

PERSPECTIVE

Balancing the Rights to Protection and Participation: A Call for Expanded Access to Ethically Conducted Correctional Health Research

Cyrus Ahalt, MPP¹, Craig Haney, PhD, JD², Stuart Kinner, PhD^{3,4,5,6,7}, and Brie Williams, MD, MS¹

¹Department of Medicine, Division of Geriatrics, University of California, San Francisco, San Francisco, CA, USA; ²Psychology Department, University of California, Santa Cruz, Santa Cruz, CA, USA; ³Centre for Adolescent Health, Murdoch Children's Research Institute, Melbourne, Australia; ⁴Melbourne School of Population and Global Health, University of Melbourne, Parkville, Australia; ⁵Griffith Criminology Institute, Griffith University, Nathan, Australia; ⁶Mater Research Institute, University of Queensland, Brisbane, Australia; ⁷School of Public Health and Preventive Medicine, Monash University, