treatment than did persons of color.

## UNINTENDED CONSEQUENCES

This observation by Hedden et al. illustrates, to our mind, the central tension in an approach to public health based on the proximal. When we are addressing problems far from their root cause-in this case, a system of incarceration that substitutes for the prevention or treatment of mental illness-we are inevitably going to fall short and, almost certainly, create inequities in who benefits most from our proximal intervention. Proximal interventions must, by definition, rest on the structure that exists, and that structure, itself serving to harm health, is definitionally going to continue exerting an adverse effect on health. That workaround may manifest in many ways, but frequently it will bring to the surface racial/ethnic or sociodemographic inequities. Given the simple observation that those with more power, privilege, and access are more likely to obtain benefit from any intervention,6 even in, for example, a jail system, it stands to reason that an intervention that targets only the more proximal mechanisms of action will result in exposing underlying inequities, potentially widening health gaps. The article of Hedden et al. is a good illustration of this general point.

This of course brings us backto where we started: How should public health act? Focusing only on structural, distal actions consigns us to far-off action that may not help many people in the long term. A radical vision of restructuring fundamental injustices may take decades to realize. We suggest that such a radical vision grounded in an understanding of the limitations of the proximal is essential. It is also important, however, to take the incremental step,7 perhaps via the programs studied by Hedden et al., that can help even a few in the short term. But we must do so with the awareness that these efforts need to be structured in a way that mitigates the limitations of the proximal approach to avoid widening health gaps. A fully realized public health approach balances both proximal and distal approaches without ever losing sight of the limitations of the former, as it aspires to the latter. >4jPH

## Sidebar

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# Behavioral Health Services Following Release From Jail: A Widening Racial Disparity Gap

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## ABSTRACT (ENGLISH)

Despite growing public awareness and bipartisan political support for policy change, the United States continues to incarcerate more people than any other country. Incarceration, whether short or long term, can have devastating health, mental health, social, and financial consequences for individuals, families, and entire communities. In 2018, 10.7 million people entered jail.1 Although this was a roughly 11% decline compared with the previous 10-year trend, we continue to house an average of nearly 740 000 people in jails every day. Black and Native people continue to be grossly overrepresented in jails at 592 and 401, respectively, per 100000 people compared with White people, who are incarcerated at a rate of 187 per 100 000.1

## FULL TEXT

Despite growing public awareness and bipartisan political support for policy change, the United States continues to incarcerate more people than any other country. Incarceration, whether short or long term, can have devastating health, mental health, social, and financial consequences for individuals, families, and entire communities. In 2018, 10.7 million people entered jail.1 Although this was a roughly 11% decline compared with the previous 10-year trend, we continue to house an average of nearly 740 000 people in jails every day. Black and Native people continue to be grossly overrepresented in jails at 592 and 401, respectively, per 100000 people compared with White people, who are incarcerated at a rate of 187 per 100 000.1

### HEALTH AND MENTAL HEALTH IN JAILS

Jails concentrate people with highly infectious and chronic diseases and untreated mental illness and substance use problems, which contributes to the health inequities in the communities to which they return.2 We see this today more than ever, with jails being vectors for spreading COVID-19.3 People spend an average of 25 days in jail1; these short stays can disrupt established mental health care and bring infectious disease home to people's families and neighbors.

Across studies, the rates of people with serious mental illness (SMI; i.e., bipolar, schizophrenia spectrum, major depression, delusional, and psychotic disorders) are higher in jails than the community.4,5 Fifty-three percent of females in jail met criteria for posttraumatic stress disorder in their lifetime,6 and more than half of people in jail used substances at the time of arrest. The overrepresentation of people with SMI in jails affects rural communities and the largest jail systems in the United States.

Jails were not designed as clinical treatment facilities. Many jails face monetary, staffing, and space-related challenges that further prohibit their ability to manage the complex clinical needs of people. Even short jail stays can affect family caregiving, employment, and financial stability. For people with SMI and other behavioral health needs, the best place to receive care is the community. Unfortunately, as Hedden et al. (p. 277) highlight in this issue of AJPH, Black people with SMI were less likely to utilize needed services in the 14 months following jail stays. White counterparts had 1.9 times greater odds of using community-based services and 4.5 times greater odds of using cooccurring disorder treatments. The postincarceration period is when people are most likely to self-harm, overdose, and have unstable housing and food insecurity. This is a critical period for connection to support services and treatments.

## DATA INTEGRATION FOR SYSTEMS CHANGE

Without integrated data systems, it is near impossible for communities to identify the racial disparities that Hedden et al. found in their work across eight Midwestern counties. This work is essential for better understanding the intervention points at which to engage people in treatment and in support services to deter reincarceration and to address mental health, substance use, and cooccurring disorders. Despite the need for data-driven policy, many communities struggle with data system integration. By integrating criminal-legal data with health systems, emergency dispatch, and homeless data, for example, communities can identify the gaps in their systems of care. Hedden et al. bridge jail and Medicaid data to explore racial disparity in jail- and community-based treatment. By merging these data, they identified that no racial disparities existed in identifying people with SMI in the jails or receiving jail-based treatment, but they did find that more White people were referred to diversion programs and engaged in communitybased treatment following their jail stay.

Accessible and integrated data are needed to identify and monitor disparities, health inequity, and opportunities for innovations in system-spanning intervention. Hedden et al. provide an example of how integrated data can produce critical place-based findings that are needed to inform and drive policy change at the local and state levels. The National Association of Counties' DataDriven Justice Initiative is one campaign that provides resources to help counties build integrated data systems. This initiative details case studies on communities such as Polk County, Iowa, and Prince George County, Maryland, which have successfully integrated health, social services, and corrections data, creating a roadmap for other counties to carry out this work. With integrated data systems, communities are able to move from awareness to action.

## SYSTEM- AND PERSONLEVEL BARRIERS

Hedden et al. produced new information on racial disparities in service utilization during the postincarceration period, but the next step in this work is arguably the most critical. We need to increase our understanding of the systemic factors as well as the individual-level barriers that get in the way of people of color accessing and utilizing needed treatment and services. Hedden et al. suggest several solutions, including the application of critical race theory to policy and practice in the criminal-legal and behavioral health fields, authentic leadership that mirrors affected populations, and culturally responsive interventions to address systemic and individual barriers. It is well established that Black and lowincome communities receive, on average, poorer quality mental health services, have fewer options for care, and distrust the mental health system. This distrust stems from historical trauma and abuse in research (e.g., the Tuskegee studies), systems of care that are not culturally responsive, and diagnostic tools and treatments that are Euro- and androcentric. Barriers such as cost, childcare, transportation, available appointments outside work hours, and location of services further widen the gap in service use.

Racism is pervasive. It invades the very systems of care that are designed to help people recover and thrive. Policy reform and the development and testing of interventions that work for people of color with SMI who enter orare at risk for entering the criminal-legal system are essential in closing the gap between need and service utilization in this critical postincarceration period. Funding is needed for community-based participatory research that builds capacity for the voices of affected communities to collaborate in intervention and policy development.

Additionally, frameworks and practices developed by Black, Latinx, and Native scholars and practitioners (e.g., critical race theory, intersectionality,7 interventions designed through the Center for American Indian Health) should be integrated into systems of care so that community-based services work for all people. Health-promotion efforts, no matter how good the policy or service, will be ineffective as long as they are embedded in systems that retraumatize, oppress, and further marginalize people. The efforts to reform our criminal-legal system must persist and expand to reduce the number of people who are incarcerated. As a next step, leaders in behavioral health and medical systems must identify policy and practice that need reform by applying critical race theory to address structural racism and prioritize culturally responsive systems of care, as suggested by Hedden et al., that embed trauma-informed policies and procedures, reduce barriers to service use, and prioritize the training and retention of diverse workforces.

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# Understanding the Ethics of Natural Experiments in a Pandemic

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## ABSTRACT (ENGLISH)

Pandemics invite natural experiments: testing hypotheses by observing the effects of interventions without manipulating exposure to the intervention.1 With novel infections like COVID-19 that spread rapidly and widely, knowledge gaps may be extensive. Quick action may be necessary and randomized trials impracticable if not downright impossible. But what can justify such interventions ethically, given that they are in some sense widescale experiments on unaware members of the public who have no opportunity to choose not to participate? And what ethical limits to them should there be?

## FULL TEXT

Pandemics invite natural experiments: testing hypotheses by observing the effects of interventions without manipulating exposure to the intervention.1 With novel infections like COVID-19 that spread rapidly and widely, knowledge gaps may be extensive. Quick action may be necessary and randomized trials impracticable if not downright impossible. But what can justify such interventions ethically, given that they are in some sense widescale experiments on unaware members of the public who have no opportunity to choose not to participate? And what ethical limits to them should there be?

John Snow's iconic 1854 experiment with the Broad Street pump handle is often cited as an admirable example of public health experimentation. Everyone in public health has no doubt heard the story: Snow meticulously tracked cholera infections in the Soho area of London, England, to households and businesses drawing water from a particular well on Broad Street, removed the pump handle, and stopped the epidemic cold.

Yet perhaps not as well recognized is Snow's prescient grasp on how to experiment ethically. Leaving aside that Snow's experiment worked spectacularly, why has his experimental intervention so unequivocally garnered acclaim? Snow began with what he viewed as the best available science of the day: the germ theory of disease. Before he began the experiment, he meticulously collected data about occurrences of infection and water sources. The experiment removed a likely risk-accessible cholera-contaminated water-without creating new risks or risks for different people. For example, Snow did not divert the water from the well to a different location to see whether a new outbreak would occur. Snow did not have an economic conflict of interest such as a competing nearby well-although he did stand to achieve reputational fame from the experiment's success. To achieve removal of the pump handle, Snow consulted the Board of Guardians of St. James Parish, the local parish.2 Finally, Snow also collected data about the results of the experiment and did his best to make them public for the benefit of all.

These observations suggest many features of Snow's experiment that are relevant to assessing it as ethical:

* It comported with the principle "do no harm."
* It was based on Snow's best assessment of the available evidence that it might be of benefit.
* It did not risk significant injustice; the intervention was not expected to treat some in a way that was significantly unjust compared with others or to further structural injustices of the day.
* Snow acted transparently, explaining to local leaders what he hoped could be done and engaging them in implementing the experiment.
* Snow was rigorous about collecting data about the experiment's impact.

These features reflect standard principles of medical ethics: nonmaleficence, beneficence, and justice. Moreover, by collecting data rigorously, Snow did his very best to obtain knowledge for everyone in the community. Although he did not obtain the "informed consent" of each community member, he engaged with the community in a manner that was open and consultative.

Another noteworthy feature of Snow's experiment is that it was planned. Snow used his best assessment of the science of the day and the likely benefits-or harms-of dismantling the pump handle to select and implement his intervention. When pandemics strike, and the need for action seems immediate, many interventions that are not planned as experiments may occur. If the effects of the intervention later appear worthy of study as natural experiments, some of the features that made Snow's experiment ethical may not be present. The intervention may have already begun, possibly initially without careful assessment of the science, reflection on likely risks or benefits, or community consultation. But this lack of planning as an experiment does not mean that the experiment's features were ethically irrelevant; rather, it may reinforce the importance of those features that can be applied. For example, It may be especially Important to acquire information in a timely manner to assess the impact of the intervention and any need for retrofitting if the intervention is going wrong.

Transparency will be critical if the intervention is seeding mistrust. Just as clinical trials have data safety monitoring boards and stopping points if unanticipated risks or clear evidence of benefits or risks in one of the trial arms emerges, interventions that later are examined as natural experiments might be scrutinized for evidence of benefit or harm or of inequity or injustice. Although the intervention itself might have occurred without community consultation, even the slightest anecdotal evidence that the intervention might be risky or beneficial to some at the expense of others may feed rumors, misinformation, and mistrust. Public health depends on public trust in pandemic times, when people may be asked to behave in ways they find uncomfortable, constraining, or seriously deleterious to their own welfare; any sense that information is being hidden or manipulated may exacerbate suspicions that trust is unwarranted. Rigorous data collection and evaluation of unplanned interventions as natural experiments may be an ethical counterbalance to these sources of mistrust.

Many recently published examples of natural experiments exemplify some but perhaps not all of these ethical features. Several involve unplanned experiments, too. For example, studies of the impact of new transit lines consider healthrelated impacts for use in making later investment decisions in public transportation, in some cases with the notice and consent of community members from whom data are collected.3 In a different kind of example, phase IV postmarketing studies of the safety and efficacy of pharmaceuticals bear some resemblance to natural experiments, as they attempt to ascertain less frequent risks when a product goes into more widespread use. London et al. argue in response to the possibility that these studies might be thinly veiled marketing efforts that an "integrity framework" must be applied in which the driving values are promotion of health and assessment of interventions driven by evidence about safety, efficacy, and value, a framework that should include oversight rather than reliance on individual informed consent.4 There are many other examples of how natural experiments can be designed in a rigorous way to answer a question that may have widely beneficial results, without causing harm or putting some at unjustly differential risk.

In the midst of the COVID-19 pandemic, many interventions are under way that might be regarded as natural experiments. Some are planned as experiments, such as the concerts held in Leipzig, Germany, under varying conditions to attempt to ascertain how COVID-19 spreads at public events. As of this writing, the results of this experiment have been published in preliminary form, and they demonstrate that concerts conducted with social distancing, wearing masks, and especially good ventilation systems have a low risk of disease transmission.5 An experiment such as this one can be assessed under the ethical features exemplified in Snow's experiment.

Many natural experiments during pandemics are not initially planned as experiments, however. Bars are opening, restaurants are serving indoors, and schools are bringing students back into classrooms with each other. Mask wearing is being required, those not wearing masks are cajoled to do so, or people are left to choose on their own, depending on the jurisdiction. These interventions may have widespread effects on people in the communities where they occur. Yet depending on how they are conducted and studied, they may not comport very well with some ofthe features of Snow's work that made it so acceptable.

One set of concerns would be whether these interventions are being structured or evaluated after the fact based on the best currently available science. Rigorous data collection to assess outcomes is critical to this assessment. Many have the potential to cause real harm to some-those at greater risk for pandemic infection-albeit also with the hope of significant benefit to others, such as the businesses that can reopen. School openings, despite extensive community spread of COVID-19, are defended because of their educational importance to children and the economic importance to their parents of being able to work. Yet school openings may put teachers, staff, and some students or their families at significant risk. Without careful data collection about how these experiments are playing out, we will lack critical knowledge about disease spread in schools and its effects on students, their families, and school personnel. Moreover, ongoing community consultation may be especially important as more is learned about the impacts ofthe intervention on so many community members.

Now more than ever, our goal should be to encourage Snow-like models of ethical inquiry to learn from our natural experiments about how to address the evolving challenges of COVID-19 and plan sensibly for pandemics to come. >4JPH

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# Relation of Driving Under the Influence Laws to Access to Firearms Across US States

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## ABSTRACT (ENGLISH)

Objectives. To determine differences among US states in how driving under the influence of alcohol (DUI) laws activate federal firearm possession and purchase prohibitions. Methods. We performed primary legislative research to characterize DUI laws in each state. The primary outcome was the number of DUI convictions an individual must be convicted ofin each state to activate the federal firearm possession and purchase prohibition. We also determined the time interval in which previous DUI convictions count for future proceedings. Results. Forty-seven states had DUI laws that activated the federal prohibition of firearm possession and purchase for a threshold number of repeated DUIs. Variation exists among states in the number of convictions (1 -4) and length of liability period (5 years-lifetime) required to prohibit firearm possession and purchase. Conclusions. Variation in state laws on DUI results in differences in determining who is federally prohibited from possessing and purchasing firearms. Future research should explore whether these federal prohibitions arising from DUI convictions are enforced and whether an association exists between stricter DUI policies and reduction in firearm crimes, injuries, and deaths. (AmJ Public Health. 2021;111:253-258. https://doi.org/10.2105/AJPH.2020.305995)

## FULL TEXT

### Headnote

Objectives. To determine differences among US states in how driving under the influence of alcohol (DUI) laws activate federal firearm possession and purchase prohibitions.

Methods. We performed primary legislative research to characterize DUI laws in each state. The primary outcome was the number of DUI convictions an individual must be convicted ofin each state to activate the federal firearm possession and purchase prohibition. We also determined the time interval in which previous DUI convictions count for future proceedings.

Results. Forty-seven states had DUI laws that activated the federal prohibition of firearm possession and purchase for a threshold number of repeated DUIs. Variation exists among states in the number of convictions (1 -4) and length of liability period (5 years-lifetime) required to prohibit firearm possession and purchase.

Conclusions. Variation in state laws on DUI results in differences in determining who is federally prohibited from possessing and purchasing firearms. Future research should explore whether these federal prohibitions arising from DUI convictions are enforced and whether an association exists between stricter DUI policies and reduction in firearm crimes, injuries, and deaths. (AmJ Public Health. 2021;111:253-258. https://doi.org/10.2105/AJPH.2020.305995)

Previous studies indicate that there is an association between alcohol misuse and increased risk of firearm injuries and deaths.1 7 Wintemute et al. found that firearm owners in California with driving under the influence (DUI) convictions had a 4- to 4.5-fold increased risk of a subsequent violent or firearm-related arrest over a median 8year follow-up period compared with firearm owners without previous criminal convictions.2 Similar results were found in an update of the previous study.3 In these studies, even among individuals who had non-DUI criminal histories, a

DUI conviction was associated with increased likelihood to commit firearm-related violent crime. Another study found an association between conviction of DUI and increased risk to be arrested for intimate partner violence.4 Alcohol misuse has been associated with intimate partner violence,5,6 interpersonal assault, and firearmrelated deaths.7 Individuals who misuse alcohol are at higher risk of dying by firearm suicide.7 Asa result of all ofthese factors, some researchers have proposed restrictions that reduce access to firearms by individuals who misuse alcohol as a potential avenue to reduce firearm suicides, injuries, and homicides.1,4,8

Pennsylvania, Maryland, and the District of Columbia specifically outlaw firearm possession and acquisition based on DUI convictions. Maryland makes the possession of firearms by a "habitual drunkard" illegal, where "habitual drunkard" is defined as someone who has been found guilty of 3 DUI offenses, 1 of which was in the past year.9 Pennsylvania forbids possession and other actions by individuals who have been convicted of DUI 3times in a 5-year period.10 In the District of Columbia, no individuals will be issued a handgun registration certificate if they have been convicted of 2 DUI offenses in the past 5 years.11 Indiana formerly forbade transferring firearms to individuals who had had 2 or more alcohol-related convictions, 1 of which occurred in the preceding 3 years, but this restriction was repealed in 2014.12 Many other states have statutes forbidding alcohol users from purchasing or possessing firearms that use vague terminology like "drunkards," "chronic alcoholics," or "habitual alcohol use."1,13 These states do not define the use of these terms with any objective criteria, and commentators have suggested that these laws are not effectively enforceable as a result.1,8 Federal law does not restrict individuals from purchasing or possessing firearms on the basis of alcoholrelated convictions or intoxication, nor for other indicators of chronic or hazardous alcohol use.1

Laws exist at the state and federal level that are not specific to DUI but nevertheless can apply to individuals based on DUI convictions. US federal law 18 USC 922(g)(1), established by the Gun Control Act of 1968, forbids firearm possession and purchase by individuals convicted in any US jurisdiction of "a crime punishable by imprisonment for a term exceeding one year"; this category is defined by 18 USC 921(a)(20) to exclude any state offense defined as a misdemeanor that is punishable by a term of imprisonment of 2 years or less. As such, if an individual is convicted of either a misdemeanor punishable by longer than 2 years imprisonment or a felony, federal law prohibits the individual from purchasing or possessing a firearm. Individuals under indictment for a qualifying offense are prohibited from firearm purchase, but not from possession. Because what constitutes an applicable crime is determined "in accordance with the law of the jurisdiction in which the proceedings were held,"14 it is subject to differences in how states choose to classify and punish DUI offenses. Researchers have found substantial differences in the strength of impaired driving policy among states.15 Those differences in impaired driving policy could be reflected in substantial differences in who becomes prohibited as a result of DUI convictions.

A comprehensive ascertainment of how the federal prohibition on firearm possession and purchase comes into effect on individuals convicted of DUI is lacking in the public health literature. In this article, we review the current landscape of state DUI laws regarding how they activate federal firearm prohibitions on possession and purchase, and we demonstrate how such firearm restrictions are related to the interplay between state and federal laws. This information will be of use to researchers assessing the effect of DUI-related firearm possession and purchase prohibitions on firearm-related injuries, deaths, and violence. State policymakers may benefit by understanding how state DUI laws, in the context of specific federal statutes, result in firearm prohibitions. In general, individuals may benefit by better understanding what factors lead to a federal prohibition from firearm possession and purchase in their states.

## METHODS

We characterized current state DUI laws through primary research using the Thomson Reuters Westlaw database, an online legal database frequently used for legislative research. We conducted our legislative research from April 1, 2020, to May 1, 2020, for the laws in effect at that time in the 50 states and the District of Columbia. We considered District of Columbia laws along with state laws because of their inclusion in past studies on DUI-related firearm restrictions.1,13 For our search, the primary variable of interest was the number of DUI offenses of which an individual must be convicted to activate federal possession and purchase prohibitions.16 State DUI laws usually provide for increasingly severe penalties for repeat convictions based on the number of prior convictions. In addition, some states also provide a set interval of time, such as 5 years, 10 years, or lifetime, for which prior DUI convictions will count toward a more severe charge and sentence length for a current conviction. For the purposes of this article, this time period is referred to as the liability period. At the expiration of the liability period, prior convictions will no longer apply toward the classification of the current crime or its sentencing.

We determined the number of DUI convictions required to qualify for the firearm possession and purchase prohibition under 18 USC 922(g)(1) by examining the charging classification and penalty for each ordinal number of convictions. For each state and the District of Columbia, we began by checking if first DUIs were either classified as a felony or carried a maximum imprisonment penalty of greater than 2 years, thus activating the federal prohibition on firearm possession and purchase. If first DUIs did not satisfy either condition, we checked the classification and penalty for second DUIs. This was repeated with further convictions until we either found a qualifying DUI conviction or found that no amount of DUI convictions would qualify for activation of the federal prohibition on firearm possession and purchase. If there was a qualifying DUI conviction, we then determined the liability period connected to it.

Both the number of required DUI offenses and the existence and length of the liability period are relevant to determination ofwho is prohibited from firearm possession and purchase under the federal statute. A lower number of DUI convictions required to qualify for 18 USC 922(g)(1) means that greater proportions of individuals convicted of DUI become prohibited from possession and purchase. A longer liability period allows more of an individual's prior DUI convictions to count toward sentencing. In other words, a longer liability period increases the chances that an individual will reach the threshold number of previous offenses needed for federal prohibition of firearm possession and purchase.

We searched for penalties for a "basic" DUI crime with a tested blood alcohol concentration (BAC) equal to or greater than the state's minimum threshold to incura "perse" DUI offense (guilty of DUI based on the BAC),8 for a licensed, noncommercial driver aged 21 years or older. We disregarded any enhancing factors, such as the presence of a child in the vehicle, property damage, injury, or death, because of their complex effects on sentencing and classification. Excluding enhancements allowed us to provide a baseline measure that applies to all individualsthatare convicted ofthe threshold number of DUIs within the liability period.

## RESULTS

Only California, the District of Columbia, New Jersey, and New York do not provide statutory language for DUI sentences that qualify for a possession and purchase prohibition under federal law. The remaining 47 states have DUI laws that include language classifying some number of DUI conviction(s) as a felony or include a maximum sentence of greater than 2 years imprisonment for a threshold number of repeated DUI offenses without enhancements (Table 1). Thus, these 47 states have DUI statutory language that would activate the federal prohibition of firearm possession or purchase. However, substantial variation exists among these 47 states with respect to the number of DUI offenses that would prohibit an individual from purchasing a firearm under federal law, ranging from 1 offense to 4 offenses, as well as the liability period for consideration of these offenses. These variations are described hereafter and summarized in the table.

Massachusetts is the only state in which a first unenhanced DUI conviction would result in a federal prohibition of firearm possession and purchase. In 4 other states (Connecticut, Indiana, New York, and Oklahoma), a second unenhanced DUI offense within a set liability period would qualify for the federal possession and purchase prohibition. In 23 states, a third repeat unenhanced DUI offense within a liability period qualifies for the federal possession and purchase prohibition. In 17 other states, a fourth DUI conviction within a liability period will qualify for the federal possession and purchase prohibition (Table 1). In 44 states, these DUI offenses qualified for the federal statute because they were classified as felonies. In South Carolina, Massachusetts, and Maine, misdemeanor DUI offenses qualified by carrying a maximum penalty of greater than 2 years imprisonment.

States varied in the length of their liability period for repeated DUI offenses. Twelve states had no maximum liability period; the remaining states had liability periods ranging from 5 to 20 years. In 2 states, the period varied depending on the number of repeat offenses committed. Kansas provides a felony classification for a third DUI conviction within a 10-year period; however, a fourth DUI conviction is always classified as a felony, regardless of when the prior convictions occurred. Ohio provides a felony classification for a fourth or fifth DUI conviction within a 10-year period, but a sixth conviction extends the liability period to 20 years.

In our review, we found that some states impose "habitual impaired driving" penalties upon certain numbers of repeat convictions. For example, in Hawaii, a third DUI conviction in 10 years makes an individual guilty of "habitually operating a vehicle under the influence of an intoxicant," which is a felony. We counted such offenses, which result necessarily from multiple DUI convictions, if they qualified for 18 USC 922(g)(1).

## DISCUSSION

These results add to the literature on the nexus of alcohol and firearms by characterizing the number of DUI offenses and relevant period that activate the federal prohibition on possessing or purchasing firearms. Previous reports noted that only Pennsylvania, Maryland, the District of Columbia, and formerly Indiana had laws that were specifically designed to outlaw firearm possession or purchase based on DUI convictions.1 Nevertheless, individuals convicted of DUI in nearly all states can be prohibited from firearm possession and purchase under federal law if the state law results in a DUI conviction as a felony or misdemeanor punishable by greater than 2 years of imprisonment. The interplay of federal and state laws, combined with the differences in DUI penalty severity and classification among states, creates a complex legal landscape. Investigators assessing firearm laws and their potential impact on firearm ownership and firearm injuries and deaths should take both state and federal laws into account.

There is significant variation among the states and the District of Columbia in how DUI offenses activate federal firearm possession and purchase restrictions. California, District of Columbia, and New Jersey do not have any statutory language on DUI convictions that would result In the application of the federal statute prohibiting firearm possession and purchase, whereas Massachusetts, alone, dictates that a single DUI conviction can result In federal restrictions on possession or purchase of firearms. Future research should explore whether an association exists between firearm purchase and possession prohibitions on Individuals convicted of DUI and reduction In firearm-related crimes, Injuries, and deaths.

### Limitations

We have attempted to summarize a nuanced legal landscape, and complexities exist In the execution of justice that are difficult to capture In a summary study. One limitation Is that we did not summarize how states punish enhancements to DUI offenses. Enhancements are special circumstances that affect crime classification and sentencing and can change how many DUI convictions are needed to activate the federal statute. Because our findings display results for DUIs without enhancements, our findings can serve as a baseline, but are not exhaustive of all situations. For example, the US Court of Appeals for the Third Circuit case Holloway v Sessions Involved the application of the federal purchase prohibition In Pennsylvania to an Individual following a second DUI conviction, which Involved a BAC of 0.192.17 Pennsylvania Is a state where activation of 18 USC 922(g)(1) cannot occur after a second DUI offense alone (without enhancements). However, with an elevated BAC, extended sentences are sufficient to activate the federal prohibition. This illustrates how enhancing circumstances can result in prohibitions after fewer offenses than our findings display. Had the offender not had a highly elevated BAC, his second DUI would likely not have resulted In disarmament under Pennsylvania and federal law. More research Is needed to summarize the effect of DUI enhancements on the activation of federal and state firearm prohibitions.

Another limitation of this study Is that It did not examine how state-level prohibitions on firearm possession and purchase Interact with state DUI laws. State-level prohibitions could be especially relevant to prohibiting Individuals from firearm possession and purchase if they are enforced more effectively than federal laws. Another possibility Is that state laws could set more restrictive thresholds for activation than federal law, resulting In Individuals not affected by federal law to become prohibited from firearm purchase or possession at the state level. Future research Is needed to synthesize state firearm laws with the DUI laws In the same states.

### Public Health Implications

From our findings, federal law prohibits individuals from possessing or purchasing firearms based on DUI convictions In 47 states. In these states, firearm policy Is coupled to DUI policy by federal law: If DUI penalization and classification are changed, the people prohibited from firearm possession and purchase change as well. If state policymakers wish to ensure stability In their firearm policy, they may choose to enact laws specifically basing firearm possession and purchase prohibitions on DUI convictions.

Many states currently have laws prohibiting individuals who misuse alcohol from firearm possession, but laws in most of these states are unenforceable because they lack objective criteria.1,8 Our findings indicate that firearm access prohibitions based on DUI convictions already operate in nearly all 50 states. Given the nearubiquityofrepeated DUIrelated mechanisms for firearms prohibitions across states, interested policymakers may choose to emphasize enforcement of these laws over additional prohibitions to avoid the political challenges associated with new laws restricting firearms. Also, if policymakers wish to adjust their DUI-based firearm possession and purchase prohibitions, they can use this article as a reference to compare their state with the others.

Researchers should use this article as a resource for future investigations on the effects of policies that prohibit firearm possession or purchase based on DUI convictions. Previous studies have supported that individuals convicted of DUI have increased risk of committing firearm crime.2,3 However, research is lacking on the effects of DUI-based firearm access restrictions on an ecological level. Our findings show that future researchers must consider state DUI laws and their interaction with federal firearm policy. zijPM

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A. G. Bowen, R.A. Tessler, and M.J. Haviland conceptualized the article. A. G. Bowen and D. Bowen were responsible for primary legal research. Initial drafting of the article was performed by R.A. Tessler, A. G. Bowen, D. Bowen, and F. P. Rivara; all authors were responsible for critical editing and changes during the drafting and revision process. D. Bowen provided essential content on legal aspects.

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# State Preemption of Local Immigration "Sanctuary" Policies: Legal Considerations

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## ABSTRACT (ENGLISH)

States have enacted a wave of statutes over the past several years preempting local government law and policies that potentially promote public health in various ways. Among these local preemption measures are statutes in at least 9 states that outlaw municipal policies providing some form of "sanctuary" to immigrants. Such policies, and their preemption, have importance both for direct access to health services and for broader social determinants of health. This article gauges the coverage and potential impact of these state preemption laws based on key informant interviews nationally and a close legal analysis of relevant laws and policy documents. It distinguishes between preemption laws focused on law enforcement cooperation and those that also encompass a wider array of "welcoming" policies and initiatives. It also distinguishes between more passive forms of preemption that prohibit barring cooperation with federal immigration forcement, and statutes that more affirmatively require active measures to assist federal enforcement. Drawing these distinctions can help municipalities determine which immigrant-supportive measures are still permitted, and how best to mitigate the adverse public health effects of these preemption laws. (Am J Public Health. 2021;111:259-264. https://doi.org/10.2105/AJPH.2020.306018) As

## FULL TEXT

### Headnote

States have enacted a wave of statutes over the past several years preempting local government law and policies that potentially promote public health in various ways. Among these local preemption measures are statutes in at least 9 states that outlaw municipal policies providing some form of "sanctuary" to immigrants. Such policies, and their preemption, have importance both for direct access to health services and for broader social determinants of health.

This article gauges the coverage and potential impact of these state preemption laws based on key informant interviews nationally and a close legal analysis of relevant laws and policy documents. It distinguishes between preemption laws focused on law enforcement cooperation and those that also encompass a wider array of "welcoming" policies and initiatives. It also distinguishes between more passive forms of preemption that prohibit barring cooperation with federal immigration forcement, and statutes that more affirmatively require active measures to assist federal enforcement.

Drawing these distinctions can help municipalities determine which immigrant-supportive measures are still permitted, and how best to mitigate the adverse public health effects of these preemption laws. (Am J Public Health. 2021;111:259-264. https://doi.org/10.2105/AJPH.2020.306018)

As social policy issues have become more divisive, there is a growing trend for municipalities (e.g., cities or counties) to adopt distinctive ordinances or policies that express the views and preferences of local majorities.1 3 Immigrant rights are 1 such social issue on which a growing number of municipalities have taken a stand, by enacting "sanctuary" or "welcoming" policies that promote immigrants' welfare in various ways.4 7

In response, a growing number of states have enacted statutes that preempt local ordinances or policies on specific social issues. To date, a dozen states have adopted statutes that bar municipalities from maintaining an immigrant "sanctuary" policy that refuses or limits cooperation with federal immigration enforcement.8 These preemption laws are a concern for public health because they interfere with municipal efforts to address various determinants of health such as freedom of movement, receipt of a range of social services, and criminal justice.9 Accordingly, the scope and effects ofthese local preemption laws merit attention from the public health policy community.

State preemption of local law resembles, but is distinct from, federal preemption of state law. For both kinds of preemption, a larger jurisdiction with superior legal authority restricts or removes a subordinate jurisdiction's lawmaking prerogative over a particular matter. Because the federal government has primary authority over immigration matters, it is able to override state and local laws that conflict with federal immigration policy. The Supreme Court ruled, for instance, that federal law preempted Arizona's 2010 law that gave local officers immigration enforcement authority, explaining that only federal law can determine immigration violations.10 Under Supreme Court precedent, states are constitutionally protected from being "commandeered" by federal law, meaning that there are limits to the extent that federal law may force states to take action.11 The tension between these 2 principles has produced litigation over whether states can, for instance, adopt a statewide policy to limit cooperation with federal immigration enforcement, as California and Washington have done,12 or whether states, acting without federal permission, may authorize local officers to arrest suspected undocumented immigrants solely for federal immigration violations.10

State preemption of local law raises different legal issues. States have inherent sovereign authority that provides some protection against federal preemption. Municipalities, however, are entirely subordinate to states; they have no inherent lawmaking authority beyond what states grant them. Some states embrace a "home rule" approach that gives municipalities greater authority, but these states typically provide that general statewide legislation overrides any contrary local law or policy.1,13

Although state authority over municipalities is broad, it is not unlimited. States may not contravene federal law, including federal immigration statutes as noted earlier. Furthermore, states must avoid violating constitutionally protected rights such as due process and equal protection. For instance, the Fifth Circuit Court of Appeals ruled that 1 portion of Texas' sanctuary preemption law violated the First Amendment by forbidding local elected officials from "endorsing] a policy" that limits federal immigration enforcement.14 Otherwise, the core of state immigration preemption laws have, so far, survived judicial challenge. A federal district court in Florida, for instance, ruled that Florida's requirement that municipal officials use "best efforts" to support federal immigration enforcement is not unconstitutionally vague.15

Considering this legal background, most of the debate over sanctuary preemption laws focuses on their coverage and reach, as well as their public policy implications. This article surveys these issues of legal scope and public policy, beginning with an overview of how these preemption laws are worded and then describing the types of protective policies that still might remain permissible under these preemption laws. This analysis is based on legal and public policy research, as well as interviews with 30 key informants familiar with how these sanctuary preemption laws function. Most informants were from 3 states that have strong preemption laws (NC, TN, TX), but some have national perspectives. Also, most were from immigrant rights organizations, but some were from law enforcement.

## SCOPE OF "SANCTUARY" PREEMPTION LAWS

The meaning and scope of immigration "sanctuary" is not well settled and, in fact, remains somewhat contentious.1619 Supportive municipal policies can range over a fairly broad spectrum. At 1 end, a strong sanctuary jurisdiction is one that shelters immigrants from federal immigration enforcement by refusing to take any proactive steps to notify or cooperate with federal authorities, and by declining to respond to most or all federal requests for information or assistance. At the other end of the spectrum, a locality might cooperate fully with federal authorities but institute policies outside the law enforcement arena that protect and advance immigrants' welfare, in domains such as health care, education, housing, and employment.

Accordingly, sanctuary preemption laws have 2 basic components: those that address law enforcement activities and those that address other civic services and functions.13,20 A further distinction is whether, in the law enforcement area, the preemption law requires only reactive cooperation (responding to requests) or instead requires localities to take more proactive steps to advance federal enforcement, as follows:

* Reactive: Requires cooperative response to federal requests for assistance.
* Proactive Type A: Forbids local policies that remove officers' discretion to inquire about immigration status.
* Proactive Type B: Requires local law enforcement to inquire about immigration status or affirmatively assist with federal immigration enforcement in other ways.

All ofthe preemption laws in question require localities to respond to federal requests for assistance. These requests include inquiries about the identity and immigration status of prisoners or people arrested, and "detainer" requests that ask local authorities to keep immigrants in custody beyond their normal release time, until federal authorities can assume custody. Federal authorities sometimes also ask to interview detainees, or ask local authorities to transport them to a federal facility. Beyond specifying these particular forms of cooperation, state laws sometimes have a more general provision that requires law enforcement to respond to federal requests for assistance "to the full extent permitted by federal law."21,22

In addition to these "reactive" forms of federal cooperation, several states require more proactive local involvement in federal immigration enforcement. These proactive provisions can take 2 forms: (1) those that require localities to adopt proactive policies, and (2) those that forbid localities from precluding the adoption of proactive policies and practices. This distinction may appear subtle, but it is critical for understanding the leeway that municipalities still have under preemption laws.

Most proactive preemption laws merely allow local law enforcement to ask about immigration status when they stop or arrest people. This precludes local policies that forbid such inquiries. Examples are the statutes in Florida, Tennessee, and Texas. Arizona, however, goes further by affirmatively requiring local law enforcement to inquire about immigration status when an officer has "reasonable suspicion" that a person is an undocumented immigrant. Other states have not gone quite this far, possibly out of respect for preserving some discretion for local law enforcement agencies and officers.

Most state preemption statutes do not explicitly apply outside the law enforcement arena. Following conventional understanding, most (but not all) of these laws define "sanctuary" in terms of law enforcement activities. Tennessee, for instance, defines "sanctuary policy" as any that "limits or prohibits any local governmental entity or official communicating or cooperating with federal agencies" to verify or report immigration status; grants undocumented persons "right to lawful presence" in the state; prevents law enforcement "from inquiring [about] citizenship or immigration status"; or "restricts in any way, or imposes any conditions on" compliance with detainers or other requests to maintain custody or to transfer custody.23 However, a few statutes potentially, or explicitly, cover various municipal civil or social services. Arizona's, for instance, says that municipalities may not prohibit local agencies and officials from "sending, receiving, or maintaining information" about immigration status for official purposes, including "determining eligibility for any public benefit, service or license," or verifying any legally required claim of residence or domicile.21

## POLICIES THAT POTENTIALLY AVOID PREEMPTION

Building on the foregoing description of the coverage and reach of sanctuary preemption laws, this section draws from key informant interviews and legal research to discuss immigrantsupporting policies that municipalities might still adopt, despite the presence of state preemption. Naturally, each of these depends on the particulars of how a preemption law is worded and interpreted by enforcement authorities.

### Law Enforcement Cooperation-Reactive

Preemption laws that require municipalities only to respond to federal requests for assistance leave open 3 possible avenues for leeway. The first is to decline more proactive forms of cooperation. For instance, these laws do not require municipalities to enter into what are termed 287(g) agreements (after the federal statutory provision that authorizes them), under which the federal government, in essence, deputizes local officers to actively enforce federal immigration law as if they were federal officers, with the authority to arrest and detain suspects for federal immigration offenses. None of the preemption laws require municipalities to go this far. At most, they require only that local officers gather and report relevant information to federal authorities.

The second strategy is to define the limits of cooperation that local officials believe would violate constitutional protection of immigrants' rights. Primarily, this entails due process rights that limit the legality of holding a detainee without probable cause, beyond the period of confinement authorized by local law.24 Thus, some local authorities have taken the position, backed by judicial precedents, that once a detainee has served the required time for a state or local infraction or met the conditions for release (such as bail or parole), it would violate the person's constitutional rights to further detain them for a federal investigation, without a judicial order. That position has been taken, for instance, by the county attorney in Shelby County (Memphis), Tennessee,25 and by the sheriff in Mecklenburg County (Charlotte), North Carolina,26 despite their states' sanctuary preemption laws.

A third avenue to consider is to adopt a "cite-and-release" policy that applies to all residents, to reduce the extent to which minor offenders engage with the law enforcement system. A number of municipalities have adopted what have been called "Freedom City" policies27 that either allow or require officers to issue those suspected of relatively minor, nonviolent offenses (such as simple drug possession, petty larceny, trespassing, etc.) a simple citation, and then to release the individual under terms similar to those for an ordinary traffic ticket, rather than to arrest the person for booking and possible detention. Municipalities do this to reduce the burden on their criminal justice system, and to counteract the disparate disadvantages of the bail system for lowincome and minority populations. This approach to law enforcement has not been sufficiently studied to know for certain whether it might have any adverse consequences, such as increasing the number or disparity of minor citations. However, an additional protective effect of not arresting, "booking," or detaining low-level offenders is to avoid triggering requirements to report immigration status to federal officials or requests to detain immigrants for federal purposes. An advantage of a citeand-release approach is that it draws together a more diverse set of constituencies, and serves broader purposes, than just support for immigrants.

Law Enforcement Cooperation-Proactive

State laws that require municipalities to assist more proactively in federal immigration enforcement also leave some avenues for leeway. Texas serves as the leading example. Its statute prohibits municipalities from "materially limit[ing]" a local officer from "inquiring into the immigration status of a person under a lawful detention or under arrest."28 Austin, Texas, however, adopted the following measures to constrain how these requirements are implemented29:

* Officers are not required to ask about immigration status; they are only permitted to do so.
* Officers may not stop someone simply to inquire about immigration status, or extend a stop longer than needed for purposes of local law enforcement, simply to check immigration status.
* Officers must write an incident report that documents the circumstances for each immigration-status inquiry they make, including the reason(s) for making the inquiry.
* Inquiries about immigration status may not be based on a person's race, skin color, or language spoken.
* When making an immigrationstatus inquiry, the office must tell the individual that he or she has the right to refuse to answer.
* Officers may not make immigrationstatus inquiries in sensitive settings, such as when interviewing victims of or witnesses to a crime, or while serving as a safety officer at schools, health care facilities, or places of worship absent exigent circumstances.

Examples of other localities adopting some or all of these constraints on immigration-status inquiries include Phoenix and Tucson, Arizona.30

Non-Law-Enforcement

Measures

Even the strictest antisanctuary state laws leave wide berth for localities to adopt various supportive policies outside the law enforcement arena. To avoid the flashpoint that the "sanctuary" label can create, many localities are phrasing such policies as "welcoming" toward immigrants.17,31 33

Welcoming policies comprise a long list of possible measures,34 starting simply with an office (or official) charged with tending to immigrant affairs and charged with helping to create a positive community attitude toward immigrants. No preemption laws appear to prohibit this general expression of support. In Arizona, for instance, whose preemption laws are among the strictest in the country, the state attorney general ruled that the law's prohibition of sanctuary policies does not preclude policies with "aspirational language" such as "welcoming."35 Were these laws to do so, they might well be challenged on First Amendment constitutional grounds. The federal court decision reviewing Texas' preemption law, for instance, ruled that it was unconstitutional to prohibit government officials from "endorsing" noncooperation policies, in the sense of expressing personal support for them.36 This protection would not likely extend, however, to official statements by municipal bodies because they, unlike, individual officers, do not have clearly recognized speech rights.

Beyond their primarily expressive content, welcoming policies can have more substantive effects. These policies often facilitate or require local agencies and officials to communicate in nonEnglish languages. Most substantively, these policies can forbid civic or social service agencies from inquiring about immigration status unless essential to the program in question, and they can reinforce nondiscriminatory service policies. These welcoming policies appear to be valid even under some of the strictest preemption statutes. Arizona's, for instance, requires that local officials be allowed to exchange or keep immigration information, but that does not necessarily equate with requiring them to collect such information, especially when the information is not essential to "determining eligibility for any public benefit, service or license." Alabama's statute, however, specifically bans most local public benefits for undocumented persons and thus would appear to require many local agencies to make immigration status inquiries.37

The extent to which local supportive policies can effectively offset hostile or restrictive state and federal policies remains unclear.38 Nevertheless, 1 helpful measure that appears to have potential in this regard is municipal ID programs. Many states limit immigrants' access to state-issued IDs such as driver's licenses, which has been found to have a negative impact on immigrant well-being.39 Accordingly, some municipalities give residents (of any immigration status) the option of obtaining valid identification in a form other than a state-issued ID, and then require local officials to accept such identification for various purposes where identification is needed.40,41 A few municipalities (e.g., New Haven, CT) do this simply by declaring that a local library card will be accepted as valid Identification for other municipally governed purposes. Preliminary studies suggest that such municipal IDs may improve access to services, with some limitations.39,42'43

Municipal IDs have not been widely adopted, nor have they been fully studied. However, where these programs exist, they appear to be legally permissible. Two exceptions, though, are North Carolina and Tennessee, which forbid municipal IDs.44,45 A handful of North Carolina communities, however, have maintained a workaround consisting of an alternative ID issued by a private nonprofit organization, which local law enforcement officials and a range of private institutions agree to accept.46,47

## Backlash Concerns

One consideration in deciding how aggressively to pursue possible workarounds to state preemption laws is whether doing so might cause an enforcement "backlash" as a form of retaliation against municipalities that follow only the letter, but not necessarily the "spirit," of these laws.18 Federal immigration authorities on a number of occasions have carried out targeted immigration enforcement activities in localities that openly support undocumented immigrants.48 Similarly, state authorities have brought enforcement actions against cities or counties they believe are not honoring their preemption statutes,49 and antiimmigration activists have called out communities they believe are too lenient.

We heard mixed views from key informants about the extent of this retaliation risk. Some thought that only the most blatant or aggressive attempts to circumvent preemption are likely to prompt enforcement backlash. Thus, it was not thought that the separate set of policies encompassed under the "welcoming" heading constitute true "sanctuary" status or were likely to draw antagonistic attention. Others, however, were concerned that embracing supportive positions too openly would cause critics to apply the "sanctuary" label inappropriately, leading to a real risk of federal or state retaliation. This viewpoint caused some officials either to back away from supportive policies or to implement them less visibly. Out of these concerns, a variety of informed sources thought that backlash concerns could be reduced with careful attention to the boundary of what constitutes acceptable versus unacceptable forms of support for immigrants under the preemption laws in place. If such lines are thoughtfully interpreted, they thought that adverse state or federal actions can be avoided without further limiting local actions to protect and advance the welfare of immigrant community members.

## CONCLUSIONS

By preempting local laws that support and protect immigrants, states exacerbate the adverse social conditions in which immigrants live that contribute to a range of physical and mental health problems. Preemption laws likely increase the climate of hostility and fear that adds to stress and reluctance to seek services, and that deters or denies tangible health care and social services. These negative impacts on social determinants of health threaten the welfare not only of immigrant persons, but also the welfare and social fabric of the broader communities in which they live and work.

Some key informants noted that, when states consider adopting preemption laws, even if defeat of the law appears unlikely, advocates still can work to narrow the law's scope before it is passed. Once enacted, municipalities can also take various steps to mitigate negative impacts. First, they can carefully evaluate states' preemption laws to determine precisely what they forbid, and thus what they allow, and then think creatively about allowable measures to maintain supportive policies. Second, they can implement additional measures that do not constitute "sanctuary" but nevertheless convey the impression and the reality of welcoming and including immigrants. Many of these inclusive policies that could be adopted have a potential positive impact on community members regardless of citizenship or nationality, thus promoting community welfare and social justice more broadly. ÂfPU

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Each author contributed to the design of this study, the collection and analysis of data, and drafting the article.

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# Congressional Budget Responses to the Pandemic: Fund Health Care, Not Warfare

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## ABSTRACT (ENGLISH)

The coronavirus outbreak is not the first crisis to affect a large swath of the nation's population: the Great Depression, World War II, and the HIV epidemic did so previously. Of the national responses to each of these examples, perhaps the most relevant would be the Manhattan Project model, as proposed by Senator Edward J. Markey (D, MA) and Peter L. Slavin, MD, of Mass General Hospital.1 In 1943 the government diverted tens of billions of dollars from civilian programs to the project to build the atomic bomb. What the COVID19 pandemic requires is the reverse: the diversion of a substantial chunk of the more than $700 billion appropriated for the Pentagon's military budget to the biomedical, public health programs desperately needed to limit the current coronavirus outbreak and prevent future pandemics. Congress needs to recognize the actual challenges to our national security and thereby sustain our people's health and promote a prosperous and just economy. We are not in danger of being invaded by Russians, Chinese, Venezuelans, or Iranians; we are in danger of having the fabric of our society undermined by our failure to invest in and protect our national health and welfare. In the scientific and medical communities, we know that the path to solving problems is investing in a focused effort. We can make quite a long list of successes that followed from concentrated federal investment: the Manhattan Project, radar development during World War II, the national interstate highway system, landing on the moon, sequencing the human genome, and developing HIV therapies, to name a few.

By contrast to the these successes, failure to invest prevents solving national problems.

## FULL TEXT

The coronavirus outbreak is not the first crisis to affect a large swath of the nation's population: the Great Depression, World War II, and the HIV epidemic did so previously. Of the national responses to each of these examples, perhaps the most relevant would be the Manhattan Project model, as proposed by Senator Edward J. Markey (D, MA) and Peter L. Slavin, MD, of Mass General Hospital.1 In 1943 the government diverted tens of billions of dollars from civilian programs to the project to build the atomic bomb. What the COVID19 pandemic requires is the reverse: the diversion of a substantial chunk of the more than $700 billion appropriated for the Pentagon's military budget to the biomedical, public health programs desperately needed to limit the current coronavirus outbreak and prevent future pandemics. Congress needs to recognize the actual challenges to our national security and thereby sustain our people's health and promote a prosperous and just economy. We are not in danger of being invaded by Russians, Chinese, Venezuelans, or Iranians; we are in danger of having the fabric of our society undermined by our failure to invest in and protect our national health and welfare.

In the scientific and medical communities, we know that the path to solving problems is investing in a focused effort. We can make quite a long list of successes that followed from concentrated federal investment: the Manhattan Project, radar development during World War II, the national interstate highway system, landing on the moon, sequencing the human genome, and developing HIV therapies, to name a few.

By contrast to the these successes, failure to invest prevents solving national problems. For example, once it became clear that the SARS-CoV-1 epidemic was under control in 2003, the nation failed to invest the sums needed to develop a SARS vaccine.2 Had that been done, we would have been better prepared to counter the SARS-CoV-2 virus strain, a cousin of SARSCoV-1. The lack of investment reflects the overall imbalance between congressional funding for military and civilian programs, which has been exacerbated under President Trump. Figure A (available as a supplement to the online version of this article at https://www.ajph.org) shows the congressional discretionary budget for 2017, with more than half the total allocated to Pentagon accounts. Subsequent years follow this same pattern.

The CARES Act directed about $1 billion to the National Institutes of Health (NIH), $4.5 billion to the Centers for Disease Control and Prevention, and $3.5 billion to the Biomedical Advanced Research and Development Authority for vaccine development.3,4 President Trump's Project Warp Speed is an attempt to respond to these needs but is more a giant BandAid than a change in national priorities and investment in the basic public health and biomedical research infrastructure needed forthe current and future threats. These investments are equal to merely a few cents on the dollar of the fiscal costs of the COVID-19 pandemic.

Although these federal investments are a step forward in responding to the coronavirus outbreak, after years of inadequate budgets for these agencies, they pale when compared with the $738 billion authorized this year by Congress for foreign wars, 800 military bases around the world, and a dangerous new nuclear arms race. As a single specific example, if an individual Ohio-class submarine were its own country, it would be the sixth most heavily armed nuclear weapons nation. The United States has 14 Ohio-class submarines. There are bipartisan plans to build 12 new "replacement" SSBN-826 nuclear submarines at more than $9 billion each. If instead of buying 12 we bought only seven, the entire budget of the NIH could be doubled with the savings. Similar examples abound. Now is the time to switch budget priorities.

Our population continues to be afflicted not only by SARS-CoV-2 infections but by many forms of cancer, heart disease, stroke, arthritis, antibioticresistant bacterial infections, and neurodegenerative diseases. The core responsibility for improved prevention, diagnosis, treatment, and therapies for these conditions falls to the NIH.5 Before the coronavirus outbreak, Congress had allotted $42 billion to the NIH, approximately 5% ofthe $738 billion authorized for the Department of Defense.

We can compare the need for and social impacts of these expenditures for just one illness, Alzheimer's disease, one of NIH's responsibilities. More than 3 000 000 Americans suffer from this tragic and debilitating illness. The care of these patients alone accounts for 20% of Medicare's and Medicaid's budgets, more than $250 billion a year.7 Yet the overall NIH investment in searching for a deeper understanding, better diagnosis, and better therapies is on the order of $1 billion per year. This is clearly an inadequate investment given the human suffering and social and economic costs entailed. For a social cost of $250 billion, perhaps 10% ofthat-$25 billion- would approach a sound and humane NIH research budget. This would indeed be like a Manhattan Project in reverse.

The congressional discretionary budget in recent years has been a boon for defense contractors but completely inadequate for protecting the health and welfare ofthe citizenry. There are alternatives to these skewed priorities. For example, the current administration is supporting spending 1.7 trillion of tax dollars over the next 30 years on upgrading all three legs ofthe nuclear weapons triad. This highly provocative action will only reduce national security and increase the risk of inadvertent or intentional nuclear exchange. These funds would make a much larger contribution to national security if they were directed to the actual threats facing our population. The adoption of Senator Markey's SANE bill would lead to an immediate savings of $75 billion in nuclear weapons spending, money that could be used for pressing health needs.

The Center for International Policy's Sustainable Defense Task Force-a group of former White House, congressional, and Pentagon budget officials; retired military officers; and experts from think tanks across the political spectrum-has developed a plan that could make the United States safer while saving more than $1.25 trillion over the next decade.6 Elements of the plan involve implementing a more restrained military strategy that would end US overseas wars and reduce the size ofthe military accordingly, take a more realistic view ofthe challenges posed by Russia and China, eliminate hundreds of billions of dollars in excess bureaucracy, and rein in the Pentagon's costly and dangerous nuclear weapons buildup. The most urgent risks facing the United States and the world-viral pandemics, the climate change crisis, and extreme income inequality-do not have military solutions. We must shift our budgetary resources accordingly.

The COVID-19 pandemic lays bare what the entire US health care system lacks: basic research into widespread diseases, the development of cures and preventative measures, and the actual delivery of patient care. It has been obvious to many that the nation needs significant reform in health care and public health funding. Now is the time to call on Congress to implement this transformation of our national priorities. /flÞH

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# COVID-19 and Nonsuicidal Self-Injury: The Pandemic's Influence on an Adolescent Epidemic

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## ABSTRACT (ENGLISH)

As many countries continue to struggle with controlling the COVID-19 pandemic, another public health frontier has come into view. The mental health sequelae of quarantineand pandemic-associated psychosocial hardship, brought about by global recession, unemployment, and an increase in domestic violence, are clearer with every recent study being published. Given an increase in several risk factors, concerns have been raised about a possible increase in many mental health conditions,1 particularly suicide. Although these are valid concerns, it remains unclear how the COVID-19 situation has affected one of the most extensive mental health epidemics among adolescents. Nonsuicidal self-injury (NSSI), the deliberate destruction of one's own body tissue without suicidal intent,2 has received increasing notice in the general public as well as in the scientific literature; for example, a 12-month prevalence rate of 17.6% was reported for a representative US adolescent sample.3 So far, no evidence is available on the effect of COVID-19 on NSSI; however, some recent studies raise the level of concern. A recent US online study reported an association between COVID19-related general distress and suicidal thoughts, with higher scores of suicidal ideation in those exposing themselves intentionally to SARS-CoV-2.4 A recent study in an Irish emergency department reported a sharp increase in self-harm patients from April to May 2020.5 Ougrin et al. compared data of March through April 2019 with data of March through April 2020 from 23 child and adolescent psychiatric emergency service locations in 10 countries. The authors observed an increase in the number of children seeking emergency services owing to self-harm (odds ratio = 1.33; 95% confidence interval = 1.07, 1.64).6 This might be understood as an early indication that NSSI should not be overlooked in times of quarantine.

## FULL TEXT

As many countries continue to struggle with controlling the COVID-19 pandemic, another public health frontier has come into view. The mental health sequelae of quarantineand pandemic-associated psychosocial hardship, brought about by global recession, unemployment, and an increase in domestic violence, are clearer with every recent study being published. Given an increase in several risk factors, concerns have been raised about a possible increase in many mental health conditions,1 particularly suicide. Although these are valid concerns, it remains unclear how the COVID-19 situation has affected one of the most extensive mental health epidemics among adolescents.
Nonsuicidal self-injury (NSSI), the deliberate destruction of one's own body tissue without suicidal intent,2 has received increasing notice in the general public as well as in the scientific literature; for example, a 12-month prevalence rate of 17.6% was reported for a representative US adolescent sample.3 So far, no evidence is available on the effect of COVID-19 on NSSI; however, some recent studies raise the level of concern. A recent US online study reported an association between COVID19-related general distress and suicidal thoughts, with higher scores of suicidal ideation in those exposing themselves intentionally to SARS-CoV-2.4 A recent study in an Irish emergency department reported a sharp increase in self-harm patients from April to May 2020.5 Ougrin et al. compared data of March through April 2019 with data of March through April 2020 from 23 child and adolescent psychiatric emergency service locations in 10 countries. The authors observed an increase in the number of children seeking emergency services owing to self-harm (odds ratio = 1.33; 95% confidence interval = 1.07, 1.64).6 This might be understood as an early indication that NSSI should not be overlooked in times of quarantine.
Because of a lack of data on the impact of the COVID-19 pandemic on NSSI in adolescents, we must rely on former works about risk factors for NSSI. As NSSI is often used as an emotionregulation strategy to decrease or end negative emotions for a short time, among the strongest risk factors for NSSI are a previous history of NSSI, hopelessness, and a cluster B personality disorder (characterized by dramatic, overly emotional, or unpredictable

thinking or behavior and interactions with others [Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, Washington, DC: American Psychiatric Association; 2013]). Parental psychopathology and family functioning also play significant roles in predicting NSSI.2

The situation imposed on adolescents worldwide during the COVID-19 crisis leads to questions about how quarantine measures might affect those with a history of NSSI. The lockdown procedures have led to a situation in which daily structure (e.g., day-night rhythm, including attending school at set times) has changed and social relationships have been restricted to social media. The lockdown conditions imposed in many countries bear the potential to aggravate existing conflicts in families, leading to an increased need to regulate emotions. Social support, found to be a protective factor against NSSI, has been available only online and access to professional support has been limited.

In a situation with reduced support structures and an accumulation of potential risk factors, it seems likely that there has been a steep increase in NSSI. Nevertheless, one should not forget that the frequency of other strong risk factors, such as bullying, school stressors, and the influence of self-injuring peers, might be reduced because of school closings and quarantine restrictions. However, because of online contacts, bullying and contact with self-injury communities may have continued even in these circumstances.

If the increase in NSSI suggested by emergency department data holds true, the question remains: how can this mental health crisis be met? Different psychotherapeutic approaches are effective in reducing NSSI, with most evidence available for dialectical behavioral therapy for adolescents.2 The COVID-19 pandemic has, however, underlined the need for alternative treatment approaches that are available online. Although there is a growing literature on apps and online diaries, so far no randomized controlled trial is available on an online treatment program, although a clinical trial is under way.7 Strengthening research on online interventions holds the potential to provide a knowledge base for future stepped care procedures as well as a valuable therapeutic option during lockdown conditions with restricted availability of face-to-face psychotherapy. Given that the COVID-19 pandemic is far from ending, attention needs to be shifted to psychosocial outcomes, especially in youths, because the possible consequences of worsened mental health may aggravate the long-term impact of the pandemic. >4JPH

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# Should E-Cigarette Regulation Be Based on Randomized Trials or Observational Studies?

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## ABSTRACT (ENGLISH)

In a systematic review, Wang et al. (p. 230) considered several types of evidence about the effects of electronic cigarettes (e-cigarettes) on smoking cessation. Synthesizing the results of randomized clinical trials (RCTs) using meta-analysis, Wang et al. found that providing free e-cigarettes probably helps some people quit smoking. This is consistent with a recent Cochrane review that found that free e-cigarettes provided in trials were more effective than nicotine replacement for smoking cessation and possibly more effective than behavioral therapy. Both reviews highlight important clinical differences across individual trials, and both reviews show that ecigarettes have small absolute benefits because most people are unsuccessful in their attempts to quit smoking tobacco. Moreover, both reviews point to concerning evidence that people use e-cigarettes longer than other smoking cessation aids. In the long-term, switching to e-cigarettes might be better than continuing to smoke tobacco; however, these trials do not show whether the short-term benefits of e-cigarettes offset their long-term harms when compared with nicotine replacement, such as gums or lozenges, which are effective for smoking cessation and used for a shorter time. Wang et al. argue that if regulators such as the US Food and Drug Administration had approached e-cigarettes as they approach drugs and medical devices, RCTs restricted to people who are motivated to quit smoking would have been appropriate for assessing their potential benefits. Although their effects on smoking cessation are small, e-cigarettes might even compare favorably with other smoking cessation therapies such as bupropion, varenicline, and nicotine inhalers.

## FULL TEXT

In a systematic review, Wang et al. (p. 230) considered several types of evidence about the effects of electronic cigarettes (e-cigarettes) on smoking cessation.

### RANDOMIZED CLINICAL TRIAL EVIDENCE

Synthesizing the results of randomized clinical trials (RCTs) using meta-analysis, Wang et al. found that providing free e-cigarettes probably helps some people quit smoking. This is consistent with a recent Cochrane review that found that free e-cigarettes provided in trials were more effective than nicotine replacement for smoking cessation and possibly more effective than behavioral therapy.1 Both reviews highlight important clinical differences across individual trials, and both reviews show that ecigarettes have small absolute benefits because most people are unsuccessful in their attempts to quit smoking tobacco. Moreover, both reviews point to concerning evidence that people use e-cigarettes longer than other smoking cessation aids. In the long-term, switching to e-cigarettes might be better than continuing to smoke tobacco; however, these trials do not show whether the short-term benefits of e-cigarettes offset their long-term harms when compared with nicotine replacement, such as gums or lozenges, which are effective for smoking cessation and used for a shorter time.2

Wang et al. argue that if regulators such as the US Food and Drug Administration had approached e-cigarettes as they approach drugs and medical devices, RCTs restricted to people who are motivated to quit smoking would have been appropriate for assessing their potential benefits. Although their effects on smoking cessation are small, e-cigarettes might even compare favorably with other smoking cessation therapies such as bupropion, varenicline, and nicotine inhalers.

### OBSERVATIONAL STUDIES

Because e-cigarettes have been regulated and sold as consumer products, Wang et al. argue, observational studies are important to assess their effectiveness in the general population, which includes nonsmokers and people who are not motivated to quit smoking. As consumer products, e-cigarettes might do more harm than good if they increase nicotine use among people who smoke and are not motivated to quit, or they might do harm if they attract new nicotine users. E-cigarettes could theoretically increase tobacco use by increasing nicotine initiation among young people who later add tobacco cigarettes or switch from e-cigarettes to tobacco cigarettes. In an accompanying editorial, Gee et al. (p. 224) highlight why concerns about young people are central to the debate about the regulation and distribution of e-cigarettes.

To help understand the effects of ecigarettes as consumer products, Wang et al. analyzed observational studies of the association between e-cigarettes and smoking cessation using two approaches. They conducted one analysis restricted to people who smoke and express motivation to quit smoking. In another analysis they included all people who smoke, regardless of motivation to quit smoking tobacco. In an accompanying editorial, Fairchild (p. 221) explains that guideline development groups have similarly grappled with the difficulty of answering closely related research questions for which different types of evidence about e-cigarettes are relevant.

### CONFLICTING RESULTS?

At first glance, results from observational studies appear to differ from the results of RCTs. As Grant (p. 227) notes, we tend to have less certainty in the observational evidence compared with evidence from RCTs. Moreover, these analyses include multiple effect estimates from some observational studies. Wang et al. used novel methods to account for the correlation between multiple estimates from the same study, and readers should interpret the consistency of these effects in light of the relationships among them.

RCTs suggest that e-cigarettes offer modest benefits, yet observational studies suggest that e-cigarettes are associated with less smoking cessation among people who express motivation to quit smoking tobacco. Considering the broader population of all people who smoke, regardless of motivation to quit, Wang et al. found that longitudinal studies indicate that e-cigarettes are, at best, modestly associated with smoking cessation. By contrast, summary effects from cross-sectional studies would be consistent with no important difference or a small decrease in smoking cessation among all people who smoke. However, results of these observational studies are so heterogeneous that the summary effects should be interpreted cautiously.

Looking deeper into their results, Wang et al. found qualitatively different associations for intense users and nonintense users of e-cigarettes. That is, intense e-cigarette use was associated with greater likelihood of smoking cessation, whereas less intense e-cigarette use was associated with lower likelihood of smoking cessation. These findings could highlight an important source of clinical heterogeneity-some people use e-cigarettes to quitsmokingtobacco whereas other people use e-cigarettes alongside tobacco cigarettes-yet heterogeneity remained even within groups stratified by intensity.

Wang et al. argue that, as consumer products in the United States, ecigarettes do not meet the standard for the "protection of public health" because it is unclear whether they increase smoking cessation across the population. Gee et al. concur, whereas Fairchild (p. 221) and others interpret the evidence differently, concluding that the profound and well-known harms of smoking tobacco justify widespread distribution of e-cigarettes. Grant suggests that closer inspection of the observational evidence might have allowed Wang et al. to say more about certainty in this body of evidence and that greater transparency would have strengthened the review.

## POLICY IMPLICATIONS

The review by Wang et al. focuses on smoking cessation and does evaluate whether "dual use" in the general population might decrease harm by reducing overall tobacco use. As Fairchild notes, observational studies of current smokers also omit people who used e-cigarettes successfully to quit smoking tobacco. Moreover, Wang et al. do not address ongoing debates about nicotine initiation, particularly in young people. Nonetheless, Wang et al. make a case for rethinking the regulatory approach to e-cigarettes.

Even if e-cigarettes do reduce tobacco smoking in the general population, the public health benefits of e-cigarettes might be separable from their availability as consumer products. Perhaps ecigarettes must be sold in places such as supermarkets and gas stations to reach all people who wish to try them; however, other methods of distribution might reach the target group of adults who are motivated to stop or reduce smoking tobacco. Wang et al. argue that e-cigarettes could be made available by prescription, like nicotine inhalers. They explain that most e-cigarette users in the general population are not daily ecigarette users, and the latter group accounts for modest increases in smoking cessation in both RCTs and observational studies. Greater efforts to limit e-cigarette availability to adults who are ready to replace tobacco with e-cigarettes, the target population for whom there is rigorous evidence that their benefits likely outweigh their harms, could realize the benefits for this target group while minimizing harm to the rest of the population. >4JPH

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## CONFLICTS OF INTEREST

I have no conflicts of interest to declare.

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# DETAILS

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# The Political Economy of Health: Revisiting Its Marxian Origins to Address 21st-Century Health Inequalities

Harvey, Michael, DRPH

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## ABSTRACT (ENGLISH)

The "political economy of health" Is concerned with how political and economic domains Interact and shape Individual and population health outcomes. However, the term is variously defined in the public health, medical, and social science literatures. This could result in confusion about the term and its associated tradition, thereby constituting a barrier to its application in public health research and practice. To address these issues, I survey the political economy of health tradition, clarify its specifically Marxian theoretical legacy, and discuss its relevance to understanding and addressing public health issues. I conclude by discussing the benefits of employing critical theories of race and racism with Marxian political economy to better understand the roles of class exploitation and racial oppression in epidemiological patterning. (Am J Public Health. 2021;111:293-300. https://doi.org/10.2105/ AJPH.2020.305996)

## FULL TEXT

### Headnote

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To address these issues, I survey the political economy of health tradition, clarify its specifically Marxian theoretical legacy, and discuss its relevance to understanding and addressing public health issues. I conclude by discussing the benefits of employing critical theories of race and racism with Marxian political economy to better understand the roles of class exploitation and racial oppression in epidemiological patterning. (Am J Public Health. 2021;111:293-300. https://doi.org/10.2105/ AJPH.2020.305996)

The term "political economy" has been variously defined since it was first used in the 17th century and then subsequently by classical economists and political theorists such as Adam Smith, David Ricardo, and Thomas Malthus. It refers to "the combined and interacting effects of economic and political structures or processes, and by extension, to the scholarly study of this domain."1(p181) It is premised on the idea that "politics and the economy cannot be separated. Politics both creates and shapes the economy. In turn, politics is profoundly shaped by economic relations and economic power."2 Those researching political economy therefore investigate "the relation of politics to the economy, understanding that the economy is always already political in both its origins and its consequences."3(p1792) Traditional objects of analysis in political economy include production (how a society organizes the production of goods and services and the generation of wealth- and under what conditions), distribution (how a society distributes these resources), and consumption (what goods and services a society makes available and to which of its members).

The study of political economy developed alongside the emergence of a novel political-economic system: capitalism.

This system is characterized by the private ownership of capital goods or "the means of production"-that is, the things used to produce the goods and services needed for human subsistence, such as factories, machinery, buildings, land, and raw materials-by capitalists or the capitalist class. To survive, the working class is compelled to seek employment from the capitalist class in the companies they own. This employment entails engagingthe means of production to produce goods and services that are then sold for a profit on the market as commodities. Some portion of the profits are distributed to the workers as wages, and the remainder is retained by the company, to be either reinvested or kept by the capitalist owners as increased wealth.

Over time, the study of the capitalist political-economic system expanded to consider the "varieties of capitalism"4,5 that subsequently developed-such as welfare state capitalism, in which a system of capitalist production coexists with various social protections (e.g., access to education, health care, housing, jobs, unemployment insurance, pensions)-as well as competing political-economic systems, such as social democracy, socialism, and communism. In broad terms, these latter systems are characterized by degrees of public- rather than private-control of capital goods by workers, the state, or otherwise democratic institutions; production decisions that are driven by social needs, rather than the realization of profit; and a commitment to expansive social protections and equality. However, as history has shown, "actually existing" capitalist, socialist, and communist systems often diverge significantly from these attributes-and both characterizing and distinguishing among these systems has been the topic of intense, centuries-long debate.

The study of political economy therefore commonly centers on political-economic systems-or the different ways of organizing political and economic life and the impact of this organization on the aforementioned domains of production, distribution, and consumption. These systems encompass the organization of the production process (i.e., ownership and control of the means of production-i.e., capital) and the associated conditions of the production process (i.e., working conditions), the distribution of economic resources (i.e., inequality), and the degree of access to social protections (i.e., the social or welfare state). In broad terms, the "political economy of health" refers to the extension of the study of political economy and politicaleconomic systems into the domain of health to explore the relationship among these topics and changing epidemiological distributions over time. The connections between political economy and health are very well characterized in the historical public health literature, even going back centuries.610

Today there is a renewed interest in political economy in the academy, with a number of centers devoted to the topic recently established at high-profile US universities (e.g., University of California, Berkeley's Network for a New Political Economy; Stanford University's Moral Political Economy Project; and the Law and Political Economy Project, which began at Yale University). Interest in political economy is also reflected in the field of public health, where there is widespread concern about the health consequences of an economy increasingly characterized by low-wage, precarious employment, ever-expanding inequality, and a political process that is unduly influenced by corporations and the wealthy.11

However, despite the relevance ofthe political economy of health to understanding and addressing contemporary health inequalities, it is not widely referenced in the public health or medical literature. When political economy is invoked in the literature, it is not always explicitly defined.12 In those instances when it is defined, no standard definition is evident. This is especially problematic because various theoretical traditions that employ the term "political economy"-such as Keynesian, neoclassical, neoliberal, institutional, rational choice, and Marxian-approach questions of political economy in often widely discrepant ways.1,13 The following sections provide a survey ofthe specifically Marxian political economy of health tradition by clarifying its historical origins and reviewing contemporary definitions of the term.

## HISTORY OF THE POLITICAL ECONOMY OF HEALTH

When the term "political economy of health" emerged in the 1970s, political economy commonly referred to a broadly Marxian approach to social scientific analysis.14 17 The political economy of health is therefore most closely associated with the works of Karl Marx, Friedrich Engels, and the Marxian theoretical tradition,18 20 even if this legacy is more often implied than stated outright in the public health literature. Early works in the political economy of health by Waitzkin and Waterman,21 Navarro,22 Doyal and Pennell,23 Laurell24 and Breilh Paz y Miño25-as well as special eds on the topic26-are situated explicitly in the Marxian tradition, incorporating concepts, theories, and problematics developed or emphasized by Marx and Engels, such as class and class struggle, material inequality, exploitation, profit or capital accumulation, working conditions, the organization of production, and global imperialism and underdevelopment.

Despite the centrality of Marx, the origin ofthe political economy of health is commonly traced to Marx's long-time collaborator, Friedrich Engels and his book The Condition ofthe Working Class in England7,27 In that work, Engels explored the health effects ofthe development of industrial capitalism on workers and their families in Manchester, England. Through a long-term, ethnographic engagement in the town, Engels shows how social and working conditions produced by this new industrial form of capitalist political economy resulted in widespread suffering and premature death among workers, while producing untold wealth for the capitalist class who owned the factories. More than 200 years later, the influential Black Report echoed Engels's insights in stating that many health inequalities in the United Kingdom can be seen as "consequences ofthe class structure: poverty, working conditions, and deprivation in its various forms."28(p334)

Engels wrote of learning from the workers about the concept of "social murder," which the workers used to refer to how their social and working environments put them and their families "under conditions in which they can neither retain health nor live long . . . [and] hurries them to the grave before their time."7(p107) Engels sympathized with the workers and noted, "Society knows how injurious such conditions are to the health and the life of the workers, and yet does nothing to improve these conditions."7(p107) Although Marx's principal concern was not with the relationship between human health and capitalism, Engels's book profoundly shaped Marx's thinking. David McLellan, a prominent historian of Marx, calls the book "the foundation document of what was to become the Marxian socialist tradition."7(pxix xx) Richard Horton, the editor of the Lancet, even claims,

"Public health was the midwife of Marxism,"29(p2026) as Engels's ethnographic descriptions of socially produced disease among English and immigrant Irish workers in Manchester provided Marx with important insights into the nature of production, exploitation, and suffering under the capitalist political-economic system.

The origins of the political economy of health are also associated with the 19thcentury European and 20th-century Latin American social medicine traditions-and the works of Rudolf Virchow and Salvador Allende.30,31 Virchow, a 19th-century physician whose name today is commonly associated with discoveries in the area of cellular pathology, read Engels's 1845 work. Like Engels, Virchow wrote about the material conditions in which disease manifested and how political and economic forces prevented social reforms aimed at alleviating poverty, food insecurity, and harsh labor conditions among the poor and working classes32(p111)

Virchow wrote that biomedical and public health interventions amongthese classes would always fail if they did not challenge upper-class political power and capitalism's economic exigencies, which together produced the social conditions that were fundamentally responsible for health inequalities. Virchow's famous dictum, "Medicine is a social science, and politics nothing but medicine on a grand scale,"33(p548) conveys his belief that acting in the political domain should be central to the practice of a reformed medicine that is based in the social sciences, rather than narrowly in biomedicine.

Another prominent figure in the genealogy of the political economy of health is Salvador Allende, Chile's first democratically elected socialist president. During his medical training, Allende received instruction from former students of Virchow who had emigrated from Germany to Chile. As the Chilean minister of health, Allende penned the report, "The Chilean SocioMedical Reality," which-in the spirit of writings by Virchow and Engels-identified the organization of labor and the working and living conditions of the working class as responsible for its outsized disease burdens.

One of Allende's unique contributions to the social medicine tradition was his interrogation of exploitative international economic relations shaped by wealthy countries and imposed on poorer ones, first under slavery and colonialism and subsequently under various forms of corporate, political, and economic neocolonialism.32^113117) Allende became a prophet of his own future, as his reforms to counter neocolonialism and improve the conditions of the poor and working classes in Chile engendered a coup d'etat in 1973 that was initiated by the Chilean upper class and assisted by the US Central Intelligence Agency, which was eager to see a popular, democratically elected socialist leader deposed, especially during the height of the Cold War.34

CONTEMPORARY DEFINITIONS

As with the term "political economy," the "political economy of health" is also variously defined. Importantly, many scholars who use the term are not drawing principally on its Marxian legacy as I have described.35,36 Among scholars working specifically in the Marxian tradition, a generally shared understanding of the political economy of health emerges from surveying their definitions of the term. I consider a number ofthese definitions.

Raphael and Bryant state that the political economy of health posits that "how a society produces and distributes societal resources among its population" is an important determinant of population health. They write that the issues considered by this perspective are "the production and distribution of wealth," "issues of capital accumulation and the organization of labor," and "the extent to which society relies on state control of the distribution of resources versus market control of such activities."37(p238) Elsewhere, Raphael38 writes about political economy in terms of economic and political systems that distribute resources based on the relative levels of power that different individuals and entities are able to exert in society. For instance, powerful organizations, such as transnational corporations, are able to shape policy to their benefit, whereas a disempowered, nonunionized working class cannot. This power imbalance, and the corporatefriendly policies such an imbalance gives rise to, ultimately results in an upward redistribution of wealth, increased inequality, and diminished population health outcomes.

Krieger writes:

The underlying hypothesis [of the political economy of health] is that economic and political institutions and decisions that create, enforce, and perpetuate economic and social privilege and inequality are root-or "fundamental"-causes of social inequalities in health.39(p670)

and

At issue are priorities of capital accumulation and their enforcement by the state, so that the few can stay rich (or become richer) while the many are poor-whether referring to nations or to classes within a specified country.39(p670)

According to the political economy of health:

Core questions include: how does prioritizing capital accumulation over human need affect health, as evinced through injurious workplace organization and exposure to occupational hazards, inadequate pay scales, profligate pollution, and rampant commodification ofvirtually every human activity, need, and desire?39(p670)

Krieger also writes that the political economy of health is "predominantly concerned with how capitalist politicaleconomic systems' imperative to maximize profit harms health."40(p178) Although Krieger echoes the role of inequitable, elite-captured institutions in perpetuating inequality, she also specifically indicates the role of capitalism and its requirement for profit maximization, which occurs at the expense of human health.

Baer writes that the political economy of health "is in essence a critical endeavor which attempts to understand health-related issues in the context of the class and imperialist relations inherent in the capitalist world-system."18(p1) Baer divides the political economy of health between "the political economy of illness" and "the political economy of health care." The former refers to the study of how illness is socially produced by the capitalist political-economic system and the latter

is concerned with the impact that the capitalist mode of production has on the production, distribution, and consumption of health services and how these processes reflect the class relations of the larger societies in which medical institutions are embedded.18(p2)

Here, Baer expands the conceptual remit of the political economy of health to include class relations, the organization of production, imperialism, and global capitalism (as a "world system").

According to Birn et al., the political economy of health perspective views health

in terms of the nature of power relations and control over resources, their implications for social inequalities, and the institutions that challenge or reinforce the distribution of power and resources at local, national, and international levels.30(p13)

Although scholars of political economy discuss the importance of social relations along intersecting axes of race, ethnicity, sex, gender, sexuality, ability, citizenship, and nationality in shaping power relations and the distribution of resources, they commonly emphasize the role of class and the political struggle between owners of capital (i.e., the capitalist class) and the working class in shaping these power relations. The balance of power in this class struggle in turn shapes the character of the political-economic system, which in turn shapes the extent of social-and health-inequality.30

From this perspective, when members of the working class are organized and thereby empowered, they can translate their material interests into social and political change, which results in transformation of the politicaleconomic system.41 For example, working-class movements have established redistributive, universal social welfare systems in the areas of health care and education, occupational safety standards, minimum wage laws, guaranteed vacation, family and medical leave policy, and guaranteed pensions in old age. They have won legal protections for workers' rights and for the civil rights of women, racial and ethnic groups, and gender and sexual minorities. Workingclass movements were also central to 20th-century decolonization, as exemplified by the work of Nelson Mandela and the African National Congress.

Working-class empowerment is accomplished through actions such as political organizing; increasing union density; labor agitation, such as taking part in labor strikes; and engaging in broad-based social movements against exploitation, oppression, hierarchy, and injustice. Some engage in electoral politics to achieve formal representation of working-class interests in the political sphere. These actions often incorporate feminist, antiracist, immigrant, LGBTQI (lesbian, gay, bisexual, transgender, questioning [or queer], intersex), and disability rights frameworks and goals out of a recognition that historically marginalized and oppressed people often face outsized material deprivation and compounded forms of discrimination and exploitation in the workplace and society writ large.

Although an empowered working class can exact concessions from the capitalist class and the state in the form of higher wages, social protections, and redistributive taxation policy, some advocate moving beyond simply a more robust welfare state and expansive social protections and embracing alternative political-economic systems altogether, such as socialism.42 This entails extending democratic control beyond the political sphere and into the economic sphere and the workplace, which are currently controlled by corporations, their capitalist owners, and the upper tiers of management and which are organized according to profit making and competition in the market rather than worker or societal well-being. Economic decisions about what to produce, howto produce it, and howto distribute those products would-at least in part-be driven by questions of social need and distributional justice, rather than commodity exchange and profit maximization. In this way, such alternative political-economic systems may overcome the contradiction between capitalism and health and result in more equitable health outcomes.

As this review demonstrates, Marxian political economy of health is concerned with a set of issues that fall broadly in a leftist political imaginary inspired by the Marxian tradition. The role of economic inequalities and class stratification is prominent. Many of these definitions emphasize social structures, institutions, and public policy as well as their role in exacerbating or ameliorating economic and health inequalities-often along the social axis of class but also along axes of sex, gender, race, ethnicity, nationality, and citizenship status. Additionally, the relationship between the capitalist class (i.e., the capital-owning class, the upper class, or-more colloquially following the Occupy Movement-"the 1%") and the working class is framed as central to understanding these inequalities and the political-economic systems from which they arise. An empowered working class that is committed to social justice can realize universal economic, social, political, and civil rights, while limiting the influence of the capitalist class and their corporations in society.

Many definitions discuss the contradictions between structural aspects of capitalism-principally the imperative of capitalists to accumulate ever more capital by maximizing the profit of their corporations-and population health outcomes. In this way, these definitions echo sentiments expressed in volume 1 of Capital, where Marx writes:

Capital therefore takes no account of the health and the length of life of the worker, unless society forces it to do so. Its answer to the outcry about the physical and mental degradation, the premature death, the torture of over-work, is this: Should that pain trouble us, since it increases our pleasure (profit)? But looking at these things as a whole, it is evident that this does not depend on the will, either good or bad, of the individual capitalist. Under free competition, the immanent laws of capitalist production confront the individual capitalist as a coercive force external to him 43(p381)&&&

For Marx, disease and injury among the working class under capitalism is not simply the result of unscrupulous business owners but rather of an imperative of the system itself: capitalists must maximize their profit in order to compete with other capitalists. Efforts to maximize profit can take various forms- for example, suppressing worker pay, increasing worker productivity, flexibilizingthe workforce, lobbying for regressive taxation policies and fewer publicly funded social protections, dismantling corporate regulations, relocating jobs to countries with fewer regulations and lower labor costs, and commodifying what were previously public domains of life, such as energy, transportation, education, and health care systems. In recent decades, the intensification of these practices has come to be referred to as "neoliberalism," which some argue characterizes contemporary global capitalism.

## TOWARD A RACIAL POLITICAL ECONOMY OF HEALTH

This call for renewed attention to the political economy of health and Marxian theory is occurring simultaneously with the development of other important social theories in public health.40,44 In recent years, theories of racism, racialization, and intersectionality and the traditions of Black radicalism, Black feminism, and critical race theory have provided important insights into the causes of racial health inequities, particularly in the United States.45 49 Rather than repeat timeworn-and often crudely reductionist-debates over "race versus class"50,51 or the relative merits of centeringthe role of capitalism or racism in explaining health inequalities, public health scholars should synthesize perspectives on racism and racial oppression with those on capitalism and labor exploitation.

In the Marxian tradition, attempts to explain the relationship between capitalism and racism constitute a rich and longstanding literature.52 62 Marx himself addressed the relationship at some length, incorporating it into the history of European colonialism and imperialism.63 Although Engels explored the impact ofindustrial capitalism on the social conditions and health of the English and Irish working classes, Marx situated England's political economy firmly in a global racial political economy defined by colonialism and the Atlantic slavery system:

Without slavery you have no cotton; without cotton you have no modern industry. It is slavery that gave the colonies their value; it is the colonies that created world trade, and it is world trade that is the precondition of large-scale industry.64

Marx's work challenging racial oppression extended well beyond analysis to his steadfast support of President Lincoln and the Union Army during the American Civil War and his involvement in the abolitionist movement in Britain. For Marx, the emancipation of enslaved people was both a matter of justice and a fundamental precondition to the broader unification of the working class in their fight against capitalism.65

From a Marxist perspective, racism serves a number of different purposes for the capitalist class.61 Importantly, it acts as a barrier to working-class solidarity and empowerment by cleaving the class along racial lines. Animosity between workers on account of racism undermines their ability to develop a shared vision and project for realizing their otherwise shared interests. Through this cleavage, the capitalist class facilitates worker exploitation. A divided working class is unable to build sufficient power to realize higher wages, safer working conditions, and broader social protections, for example, or to pursue alternative political-economic systems. This division results in higher profits accruing to the capitalist class. Moreover, it facilitates the hyperexploitation of the oppressed subclass of racialized workers, who do not-on average-enjoy the same benefits as the rest of the working class. They work for even lower wages, for longer hours, and with even fewer workplace and social protections. Finally, racism entails racist ideology, the purpose of which is to rationalize and thereby justify racial hierarchy, often through claims of biological, behavioral, cultural, or moral inferiority among the racialized subclass. Such ideology also serves to obscure capitalism's failings by directing popular anger and frustration away from the workings of an unjust political-economic system and toward spurious social and moral pathologies of the racialized subclasses.

Similar ideas were recently expressed by Thomas LaVeist during the closing general session of the 2019 American Public Health Association conference, 1619-2019: Health and Justice Denied, when he stated, "I would go as far as to say, the ideology, White supremacist ideology, racism, is in service to the capitalism, because it's really all about exploiting labor and how do you position yourself to be able to exploit the labor."66 Deepening this engagement between theories of racism and Marxian theories of political economy is a promising approach to investigating and addressing imbricated race- and class-based health inequalities-as well as the systems that produce them-in the United States and globally. Indeed, recent work in public health takes up the generative concept of "racial capitalism"67 69 in relation to health inequalities.49,70,71

## CONCLUSIONS

Although there have been important additions to scholarship on the political economy of health in the past decade,40,72 79 it is not a mainstream area of public health research or practice. I have reviewed the political economy of health literature, clarified its specifically Marxian legacy, surveyed contemporary definitions, and discussed its relevance to understanding and addressing pressing public health issues. The political economy of health is necessary for explaining and addressing persistent health inequalities and emerging public health crises under global capitalism, a political-economic system that shapes nearly all aspects of our lives but that attracts relatively little attention in the field of public health. If public health is to fully engage with the structural determinants of health and the system that produces them, the political economy of health will have to move from the field's margins to the mainstream. /fIPH

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## DETAILS

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# Blood Donation and COVID-19: Reconsidering the 3-Month Deferral Policy for Gay, Bisexual, Transgender, and Other Men Who Have Sex With Men

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## ABSTRACT (ENGLISH)

In April 2020, In light of COVID-19-related blood shortages, the US Food and Drug Administration (FDA) reduced the deferral period for men who have sex with men (MSM) from its previous duration of 1 year to 3 months. Although originally born out of necessity, the decades-old restrictions on MSM donors have been mitigated by significant advancements in HIV screening, treatment, and public education. The severity of the ongoing COVID-19 pandemic-and the urgent need for safe blood products to respond to such crises-demands an immediate reconsideration of the 3-month deferral policy for MSM. We review historical HIV testing and transmission evidence, discuss the ethical ramifications of the current deferral period, and examine the issue of noncompliance with donor deferral rules. We also propose an eligibility screening format that involves an individual risk-based screening protocol and, unlike current FDA guidelines, does not effectively exclude donors on the basis of gender identity or sexual orientation. Our policy proposal would allow historically marginalized community members to participate with dignity in the blood donation process without compromising blood donation and transfusion safety outcomes. (Am J Public Health. 2021;111:247-252. https://doi.org/10.2105/ AJPH.2020.305974)

## FULL TEXT

### Headnote

In April 2020, In light of COVID-19-related blood shortages, the US Food and Drug Administration (FDA) reduced the deferral period for men who have sex with men (MSM) from its previous duration of 1 year to 3 months. Although originally born out of necessity, the decades-old restrictions on MSM donors have been mitigated by significant advancements in HIV screening, treatment, and public education. The severity of the ongoing COVID-19 pandemic-and the urgent need for safe blood products to respond to such crises-demands an immediate reconsideration of the 3-month deferral policy for MSM.

We review historical HIV testing and transmission evidence, discuss the ethical ramifications of the current deferral period, and examine the issue of noncompliance with donor deferral rules. We also propose an eligibility screening format that involves an individual risk-based screening protocol and, unlike current FDA guidelines, does not effectively exclude donors on the basis of gender identity or sexual orientation. Our policy proposal would allow historically marginalized community members to participate with dignity in the blood donation process without compromising blood donation and transfusion safety outcomes. (Am J Public Health. 2021;111:247-252. https://doi.org/10.2105/ AJPH.2020.305974)

In March 2020, as COVID-19 rapidly proliferated in its new epicenter, New York City's blood supply dwindled. With social distancing measures and home orders effect, blood drives were cancelled citywide, cutting off more than 75% of the city's blood supply sources.1 During a call for blood donations in the initial weeks of the shortage, one group was consistently denied the chance to donate solely on the basis of sexual practices: men who have sex with men (MSM).2 According to the recommendations of the US Food and Drug Administration (FDA), men who had sex with other men within the past year were ineligible to donate and were required to stay celibate for at least a year to regain eligibility. However, the deteriorating blood supply, as well as pressure from the media and various advocacy organizations, catalyzed changes in the federal recommendation. On April 3,2020, the FDAshortened the blood donation deferral period for MSM from 1 year to 3 months.3

Shortly afterward, the need for donations surged again as researchers investigated convalescent plasma as a promisingtherapeutic option forCOVID-19. MSM who had recovered from the novel coronavirus and had not had sex with another man in more than 3 months eagerly pursued donation at blood centers. Despite this change, many blood centers continued to turn away MSM donors.2 Mainstream media outlets such as NBC News and The Daily Show captured the public's attention by opening the doors to a nationwide conversation about this policy.2,4 Organizations such as the National Alliance of State and Territorial AIDS Directors and the HIV Medicine Association also addressed the issue, asking for a complete rescission of the deferral period in their comments on the most recent regulation (https://www. regulations.gov/comment?D=FDA2015-D-1211-0109).

The FDA officially placed the first lifelong ban on blood-product donations from MSM in 1985 during the early phase of the US AIDS epidemic. At the time, the ban was necessary because HIV had not been fully characterized, no effective treatment existed, and diagnostics were severely constrained by high false-negative rates and a lengthy period between HIV infection and test positivity. There was also a perception that policymakers were slow to implement a ban on then high-risk groups, leading to thousands of new HIV cases that arose from the blood supply.4,5 The 3-decade span between the 1985 MSM ban and the 2015 MSM 1-year deferral policy was partly the result ofthe morbidity and mortality related to transfusion-associated HIV; importantly, however, it also arose from homophobic public perceptions of lesbian, gay, bisexual, transgender, and queer people that led to an incoherent approach to blood donor qualification policies.

Today, testing is highly accurate and sexual preference is not synonymous with risk status. In developing equitable screening practices, we must remember to continually assess standing policies and be willing to change them in light of new information. Here we propose an individual risk assessment-based screening tool as an alternative to the FDA's current MSM deferral policy. We review the current best evidence surrounding HIV testing and transmission rates, examine the limitations ofthe FDA's current recommendations, and discuss the social implications of such blood donation policies. As we evaluate current regulations and petition for new ones, we emphasize that the ethics surrounding blood donation policies exist at the intersection of public health and human rights and should be considered within that context.

## TESTING AND TRANSMISSION: CURRENT EVIDENCE

The first-generation HIV diagnostic test, which came to market in 1985, had a sensitivity of 99% and a specificity of 95% to 98%. However, the accompanying serological test had a window period of up to 10 weeks and therefore could not effectively detect a new HIV infection until several months after exposure.1,6,7 At the time, blood transfusions conferred a risk of HIV transmission in 1 of 153123 units.8

Decades of HIV research and technological advancements have since revolutionized HIV testing. At present, there are several HIV screening and diagnostic options available, including a chemiluminescent immunoassay to detect HIV-1 and HIV-2 antibodies and a duplex nucleic acid test with confirmatory western blots and enzyme-linked immunosorbent assays.9 The nucleic acid test, in particular, has a sensitivity and specificity of virtually 100% and boasts a window period of just under

3 days, although more conservative organizations report a window of up to 7 to 10 days.10,11 Currently, the Centers

for Disease Control and Prevention requires a 2-pronged approach to testing blood donations for HIV-1 and HIV-2, and every donated unit undergoes both nucleic acid and antibody testing.11 Given these newer testing parameters, recent studies have estimated the risk of HIV transmission through blood products to be 1 in 1.5 million.12 For perspective, the risk of other transfusion-related complications, such as transfusion-related acute lung injury, is far greater.5,13

Furthermore, prophylactic measures for HIV prevention have simultaneously become more pervasive. From 2014 to 2017, knowledge of preexposure prophylaxis increased from 60% to 90% among MSM, and the prevalence of its use increased from 6% to 35%.14 Daily preexposure prophylaxis is highly effective in reducing the risk of seroconversion after exposure by up to 99%.15,16 Concerns regarding false-negative screening results may also be assuaged by an open-label randomized trial conducted by McCormack et al., who found no cases of breakthrough HIV infections in a study of 544 participants taking preexposure prophylaxis.17

## FOREIGN BLOOD TRANSFUSION POLICIES

Nations around the world employ one of a pair of broad blood donation strategies: time-based deferrals or risk-based deferrals. Time-based strategies, such as those used in Australia, Canada, France, New Zealand, and the United Kingdom, delineate groups of potential donors according to risk and defer the members of each group identically.18 Currently, the shortest deferral period for MSM is 3 months, which is nearly 10 times longer than even the most conservative window period for the HIV nucleic acid test. Empirical and modeling studies in various countries have repeatedly shown that shortening deferral periods does not meaningfully increase rates of HIV transmission.18 21

By contrast, risk-based strategies, as implemented in countries such as Italy and Spain, stratify donors individually on the basis of self-reported questionnaires.18 Donors typically undergo an interview with a provider to determine their risk, which is based on factors such as having sex with a partner whose HIV status is unknown and having unprotected sex. These behaviors, among others, result in a deferral period that can span any duration from weeks to lifelong.18 Importantly, after Italy shifted from a time-based to a risk-based strategy in 2001, a study by Suligoi et al. showed no significant increase in MSM donor seropositivity relative to heterosexual donors. In addition, the study researchers reviewed patients' awareness of sexually risky behavior and found no difference between the 2 groups, suggesting that education initiatives rather than deferral periods could improve outcomes.22

In September 2015, Argentina implemented a risk-based approach that was "gender neutral" and did not enforce policies on the basis of sexual orientation or gender identity.23 In 2020, a large cohort study by Blanco et al. demonstrated no significant difference in the prevalence of HIV in the blood donor population, despite an increase in the total number of donors.24 This is clear evidence that inclusive donor qualification policies do not confer increased risk to the blood supply.

Whereas time-based deferral mitigates donation-associated transmission of HIV, risk-based deferrals provide equal public safety and are a reflection of just policy-making.

## ETHICAL AND LOGICAL PERSPECTIVES

We must also consider the social implications of an MSM deferral policy. The desire to donate blood alone should not outweigh the recipient's right to receive safe blood. However, consideration of the evidence outlined here indicates that including greater numbers of MSM in the donor pool would not threaten blood safety. Instead, turning away MSM donors during times of great need and public solidarity, such as after the 2016 Pulse nightclub shooting or during the COVID-19 crisis, stigmatizes these individuals by deeming them unworthy and dangerously perpetuates the myth of HIV as a purely "gay disease."25,26 Furthermore, given that MSM are estimated to compose 2% of the overall United States population27 and that approximately 10% of eligible donors donate blood on an annual basis,28 revising eligibility guidelines to include more MSM could add up to 600 000 annual donors to the blood supply.

Beyond these considerations, there are several inconsistencies in the FDA's MSM deferral policy. One is the FDA's recommendation that gender be "selfidentified" or "self-reported" in donor questionnaires.3 For instance, gender nonbinary individuals or heterosexual trans women, despite being recorded as male at birth, are eligible to donate blood even if they have cis male sexual partners. In addition, cis females who have had sex with cis MSM partners are deferred, relying entirely on the expectation that an individual could know every sexual partner's partners, making enforcement impractical if not impossible. Moreover, non-MSM donors may engage in risky behaviors. As noted by Galarneau, sexual orientation "is not a valid proxy for high-risk behavior,"26(p36) and sexual intercourse between men is not synonymous with high-risk sexual behavior.

Also, the FDA's current recommendations police at-risk populations inconsistently. For instance, the FDA tests all donated units of blood for Trypanosoma cruzi,29 a pathogen endemic to Latin America that afflicts up to 300 000 people in the United States. This parasite causes Chagas disease, which is often asymptomatic.30 Although blood banks test all blood samples for this pathogen, they do not screen specifically for Chagas disease when considering donors who have spent time in Latin America.31,32 This allows donors who may be unaware of a latent infection to donate blood. Screening practices should be consistent among all high-risk groups.8,33

ISSUES RELATED TO NONCOMPLIANCE

In a survey of male blood donors in the United States before the FDA instituted a 1-year deferral policy in 2015, 2.6% of respondents reported that they had, in fact, not complied with the lifelong ban and donated blood despite a history of having sexual encounters with other men. In a more recent study, Wentz et al. reported that 70% of 305 young MSM who had donated blood had done so within 12 months of having unprotected anal intercourse.34 Many voiced concerns about stigma stemming from this discriminatory policy as a reason for noncompliance, whereas others noted a widespread desire for equity and confidence surrounding one's negative HIV status.23,34,35 In this way, perceptions of a policy's injustice can engender distrust of the policy itself, and many sexually active MSM have expressed frustration with the policy's outdated rationale.34,35 Moreover, shortening deferral periods has paradoxically improved compliance with blood donation regulations.18

Another frequently cited reason for noncompliance in other countries is ambiguity in or miscommunication of the regulations themselves. Inaccessible medical jargon and ill-defined "high-risk" behaviors often confuse the selfreporting donor and impair a proper assessment of that individual's eligibility.20'36 This complication is not specific to MSM; in a study of 32 HIV-positive participants, most of whom were not MSM, several donors did not read the screening form carefully enough to individually assess and answer each item.25 As such, incorrect completion of screening questionnaires affects all blood donors, and new screening policies must address this contributor to noncompliance to ensure the safety of the blood supply.

PROPOSED ELIGIBILITY SCREENING FORMAT

In light of this evidence, we propose an individual risk-based screening protocol that is not informed by a donor's sexual orientation or gender identity and integrates a branched question format. Figure 1 provides a blueprint for branched risk stratification that will quire input and interdisciplinary collaboration for protocol design. Many have advocated for a risk-based protocol in the past decade, including Cohen et al., who stated that "a thoughtfully reformulated risk level- focused assessment of donor eligibility should be coupled with rigorous testing (and retesting)."37'38(p338) With this approach, all potential blood donors would be asked to answer the same set of risk stratification questions. Donors classified as low risk would be eligible for blood donation, whereas donors classified as high risk would undergo a deferral period.

We suggest that these screening questions be simple and free of medical jargon and acknowledge that specific behaviors are associated with an increased risk for blood-borne diseases. Potential risk stratification questions include "Have you had unprotected sex in the last month?" and "How many sexual partners have you had in the last month?" If the algorithm suggests higher risk, the individual would be prompted to answer additional questions. For instance, individuals indicating that they recently had unprotected sex would subsequently be asked "Have you been tested for sexually transmitted infections since this encounter?"

After stratifying donors, we recommend deferring high-risk individuals on the basis of empirically determined window periods for infectious bloodborne diseases. These periods can be conservatively extended to 7 to 10 days to uphold maximum blood supply safety. We acknowledge that the FDA is currently assessing the feasibility of behavioral risk assessments for MSM donors and that time, resources, and personnel are all nontrivial limitations to implementing our recommendations. However, our aim is to draw renewed attention and focus to this critical issue. AsJay Epstein, director of the FDA Office of Blood Research and Review, stated more than 20 years ago: "The FDA is not supposed to look at cost. We're supposed to look at... safety, effectiveness. We can go as far as to look at... public health, risk/ benefit, but not the C word."26(p33)

## ADDRESSING COUNTERARGUMENTS

There is valid concern that shifting to a risk-based deferral policy could allow an influx of eligible MSM into the donor pool but disqualify otherwise eligible non-MSM donors. In the interest of public safety, however, all individuals, regardless of sexual orientation or gender identity, should be screened for high-risk sexual behaviors.

Others note that the prevalence of HIV in the MSM population in the United States is roughly 11% to 12%,3 representing a disproportionate percentage of HIV cases. However, according to the FDA's revised April 2020 recommendations, the prevalence of HIV among MSM blood donors is just 0.25%. Put simply, the prevalence of HIV among MSM who seek out blood donations is demonstrably lower than the prevalence in the general population. Self-selection among MSM donors likely contributes to this discrepancy, but regardless of the reason, it is critical to note that increased HIV prevalence among MSM is not proportionally associated with increased MSM donor prevalence.35

Proponents of a 3-month deferral period contend that these policies protect not only against HIV transmission but also against other blood-borne illnesses. Although the window period for HIV is short, the period for hepatitis B virus is notably longer.9 Still, a recent survey of HIV-positive blood donors showed that 5.8% of those who reported a hepatitis B diagnosis and 4.8% of those who reported a hepatitis C diagnosis were MSM donors. MSM donors made up 60% of the HIV-positive blood donor cohort in that study, suggesting that rates of these other blood-borne illnesses among MSM donors are appreciably lower than is the case with HIV.3,39 Thus, MSM self-identification cannot justify a lengthy deferral period for these other diseases when transmission has demonstrated a stronger relationship with other high-risk behaviors such as intravenous drug use.

## CONCLUSION

Although born out of necessity, the current national blood product donation policy as it relates to MSM is anachronistic. Currently, there is substantial evidence that individual riskbased policies are equally effective in protecting the safety of the blood supply. The existing policy defers a group in a manner that is inextricably linked with donors' sexual orientation and gender identity. By discounting current evidence and relying on factors bound up with past and present bias, this policy has shown itself to be particularly susceptible to noncompliance, public dissatisfaction, and missed opportunities to strengthen the blood supply.

In lieu ofthese shortcomings, we hope that the FDA will adopt a policy that reflects scientific evidence and rejects the illogical and unsubstantiated premise that fundamental aspects of personal identity dictate the suitability of one's blood to save another's life. As physicians and scientists, we must advocate for policies rooted in science and against ones that unnecessarily marginalize groups of people. The ongoing crisis calls for reconsideration of blood donation screening practices and provides the opportunity to champion equity without compromising public safety.

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CONFLICTS OF INTEREST

The authors declare no conflicts of interest.

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No protocolapprovalwas needed for this research because no human participants were involved.

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# Use and Visualization of Electronic Health Record Data to Advance Public Health

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## ABSTRACT (ENGLISH)

The COVID-19 pandemic has underscored the importance of strong public health infrastructure and timely health surveillance data. Electronic health record (EHR) networks such as MDPHnet can help meet both emergency and routine public health data needs.

In this issue of AJPH, Cocoros et al. (p. 269) describe RiskScape, a unique and powerful data visualization platform that makes data easy to access and interpret by providing clear figures, maps, and tables. RiskScape also allows stratification by variables of interest and runs statistical testing in the background to determine whether observed differences are statistically meaningful. RiskScape is based on aggregated data from MDPHnet, an EHR network used to facilitate notifiable disease reporting, examine the cascade of care (e.g., for diabetes), estimate disease prevalence, and monitor the effectiveness of public health interventions. RiskScape is primarily used by the Massachusetts Department of Public Health for surveillance, planning, and advocacy.

## FULL TEXT

The COVID-19 pandemic has underscored the importance of strong public health infrastructure and timely health surveillance data. Electronic health record (EHR) networks such as MDPHnet can help meet both emergency and routine public health data needs.

In this issue of AJPH, Cocoros et al. (p. 269) describe RiskScape, a unique and powerful data visualization platform that makes data easy to access and interpret by providing clear figures, maps, and tables. RiskScape also allows stratification by variables of interest and runs statistical testing in the background to determine whether observed differences are statistically meaningful. RiskScape is based on aggregated data from MDPHnet, an EHR network used to facilitate notifiable disease reporting, examine the cascade of care (e.g., for diabetes), estimate disease prevalence, and monitor the effectiveness of public health interventions. RiskScape is primarily used by the Massachusetts Department of Public Health for surveillance, planning, and advocacy.

COVID-19 highlights the potential of platforms such as RiskScape to help monitor and respond to a rapidly changing situation. The ability to quickly identify disease hotspots may be one of the most valuable uses of EHR networks, providing data that are timely enough to monitor changes essentially in real time. EHR networks can also greatly improve public health surveillance by increasing notifiable disease reporting through automation, decreasing paperwork, and streamlining laboratory testing reporting.

In New York City, two large EHR networks, the Bronx Regional Health Information Organization (Bronx RHIO) and Healthix, have integrated electronic lab reporting data and flag patients with COVID-19, alerting providers in ambulatory and inpatient settings.1,2 Outpatient providers can also be notified when patients are hospitalized, and hospital providers can easily learn about a patient's underlying risk factors for more severe COVID-19. The Bronx RHIO is using EHR data to learn more about associations with social determinants of health (e.g., housing and neighborhood poverty) and rare outcomes, such as multisystem inflammatory syndrome.1 Both the Bronx RHIO and Healthix have worked closely with the New York City Health Department in the COVID-19 response.

Just as RiskScape can calculate patient cardiovascular risk scores, which Cocoros et al. note can be used for prevention at the provider level and to assess the overall health of the larger population, one could imagine creating a risk score for COVID-19, making it possible to identify patients and practices with higher risk of developing severe disease. COVID-19 has had a disproportionate impact on those of Black and Hispanic race/ethnicity, older adults, and those with chronic conditions such as diabetes and heart disease.3 Higher-risk patients and practices could be selected for public health interventions and educational campaigns to decrease transmission, reduce inequities, and encourage patientswith symptoms to seek care early. Now that COVID-19 vaccines have been approved and we need to prioritize certain groups for early vaccination, EHR networks could be useful in identifying such patients and tracking the proportion that have been vaccinated. Platforms such as RiskScape could be used to visualize data on high-risk neighborhoods and to monitor vaccination efforts.

EHRs could also potentially be used to examine social determinants of health associated with increased risk for COVID-19, including certain occupations, crowded housing and congregate settings, and intergenerational households.4 More generally, education, employment, housing stability, food security, and social support are all important predictors of health.5 However, current data limitations may preclude such analyses. There is a lack of evidence-based, standardized patientlevel measures and a need for the development of such measures, as well as support and incentives for providers to collect this information.6,7 Another related data limitation in exploring health inequities is missing or incorrect race/ethnicity data in the EHR.8 This could be improved by incentivizing documentation and focusing on patient self-report of race and ethnicity.

Even in the absence of patient-level data, social determinants of health can be examined by linking EHR data with neighborhood-level data, for example, average household income, housing characteristics, access to parks, crime, and density of fast food and alcohol stores. Neighborhood-level information can provide a helpful context for health risk factors and outcomes.7,9 Furthermore, linking EHRs to neighborhood-level resources could help providers connect patients in need to nearby food pantries, community centers, and housing assistance.

Other jurisdictions that want to use EHR data for population health estimates, as MDPHnet does, should assess the accuracy and validity of their data and whether those in the EHR network represent the larger population. MDPHnet data are from three large clinical groups that cover about 20% of the population, which is concentrated in the eastern part of Massachusetts. Previous comparisons with Behavioral Risk Factor Surveillance System (BRFSS) data and the Centers for Disease Control and Prevention's 500 Cities estimates (based on BRFSS) showed similar prevalence estimates with EHR-based data.10 It is noteworthy that Massachusetts has unusually high insurance coverage, with only 2.9% uninsured in 2019,11 which increases the generalizability of the MDPHnet system to the population as a whole. In states where less of the population is insured and seeking care, it is likely that greater differences will exist between EHR-derived population health estimates and the health of the general population.

Although conditions such as hypertension, diabetes, obesity, and smoking may be good candidates for EHR-based surveillance,10,12,13 other conditions may be more difficult to monitor with EHR data. As Cocoros et al. note, patients may seek care outside an EHR network. This may particularly be true for cancer and rare diseases, for which patients often seek care in specialty hospitals or from providers specializing in certain conditions. To assess the accuracy and validity of an EHR-based health indicator, whenever possible it is important to compare EHR-based health estimates against established surveys or registries of disease. A second limitation the authors discuss is the inability of MDPHnet and some other EHR networks to de-duplicate records across practices, so a patient with hypertension seeking care from an internist and a cardiologist might be double counted in the system. This protects privacy but can affect data quality.

As Cocoros et al. mention, the future of RiskScape might include linkage to and visualization of hospitalization data, claims records, and mortality data. Clearly there are challenges in linking data from different sources, including how to link and match data, how to protect privacy, and obtaining institutional review board permission.14 Yet such linkages could lead to a greater understanding of risk factors for disease, hospitalization and death, and the development of interventions for and targeted outreach to special populations. For COVID-19, one could potentially learn more about the progression of disease, time to seeking treatment, and risk factors for hospitalization and death.

The ability to clearly share data and communicate important messages is key. This is especially true in an urgent and rapidly changing public health situation such as the COVID-19 pandemic. Data visualization platforms are often difficult to use and have poor graphic design, reflecting the need for increased collaboration among those knowledgeable about data, data programmers, and graphic designers. RiskScape is a model for good design, easy navigation, and presentation of data in an easily interpretable way. By developing and freely sharing the code and documentation for the platform, MDPHnet researchers have provided a valuable resource for other jurisdictions. Other jurisdictions and health departments can benefit from this valuable tool but need to have a good understanding of the strengths and limitations of their own data to use it appropriately.

Access to RiskScape data is currently limited to participating practices, MDPHnet researchers, and the Massachusetts Department of Public Health. With appropriate explanation of the data and its limitations, RiskScape (or a more limited version) might be made available to researchers and the public, as both could greatly benefit from being able to access these data. In Colorado, CHORDS (the Colorado Health Observation Regional Data Service) has publicly available interactive maps of some health indicators using data from an EHR network covering the Denver metropolitan area.15The ability to clearly and transparently share data can help make science more accessible and increase support for public health.

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CONFLICTS OF INTEREST

I have no conflicts of interest to disclose.

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# DETAILS

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# The Contribution of Prisons and Jails to US Racial Disparities During COVID-19

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## ABSTRACT (ENGLISH)

The United States has the unenviable distinction of having the highest rate of incarceration and the most people under correctional control-more than 6.7 million people. Although we often refer to this as "mass" incarceration, the criminal legal system's discriminatory impacts are disproportionately concentrated in Black and Latino communities: one in three Black men and one in six Latino men born in 2001 can expecttogo to jail or prison at some point in their lifetime. At this magnitude, mass incarceration is a key structural driver of not only individual and population health but also racial health disparities across numerous health outcomes.Although the role of incarceration in driving many racial health inequities has been long recognized, during the COVID19 pandemic this attention was amplified because correctional facilities comprise the largest number of single-site cluster outbreaks. Given that Black, Latino, and Native American people are overrepresented in correctional settings, from a population health perspective, these groups will most certainly be most affected by COVID-19 outbreaks in prisons and jails. According to COVID Prison Project data, as of October 2020 more than 10% of the US prison population has been infected with SARS-CoV-2 and more than 1200 people in prison have died from the COVID-19.

There are now documented racial disparities in COVID-19 case, testing, and mortality rates in the general population. In particular, there are large disparities in COVID-19-related deaths, with Black people having the highest mortality rate across age groups.2 Yet, the role of incarceration in contributing to disparities is still being explored. Preliminary research from Cook County, Illinois shows that jail churn-the cycling of people in and out of jails-is associated with 15.9% of all COVID-19 cases in Chicago, making it a stronger predictor than other factors known to be associated with COVID-19 spread.3 Although race was not directly assessed in the study, the authors noted, "In Chicago, although Black residents make up only 30% of the population, they represent 75% of the Cook County Jail population and 72% of the city's COVID-19-related deaths."3(p1417) Greater data transparency with demographic disaggregation on the part of prisons and jails is necessary to understand inequities in prisons and jails as well as the role of correctional institutions in broader community-level disparities.

## FULL TEXT

The United States has the unenviable distinction of having the highest rate of incarceration and the most people under correctional control-more than 6.7 million people. Although we often refer to this as "mass" incarceration, the criminal legal system's discriminatory impacts are disproportionately concentrated in Black and Latino communities: one in three Black men and one in six Latino men born in 2001 can expecttogo to jail or prison at some point in their lifetime. At this magnitude, mass incarceration is a key structural driver of not only individual and population health but also racial health disparities across numerous health outcomes.1

Although the role of incarceration in driving many racial health inequities has been long recognized, during the COVID19 pandemic this attention was amplified because correctional facilities comprise the largest number of single-site cluster outbreaks. Given that Black, Latino, and Native American people are overrepresented in correctional settings, from a population health perspective, these groups will most certainly be most affected by COVID-19 outbreaks in prisons and jails. According to COVID Prison Project data, as of October 2020 more than 10% of the US prison population has been infected with SARS-CoV-2 and more than 1200 people in prison have died from the COVID-19.

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### DEMOGRAPHIC DISAGGREGATION

Early in the US pandemic, activist scholars raised legitimate concerns about racial equity in testing and transparency in reporting racial demographic data for COVID-19 cases and deaths.4 In June 2020, the US Department of Health and Human Services released new requirements for states reporting data based on race, ethnicity, age, and sex to have a clearer picture of COVID-19-related disparities. However, many state departments of health reporting racial demographic data have a substantial amount of missing data, and county-level data remain sparse.

The departments of correction of only four states are reporting any demographic information about COVID-19: Massachusetts, Vermont, Tennessee, and Washington (Table 1). The Vermont Department ofCorrections has the most comprehensive reporting, including COVID-19 testing and case counts by race/ethnicity, along with point-in-time population estimates. Given that Vermont is one of a handful of states to implement a universal testing strategy, it is not surprising that there are no large discrepancies in testing. Whites comprise 86.7% ofthe population and 86.7% of those who have been tested. Blacks comprise 8.6% ofthe population and 7.7% of those who have been tested. The cumulative prevalence for Black and White residents is 6.0% and 2.6%, respectively. In other words, in a context of universal testing, Black prison residents have 2.3 times the risk for COVID-19 that White prison residents have. Black people comprise 16.4% of COVID-19 cases (test positivity: 6.0%), and White people comprise 80.0% of COVID-19 cases (test positivity: 2.6%).

The Tennessee Department of Correction is reporting race/ethnicity information for testing only, with 75% categorized as "unknown" race. Tennessee has also implemented a universal testing strategy. Population data from the Bureau of Justice Statistics show that White people comprise 55.1% of the incarcerated population, Black people 42.3%, and Hispanic people 2.12%. The distribution of COVID-19 testing is 59.2%, 38.4%, and 2.1%, respectively.

Similar to Tennessee, the Massachusetts Department of Correction is reporting demographic data for testing. However, these data are not being reported cumulatively, and counts less than five are masked, making the data uninterpretable. The Washington State Department of Corrections is reporting race/ethnicity information for cases only and provides proportions for racial/ethnic categories for the total population. Washington has tested only an estimated 31.6% of the prison population. Based on these data, there do not appear to be substantial race/ethnic disparities in COVID-19 cases.

## WE NEED MORE DATA TRANSPARENCY

Table 1 details the sum total of available COVID-19 data by race/ethnicity in US prison systems to date, which is unacceptable if we truly want to combat this pandemic equitably. It is nearly impossible to monitor the degree to which the racial/ethnic disparities in COVID-19 cases, hospitalizations, and mortality present in the general population are also present in prison systems and how prisons and jails may be contributing to population-level disparities in COVID-19. It took great advocacy efforts to have this information systematically reported by departments of public health for the general population (e.g., http://d4bl.org/ action.html), but we have yet to see this detailed level of reporting by departments of correction. In August 2020, Senator Elizabeth Warren (D, MA) and other congresspeople introduced the COVID-19 in Corrections Data Transparency Act, which would require federal, state, and local correctional facilities to submit comprehensive data on COVID-19 to the Centers for Disease Control and Prevention, including mandating that the data collected and reported be disaggregated by demographic characteristics.5

Beyond documenting disparities, comprehensive and disaggregated COVID-19 data should be used to take action, such as ensuring equitable testing in correctional facilities. Testing rates and test positivity rates vary substantially among prison systems, with only a small number of prison systems engaging in universal repeat testing. There are known racial inequities in diagnosis and in access and timeliness of health care, which extend to our prisons. Prisons, overall, have received less policy attention and COVID-19 resources than other group living quarters (e.g., skilled nursing facilities). With limited resources, it is imperative that COVID-19 testing and treatment be administered equitably in prisons. Additionally, these data should inform the release of individuals from jails, prisons, and Immigration and Customs Enforcement detention centers. Correctional facilities should, at a minimum, reduce their population to a level that allows proper social distancing and should provide equitable, comprehensive, and responsible discharge planning so people can safely reenter communities.6

To stem community spread following decarceration, resources should be devoted to testing upon release, access to safe places to quarantine, and retesting at 14 days during community reentry. Looking ahead, vaccine administration should be prioritized in prisons and jails given the heightened vulnerability of the population to COVID-19, and protocols for vaccine administration should be codeveloped with incarcerated and formerly incarcerated people.7

Mass incarceration is a key driver of racial health disparities in the United States, and prisons and jails are amplifiers of diseases. It is critical that we have timely, accurate, comprehensive, and disaggregated data about COVID-19, including information on testing, symptoms, cases, and outcomes (e.g., hospitalizations, recovery, death) to document and act on racial inequities. >4jPH

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## CONTRIBUTORS

The authors contributed equally to this editorial.

## CONFLICTS OF INTEREST

The authors disclose no conflicts of interest.

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## DETAILS

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# COVID-19 Among African Americans: An Action Plan for Mitigating Disparities

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## ABSTRACT (ENGLISH)

As the COVID-19 pandemic has unfolded across the United States, troubling disparities in mortality have emerged between different racial groups, particularly African Americans and Whites. Media reports, a growing body of COVID-19-related literature, and long-standing knowledge of structural racism and its myriad effects on the African

American community provide important lenses for understanding and addressing these disparities. However, troubling gaps in knowledge remain, as does a need to act. Using the best available evidence, we present risk- and place-based recommendations for how to effectively address these disparities in the areas of data collection, COVID-19 exposure and testing, health systems collaboration, human capital repurposing, and scarce resource allocation. Our recommendations are supported by an analysis of relevant bioethical principles and public health practices. Additionally, we provide information on the efforts of Chicago, Illinois' mayoral Racial Equity Rapid Response Team to reduce these disparities in a major urban US setting. (Am J Public Health. 2021;111: 286-292. https://doi.org/10.2105/AJPH.2020.305990)

## FULL TEXT

### Headnote

As the COVID-19 pandemic has unfolded across the United States, troubling disparities in mortality have emerged between different racial groups, particularly African Americans and Whites. Media reports, a growing body of COVID-19-related literature, and long-standing knowledge of structural racism and its myriad effects on the African American community provide important lenses for understanding and addressing these disparities.

However, troubling gaps in knowledge remain, as does a need to act. Using the best available evidence, we present risk- and place-based recommendations for how to effectively address these disparities in the areas of data collection, COVID-19 exposure and testing, health systems collaboration, human capital repurposing, and scarce resource allocation.

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Since April 2020, striking disparities in COVID-19 mortality between African Americans and Whites have been reported in US cities and states. For example, 51% of deaths in South Carolina have been among African Americans despite their representing only 30% of the population.1 In Chicago, Illinois, African Americans constituted 70% of early COVID-19 deaths despite composing only 30% of the population, and deaths continue to cluster in neighborhoods where more than 90% of the residents are African American.2

A national analysis of county-level data confirmed what many scholars predicted: that place matters in COVID-19 racial disparities. Counties with higher proportions of African Americans have higher numbers of COVID-19 cases and deaths; these counties have more crowded living conditions and lower social distancing scores, higher unemployment, lower rates of health insurance, and higher burdens of chronic disease.3 Structural racism and residential segregation have forced a disproportionate number of African Americans into low-income neighborhoods that are more physically crowded and have fewer resources.4 As a result, social isolation practices can be more challenging to implement; people must travel farther for necessary supplies, often utilizing public transportation, and return to homes with less personal space because of multigenerational living.

Individual risk also matters. Although not all African Americans live in racially segregated neighborhoods, all African Americans, to varying degrees, are affected by economic and sociopolitical burdens of racism that may increase their risk for COVID-19 morbidity and mortality. Structural racism has led to inequities in education, employment, income, policing and incarceration, health care access, chronic stress, and multiple other factors that affect health.5,6 For example, African Americans are more likely to be employed as low-wage essential workers, in areas such as mass transit and airport facilities, food production, and pharmacies.7 9 In New York City, African Americans constitute 30% of the essential workforce-more than any other racial group.10 Those workers, who have kept critical services operating, have too often been left without adequate personal protective equipment.11

Consequently, addressing racial disparities in COVID-19 must use both place-based and individual risk-based strategies grounded in public health practices that utilize data, boost public health infrastructure, leverage crosssector collaboration, and mobilize community partnerships.

We can draw upon the bioethical principles offairness, distributivejustice, and reciprocity to provide guidance for understanding resource allocation and the sharing of burdens and benefits across society. Fairness is essential to building public trust in pandemic-related processes. Although it is often thought of as "to each person an equal share," it can also be defined as "to each person according to need."12 Distributive justice, as defined by John Rawls, offers an additional health equity lens by proposing that institutions, processes, and structures should be allocated in a manner that seeks to improve the wellbeing of the least advantaged in society, whose social positions exist because of limitations placed on their opportunities.13 Finally, the principle of reciprocity argues that it is our collective responsibility to ensure that those being placed in harm's way are prioritized and protected.14

Thus, it is the ethical obligation and civic duty of our governments, hospitals, and public health agencies to address COVID-19 racial disparities that our society has helped to create. With these principles in mind, we make the following recommendations for policy and practice. We highlight examples from the Chicago Racial Equity Rapid Response Team formed to address the city's COVID-19 disparities (see the boxes on pages 288 and 289).15 This discussion is of critical import, not only for the current crisis but also as we reopen, rebuild, and reinvest in communities moving forward.

## RECOMMENDATIONS

The following recommendations for reducing COVID-19 disparities among African Americans are based in public health and bioethical principles designed to promote the health of the most marginalized populations.

Recommendation #1: Require collection of race/ethnicity data with COVID-19 reporting. Such data are fundamental and essential to operationalize distributive justice. In spite of recommendations set forth by the National Standards for Culturally and Linguistically Appropriate Services for universal collection of sociodemographic data, state-level data on COVID-19 cases, deaths, and testing are missing for 3, 5, and 46 states, respectively. For those that have reported, an estimated 50% of patients were missing race/ethnicity data in May 2020.16,17 On May 1, the Centers for Disease Control and Prevention updated the COVID-19 reporting form, but race/ ethnicity data are still not required. Such standards will allow better tracking of disease burden in different communities across the United States and inform just allocation of critical resources (e.g., remdesivir, ventilators) and infrastructure (e.g., field hospitals).

Recommendation #2: Utilize risk- and place-based strategies to decrease COVID-19 exposure. Reciprocity demands that essential workers be outfitted with personal protective equipment and physical barriers (e.g., plexiglass partitions) because of the increased assumed risks associated with their work. Partnerships with community-based organizations to disseminate resources, such as COVID-19 prevention kits (e.g., soap, gloves, facial masks, educational materials) within high-risk communities will be important. Community policing practices must not counter these public health efforts, as evidence has emerged of racial profiling among African American men wearing facial masks.18 Persons living and working in congregant, densely populated settings (e.g., prisons, skilled nursing facilities) should have facial masks or coverings. In addition, we recommend that prison systems identify and safely release low-risk, nonviolent offenders, as has been done successfully in numerous countries and US states, to reduce unnecessary overcrowding that puts the entire population at risk for COVID-19 infection.19,20

Recommendation #3: Utilize risk- and place-based strategies to increase COVID-19 testing. Racial/ethnic minorities have had disparate access to COVID-19 testing. Recent survey data suggest that 23% of federally qualified health centers and similar community-level care settings, where African Americans are more likely to receive care, do not currently offer drive-through or walk-up testing.21,22 Although many academic medical centers have developed in-house tests to increase capacity and decrease the wait time for results, African Americans have reduced access to such centers in some areas.23 This violates the fairness principle. We must implement universal screening in high-prevalence areas, based on epidemiological modeling and hot spot analyses, with subsequent contact tracing. Drive-through centers and pop-up clinics in trusted community spaces (e.g., churches) within high-risk neighborhoods will be critical, but insufficient.24 In the short term, there needs to be a coordinated investment in and involvement of public health nurses, community health workers, and trained civilians to successfully identify, reach, and test populations that have been marginalized from health care institutions for generations.25 28 In the long term, there needs to be an expansion of the proportion of underrepresented-inmedicine minority physicians, who help create trusted spaces for racial/ ethnic minority patients and disproportionately work to address historical injustices that have caused many African Americans to distrust health care systems. Larger medical centers will need to share testing resources with smaller, community-based clinics and hospitals.

Recommendation #4: Repurpose ambulatory staff and infrastructure for COVID-19 prevention, support, and monitoring. Chronic diseases such as diabetes and hypertension, which disproportionately burden African Americans, are associated with severe forms of COVID-1 9.29 31 Reduced inperson ambulatory volume creates opportunities to reorganize human capital and infrastructure to provide high-risk patients with enhanced telehealth monitoring, education, social risks screening, and supplies to help manage chronic disease and mitigate coronavirus risk. Oak Street Health, a network of outpatient clinics serving primarily low-income, elderly, minority patients, has redirected their front desk and outreach staff to call patients to screen for social risks (e.g., food insecurity) and behavioral health issues when their offices are virtual during the pandemic. Their social work team assesses those who screen positive, and patient transport vans are used to deliver food, thermometers, pulse oximeters, medicine, and other supplies.32

Recommendation #5: Safely isolate and support COVID-19 patients from highrisk living conditions. This would involve collaboration between health care organizations; housing agencies, hotels, and other housing facilities; food banks and food distribution services; mental and behavioral health services; and other social service agencies to facilitate safe social isolation and support services for COVID-19-positive, low-income persons living in overcrowded living conditions. These efforts must be led by public health campaigns that are socio-culturally and linguistically appropriate for the intended population, utilize multimedia dissemination strategies, and include accurate and understandable information about COVID-19 risks, prevention, testing, contact tracing, treatment, and recovery.

Recommendation #6: Implement cityand statewide plans to share resources and patients across hospital systems. African Americans are more likely to live in health care deserts (with no nearby hospital) and more likely to receive medical care at resource-limited health care systems.22,33,34 A landmark study of Medicare recipients found that 80% of African Americans received their health care from 22% of US physicians, and these providers were less likely to have access to subspecialists and diagnostic tests.35 Community hospitals have smaller intensive care units with fewer ventilators and trained personnel. Thus, efficient and data-driven resource sharing not only advances distributive justice, but can save lives. Some have suggested protocols that use zip codes to assign ventilators and other scarce resources to ensure fair distribution across communities based on need.36 Having statewide crisis care standards reduces interhospital variability and can facilitate dissemination of bestpractice updates from centers of excellence. Academic medical centers and large hospital networks have the ethical obligation to share testing, personal protective equipment, and other critical resources with smaller, less-resourced hospitals to help maximize patient and employee safety and health. Finally, all hospitals should commit to the comprehensive care of coronavirus patients regardless of their ability to pay, and to transferring patients across health systems to align patient volume and acuity with hospital capacity.

Recommendation #7: Allocate scarce medical resources to reduce racial inequities. Early in the pandemic, the possibility that the health care system would be overwhelmed was very real. Although the United States has generally avoided widespread shortages of critical care resources such as ventilators, we will soon be faced with allocation challenges concerning novel therapies and vaccines.37,38 The national conversation on the allocation of scarce health care resources has focused on developing objective priority scores, but there are growing concerns that these algorithms would be unfair to racial/ethnic minorities, exacerbate mortality disparities, and further undermine the African American community's trust of physicians.39,40 Priority scores that use chronic diseases as part of their calculations result in the disproportionate assignment of lower scores to African Americans in 2 distinct ways. First, these scores may inaccurately predict mortality risk for African Americans (because there is variability in life span associated with different chronic diseases). Second, systemic inequities have unfairly disadvantaged African Americans by increasing their chronic disease burden, which then makes them less eligible for life-saving resources. To date, these points have been largely underrepresented in the national conversation. Most plans published thus far suggest ignoring race and ethnicity,41,42 but these proposals clearly will not address the problem, as severity of illness and chronic diseases are strongly correlated with race. Although there may be no single best answer, we must consider potential options. With fairness, distributive justice, and reciprocity in mind, we suggest that (1) predictive models used in scarce resource allocation systems be validated in minority populations (Miller et al., unpublished data) and (2) additional priority be given to persons from marginalized populations. One approach has been developed in Pennsylvania, where individuals from areas with high area deprivation indices receive additional priority.43,44 This strategy seeks to address the increased COVID-19 risk (and subsequent mortality) created as a primary consequence of structural racism: residential segregation and racialized poverty.45 By considering economic disadvantage rather than race in general, this strategy allows a closer alignment between identifying subgroups of high-risk populations (among racial/minorities) for mitigation efforts.

## SUMMARY AND CONCLUSIONS

Our recommendations for reducing COVID-19 disparities among African Americans are based in public health and bioethical principles designed to promote the health of the most marginalized populations. It is our moral obligation to right these wrongs. Grounded in bioethical principles of fairness, distributive justice, and reciprocity, these recommendations include required reporting of COVID-19 race/ ethnicity data; strategies to decrease COVID-19 risk and increase COVID-19 testing; opportunities for health care systems to repurpose infrastructure to enhance COVID-19 prevention, support, and monitoring; strategies for health care systems to collaborate with other health care systems, public health agencies, and community-based organizations to share data, resources, and patients; and suggestions to bring racial equity to scarce resource allocation protocols.

Our recommendations can reduce racial disparities in COVID-19 outcomes and also rebuild trust between African Americans and the systems designated to care for them. Sustained and reciprocal community partnerships, through community-engaged programs and community-based participatory research, will be a critical part of this rebuilding, especially as we continue implementing treatments (e.g., remdesivir, monoclonal antibodies) and make plans for population-based COVID-19 vaccination.

It is important to note that this article has explicitly focused on direct action recommendations for health care delivery and public health sectors. For example, we do not address health insurance and the need for millions of persons in the United States to access insurance exchanges through the Affordable Care Act. Nor do we address the disparate impact that the growing economic crisis is having on the African American community and COVID-19 outcomes. In addition, it is important to recognize that we focused our attention on African Americans, the group for which the most data currently exist and whose disparities have been most highlighted in national discourse. Yet other marginalized populations-the Latinx community, low-income persons, immigrants, and others-are also suffering from COVID-19 disparities because of structural inequities. Many of our recommendations may apply to those populations and communities as well.

These recommendations require leadership at the local, state, and federal levels, and a willingness to engage in difficult conversations about both data and race. Indeed, the legacy of racism remains our nation's albatross, posing some of the most fundamental challenges that we face as a country. Our response determines the health and hope not only for our most vulnerable, but for us all. Ultimately, we will rise or fall as a nation based on how we empower and take care of the most marginalized among us. Chicago and other cities have begun to answer this call. In less than 2 months, the proportion of African American COVID-19 deaths in Chicago decreased from 72% to 47% of the total COVID-19 deaths.46 We can do this. The choice is ours. >4JPH

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M. E. Peek and B. Tucker Edmonds performed article design, preparation, and editing. R.A. Simons and W. F. Parker performed article preparation and editing. D.A. Ansell and S.O. Rogers performed article editing. All authors made significant intellectual contributions.

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This article was exempt from protocol approval because it did not involve human participants or primary data.

**Sidebar**

The Racial Equity Rapid Response of the City of Chicago, Illinois

The majority ofCOVID-19-related deaths in Chicago are people of color. Though racial disparity in health care is a historic and ongoing problem in Chicago, the intensity and immediate life-and-death impact of disparity during the COVID-19 crisis calls for an urgent and forceful response from the city. To help save the lives of those most vulnerable and to mitigate effects from the crisis caused by racial disparities, the city mounted the Racial Equity Rapid Response-a data-driven, community-based and community-driven mitigation of COVID-19 illness and death in African American and Latinx Chicago communities.

The goals of this endeavor are to

* Flatten the COVID-19 mortality curve in African American and Latinx communities in Chicago.
* Build a groundworkfor future work to address long-standing and systemic inequities in African American and Latinx communities (health, economic, and social).

To meet these goals we will need to

* Develop a citywide community mitigation operation that works hyperlocally in partnership with African American and Latinx community organizers and leadership to mitigate COVID-19 illness and death.
* Listen and respond to community-identified needs within the context of partnership that is mutual and centered around benefiting, not burdening, African American and Latinx communities.
* Marshal data, screening tools, testing, and human resources needed to respond to community-identified barriers and needs.

The response is organized into 4 categories

* Education: Provide communication and updates that are relevant for residents and speak to realities of their lives.
* Prevention: Work to ensure residents have the resources and information needed to protect themselves and their families.
* Testing and treatment: Work alongside our health department to ensure the expansion oftesting and treatment goes to areas in greatest need and lowers, or eliminates, barriers to access.
* Support services and resources: Work to ensure people have access to supportive services and resources that sustain their livelihoods.

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# Wodak and Mendelsohn Respond

Wodak, Alex, MBBS [1] ; Mendelsohn, Colin P, MBBS [2] [1] emeritus consultant at St Vincent's Hospital, Sydney, Australia [2] founding chairman of the Australian Tobacco Harm Reduction Association, Sydney, Australia

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## FULL TEXT

We note that Professors Mike Daube and Simon Chapman do not challenge any of our arguments. But once again they claim we have a conflict of interest. This is a claim that they have often raised before, and we have always answered.

We confirm once again that neither of us has a conflict of interest. As a registered charity, the Australian Tobacco Harm Reduction Association accepts donations from individuals and organizations; it does not accept money from tobacco or vape companies or their subsidiaries. Knowledge Action Change is a private organization that made a one-off unconditional donation.

Readers may draw their own conclusions from the reluctance of Professors Daube and Chapman to question our arguments but instead repeatedly claim we have a conflict of interest. /4JPH

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# The Need for Novel Approaches in Assessing the Value of COVID-19 Vaccines

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## ABSTRACT (ENGLISH)

Numerous coronavirus disease 2019 (COVID-19) vaccine development programs are under way, and several vaccines with potentially differing clinical and manufacturing profiles are expected to reach the market.1 We argue for the need to adopt new approaches for assessing the value of COVID-19 vaccines, calling for clinical, manufacturing, and cost aspects to be complemented by societal value considerations to inform the vaccines' further development, reimbursement, and pricing decisions.

## FULL TEXT

Numerous coronavirus disease 2019 (COVID-19) vaccine development programs are under way, and several vaccines with potentially differing clinical and manufacturing profiles are expected to reach the market.1 We argue for the need to adopt new approaches for assessing the value of COVID-19 vaccines, calling for clinical, manufacturing, and cost aspects to be complemented by societal value considerations to inform the vaccines' further development, reimbursement, and pricing decisions.

DISEASE, MANUFACTURING, AND CLINICAL VALUE ASPECTS

The World Health Organization2 (WHO) has published Target Product Profiles for minimally acceptable and preferred COVID-19 vaccine profiles to guide their clinical development for high-risk populations and outbreaks. Aspects of value considered in WHO Target Product Profiles relate to target population, posology, formulation, production, efficacy, and safety, as illustrated in the top branches of Figure 1, together with examples of relevant indicators for assessing product performance.

Clinical end points for COVID-19 range from infection protection to modification of viral replication and disease; the most commonly used are protection from infection as defined by seroconversion and prevention of clinical symptomatic disease, including decrease in need for high-intensity medical care and hospitalization.3 In terms of safety, vaccine-induced infection severity is a critical concern for all vaccines; together with antibody-dependent enhancement of viral replication and vaccine-associated enhanced respiratory disease, they have been suggested to be potential risks associated with COVID-19 vaccine development. Durability of clinical effects, product stability, and storage characteristics, including distribution and cold-chain requirements, are also crucial to consider.3 Supply chain, logistics, and service delivery infrastructure account for the largest cost share of existing immunization programs in low- and middleincome countries, with human resources and cold-chain equipment and overhead constituting the largest portion of such non-vaccine-related cost at the health system level.

## ECONOMIC AND SOCIETAL VALUE ASPECTS

The WHO Target Product Profile focuses on vaccines' effects, together with product quality and manufacturing and disease population aspects. Once a new vaccine is authorized or approved by regulatory agencies, direct costs form a key consideration in reimbursement and pricing decisions by payers and insurance bodies (Figure 1). Traditionally, pricing and reimbursement decisions for new health interventions are informed with economic evaluations that focus on cost per health outcome metrics per patient, failing to account for vaccines' full societal benefits contributed to the community.4

A societal perspective considers socioeconomic implications beyond clinical outcomes and costs, to capture additional benefits and contextual considerations.5 These relate to burden of disease (e.g., disease severity and unmet need), equity (distribution of health benefits in the population, e.g., in terms of age, sex, gender, health status, and welfare), innovation (e.g., mechanism of action, spillover effects enabling further product development), indirect costs (e.g., absenteeism, presenteeism, early retirement), public health benefits, financial risk benefits, and fear of contagion benefits; the latter three value aspects are specific to prophylactic interventions such as COVID-19 vaccines, capturing broader societal benefits for the entire population at risk.

Public health benefits relate to reducing the risk of developing and transmitting a disease among healthy individuals (including the population not receiving the intervention), effectively reflecting a societal value dimension for physical risk reduction and prevention and also accounting for any herd immunity effects.5 For example, the effect of a new COVID-19 health intervention against such a value aspect may range from no risk reduction (e.g., for a symptomatic pharmacological treatment), to reduction of prevalence risk factors, to reduction in transmission, to prevention and prophylaxis from the disease (e.g., for an effective vaccine).

Protection against financial implications is complementary to the physical risk reduction and prevention aspects of public health benefits for the population at risk (i.e., healthy individuals).6 For example, the relevant financial implications for the population at risk may range from health care expenses resulting after becoming infected and needing medical attention to productivity losses resulting from physical and social distancing measures such as travel bans and public quarantines, which became nearly universal in COVID-19. Once new COVID-19 vaccines become available, their protective effect on this value aspect could be measured by the amount of financial expenditures avoided or gains accumulated as a percentage of income-for instance, by determining the difference with earlier waves of the disease. Together, these two aspects of physical risk reduction and financial protection have been referred to as "insurance value."6

Fear of contagion benefits relating to emotional risk reduction and prevention is another relevant societal value component.6 Fear of contagion corresponds to the emotional state of stress or anxiety because of the risk of future exposure to and spread of a disease. This includes the fear of a disease's nonhealth-related consequences, such as fear of staying in quarantine for an extended time or the actual stress or anxiety once quarantine has been imposed. Given that COVID-19 poses a universal health risk and that the nonhealth-related consequences are relevant for everyone, such an emotional state affects the entire society (including healthy populations), and evidence already suggests that psychological effects and mental health burden from COVID-19 are widespread. Therefore, vaccine benefits include reduction of emotional risk as a result of decreased anxiety and worry because of less uncertainty in future outcomes.4

## MEASUREMENT OF COVID19 VACCINES' VALUE

Multiple criteria decision analysis (MCDA) allows appraisal of COVID-19 vaccines on disease, manufacturing, clinical, economic, and societal aspects by quantifying their values, trade-offs, and uncertainties.7 MCDA has been advanced for drug benefit-risk assessment by the European Medicines Agency8 and has been recommended as a methodology for consistent decisionmaking across the life cycle of newdrugs by the US National Academies of Sciences, Engineering, and Medicine.9 The US Institute of Medicine has successfully applied MCDA in vaccine development to inform funding decisions by public health payers,10 and it has been recommended by the WHO and European experts for transparently presenting and integrating vaccines' health economic evidence to support decisionmaking.11

MCDA can incorporate societal values to inform resource allocation decisions in two main ways. First, a cost per health outcome threshold could be extrapolated proportionally to how much of the MCDA model's weight corresponds to non-health-related outcome value components, to create an extended value threshold. In practice, the establishment of a standardized and comprehensive value function accounting for all technologies could be required, mapping out a conversion of an economic evaluation threshold to an MCDA value threshold. For this, the value of a COVID-19 vaccine would need to be estimated against other health interventions, which can be informed through large-scale surveys of public preferences with established methodologies such as discrete choice experiments. Second, vaccines' purchasing costs could be used to derive cost-value ratios to inform resource allocation decisions within a fixed budget, similar to a portfolio optimization approach. The latter approach could also accommodate a reduction in the "acceptable" cost ofthe vaccines if this were deemed ethically or practically necessary-for example, as recommended in buying their patent rights and dropping their price to convert them into global public goods.12

## CONCLUSIONS

Novel approaches are needed to measure the value of COVID-19 vaccines for development, reimbursement, and pricing decisions. Resource allocation in vaccine development should be conducted with WHO Target Product Profiles as guidelines while considering the potential trade-offs among candidates when ideal Target Product Profile levels cannot be reached. For reimbursement and pricing, the value of any COVID-19 vaccine extends beyond health outcomes and costs, encompassing wider societal benefits that ideally need to be evaluated with public preferences to inform access policies and maximum vaccine prices. Only in this way can the evaluation processes capture, rigorously and transparently, what matters most to the relevant experts and societies as a whole. AjPU

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A. Angelis wrotethe original draft ofthe editorial. All authors contributed to the conceptualization, review, and editing of the editorial.

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A. Angelis is cofounder of a software company developing tools for better decision-making in health care evaluation. T.Tervonen is employed by Evidera Ltd.

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## DETAILS

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# ERRATUM

Anonymous

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## FULL TEXT

A recent coding error on the website has come to our attention regarding the "peer review" designation for certain articles. Unfortunately, this error resulted in several Comment article types being coded as "peer reviewed" even though they had not been sent out for external review prior to publication. To ensure that the website is providing the most accurate and up-to-date designation, we will be removing the erroneous code for the affected articles. In addition, we will be resupplying new articles to the various databases that index our content, to ensure the error is not being replicated in those repositories. The PDF of each article accurately omits the phrase "peer reviewed" and therefore does not require correction.

The affected articles were:

Nestle M. Primer on US food and nutrition policy and public health: Marion Nestle comments. AmJ Public Health. 2019; 109(7):985-986. https://doi.org/10.2105/AJPH.2019.305143

Collins C. Austerity and mortality in Spain: the perils of overcorrecting an analytic mistake. AmJ Public Health. 2019;109(7): 963-965. https://doi.org/10.2105/AJPH.2019.305146

Ayres A. Alice Ayres comments. Am J Public Health. 2019;109(7):998-999. https://doi.org/10.2105/AJPH.2019.305134

Concannon KW. Primer on US food and nutrition policy and public health: Kevin Concannon comments. AM J Public Health. 2019;109(7):991-992. https://doi.org/10.2105/AJPH.2019.305165

Bentwich ME. Miriam Bentwich comments. AM J Public Health. 2019;109(12):1691. https://doi.org/10.2105/AJPH.2019. 305385

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Rodu B. The Food and Drug Administration is not positioned to deter adolescent e-cigarette use. Am J Public Health. 2020;110(6):778-779. https://doi.org/10.2105/AJPH.2020.305671

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# Misinformation

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ProQuest document link

## ABSTRACT (ENGLISH)

In their article, the authors acknowledged that misinformation (disseminated via social media) is damaging and sows distrust in public health: this has been well established.2 Misinformation and its more nefarious relative, disinformation, are indeed a problem for public health scientists whose interest is promoting health. AstraZeneca's release of their coronavirus disease 2019 vaccine clinical trial protocol is a proactive example (an "inoculant" in the framework's terminology) of transparency to strengthen public confidence.5 An open and transparent science is crucial in the era of the "reproducibility crisis. From "infodemics" to health promotion: a novel framework for the role of social media in public health.

## FULL TEXT

In the September 2020 issue of AJPH, Schillinger et al.1 used an innovative epidemic metaphor to propose a framework that examines how social media affects public health. In their article, the authors acknowledged that misinformation (disseminated via social media) is damaging and sows distrust in public health: this has been well established.2 Misinformation and its more nefarious relative, disinformation, are indeed a problem for public health scientists whose interest is promoting health. Many individuals in the public feel alienated from science-which may fuel distrust3-and social media platforms provide an opportunity to engage with others, potentially even instigating debate on a topic. Should a misinformation campaign gain considerable traction, scientists and public health practitioners will take notice and act to dispel the myth and, in some cases, conduct further scientific inquiry.

Yet occasionally there may be indirect and unrealized benefits of misinformation for public health, and this should be acknowledged in frameworks such as the one being proposed. Analogy for this comes from the unfortunate and fallacious claim that the measles-mumpsrubella vaccine causes autism. This debunked yet widely disseminated claim has spurred many observational studies,4 and confidence in the safety of this vaccine has been further bolstered by vaccine misinformation. Sadly, the number of individuals harmed from not vaccinating because of this misinformation may outweigh any benefits from these additional studies. As another example, the availability of thimerosalfree vaccines is in part a result of misinformation surrounding the preservative and its role in autism despite no causal relation.4

Public engagement with social media also motivates accountability and transparency for scientists and public health practitioners. A deliberate misinformation campaign based on an obscure research article suggests that there was an opportunity for full disclosure of research protocols, analytic codes, and data. AstraZeneca's release of their coronavirus disease 2019 vaccine clinical trial protocol is a proactive example (an "inoculant" in the framework's terminology) of transparency to strengthen public confidence.5 An open and transparent science is crucial in the era of the "reproducibility crisis."6

This is not a case ofthe ends justifying the means. This is an opportunity to be introspective as a field to better understand our shortcomings with respect to communication and dissemination. Frameworks such as those proposed by Schillinger et al.1 are useful in this regard, provided we share the onus for misinformation, which may lead to further scientific inquiry or greater transparency in our work. ÂfPU

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The author has no conflicts of interest to disclose.

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# Innovation Theory and Local Health Department Accreditation

Cilenti, Dorothy, DRPH MPH MSW [1] [1] Department of Maternal and Child Health at the University of North Carolina Gillings School of Global Public Health in Chapel Hill, NC

ProQuest document link

## ABSTRACT (ENGLISH)

In this issue of AJPH, Leider et al. (p. 301) describe an innovative approach using latent class analysis to understand how activities and service mix may influence decision-making by small local health departments (LHDs) to apply for accreditation. They also make a compelling case for why this is an important matter to pursue given the current response to the pandemic and the need for a strong public health system. They note that by the end of 2019, only 8% of small LHDs had applied for public health accreditation. The authors explore reasons for the lack of applications, including staff size, per-capita public health spending, and service mix, and offer ways to improve uptake.

## FULL TEXT

In this issue of AJPH, Leider et al. (p. 301) describe an innovative approach using latent class analysis to understand how activities and service mix may influence decision-making by small local health departments (LHDs) to apply for accreditation. They also make a compelling case for why this is an important matter to pursue given the current response to the pandemic and the need for a strong public health system. They note that by the end of 2019, only 8% of small LHDs had applied for public health accreditation. The authors explore reasons for the lack of applications, including staff size, per-capita public health spending, and service mix, and offer ways to improve uptake.

### DIFFUSION OF INNOVATION AND ACCREDITATION

Diffusion of innovation theory, developed by E. M. Rogers in 1962, provides a useful framework for considering howto increase uptake of public health accreditation among small LHDs in the United States.1 People or systems that adopt innovations early on are different than those who adopt later or never adopt. Rogers's theory comprises five categories of adopters:

1 innovators who want to be first,
2 early adopters who tend to be opinion leaders and basically need to know how to implement the innovation but do not require a lot of convincing,
3 early majority who need evidence and success stories,
4 late majority who are skeptical and will only adopt after the innovation has been tried by the majority, and
5 laggards, who are hardest to bring on board and usually need pressure from the adopters.

In the study by Leider et al., the small LHDs fall largely in the late majority and laggards categories.

The reasons for the lack of applications from the small LHDs described in the study by Leider et al. are congruent with the five factors of Rogers's theory that influence adoption of new innovations, such as public health accreditation. Addressing these factors is necessary to increase the likelihood that small LHDs will eventually adopt the innovation of public health accreditation.

The first factor is whether the innovation offers a relative advantage to the status quo. The fact that few small LHDs from states with state-based accreditation programs applied for national accreditation suggests that these LHDs did not perceive an advantage to receiving national accreditation when they have already been accredited within their state systems. The board of directors of the Public Health Accreditation Board should consider a process whereby smaller health departments from these states could simultaneously prepare for state-specific accreditation and national accreditation, thus reducing the additional time and resources needed to pursue accreditation through separate mechanisms. For small LHDs that are not from states with accreditation programs, greater incentives for achieving accreditation may need to be offered. In their review of incentives for public health accreditation, Thielen et al. highlighted that state health departments and LHDs valued financial incentives, support for infrastructure and quality improvement, and grant application flexibility.2

The second and third factors are compatibility and complexity, or how consistent accreditation is with the values, experiences, needs, and capacities of the LHDs. The authors' findings that small LHDs did not feel the accreditation requirements matched their agencies' services and activities reflect poor compatibility between the current accreditation program and the service mix of small LHDs. The authors' suggestion to develop a set of standards and a process that might better fit smaller LHD capacities would enhance compatibility. A more limited set of requirements would also address the complexity of the innovation. For example, the fact that a strategic plan is required to apply for accreditation makes it difficult to pursue accreditation for small LHDs with nearly half of them stating that their agencies do not have a strategic plan. Helpingsmaller LHDs meet requirements like the strategic plan may simplify the process and, as the authors suggest, could be done through technical assistance or learning collaboratives, with accredited smaller LHDs providing guidance and support to LHDs that have not yet applied for accreditation.

The fourth factor that has an impact on adoption of an innovation is triability, or the opportunity to test or experiment with the innovation before making a commitment to use. The current accreditation process requires a significant commitment of funding, time, and staff resources up front. The authors' suggestion to offer an accreditation "light" process for smaller LHDs with limited staff and funding may offer an opportunity for triability that is not currently part of the accreditation program.

The fifth factor is observability, which means the innovation must provide tangible results. Evaluation ofthe public health accreditation program has demonstrated a range of tangible results.3 However, these results must be linked to a visible, high-priority community need to garner strong political support for accreditation from policymakers and elected officials.4 Further research is needed regarding the extent to which local officials and county administrators understand and value having an accredited LHD serving their jurisdictions given competing priorities and strained resources.

## RESOURCES NEEDED FOR ACCREDITATION UPTAKE

One limitation ofthe diffusion of innovation theory is that it does not consider an individual's or system's resources to adopt the innovation. In the case of public health accreditation, lack of resources presents a significant barrier to pursuing accreditation even if all the other conditions for adopting accreditation as an innovation are addressed. Similar to other studies, the analysis by Leider et al. found that even among small LHDs, those with larger budgets and staff were more likely to apply for accreditation. Providing additional financial resources to enable smaller LHDs to recruit and retain a competent workforce is one way to build greater equity in public health capacity. Alternatively, cross-jurisdictional or regional approaches to delivering public health services have the potential to enhance the quantity and quality of public health services available at the local level, improve efficient use of resources, and increase accreditation readiness.5 It is likely that a mix of strategies will be necessary to observe significant increases in applications for accreditation from small LHDs.

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# 12 Weeks to Change a Life by Max Greenberg: Youth Violence Prevention as a Tool of Structural Violence

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## ABSTRACT (ENGLISH)

12 Weeks to Change a Life: At-Risk Youth in a Fractured State By Max A. Greenberg Berkeley, CA: University of California Press; 2019

## FULL TEXT

With 12 Weeks to Change a Life, Max Greenberg delivers an insightful analysis of the violence prevention field rife with the unblinking honesty of young people in prevention programs. As a scholar in the field of structural violence and violence prevention, I recognize that the keen depth of his understanding is only possible through the kind of lived ethnographic research on which the book is based. Many colleagues in the field take issue with the term "at risk" and the ways it has been used both to label young people and, consequently, to attempt to program the risk out of them. Greenberg dives into this phenomenon, illuminating the multifaceted kinds of harm ultimately done by well-intended programs and interventionists, largely because ofthe structures in which they exist.

A sociologist by training, Greenberg draws on his experience as a facilitator of youth violence prevention programs in Los Angeles, California, to paint a complex but accessible picture ofthe vast distance between such programming and young people's lived experiences. He argues:

Risk factors shift our gaze onto the markers of risk and away from the facts of young people's experiences with violence. ... To begin the story with risk factors-trauma, disengagement, isolation, or distrust-erases the forces that gave rise and shape to them. These things are not just factors that produce harm, they are harm themselves, beget by specific arrangements of history and structure.(p57)

This undergirds the argument ofthe book, which problematizes the quantification of risk and the use of population risk data in the context of disjointed systems responsible for the social welfare of young people. This "fractured state," rather than supporting young people and fostering their success, feigns its own success through carefully curated methods, measures, and narratives. Greenberg explains:

I am interested in a paradox of change programs: If programs do in fact signal a transformation in narrative and norms, then cultural norms are stunningly unstable-alterable in one hour a week for 12 weeks-and the deeply held narratives that give us meaning are fleeting. If not, however, then we must reckon with why evaluations show a change that is not there.(p114)

Although Greenberg could have delivered this message as an indictment, he builds a compelling case, pointing out, "We have it backwards. The problem is not that young people should change. The system should."(p183) He empathetically captures the internal conflict of people who work in violence prevention programs and how they negotiate the tension of seeking justice for young people and the ongoing injustices of the state.

### A VIOLENT, FRACTURED STATE

Greenberg describes the fractured state as taking three distinct forms: the slow state, the ephemeral state, and the shadow state, which roughly mirror governmental, nongovernmental, and quasigovernmental systems, respectively. He defines the slow state as largely inert bureaucracies that use waiting as a means of control. The ephemeral state, he argues, is driven by nonprofits that deliver short-lived programming to try to fill the gaps left by the slow state. The shadow state, then, is composed of nonprofit organizations that parallel the prison and militaryindustrial complexes and also fills gaps, however punitively, left by the government's divestment of its responsibility for social welfare. Adults and young people experience these disjointed systems differently, which he argues has harmful implications for young people. Adults experience the state largely as a faceless institutional bureaucracy, but young people experience the state personally through relationships and interactions with adults who serve as representatives ofthe state as they engage directly with youth as "policy in person":

For young people, the cumulative effect of the spatial and temporal fracturing of state institutions was a kind of social whiplash: disorientation and injury that comes from quick and extreme shifts in social expectations. It is the emotional and physical pain of needing to move constantly between contexts with unclear rules and responsibility and expectations. It is the result of one's focus and attention being jerked and spun constantly. Social whiplash makes it very difficult and emotionally trying to relate to individuals in institutions. In this way, it creates distance.(p177)

Invoking Max Weber, Greenberg reminds us that "the state and violence are historically and theoretically linked,"(p17) as the state itself is defined by holding the rights to legitimized violence-which then is not named as violence-within its territory to maintain its interests. This structural violence is then manifested when the interests of marginalized young people fail to align with those ofthe state.

## THE CENTRALITY OF NARRATIVE

Replete with firsthand accounts from young people, a central facet of Greenberg's argument relates the critical power of narrative and storytelling in making sense of and giving meaning to our experiences and subsequently in shaping our identities: "Stories can also organize the disjointed raw material of experience into an identity and in turn drive personal action and meaning."(p17) Here, he highlights the necessity of programs reflecting narratives that are meaningful to the young people they aim to serve. In sharp contrast to the narrative of risk, Greenberg's data show that "love, support, and agency-these were the key points ofthe story that young people told about preventing violence."(p143) Further, the "narrative[s] of risk that animate troves of research,"(p70) and numerous violence prevention programs typically do not resonate with the young people they claim to represent. Instead, the ephemeral state exercises its power in commodifying prevention and controlling the story, using "narratives as the core mechanism of policy action, from the statistical stories of risk data, to the transformation stories of evaluation."(p17) These narratives perpetrate unique harm and perpetuate structural violence against marginalized young people by erasing and thus ignoring how societal systems and structures create the context in which young people are labeled and treated as "at risk." Explaining how, Greenberg states:

Risk data, I contend, converts the byproducts of structural inequalities into legible interpersonal health patterns. Social inequalities, particularly racism, poverty, and heterosexism, are aggregated and resorted into new categories. . . . Drawing on risk data, prevention locates risk in the small-scale world ofbehavior and personal experience, disconnected from institutions and identity. The causesare madeto be interpersonal, emotional, habitual, but not economic, medical, or political.(p56)

Through a political strategy termed "responsibilization," these narratives shift the burden of responsibility for harm and safety away from government and society and solely onto individuals. Greenberg argues that by focusing on individual factors and behaviors, the system does not have to acknowledge the structural inequities that produce disproportionate harm. To the extent that the distribution of "risk," then, is unequally distributed by race, gender, and socioeconomic status, the internalization of these narratives by the young people targeted translates into internalized racism, sexism, and classism. These structures then perpetuate themselves in the interest ofthe state, and the violence waged by them against young people is legitimized by the state and thus neither named nor addressed as violence.

## "LOVE, SUPPORT, AND AGENCY"

The book's consistent shifting of background to foreground echoes Keith Payne's analogy of a murmuration of starlings, in which he illustrates that it is nearly impossible to focus simultaneously on an individual and a system.1 Greenberg homes in on this tension where systems shift the focus to individuals (young people labeled "at risk"), while simultaneously individuals working in the systems wrestle with the need for consciousness raising with young people and the rigid constraints of the programs they are funded to implement. Young people's emphasis on love, support, and agency as key components of violence prevention reinforces the importance of consciousness raising, directing those desiring to serve young people toward Paulo Freire's critical pedagogy and praxis.2

This book should be required reading for public health policymakers, funders, leaders, researchers, and practitioners involved with prevention programming focused on young people, if for no other reason than to catalyze critical reflection about the structures in which we work. Greenberg acknowledges that social science and its data are necessary, and he calls on us to recognize the significance of what the data exclude that must be attended to for meaningful change. He rightly points out the limitations of our science in supporting social change:

We do not have an empirical framework for understanding outcomes when we are talking about systemic and often generational inequalities. Real social change takes too long to measure on evaluations.(p184)

He makes several broad recommendations about how the field can constructively move forward, but he also misses the opportunity to highlight specific research and practice that is doing the very work he exhorts us to: social justice youth development.3 6 The future of youth violence prevention hinges on our ability to dismantle violent systems and structures, and Greenberg makes a compelling case for why. ÂfPU

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# All Not Quiet (but Quite Well) on the AJPH Bibliometric Front

Costanza, Michael C, PhD [1] ; Kapadia, Farzana, PhD, MPH [2] [1] AJPH Rushden, Northamptonshire, UK [2] AJPH New York, NY

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## FULL TEXT

In this summary, as In the previous one In 2018 (https://bt.ly/3r1Y5fY), we hope to keep you up-to-date on the work of the editorialteam at AJPH. As always, we seek to provide key Information for authors who submit their articles to AJPH, as wellasfor allAJPH readers. Our aim is to be open and transparent about the significant amount of work that has been happening behind the scenes and how this has affected the bibliometrics we present here. We also hope this information can help you in deciding whether AJPH is the best venue for presenting your scholarship.

In the 39-month period from June 2015 through September 2018, we processed just over 10 000 submissions. In the 26 months from October 2018 through November 2020, the AJPH editorialteam received and processed more than 10 000 additionalsubmissions, bringing the totalnumber of submissions to more than 20 000 since June 2015, when Alfredo Morabia became editor in chief. Was the increase in submissions between these two periods owing solely to submissions addressing the COVID-19 pandemic? No. In fact, about 1600 of the additionalsubmissions in 2020 were COVID-19 related, but 600 were not. So, we continue to publish broadly on public health topics that are of consequence to the health and well-being of populations and that have direct relevance to public health policy, prevention, and practice.

You might also ask, "Beyond the increase in submissions, how is AJPH really doing and why should I publish my scholarship in AJPH?' Because a review of the number of submissions processed is only one metric that the journal tracks, measuring its broader impact on the field of public health is what we are interested in discussing. Table A (available as a supplement to the online version of this article at http://www.ajph.org) presents details from Clarivate on key bibliometric measures that provide further insight into how AJPH is doing.

First, the AJPH citation footprint (yearly article citations) increased from 32 270 in 2015 to 41 022 in 2019. For more context, note that in the Science Citation Index Expanded and the SocialSciences Citation Index, AJPH ranked third highest of 193 journals and second highest of 171 journals, respectively, in the Clarivate Public, Environmental OccupationalHealth (PEOH) journalcategory. So, although 41 022 citations in one year is indeed quite a lot, AJPHs rank as the second and third highest journal in the PEOH category is another indicator of its influence on public health. Second, the 2019 journalimpact factor of 6.464 indicates that on average, among all journal articles in the Clarivate database, each AJPH article published in the two-year period from 2017 to 2018 was cited approximately six times in 2019. Third, the 2019 Eigenfactor score of (around) 0.058 indicates that each AJPH article published in the fiveyear period from 2014 to 2018 was highly cited by articles published in other highly influentialjournals in 2019. Finally, a bibliometric that may be more meaningful to you concerns how often an AJPH published article is read. Well, article downloads increased from 1.1 million in 2015 to 5.0 million in 2019. And by the end of 2020, AJPH is projected to reach 7 million downloads.

So, the moralof this story is that work at AJPH has not been very quiet of late and the journal is doing well according to the bibliometrics presented here. We hope that this information helps you decide whether to submit your scholarship to the journal. And we thank all of our associate editors and the journalproduction staff at the American

Public Health Association for keeping our work moving forward smoothly! AfPU

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# Schillinger and Ramírez Respond

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## ABSTRACT (ENGLISH)

Over more than a decade, the misinformation campaign related to childhood vaccines and autism led to preventable suffering and countless deaths across the globe as well as the diversion of precious public dollars that could have been dedicated to better understanding and treating this disorder as well as funding that could have been spent on immunization and related advances.1 Furthermore, disproving this misinformation occupied time and attention from the scientific community that could have been better spent elsewhere. Tracking misinformation can help public health communicators develop inoculation and countermessaging campaigns to advance public health.2 Analyzing themes or narratives that underlie arguments made in misinformation campaigns can provide insights into contemporary tensions in the relationship between society and the scientific and medical communities, insights that can be harnessed to promote a healthier relationship.3 We agree that the public cannot be a passive recipient of scientific and medical information; it has an important role to play in informing, shaping, and regulating science. ACKNOWLEDGMENTS D. Schillinger was supported by the Robert Wood Johnson Foundation (Culture of Health grant) and the National Institutes of Health (grants R01 NLM012355-01A1 and 2P30 NIDDK092924).A.S.

## FULL TEXT

We appreciate the acknowledgment that misinformation and disinformation, the effects of which can be amplified via social media channels, are serious problems. However, the claim that they are "a problem for public health scientists" is not expansive enough because this type of communication does not just make scientists' work more challenging; it jeopardizes the public's health. Although the SPHERE (Social media and Public Health Epidemic and REsponse) framework presented in our article can inform the work of scientists, its overarching objective is to enable a clearer understanding of how social media can influence public health.

In addition to the obvious harms that misinformation can generate, other harms also may result. Such forms of communication do not represent an efficient, ethical, or reliable means to foster the scientific transparency, accountability, and responsiveness that Goldstein rightly demands. Over more than a decade, the misinformation campaign related to childhood vaccines and autism led to preventable suffering and countless deaths across the globe as well as the diversion of precious public dollars that could have been dedicated to better understanding and treating this disorder as well as funding that could have been spent on immunization and related advances.1 Furthermore, disproving this misinformation occupied time and attention from the scientific community that could have been better spent elsewhere. Funding to support science, and the time and attention of scientists, are not limitless public resources. Responding to misinformation is not a sound mechanism to drive scientific policy, budgets, or research agendas.

We do agree that there is value in understanding misinformation. Tracking misinformation can help public health communicators develop inoculation and countermessaging campaigns to advance public health.2 Analyzing themes or narratives that underlie arguments made in misinformation campaigns can provide insights into contemporary tensions in the relationship between society and the scientific and medical communities, insights that can be harnessed to promote a healthier relationship.3

We agree that the public cannot be a passive recipient of scientific and medical information; it has an important role to play in informing, shaping, and regulating science. History has taught us that scientific "truth" is a moving target, that science can be hijacked in ways that jeopardize rather than promote public health,4 and that the authority of science can even be harnessed to justify inhumane policies.5 As such, fostering open and reasoned critical public discourse about science and health indeed is in the public interest. The challenge before us is how to create online spaces that allow productive, bidirectional communication between influencers from the public sector and communicators from science to advance public health. zflPH

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D. Schillinger created the firstdraft ofthe letter and submitted the final version. A.S. Ramírez edited a draft of the letter.

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# E-Cigarettes: A Public Health Threat, Not a Population Health Intervention

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## ABSTRACT (ENGLISH)

Cigarette smoking is the single most deadly personal behavior in human history and remains a potent population health threat. Today in the United States, one in five deaths can be attributed to cigarette smoking. Recent models suggest that even if we were to magically cease cigarette smoking today, some 200 000 life-years will be lost in coming years because of past cigarette smoking.1 Over decades, billions of dollars have been invested in smoking cessation efforts, and clinicians, policymakers, and public health professionals have fought to limit future tobacco use through a variety of mechanisms. Within a period of a few years, e-cigarettes have imperiled these efforts and created unprecedented opportunities for a new generation of youths to become addicted to nicotine and tobacco products.

Before the advent of e-cigarettes, promising declines were seen in national tobacco smoking rates. From 1965 to 2000, combustible tobacco use declined by half.2 Such declines were aided by tobacco taxes, mass media campaigns, nicotine replacement therapies, prescription drugs, and education on the dangers of smoking. Despite these herculean efforts, many people struggle with nicotine addiction throughout their lives, and hundreds of thousands of Americans die annually from the consequences of their addiction. The best way to prevent deaths from tobacco use is to prevent nicotine addiction. Preventing youth exposure is of particular importance because nearly 90% of adults who smoke cigarettes daily tried smoking cigarettes by 19 years, and almost all of them started smoking cigarettes by 26 years.3

We now know from 17 years of data that, in fact, e-cigarettes have not led to declines in combustible tobacco use but instead have been associated with unprecedented youth smoking rates. The experience of our home state of Louisiana is instructive. Although tobacco smoking rates among youths had been on a downward trend for the past several years, there has been a spike in e-cigarette use among high school students, with more than 45% of high school youths in Louisiana reporting having used an e-cigarette.4 This high use is in part attributable to corporate marketing practices specifically aimed at children and youths, such as products with fruit and candy flavorings.

## FULL TEXT

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The impacts of e-cigarettes on adults, however, are less conclusive, and many have advocated using e-cigarettes as cigarette-smoking cessation tools in targeted populations. In their metaanalysis, Wang et al. seek to understand the association between e-cigarette use and smoking cessation in adults and make an important contribution to the literature. Before this study, only two metaanalyses of the effect of e-cigarette use on smoking cessation included at least 10 studies, and these had mixed results.

Instead of examining findings on ecigarettes in all populations, this study shrewdly separated studies by target population and method of exposure. Wang et al. examined studies that considered (1) the impact of e-cigarette use on all people who smoke regardless of their intention, (2) the effect of e-cigarette use on smoking cessation among people who express some motivation to quit, (3) the effect of intense e-cigarette use on smoking cessation among smokers, and (4) the effect of providing free e-cigarettes as a smoking cessation therapeutic interaction.

The intriguing finding of this analysis is that how one comes to use e-cigarettes matters. For nonsmokers, e-cigarette use may lead to combustible tobacco use. For people who smoke, starting ecigarettes without clinical supervision does not serve as an effective cessation tool. Wang et al. found that e-cigarettes can be an effective diversion from combustible tobacco if provided as a targeted smoking cessation tool accompanied by a program prescribed by a medical professional.

The policy implication of the research is clearly stated by the authors: "E-cigarettes should not be approved as consumer products but may warrant consideration as a prescription therapy" (p. 230). This study and population trend data on youth smoking and vaping indicate that public health professionals cannot continue to consider e-cigarettes a public health intervention and that e-cigarette use at the population level should be discouraged.

Policymakers should consider these findings as another incentive to shift the regulatory policy environment with a particular focus on curbing youths' e-cigarette use. Raising the legal age to purchase tobacco products has demonstrated promising results. Only nine months after Oregon raised the minimum age to purchase tobacco products to 21 years, initiation of tobacco use decreased by 26% among youths aged 13 to 17 years and by 22% for youths aged 18 to 20 years.5 In California, which raised its minimum age to purchase tobacco to 21 years in 2016, sales to youth decoys younger than 18 years was reduced by 45%.6 E-cigarette regulation is complicated by the fact that many products are sold in shops with aftermarket additives, such as cannabis products, and can be more difficult to regulate.

There are several notable recent efforts to curb e-cigarette and tobacco use by youths. In December 2019, legislation raised the federal legal age for purchasing tobacco from 18 to 21 years. However, some state laws prevent enforcement of this federal rule. To date, only 33 states have passed state laws that enable the federal law to be fully operational.7 Additionally, the US Food and Drug Administration (FDA) has taken steps to prioritize the enforcement of unauthorized flavored e-cigarette products, especially those that are cartridge based. These are critical steps given that such flavored products are prevalent among youths using e-cigarettes. Further steps may include penalizing companies for high rates of youth uptake. Alternatively, or additionally, the FDA could issue regulations to reduce the level of nicotine in all smoking products to nonaddictive levels.

Considering these findings, how do we as public health professionalstell this story? Should e-cigarettes play a role in public health when the health of the population is of concern? Given overwhelming data on an epidemic of youths' nicotine exposure caused by e-cigarettes and the findings of this and other studies that do not show a clear benefit for adult populations, e-cigarettes have no role in public health. At best, e-cigarettes should be used in clinical settings informed by counseling, desire to quit, and personal history. These factors are outside the purview of public health agencies and squarely in the purview of clinicians.

The tobacco industry has fought a hard, yet predictable, fight to tout ecigarettes as an attractive alternative for, and panacea to, the ills of combustible tobacco use. These targeted advertising efforts have already had an inequitable impact on youths, people of color, and members of the LGBTQ+ (lesbian, gay, bisexual, transgender, queer or questioning) community in uptake of ecigarette products.8 As evidence piles up that refutes claims of health benefits of e-cigarettes, public health practitioners and health communications experts must be at the ready to use good data to counteract the industry's attempts to muddy the waters.

Public health professionals should focus messaging and communications strategies on where the public health data lead us. Population health data indicate, and the meta-analysis by Wang et al. supports, that e-cigarettes are not a viable tool to combat tobacco smoking as a mass market consumable. Public health professionals should discourage their use, and these products should be tightly regulated. Any recommendation of e-cigarette use should be relegated to clinicians as a targeted clinical intervention for smoking cessation. Preventing initiation of smoking of both combustible tobacco products and e-cigarettes and increasing successful cessation must continue to be top public health priorities. E-cigarette use, at best, has a limited role to play. /flPH

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# Increasing Access to Buprenorphine in Safety-Net Primary Care Clinics: The New York City Buprenorphine Nurse Care Manager Initiative

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## ABSTRACT (ENGLISH)

The Buprenorphine Nurse Care Manager Initiative (BNCMI) sought to increase access to opioid use disorder treatment in underserved New York City populations by expanding buprenorphine treatment capacity in safety-net primary care clinics. During 2016 to 2020, BNCMI added 116 new buprenorphine providers across 27 BNCMI clinics, and 1212 patients were enrolled; most patients identified as Latinx or Hispanic and were Medicaid beneficiaries. BNCMI increased access to buprenorphine, reached underserved populations, and is part of the New York City Health Department's multipronged approach to reducing opioid overdose deaths.

## FULL TEXT

### Headnote

The Buprenorphine Nurse Care Manager Initiative (BNCMI) sought to increase access to opioid use disorder treatment in underserved New York City populations by expanding buprenorphine treatment capacity in safety-net primary care clinics.

During 2016 to 2020, BNCMI added 116 new buprenorphine providers across 27 BNCMI clinics, and 1212 patients were enrolled; most patients identified as Latinx or Hispanic and were Medicaid beneficiaries.

BNCMI increased access to buprenorphine, reached underserved populations, and is part of the New York City Health Department's multipronged approach to reducing opioid overdose deaths. (Am J Public Health. 2021;111:215-218. https://doi.org/10.2105/AJPH.2020.306000)

Opioid overdose deaths are a public health crisis in New York City. In 2018,1444 unintentional drug overdose deaths were reported in New York City; 80% involved an opioid.1 These deaths are preventable.

Buprenorphine is a safe and effective medication for treatment of opioid use disorder that can be prescribed in primary care settings. Despite its effectiveness, buprenorphine is underused; 56% of US counties have no buprenorphine providers.2 In addition, disparities in use exist by race/ethnicity and poverty level. National data indicate that patients who receive buprenorphine treatment for opioid use disorder are more likely to be White and to have low household poverty.3 Similarly, in New York City, buprenorphine prescription rates have been inequitably concentrated in areas with the highest incomes and the lowest percentage of Black and Latinx or Hispanic residents.4

Underuse of buprenorphine is a result of multiple factors, including implementation barriers in primary care settings, such as insufficient nursing support, administrative support, time, and opioid use disorder education.5

## INTERVENTION

To increase buprenorphine treatment access for underserved New York City populations, the New York City Department of Health and Mental Hygiene (DOHMH) funded establishment of the Buprenorphine Nurse Care Manager Initiative (BNCMI). This initiative expands the capacity (i.e., ability and volume) of primary care providers in safety-net settings (i.e., clinics whose population served is at least 35% Medicaid or Medicare beneficiaries, uninsured, or underinsured) to offer buprenorphine treatment. BNCMI was adapted from the Massachusetts Model of OfficeBased Opioid Treatment With Buprenorphine.

BNCMI provides funding for nurse care managers as well as technical assistance, education, and mentorship to new buprenorphine providers in primary care clinics to begin offering buprenorphine treatment. Nurse care managers are registered nurses with backgrounds in substance use disorders or mental health; they facilitate screening and intake procedures, patient coordination, care management, pharmacy navigation, and other timeintensive care, and administrative responsibilities. In this way, nurse care managers support patients' treatment engagement and retention in care, freeing provider time to treat additional patients. BNCMI uses a harm reduction approach with strategies aimed at reducing negative consequences associated with drug use.6

The goals of BNCMI are to increase the number of new buprenorphine providers and the number of patients receiving buprenorphine treatment; serve patients who reside in highpoverty neighborhoods and who are Black and Latinx or Hispanic, thereby reducing inequitable access to buprenorphine treatment; and offer buprenorphine treatment that is aligned with harm reduction principles, including naloxone provision, fentanyl education, and a nonpunitive treatment approach.

## PLACE AND TIME

BNCMI was established in 2016 in 10 safety-net primary care clinics across New York City. The initiative expanded in 2018 and, as of 2020, operates in 27 clinics; among these, 24 clinics are Federally Qualified Health Centers.

## PERSON

BNCMI targets safety-net primary care providers with limited or no experience offering buprenorphine treatment and patients interested in receiving buprenorphine treatment.

## PURPOSE

BNCMI is part of DOHMH's multipronged approach to reducing opioid overdose deaths in New York City, a key component of which is increasing access to effective medications for opioid use disorder. The initiative addresses the low rates of buprenorphine use in New York City, particularly in low-income neighborhoods with primarily Black and Latinx or Hispanic residents. Notably, buprenorphine is available in outpatient settings and can be taken at home, unlike methadone (the other gold standard treatment for opioid use disorder), which commonly requires inperson dosing at highly regulated and often stigmatized opioid treatment programs. DOHMH focused BNCMI on the primary care setting to reduce stigma and increase access for people with opioid use disorder who may not intersect with opioid treatment programs.

## IMPLEMENTATION

Through a competitive grant, DOHMH selected 14 agencies to receive $150 000 per year to operate BNCMI. Some agencies run the initiative at a single location and others at multiple clinics.

At start-up, agencies identified a buprenorphine provider champion to advocate for the initiative with other staff and hired one full-time nurse care manager. Agencies identified at least four providers to begin offering buprenorphine treatment. All providers and nurse care managers attended the federally mandated buprenorphine waiver training. In addition, champions and nurse care managers received training on the model, harm reduction, and motivational interviewing. New nurse care managers shadowed experienced nurse care managers.

Clinics received technical assistance from DOHMH staff to support workflow design, billing and insurance, patient referrals, and pharmacy collaboration.

DOHMH provided individualized clinical mentorship (by buprenorphine experts) and facilitated quarterly learning communities for providers and nurse care managers. Learning communities included topics such as home induction, harm reduction, and racial equity. Additionally, nurse care managers participated in quarterly trainings on related topics, including trauma-informed care, hepatitis C, and care for people with justice involvement.

Clinics advertised buprenorphine treatment and developed warm handoff protocols with emergency departments, drug treatment programs, jails, and other community-based referral sources.

EVALUATION

BNCMI was evaluated in two domains: (1) number of new buprenorphine providers (defined as having little or no buprenorphine prescribing experience before the initiative) and (2) number of patients prescribed buprenorphine and their demographic characteristics from an enrollment intake survey, implemented in January 2017.

As of January 2020, 116 new buprenorphine providers (64 internists, 27 nurse practitioners, 17 family medicine physicians, four pediatricians, three physician assistants, and one obstetrician-gynecologist) started prescribing buprenorphine across the 27 clinics.

Atotal of 1212 patients (de-duplicated by enrollment site) enrolled during December 2016 to January 2020; among these, intake data were available for 993 patients. Most patients identified as men (74%), were Medicaid beneficiaries (72%), and identified as Latinx or Hispanic (42%) or Black (21%); 41% reported living in their own home (Table 1).

ADVERSE EFFECTS

No adverse effects were reported during the initiative.

SUSTAINABILITY

DOHMH continues to fund BNCMI, beyond the initial three-year commitment. The initiative is a public health funding priority, given the success in increasing the number of buprenorphine providers and delivering buprenorphine care to patients who are underserved. However, to support long-term expansion and sustainability, clinics must be able to bill third-party payers for substance use disorder care management delivered by nurses. At present, this is not a reimbursable service in New York State.

PUBLIC HEALTH SIGNIFICANCE

BNCMI successfully increased buprenorphine access in the primary care setting and reached underserved populations. Citywide buprenorphine prescribing indicators also increased over the period that BNCMI has been operational. Of note, race/ethnicity and income data are not collected when prescriptions are filled and therefore not reported here. The number of New York City residents who filled prescriptions increased by 20% during 2016 to 2019 (from 13 612 to 16 383 residents). Also, the number of buprenorphine prescriptions filled annually increased by 25% during this same period (from 107 867 to 134647 prescriptions). In 2019, these indicators were the highest ever on record for New York City.7 These trends are promising, suggesting that DOHMH's comprehensive approach to increasing buprenorphine access through multiple initiatives (including BNCMI) is having a population-level effect. Similar interventions that target underserved patients and support providers in expanding buprenorphine capacity are necessary to reduce inequities in treatment access and to improve care for people with opioid use disorder. Local health departments have a crucial role in supporting expansion of effective treatment and should consider implementing similar models as part of their approach to addressing the opioid crisis. >4jPH

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CONTRIBUTORS

M. Kaplan-Dobbs led the writing of the article, designed and directed the initiative, and contributed to evaluation conceptualization and design and data analysis and interpretation. J. A. Kattan contributed to initiative design, evaluation conceptualization and design, data interpretation, and drafting and revising of the article. E. Tuazon contributed to evaluation conceptualization and design, data analysis and interpretation, and drafting and revising of the article. C. Jimenez contributed to evaluation design, data analysis and interpretation, and revising of the article. S. Saleh contributed to evaluation design and data collection. H.V. Kunins conceptualized the initiative, contributed to initiative design, and contributed to drafting and revising of the article.

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The New York City Department of Health and Mental Hygiene institutionalreview board determined this initiative to be program evaluation.

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## DETAILS

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# Application for Public Health Accreditation Among US Local Health Departments in 2013 to 2019: Impact of Service and Activity Mix

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## ABSTRACT (ENGLISH)

Objectives. To examine correlates of applying for accreditation among small local health departments (LHDs) in the United States through 2019. Methods. We used administrative data from the Public Health Accreditation Board (PHAB) and 2013, 2016, and 2019 Profile data from the National Association of County and City Health Officials to examine correlates of applying for PHAB accreditation. We fit a latent class analysis (LCA) to characterize LHDs by service mix and size. We made bivariate comparisons using the t test and Pearson $\chi^2$. Results. By the end of 2019,126 small LHDs had applied for accreditation (8%). When we compared reasons for not pursuing accreditation, we observed a difference by size for perceptions that standards exceeded LHD capacity (47% for small vs 22% for midsized [P<.001] and 0% for large [P<.001]). Conclusions. Greater funding support, considering differing standards by LHD size, and recognition that service mix might affect practicality of accreditation are all relevant considerations in attempting to increase uptake of accreditation for small LHDs. Public Health Implications. Overall, small LHDs represented about 60% of all LHDs that had not yet applied to PHAB. (Am J Public Health. 2021;111:301 -308. https://doi.org/10.2105/ AJPH.2020.306007)

## FULL TEXT

### Headnote

Objectives. To examine correlates of applying for accreditation among small local health departments (LHDs) in the United States through 2019.

Methods. We used administrative data from the Public Health Accreditation Board (PHAB) and 2013, 2016, and 2019 Profile data from the National Association of County and City Health Officials to examine correlates of applying for PHAB accreditation. We fit a latent class analysis (LCA) to characterize LHDs by service mix and size. We made bivariate comparisons using the t test and Pearson $\chi^2$.

Results. By the end of 2019,126 small LHDs had applied for accreditation (8%). When we compared reasons for not pursuing accreditation, we observed a difference by size for perceptions that standards exceeded LHD capacity (47% for small vs 22% for midsized [P<.001] and 0% for large [P<.001]).

Conclusions. Greater funding support, considering differing standards by LHD size, and recognition that service mix might affect practicality of accreditation are all relevant considerations in attempting to increase uptake of accreditation for small LHDs.

Public Health Implications. Overall, small LHDs represented about 60% of all LHDs that had not yet applied to PHAB. (Am J Public Health. 2021;111:301 -308. https://doi.org/10.2105/ AJPH.2020.306007)

The Public Health Accreditation Board (PHAB) is the national voluntary accreditation program for public health departments in the United States, including state, tribal, local, and territorial health departments, as well as Army Installation Departments of Public Health. As of June 2020-about 7 years after the first health department was accredited- a total of 296 health departments and 1 centralized public health system were accredited. Among those accredited, 255 were local health departments (LHDs).1

Accreditation is based on a set of standards and measures that were developed through a consensus process. Health departments' conformity with these standards is assessed by trained peer reviewers.2 An ongoing evaluation has revealed a variety of benefits as reported by accredited health departments relating to quality improvement and performance management, accountability and transparency, and collaboration, among other areas.3 8 Research studies comparing data from health departments engaged in accreditation and those not engaged have reported relationships between pursuit of accreditation and quality improvement and performance management,9 classification of jurisdictions as comprehensive public health systems,10 prevalence of evidence-based decision-making and practices,11,12 and policy involvement.13

However, the rate of accreditation uptake has not been uniform among all health departments. Identified barriers include limited staff time, competing priorities, staff turnover, standards exceeding capacity, and costs.14,15 Several studies have focused on the challenges facing small or rural health departments, which have historically been less likely to pursue accreditation. In addition to the aforementioned challenges, small LHDs point to the many different roles that limited staff may be asked to play and a lack of examples of accreditation documentation relevant to smaller health departments.14,16 Recognizing that smaller health departments are underrepresented among accredited health departments, the PHAB Board of Directors and the Board of Directors of the National Association of County and City Health Officials (NACCHO) formed a Joint Task Force to explore this issue. The JointTask Force met in 2019 and 2020 to better understand the needs of small LHDs and consider accreditation support and related interventions. This article represents the empirical examination of the Joint Task Force's interest in further exploring the following: (1)the rates of accreditation uptake among small health departments over time and by budget and staff size, (2) the factors contributing to their decision to not apply, and (3) whether the service mix of small LHDs is associated with likelihood of applying.

## METHODS

We analyzed data from NACCHO's National Profile of Local Health Departments (Profile) study and administrative data collected by PHAB from applicants.17 Primary objectives of the study were to track trends in application among small LHDs, defined inthis article as those serving jurisdictions of fewer than 50 000 people, compared with midsized (50 000-499 999 people) and large (> 500 000 people) LHDs. In addition, we sought to understand small LHDs' barriers to accreditation and characterize the heterogeneity among small LHDs in service mix for use in determining if different groups of LHDs differentially applied to PHAB.

NACCHO surveys all LHDs in the United States. We used data from the 2013, 2016, and 2019 Profile studies in this analysis. We captured population data from the Census Bureau for the LHD jurisdictions. We examined LHD staffing, as well as service mix data from the most recently available year as part of an LCA. Otherwise, we used data from Profile respondents from each year when examining trends over time. Overall response rates for the Profile studies were 79% in 2013, 76% in 2016, and 61% in 2019. Response rates for small LHDs were 74%, 71%, and 56% in 2013, 2016, and 2019, respectively. Staffing and spending levels were cleaned and examined for outliers, and descriptive statistics were generated on Profile data.

We merged PHAB data, collected through the application process, by NACCHO identification number. We designated LHDs in analysis if they were applicants from the states of Florida or Ohio. In Florida, the centralized public health system, comprising all 67 LHDs, was accredited, rather than the individual LHDs. In Ohio, a statute required all 113 LHDs to apply for PHAB accreditation by 2018.

We conducted an LCA to examine activity and service mix among LHDs. The LCA constituted classes by characterizing the number and types of activities LHDs conducted as well as the proportion of activities by type. The primary types of activities were clinical, inspection and regulation, and population-based prevention and epidemiology. We grouped activity types in line with existing NACCHO activity domains.18 We examined goodness of fit for 2 to 7 classes using likelihood ratio y2. We also examined model and fit performance for conceptual delineation, finding the best performance at 3 and 5 classes. For purposes of this article, we selected 5 classes because of greater explanatory power. We conducted the LCA for all available LHDs under the rationale that it is desirable to characterize the service mix across LHDs in the United States to better understand how small LHDs fit into the national picture.

We generated descriptive statistics to examine application trends over time. We made bivariate comparisons for application status for LHD staff size and per-capita expenditures in a given year by using the Student t test. We made bivariate comparisons to identify associations between the reasons for not applying for PHAB accreditation among small LHDs and completion of select accreditation prerequisites, workforce size, or budget size. We calculated application status by latent class and population size. We ran a sensitivity analysis to separate states with statespecific accreditation programs (either voluntary or mandatory), including Illinois, Michigan, Missouri, and North Carolina. We also conducted stratified analyses in the under-50 000 population size to characterize heterogeneity of service provision within the group. We collected data in the Qualtrics Web platform (Qualtrics LLC, Provo, UT), managed and analyzed in Stata version 16.1 (StataCorp LP, College Station, TX), and visualized in Tableau (Tableau Software, Seattle, WA).

## RESULTS

By the end of 2019, 455 LHDs had applied for accreditation through PHAB. These included 126 small LHDs, 249 midsized LHDs, and 80 large LHDs (Figure 1). Among small LHDs, this represents an increase from 41 LHDs that had applied by 2013. Overall, by 2019, about 8% of all small LHDs had applied, though most of these were associated with statewide accreditation efforts by the Florida Department of Health (20% of small applicant LHDs) or as part of Ohio's legislative requirement that all of its LHDs apply for PHAB accreditation by 2018 (44% of small applicant LHDs). Approximately 3% of small LHDs had applied nationwide as of 2019, excluding those in Florida and Ohio (45/1403). Comparatively, 171 (23%) of midsized LHDs and 64 (48%) of large LHDs had applied by 2019, excluding Florida and Ohio.

We observed differences in expenditures and staff size between small LHDs that applied to PHAB versus those that had not applied (Figure 2). In 2013, small LHDs that had not applied to PHAB spent a median of $38 per capita, or $630 000 total, while small LHDs that applied spent about $94 per capita or $2.1 million total ($56 per-capita difference in the median, $46 per-capita difference in mean; P<.001). We observed differences in staff size in 2013 as well, with the median staff size for nonapplicants being 11, and 35 for small LHD applicants (24 staff difference on median, 29 on mean; P< .001). These gaps narrowed by 2019, with per-capita spending at $39 for nonapplicants and $66 for applicant small LHDs ($27 difference on median, $22 on mean; P =.001). There was also a difference observed in staff size between small LHD applicants and small LHDs that had not applied to PHAB by 2019 (24 vs 10 staff, 14 staff difference on median, 12 staff difference on mean; P <.001).

LHDs that had decided not to pursue PHAB accreditation indicated their reasons for not doing so in the 2013 and 2019 Profile studies (Figure 3). In 2013, the top reason for not pursuing accreditation among small LHDs was listed as the application "requiring too much time and effort," while in 2019, PHAB accreditation fees (56%) and the standards exceeding their capacity (47%) were the most commonly reported barriers.

When we compared 2019 reasons for not pursuing accreditation among small LHDs and LHDs of other sizes, there was no significant difference for fees, but we observed a difference for the standards exceeding capacity (47% for small vs 22% for midsized [P<.001] and 0% for large [P<.001]). To apply for accreditation, LHDs must complete a community health assessment, community health improvement plan, and strategic plan within the previous 5 years. In 2019,72% of small LHDs had completed a community health assessment within 5 years, 64% had completed a community health improvement plan, and 55% had completed a strategic plan. Of these 3 requirements, there was no association between completing a community health assessment or community health improvement plan within 5 years and the standards exceeding capacity as a barrier for small LHDs, but there was a negative association for completing a strategic plan (P =.001). We also examined the size of the LHD workforce and amount of expenditures in relation to this barrier; while the size of the LHD workforce was not associated with capacity barriers, the amount of expenditures had a negative association (P =.008).

We also observed a difference for small LHDs compared with large LHDs for the standards not being appropriate for the LHD (16% for small vs 0% for large; P<.001) as a barrier to PHAB accreditation. Completion of a community health assessment, community health improvement plan, or strategic plan was not associated with this being a barrier among small LHDs. The number of fulltime equivalents employed by the LHD was negatively associated with this barrier among small LHDs (P<.001), while the amount of expenditures was not associated.

We conducted an LCA on LHDs to identify potential groups of departments by their activity and service mix (Appendix Figures A-D, available as supplements to the online version of this article at http://www.ajph.org). Using a 5-class analysis, we identified small LHDs that had not applied to PHAB as of 2019. The 5-class model showed significant variation by service mix, with classes 1 and 3 being heavily inspection focused, class 2 being less focused on inspection and regulation, and classes 4 and 5 being a mix of clinical, inspection and regulation, and population-based prevention, with class-5 LHDs providing more activities on average, as well as more maternal and child health services in particular. Class membership was somewhat dependent on geographic region, with class 1 being most heavily concentrated in the Northeast, class 3 in the Northeast and Midwest, class 2 in the Midwest, and classes 4 and 5 spread throughout the lower Midwest and South.

After we excluded LHDs that applied through the Florida integrated public health system accreditation process and Ohio LHDs (given its statute requiring pursuit of PHAB accreditation), we crosstabulated application status by latent class (Figure 4). None of the small LHDs in class 1 had applied for accreditation as of 2019. Between 2% and 3% had applied in classes 2 through 4, and 9% had applied in class 5. Overall, small LHDs represented 59% of all LHDs that had not yet applied to PHAB. LHDs from states that had state-specific accreditation programs had applied to PHAB at lower rates generally, and no small LHDs from these states had applied to PHAB (Figure D).

We conducted sensitivity analyses that examined potential heterogeneity by population sizes of fewerthan 50 000 (Figure B and Table A, available as supplements to the online version of this article at http://www.ajph.org); service mix was similar across small LHDs and latent class membership varied (e.g., 7% of LHDs serving <12 500 people were part of class 5 compared with 12% of LHDs serving 12 500-24999 people and 67% of LHDs serving 25 000-49 999 people). The proportion of LHDs that had applied to PHAB were similar across small LHDs of all jurisdiction size categories.

## DISCUSSION

One of the ultimate outcomes in the PHAB logic model is to "achieve greater equity in public health capacity."19 Inherent in this goal is that accreditation will help "raise all boats," rather than continue to advance performance only among health departments that already had greater capacity. In light of this goal, it is important to understand variations in the characteristics of health departments that do and do not pursue accreditation. This study presents information about accreditation application rates of LHDs by size, budget, and staffing from 2013 (shortly after the accreditation program's launch) and 2019. It also looks at the reasons small LHDs have given for not pursuing accreditation and the intersection between service mix and likelihood of application.

More than 100 small LHDs have applied for accreditation, but there is much work ahead if accreditation isto become more widespread among LHDs serving populations of fewer than 50 000 people. To dig deeper into this disparate pursuit of accreditation, we examined the reasons why LHDs decided not to pursue accreditation. Smaller LHDs were far more likely to indicate that the accreditation standards exceeded capacity or that the standards were not appropriate for their agency. This study also included an LCA to explore how differences in service mix related to likelihood to apply for accreditation. That analysis revealed that small LHDs that provide a mix of services were more likely to pursue accreditation. These LHDs were also more likely to have more staff and expenditures per capita than their small peers. While there were barriers to accreditation that cut across LHDs of varying sizes (e.g., fees), this study focused on the concerns that were particularly salient for small LHDs. Considering that small LHDs were more likely to indicate challenges in having the capacity to meet standards and the findings related to their service mix, there appear to be 3 potential strategies targeted at increasing accreditation uptake among smaller LHDs: bolstering LHD capacity, considering a set of standards that may help health departments on their journey toward accreditation, and focusing on groups of health departments (based, in part, on their service mix) that might be best able to meet accreditation standards.

The first strategy comprises strengthening the capacity of LHDs and could be achieved through several mechanisms including bolstering funding. It is important to acknowledge the chronic underfunding of public health systems in the United States.20 Additional financial resources are needed to allow health departments to hire individuals with the expertise and skills to promote and protect health in their communities. Similar to previous findings,14,21 this analysis indicates that, even among small LHDs, those with larger budgets and staff are more likely to apply. Technical assistance may also be key to helping health departments achieve accreditation standards. For example, health departments that had not conducted a strategic plan were more likely to report that the standards exceeded capacity. Helping smaller health departments meet core requirements like the strategic plan may be part of the approach, and providing detailed examples that are more specific to the small LHD setting may be 1 tool in such a toolkit.16 Finally, it is important to consider alternate arrangements for delivering public health services. This could be through cross-jurisdictional sharing arrangements, whereby health departments enter into agreements to share staff, laboratory, or other capacity.

The second strategy entails consideration of a set of standards and process that might better fit smaller LHD capacities. PHAB is currently exploring whether a product(s) could be developed that would support LHDs on their journey to accreditation. Based on the work of the Joint Task Force of the NACCHO and PHAB boards of directors, PHAB is developing models to test what it might look like to recognize health departments that are able to demonstrate that they meet a set of requirements that are more limited than the complete set of PHAB standards and measures. LHDs would have the option of achieving this recognition and "stopping" there, but could see this as a stepping stone toward accreditation.

The third strategy relates to the findings from the LCA, which may be able to inform which ofthe smaller LHDs could be the next group to pursue accreditation. It is perhaps not surprising that health departments that provide a greater mix of services are more likely to pursue accreditation as the accreditation standards and measures mirror the 10 Essential Public Health Services framework and therefore call upon health departments to demonstrate a wide array of capacities.

## Limitations

There were several limitations to this study. There were potential validity concerns attributable to differential nonresponse by size in the NACCHO data. Response rates to the Profile studies decreased from 2013 to 2019, especially among small LHDs. The approach to conduct the LCA utilized the most-recently reported activity data from LHDs; there is potential for unmeasured changes in service mix among nonrespondent LHDs. In addition, LHDs applying in between Profile study cycles were not counted until the subsequent one in our analyses (e.g., applicants in 2018 would be captured in the 2019 cycle). Finally, there were a number of states with state-specific voluntary or mandatory accreditation that may have also reduced desire to seek accreditation (e.g., Illinois, Michigan, Missouri, North Carolina)-about 6% of responding LHDs in 2019 that were not accredited said it was in part because of another accreditation program.

This is an exploratory study that invites future research. For example, additional data should be collected to gather a more nuanced understanding than the single question in the NACCHO profile about barriers to accreditation among those who have not applied and why that has changed over time. It will also be helpful to understand better the relationship between service mix and accreditation pursuitto develop and evaluate interventions focused on bolstering accreditation among small LHDs.

## Conclusions

Through evaluation surveys, accredited health departments report many perceived benefits of accreditation. Research studies are emerging that note differences between accredited and nonaccredited health departments, particularly with regard to quality improvement, evidence-based practice, and being part of a comprehensive public health system. Given these findings, and the benefit to the populace of accreditation,3 it is important to examine why some health departments are more likely to pursue accreditation than others. This study highlights that smaller

LHDs are less likely than larger ones to apply for accreditation. Furthermore, it notes disparities among smaller LHDs by indicating that those with more funding and staff are applying at greater rates. Additional support may be needed to ensure that more small LHDs are able to experience the performance improvement benefits of accreditation. >4jPH

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The project was conceptualized by J. P. Leider, V.A. Yeager, andJ. Kronstadt. Data were analyzed by J. P. Leider, K. Hall, andJ. Kronstadt. The article was initially drafted by J. P. Leider, J. Kronstadt, V.A. Yeager, and K. Hall. Criticalreview was performed by C. K. Saari, A. Alford, L.T. Freeman, and P. Kuehnert.

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The project involved secondary data analysis of public health organizations.

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# DETAILS

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# Firearm Access and Suicide: Lethal Means Counseling and Safe Storage Education in a Comprehensive Prevention Strategy

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## ABSTRACT (ENGLISH)

Most firearm-related deaths are deaths by suicide, and approximately half of all suicide deaths involve a firearm.1 Recent research has identified a sustained risk of suicide by firearm for those who own handguns and has suggested that risk for suicide peaks just after an individual's first handgun purchase.2 During the coronavirus disease 2019 pandemic, the United States has seen record-breaking gun sales, and many purchasers are first-time owners, which may mean that a large section of the population is at newly elevated risk for suicide.3 Although policymakers tend to focus on certain laws to reduce gun violence, these laws are not sufficient to fully address suicide risk when an individual's risk is not apparent.

In this issue of AJPH, Anestis et al. (p. 309) describe the potential ofpreventive individual-level interventions-lethal means counseling and safe storage education-to spur members of the Mississippi National Guard to safely store firearms and reduce suicide risk. Using these findings, I explain the problems with relying solely on law to prevent suicide and outline the need for a comprehensive approach to firearm suicide prevention that incorporates evidence-based practices and leverages existing policy mechanisms.

## FULL TEXT

Most firearm-related deaths are deaths by suicide, and approximately half of all suicide deaths involve a firearm.1 Recent research has identified a sustained risk of suicide by firearm for those who own handguns and has suggested that risk for suicide peaks just after an individual's first handgun purchase.2 During the coronavirus disease 2019 pandemic, the United States has seen record-breaking gun sales, and many purchasers are first-time owners, which may mean that a large section of the population is at newly elevated risk for suicide.3 Although policymakers tend to focus on certain laws to reduce gun violence, these laws are not sufficient to fully address suicide risk when an individual's risk is not apparent.

In this issue of AJPH, Anestis et al. (p. 309) describe the potential ofpreventive individual-level interventions-lethal means counseling and safe storage education-to spur members of the Mississippi National Guard to safely store firearms and reduce suicide risk. Using these findings, I explain the problems with relying solely on law to prevent suicide and outline the need for a comprehensive approach to firearm suicide prevention that incorporates evidence-based practices and leverages existing policy mechanisms.

## LIMITATIONS OF STATE GUN LAWS

Many gun laws popular among advocates have shown the capability to reduce firearm suicide but have inherent limitations. These laws focus on firearm access; because firearms are so lethal, individuals in the midst of a crisis with access to a firearm are at high risk for fatal harm.1 Laws like purchaser licensing and Extreme Risk Protection Orders can reduce firearm suicide but rely on identifying and acting on risk.4,5 Purchaser licensing laws keep those with a statutory prohibiting condition from acquiring firearms. Extreme Risk Protection Order laws are intended to remove firearms from the home of someone at high risk for harming himself or herself or others. Because suicide is often an impulsive act taken in response to acute stressors, it is not always possible to preemptively identify and act on risk of suicide.1 A person experiencing a transient crisis may not satisfy any statutory or other legal criteria prohibiting gun acquisition. For individuals in this scenario, the lethality of immediately available means of harm is quite important.

Removing a gun from the home or preventing a gun from entering a home may be ideal when someone is at risk for harming himself or herself, but safe storage is another evidence-driven strategy for reducing risk. The hallmarks of safe storage are (1) locking the firearm, (2) storing the firearm unloaded, and (3) storing the firearm separate from ammunition. Child access prevention laws require gun owners to store guns safely if they live in a house with children. These laws are associated with reductions in adolescent suicide mortality.6 Child access prevention laws are very difficult to enforce, may have low compliance, and apply to only certain households, but the evidence is instructive-if guns are stored safely, access is reduced, and suicide risk decreases. This principle can contribute to a comprehensive, multilevel approach to suicide prevention.7

## PREVENTIVE INDIVIDUALLEVEL INTERVENTIONS

Researchers, advocates, and policymakers have promoted efforts to educate the public and expand the use of safe storage. These efforts include community-level interventions like the Gun Shop Project that seek to use gun shops and firing ranges to distribute educational materials about suicide prevention and provide gun storage maps that help community members find retailers and law enforcement agencies that will temporarily store firearms. This work also has included individual-level interventions like lethal means counseling and safe storage education that seek to work with individuals to limit their access to specific means of self-harm.7 As Anestis et al. note, little previous research is available on this type of counseling-it has been difficult to determine whether counseling actually leads to safer storage, and some previous studies have focused solely on those for whom a suicidal crisis has already emerged.

Anestis et al. make a crucial point about lethal means counseling that also illustrates a problem with many firearm laws: "Because 90% of suicide attempts with firearms are fatal, lethal means counseling cannot only be offered after a suicidal crisis has emerged, as this would result in many high-risk individuals not being exposed to the intervention." This is true for counseling but also for gun laws-if the laws rely on apparent or articulated risk, many experiencing suicidal crises will not benefit from any protection afforded by these laws. Anestis et al. use a strong methodology to show that in a population in which firearm suicide is a significant problem-military personnel-a preventive approach using lethal means and safe storage counseling can result in sustained adoption of safe storage practices. Importantly, the findings also show that the intervention was acceptable to the study population.

Anestis et al. make an important contribution to the lethal means and firearm suicide prevention literature, but a few remaining questions are ripe for future work. The authors asked participants about safe storage practices but did not ask about separately storing ammunition, which is a key component of safe storage. Future iterations of this work should incorporate that practice. It would also be interesting to know more about the households of the study population. The counseling interventions were offered to gun owners, but those gun owners may not be the members of their households at the highest risk for death from suicide. Children, for example, may be at higher risk but may benefit from safer storage to an even greater extent than the gun owners themselves. Finally, researchers should seek to evaluate similar interventions in other populations. The studied interventions were tailored to a specific, high-risk population, and the authors appropriately caution against generalization. Future work should use similar practices to identify strategies for intervening with other high-risk populations and with the general public.

Policymakers and practitioners can leverage existing policy mechanisms to implement lethal means and safe storage counseling. Lethal means counseling is usually offered in clinical settings, but the principles may be applicable in other contexts. Many people who purchase or own guns will have contact with the state or with firearm sellers. These interactions provide opportunities for creative interventions that can educate new gun owners about safe storage and the link between suicide risk and firearm access. For example, many states require training courses before receiving a license to purchase or carry a handgun. These courses may already discuss safe storage practices, but that discussion could be expanded to discuss suicide explicitly and perhaps even to offer individualized counseling. If the right language, communication strategies, and messengers are chosen, the findings of Anestis et al. suggest that gun owners might be amenable to such an intervention.

CONCLUSIONS

Despite the protective effects of certain state laws, the gaps in coverage mean that they do not directly reduce suicide risk for many individuals. Importantly, even to the extent they do provide uniform protection, the laws are not universally adopted and face political and legal threats. Many states have not adopted these laws and may not ever adopt them. In addition, the new ideological composition of the Supreme Court suggests that gun rights may be expanded, and certain gun laws may face significant judicial scrutiny. Policymakers, practitioners, and advocates in search of an effective strategy for firearm suicide prevention must use a comprehensive approach, including laws and tailored community- and individual-level interventions.

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In their "Conflicts of Interest" statement, Wodak and Mendelsohn note that they are board members of the Australian Tobacco Harm Reduction Association (ATHRA), which they describe as "a health-promotion charity,"1 although it appears to have no membership beyond its three board members.2 They refer to funding from "small Australian vape businesses" but specify neither the businesses nor the amounts.1 They do not note that ATHRA has received funding from the UK-based Knowledge Action Change (KAC) organization, in whose events they have both participated. "4 The FSFW has also been criticized by the World Health Organization (WHO), which has referred to "a number of clear conflicts of interest involved with a tobacco company funding a purported health foundation"5 and has advised that "WHO will not partner with the Foundation. "9 We believe that Wodak and Mendelsohn should have declared a conflict of interest in relation to KAC as a tobacco industry-funded organization and that their comment should be amended to include this. /flPH CORRESPONDENCE Correspondence should be sent to Emeritus Professor Mike Daube, PO Box 834, Western Australia 6904(e-mail: m.daube@curtin.edu.au).

Bruhn, Roberta L,PhD., M.S. (2021). Individual risk-based assessment for blood donation in the united states-is it time? American Journal of Public Health, 111(2), 188-189. Retrieved from https://www.proquest.com/scholarly-journals/individual-risk-based-assessment-blood-donation/docview/2486203951/se-2?accountid=211160

The COVID-19 pandemic has focused attention on two issues that have been of ongoing discussion and public health concern in the United States: continued declines in blood product utilization coupled with even larger declines in blood donation collection. These issues have resulted in a tenuous situation of a product with limited supply and limited shelf life. The pandemic has highlighted the effort required to maintain an already delicate balance of blood collection and supply and exacerbated the ramifications of such a limited supply by causing an additional, immediate, and significant reduction in the number of voluntary blood donations across the United States because planned blood drives following shelter-in-place orders were canceled. In April 2020, the US Food and Drug Administration (FDA) issued recommendations that included a reduction of the then deferral period for men who have sex with men (MSM) from 12 months to 3 months from last sexual contact with a man.1 These changes were long in the making and were issued following a dramatic decrease in blood product availability following the COVID19-related significant and abrupt drop in blood donation. Although the reduction in the MSM deferral period was not the only change made to donor deferral criteria, reductions in time-associated deferrals for travel-associated malaria, Creutzfeldt-Jakob disease, and variant Creutzfeldt-Jakob disease would not be expected to have similar import; removing the MSM time-based deferral is estimated to provide upward of a half million donations per year. Yet, following the issuance of this recommendation, a response to the call for blood donors who have recovered from COVID-19 (convalescent plasma) still resulted in some MSM being turned away from donation. Changes to the blood collection and testing infrastructure must be made timely and adopted uniformly to ensure that the safety of blood recipients remains the priority, while balancing the residual risk of any donated blood product with the availability of those products.

Bender, Annah K,PhD., M.S.W., & Lauritsen, J. L., PhD. (2021). Violent victimization among lesbian, gay, and bisexual populations in the united states: Findings from the national crime victimization survey, 2017-2018. American Journal of Public Health, 111(2), 318-326. doi:https://doi.org/10.2105/AJPH.2020.306017

Objectives. To estimate US nonlethal violent victimization rates for lesbian, gay, and bisexual (LGB) males and females aged 16 years and older and to compare disparities among LGB and straight males and females, controlling for other correlates of victimization. Methods. We used data from the 2017 and 2018 National Crime Victimization Survey (NCVS) to provide nationally representative rates of various forms of violent victimization for self-identified LGB and straight persons. Multivariable models assessed the risk for violence associated with LGB status. Results. Total violence rates were 2 to 9 times higher among LGB persons compared with heterosexuals. For some forms of violence (e.g., rape and sexual assault, violence with serious injuries, and multiple offender violence) there were notably high disparities between bisexuals and heterosexuals. With adjustment for covariates, LGB orientation was associated with odds ratios nearly 2 to 4 times those of heterosexuals. Conclusions. This is one of the first known uses of NCVS data to estimate LGB victimization, revealing substantially higher rates of violence directed at LGB individuals. Public Health Implications. Sexual orientation and gender identity questions in federal surveys such as the NCVS enable monitoring of violent victimization rates and should continue. Collecting these data can help researchers understand victimization risk and guide appropriate resources toward victim services, especially important given the high violent crime levels experienced by LGB individuals. (AmJ Public Health. 2021;111:318-326. https://doi.org/10.2105/AJPH.2020.306017)

Chor, Julie,M.D., M.P.H., & Haider, Sadia,M.D., M.P.H. (2021). Optimizing access to preventive reproductive health care: Meeting patients where they are at. American Journal of Public Health, 111(2), 209-211. Retrieved from https://www.proquest.com/scholarly-journals/optimizing-access-preventive-reproductive-health/docview/2486203881/se-2?accountid=211160

Today, we hear ourselves repeating this wise attending's words while working in our hospital's family planning clinic in response to a question we sometimes hear from learners: "Why do you think she waited so long to have her abortion?" Patients seeking abortion care and those pursuing preventive reproductive health care describe many of the same psychosocial, interpersonal, and structural barriers to obtaining care.1,2 Notable psychosocial challenges to obtaining care include medical mistrust and not prioritizing one's personal health amid competing demands; interpersonal barriers include parenting and caregiving for adult family members; and structural barriers include instability around insurance, transportation, and childcare.1 Although many barriers to seeking abortion and preventive reproductive health care coincide, those seeking abortion care face additional challenges, including stigma and antiabortion legal restrictions. The Turnaway Study was a landmark five-year longitudinal study that followed individuals who presented for abortion just before or after the gestational age limits at 30 abortion clinics across the United States.2 Participants who presented after the clinics' gestational age limits and were unable to obtain a desired abortion were more likely to experience economic hardship and report being in fair or poor health years later, compared with those who presented in time to obtain their desired abortion.2,3 Furthermore, what is often called the "wellwoman visit," which we refer to as the "preventive reproductive health visit" in recognition that not all individuals assigned female at birth identify as women, is an important opportunity to provide health screening, counseling, immunizations, contraception, and preconception care to help address individual and population-level reproductive health disparities.

Hedden, B. J., M.S.W., Comartin, Erin,PhD., M.S.W., Hambrick, N., M.S.W., & Kubiak, Sheryl,PhD., M.S.W. (2021). Racial disparities in access to and utilization of jail- and community-based mental health treatment in 8 US midwestern jails in 2017. American Journal of Public Health, 111(2), 277-285. doi:https://doi.org/10.2105/AJPH.2020.305992)

Objectives. To examine the dual disproportionality that individuals with serious mental illness and people of color (P°C) occupy in the criminal-legal system. Methods. This study follows a cohort of 623 individuals who screened positive for mental health issues at booking in 8 Midwestern jails in 2017. We followed individuals through the jails' practices of jail-based mental health treatment, and we used Medicaid billing data to assess community-based behavioral health treatment engagement in the postyear period after jail release. The aim was to examine if an individual's race/ethnicity was associated with their access to jail- and community-based mental health treatment. Results. We did not find any racial disparities in jail-based treatment, although 3 community-based outcomes significantly differed. Compared with P°C, White people had 1.9 times greater odds of receiving community-based mental health and substance use treatment and 4.5 times greater odds of receiving co-occurring disorder treatment. Conclusions. Barriers that individuals released from jail face adversely affect P°C, resulting in reduced access to treatment. Critical race theory can expose the assumptions and functions of systems of care and the possible reproduction of implicit bias in potential solutions. (Am J Public Health. 2021;111:277-285. https://doi.org/10.2105/AJPH.2020.305992)

Kumar, N. R., M.D., Borders, A.,M.D.M.P.H.M.Sc, & Simon, M. A.,M.D.M.P.H. (2021). Postpartum medicaid extension to address racial inequity in maternal mortality. American Journal of Public Health, 111(2), 202-204. Retrieved from https://www.proquest.com/scholarly-journals/postpartum-medicaid-extension-address-racial/docview/2486203849/se-2?accountid=211160

The United States has one of the highest maternal mortality rates among high-income countries, with deeply troubling disparities that demonstrate long-standing inequity rooted in racism in our health care system. The US pregnancy-related mortality ratio, defined as the number of deaths of women while pregnant or up to one year after delivery from any cause related to or aggravated by the pregnancy or its management, has increased from 14.5 pregnancy-related deaths per 100 000 live births in 2007 to 16.9 per 100 000 in 2016.1 Nearly a quarter of pregnancyrelated deaths occur between 43 days and one-year postpartum, with cardiovascular conditions being the leading cause of death. State-level data show that substance use disorder and poor perinatal mental health are among the leading causes of postpartum mortality. Two of three pregnancy-related deaths may be preventable. The racial disparities in pregnancy-related mortality in the United States are deeply troubling. Between 2007 and 2016, there were 40.8 pregnancy-related deaths per 100 000 live births among non-Hispanic Black mothers and 29.7 pregnancy-related deaths per 100 000 live births among non-Hispanic American Indian/Alaska Native mothers compared with 12.7 pregnancy-related deaths per 100 000 live births among non-Hispanic White mothers. Recent events have drawn public attention to structural racism, or "the totality of ways in which societies foster racial discrimination through mutually reinforcing systems.. . that] in turn reinforce discriminatory beliefs, values, and distribution of resources."3(p1453)Biases embedded in algorithms, clinicians' screening tools and predictive models, and underrepresentation of minorities in the provider workforce demonstrate that structural racism is embedded in every aspect of our health care system, which leads to unacceptable health outcomes. The ongoing COVID-19 pandemic has highlighted and exacerbated these issues: Black Americans have more than twice the odds of hospital admission, and Native Americans are infected at up to four times the rate of their White counterparts. Bias and systemic racism in health care must be addressed, given the differences in maternal mortality that Black women experience after accounting for other sociodemographic risk factors.

Wang, R. J., M.D., Bhadriraju, S., M.D., & Glantz, S. A., PhD. (2021). E-cigarette use and adult cigarette smoking cessation: A meta-analysis. American Journal of Public Health, 111(2), 230-246. doi:https://doi.org/10.2105/AJPH.2020.305999)

Objectives. To determine the association between e-cigarette use and smoking cessation. Methods. We searched PubMed, Web of Science Core Collection, and EMBASE and computed the association of e-cigarette use with quitting cigarettes using random effects meta-analyses. Results. We identified 64 papers (55 observational studies and 9 randomized clinical trials RCTs]). In observational studies of all adult smokers (odds ratio OR] = 0.947; 95% confidence interval CI] = 0.772, 1.160) and smokers motivated to quit smoking (OR = 0.851; 95% CI = 0.684,1.057), e-cigarette consumer product use was not associated with quitting. Daily e-cigarette use was associated with more quitting (OR= 1.529; 95% CI = 1.158, 2.019) and less-than-daily use was associated with less quitting (OR = 0.514; 95% CI = 0.402,0.665). The RCTs that compared quitting among smokers who were provided e-cigarettes to smokers with conventional therapy found e-cigarette use was associated with more quitting (relative risk= 1.555; 95% CI = 1.173, 2.061). Conclusions. As consumer products, in observational studies, e-cigarettes were not associated with increased smoking cessation in the adult population. In RCTs, provision of free e-cigarettes as a therapeutic intervention was associated with increased smoking cessation.

Grant, Sean,D.Phil, M.Sc. (2021). Reporting certainty of evidence on E-cigarette use for adult smoking cessation. American Journal of Public Health, 111(2), 227-229. Retrieved from https://www.proquest.com/scholarly-journals/reporting-certainty-evidence-on-e-cigarette-use/docview/2486203683/se-2?accountid=211160

The National Academy of Medicine recommends evaluating the quality of the body of evidence for each outcome in a systematic review.1 Endorsed by more than 100 organizations internationally, Grading of Recommendations Assessment, Development, and Evaluation (GRADE) provides an explicit, systematic, and transparent approach to this assessment of the quality of evidence (or "certainty of evidence").2 It is designed for evaluating the certainty of evidence from randomized clinical trials (RCTs) on therapeutic interventions to inform clinical decision making as well as observational studies on exposures to inform public health decision making.3 Consequently, GRADE can be used to assess certainty of evidence in the two distinct bodies of evidence that Wang et al. discuss in their article (this issue of AJPH, p. 230) on e-cigarette use for adult smoking cessation: RCTs of e-cigarettes as a prescription therapy and observational studies of e-cigarettes as consumer products.Wang et al. used the GRADE approach to assess certainty of RCT evidence on e-cigarettes as a prescription therapy. They specified their interest in the effect of providing free nicotine e-cigarettes (compared with counseling alone or combined with pharmacological support) on smoking cessation among adult populations who smoke cigarettes at any duration and frequency. In addition to specifying the review question, GRADE emphasizes the need to specify the definition of "certainty of evidence" as well. GRADE currently recommends "the certainty that a true effect lies on one side of a specified threshold or within a chosen range,"4(p4) with review teams choosing the most appropriate threshold or range for the intended decision-making context. As Wang et al. do not define certainty in the PROSPERO registration or article, an explicit definition is needed to ensure a coherent conceptual basis for their certainty ratings and appropriate reader interpretation of findings.

Krieger, N., PhD., Nethery, R. C., PhD., Chen, J. T., ScD., Waterman, P. D., M.P.H., Wright, E., B.A., Rushovich, T., M.P.H., & Coull, B. A., PhD. (2021). Impact of differential privacy and census tract data source (decennial census versus american community survey) for monitoring health inequities. American Journal of Public Health, 111(2), 265-268. Retrieved from https://www.proquest.com/scholarly-journals/impact-differential-privacy-census-tract-data/docview/2486203596/se-2?accountid=211160

Objectives. To investigate how census tract (CT) estimates of mortality rates and inequities are affected by (1) differential privacy (DP), whereby the public decennial census (DC) data are injected with statistical "noise" to protect individual privacy, and (2) uncertainty arising from the small number of different persons surveyed each year in a given CT for the American Community Survey (ACS). Methods. We compared estimates of the 2008-2012 average annual premature mortality rate (death before age 65 years) in Massachusetts using CT data from the 2010 DC, 2010 DC with DP, and 2008-2012 ACS 5-year estimate data. Results. For these 3 denominator sources, the age-standardized premature mortality rates (per 100 000) for the total population respectively equaled 166.4 (95% confidence interval CI] = 162.2, 170.6), 166.4 (95% CI = 162.2, 170.6), and 166.3 (95% CI = 162.1, 170.5), and inequities in the range from best to worst quintile for CT racialized economic segregation were from 103.4 to 260.1, 102.9 to 258.7, and 102.8 to 262.4. Similarity of results across CT denominator sources held for analyses stratified bygenderand race/ ethnicity. Conclusions. Estimates of health inequities at the CT level may not be affected by use of 2020 DP data and uncertainty in the ACS data. (Am J Public Health. 2021;111:265-268. https://doi.org/10.2105/AJPH.2020.305989)

Anestis, M. D., PhD., Bryan, C. J., PsyD., Capron, D. W., PhD., & Bryan, A. O., M.S. (2021). Lethal means counseling, distribution of cable locks, and safe firearm storage practices among the mississippi national guard: A factorial randomized controlled trial, 2018-2020. American Journal of Public Health, 111(2), 309-317. doi:https://doi.org/10.2105/AJPH.2020.306019

Objectives. To examine whether lethal means counseling and provision of cable locks prompt safe firearm storage relative to control among firearm-owning members of the Mississippi National Guard. Methods. This randomized controlled trial utilized a 2 x 2 factorial design (lethal means counseling vs control, provision of cable locks vs no cable locks). Follow-up assessments took place at 3 and 6 months after baseline. Data were collected (n = 232; 87.5% male; mean age = 35.01 years; 77.2% White) from February 2018 through July 2020. Results. Relative to control, lethal means counseling and provision of cable locks resulted in greater adoption of several safe storage methods overtime. Lethal means counseling outperformed control (3 months: 55.0% vs 39.0%; odds ratio OR] = 1.91). Cable locks outperformed control at 3 and 6 months on number of storage methods (1.41 vs 1.11; d = 0.29 and 1.34 vs 1.16; d = 0.15, respectively) and locking devices (59.8% vs 29.9%; OR = 3.49 and 58.4% vs 35.8%; OR = 2.52, respectively) Conclusions. Lethal means counseling and cable locks can result in sustained changes in firearm storage. Public Health Implications. The military may benefit from lethal means counseling, perhaps administering at point of entry. Trial Registration. Clinical Trials.gov identifier: NCT03375099. (Am J Public Health.

2021;111:309-317. https://doi.org/10.2105/AJPH.2020.306019)

Fairchild, Amy Lauren,PhD., M.P.H. (2021). Is good enough good enough? E-cigarettes, evidence, and policy. American Journal of Public Health, 111(2), 221-223. Retrieved from https://www.proquest.com/scholarly-journals/is-good-enough-e-cigarettes-evidence-policy/docview/2486203515/se-2?accountid=211160

In 2017, under the leadership of Scott Gottlieb, the US Food and Drug Administration (FDA) opened the door to considering e-cigarettes as a harm-reduction product. In January 2020, the agency signaled its intention to continue to chart that path, writing, T]he potential for electronic nicotine delivery systems] to act as a substitute for cigarettes, thereby encouraging smokers to seek to switch completely away from combustible cigarettes, may be dependent, in part, upon the product having acceptability and abuse liability more comparable to a cigarette. Yet what has always remained unclear is what evidentiary standard the FDA will apply as it reviews products and evaluates public health benefit.

Cocoros, Noelle M,D.Sc, M.P.H., Kirby, Chaim,M.A., J.D., Zambarano, B., PhD., Ochoa, A., M.P.H., Eberhardt, K., B.S., Rocchio, C., S.B., . . . Klompas, Michael,M.D., M.P.H. (2021). RiskScape: A data visualization and aggregation platform for public health surveillance using routine electronic health record data. American Journal of Public Health, 111(2), 269-276. doi:https://doi.org/10.2105/AJPH.2020.305963

Automated analysis of electronic health record (EHR) data ¡s a complementary tool for public health surveillance. Analyzing and presenting these data, however, demands new methods of data communication optimized to the detail, flexibility, and timeliness of EHR data. RiskScape is an open-source, interactive, Web-based, user-friendly data aggregation and visualization platform for public health surveillance using EHR data. RiskScape displays near-real-time surveillance data and enables clinical practices and health departments to review, analyze, map, and trend aggregate data on chronic conditions and infectious diseases. Data presentations include heat maps of prevalence by zip code, time series with statistics fortrends, and care cascades for conditions such as HIV and HCV. The platform's flexibility enables it to be modified to incorporate new conditions quickly-such as COVID-19. The Massachusetts Department of Public Health (MDPH) uses RiskScape to monitor conditions of interest using data that are updated monthly from clinical practice groups that cover approximately 20% of the state population. RiskScape serves an essential role in demonstrating need and burden for MDPH's applications for funding, particularly through the identification of inequitably burdened populations. (Am J Public Health. 2021; 111:269-276. https://doi.org/10.2105/AJPH.2020.305963)

Blosnich, John R,PhD., M.P.H. (2021). Violent victimization of sexual minorities: A clearer lens on a wicked problem, but solutions remain obscured. American Journal of Public Health, 111(2), 190-192. Retrieved from https://www.proquest.com/scholarly-journals/violent-victimization-sexual-minorities-clearer/docview/2486203406/se-2?accountid=211160

In this issue of AJPH, Bender and Lauritsen (p. 318) use the National Crime Victimization Survey (NCVS) since it began including sexual orientation and gender identity data in 2017 to detail sobering findings about violence endured by sexual minorities in the United States. For example, compared with heterosexual women, gay and bisexual men and lesbian and bisexual women all had greater odds-ranging from 90% to 261% increased odds-of reporting violent victimization in the last six months, including serious crimes like sexual and physical assault. Such a clear, nationally representative picture of how the wicked problem of violence disproportionately burdens sexual minority communities has, heretofore, been largely elusive, although the study results are not entirely surprising.

Galea, Sandro,M.D., DrP.H., & Vaughan, Roger,D.R.P.H., M.S. (2021). The public health penalty of attending to the proximal. American Journal of Public Health, 111(2), 193-194. Retrieved from https://www.proquest.com/scholarly-journals/public-health-penalty-attending-proximal/docview/2486203404/se-2?accountid=211160

Four years ago, we stated in this same column that we were "on the cusp of a new administration in the United States," and we predicted, "In the coming four years, our social divides and health divides both will deepen, unfortunately reinforcing each other."1(p203) That has sadly been the case. Today, we are again on the cusp of a new presidential administration with the hope that we can begin the work of healing those divides and resulting inequities. In this context, the work of public health has never been more important. We are in the middle of a global pandemic, and public health is at the heart of the national conversation as perhaps never before. This moment has taught the world that our collective health is fragile and that we are vulnerable unless we build the structures that create a healthier world. As we aspire to do so, we have an unprecedented opportunity to illuminate the core concepts that inform how we do what we do and why we, and the world, should approach the task of public health in a particular way. In last month's perspective,2 we discussed the role of prevention and how a critical way forward will be to embed the ethos of prevention into all that we do and to move beyond an approach that is reactive to one that aims to anticipate and mitigate adverse health. Considering prevention, then, to be why we should act, we now focus on how we should act. If we consider maintaining good health and preventing sickness important core values for public health, how do we best achieve that?

Canada, K. E., PhD. (2021). Behavioral health services following release from jail: A widening racial disparity gap. American Journal of Public Health, 111(2), 178-179. Retrieved from https://www.proquest.com/scholarly-journals/behavioral-health-services-following-release-jail/docview/2486203366/se-2?accountid=211160

Despite growing public awareness and bipartisan political support for policy change, the United States continues to incarcerate more people than any other country. Incarceration, whether short or long term, can have devastating health, mental health, social, and financial consequences for individuals, families, and entire communities. In 2018, 10.7 million people entered jail.1 Although this was a roughly 11% decline compared with the previous 10-year trend, we continue to house an average of nearly 740 000 people in jails every day. Black and Native people continue to be grossly overrepresented in jails at 592 and 401, respectively, per 100000 people compared with White people, who are incarcerated at a rate of 187 per 100 000.1

Francis, Leslie P,J.D., PhD. (2021). Understanding the ethics of natural experiments in a pandemic. American Journal of Public Health, 111(2), 212-214. Retrieved from https://www.proquest.com/scholarly-journals/understanding-ethics-natural-experiments-pandemic/docview/2486203295/se-2?accountid=211160

Pandemics invite natural experiments: testing hypotheses by observing the effects of interventions without manipulating exposure to the intervention.1 With novel infections like COVID-19 that spread rapidly and widely, knowledge gaps may be extensive. Quick action may be necessary and randomized trials impracticable if not downright impossible. But what can justify such interventions ethically, given that they are in some sense widescale experiments on unaware members of the public who have no opportunity to choose not to participate? And what ethical limits to them should there be?

Bowen, A. G., B.A., Tessler, Robert A,M.D., M.P.H., Bowen, Deirdre,J.D., PhD., Haviland, Miriam J,PhD., M.S.P.H., Rowhani-Rahbar, A., & Rivara, Frederick P,M.D., M.P.H. (2021). Relation of driving under the influence laws to access to firearms across US states. American Journal of Public Health, 111(2), 253-258. doi:https://doi.org/10.2105/AJPH.2020.305995

Objectives. To determine differences among US states in how driving under the influence of alcohol (DUI) laws activate federal firearm possession and purchase prohibitions. Methods. We performed primary legislative research to characterize DUI laws in each state. The primary outcome was the number of DUI convictions an individual must be convicted ofin each state to activate the federal firearm possession and purchase prohibition. We also determined the time interval in which previous DUI convictions count for future proceedings. Results. Forty-seven states had DUI laws that activated the federal prohibition of firearm possession and purchase for a threshold number of repeated DUIs. Variation exists among states in the number of convictions (1 -4) and length of liability period (5 years-lifetime) required to prohibit firearm possession and purchase. Conclusions. Variation in state laws on DUI results in differences in determining who is federally prohibited from possessing and purchasing firearms. Future research should explore whether these federal prohibitions arising from DUI convictions are enforced and whether an association exists between stricter DUI policies and reduction in firearm crimes, injuries, and deaths. (AmJ Public Health. 2021;111:253-258. https://doi.org/10.2105/AJPH.2020.305995)

Hall, M. A., J.D., Mann-Jackson, L., & Rhodes, S. D., PhD. (2021). State preemption of local immigration "sanctuary" policies: Legal considerations. American Journal of Public Health, 111(2), 259-264. doi:https://doi.org/10.2105/AJPH.2020.306018)

States have enacted a wave of statutes over the past several years preempting local government law and policies that potentially promote public health in various ways. Among these local preemption measures are statutes in at least 9 states that outlaw municipal policies providing some form of "sanctuary" to immigrants. Such policies, and their preemption, have importance both for direct access to health services and for broader social determinants of health. This article gauges the coverage and potential impact of these state preemption laws based on key informant interviews nationally and a close legal analysis of relevant laws and policy documents. It distinguishes between preemption laws focused on law enforcement cooperation and those that also encompass a wider array of "welcoming" policies and initiatives. It also distinguishes between more passive forms of preemption that prohibit barring cooperation with federal immigration forcement, and statutes that more affirmatively require active measures to assist federal enforcement. Drawing these distinctions can help municipalities determine which immigrant-supportive measures are still permitted, and how best to mitigate the adverse public health effects of these preemption laws. (Am J Public Health. 2021;111:259-264. https://doi.org/10.2105/AJPH.2020.306018) As

King, J., PhD., Goldenberg, D., PhD., Goldstein, G., PhD., Hartung, W., PhD., Royer, C., PhD., Sundberg, E., PhD., . . . Roberts, R., PhD. (2021). Congressional budget responses to the pandemic: Fund health care, not warfare. American Journal of Public Health, 111(2), 200-201. Retrieved from https://www.proquest.com/scholarly-journals/congressional-budget-responses-pandemic-fund/docview/2486203270/se-2?accountid=211160

The coronavirus outbreak is not the first crisis to affect a large swath of the nation's population: the Great Depression, World War II, and the HIV epidemic did so previously. Of the national responses to each of these examples, perhaps the most relevant would be the Manhattan Project model, as proposed by Senator Edward J. Markey (D, MA) and Peter L. Slavin, MD, of Mass General Hospital.1 In 1943 the government diverted tens of billions of dollars from civilian programs to the project to build the atomic bomb. What the COVID19 pandemic requires is the reverse: the diversion of a substantial chunk of the more than $700 billion appropriated for the Pentagon's military budget to the biomedical, public health programs desperately needed to limit the current coronavirus outbreak and prevent future pandemics. Congress needs to recognize the actual challenges to our national security and thereby sustain our people's health and promote a prosperous and just economy. We are not in danger of being invaded by Russians, Chinese, Venezuelans, or Iranians; we are in danger of having the fabric of our society undermined by our failure to invest in and protect our national health and welfare. In the scientific and medical communities, we know that the path to solving problems is investing in a focused effort. We can make quite a long list of successes that followed from concentrated federal investment: the Manhattan Project, radar development during World War II, the national interstate highway system, landing on the moon, sequencing the human genome, and developing HIV therapies, to name a few.By contrast to the these successes, failure to invest prevents solving national problems.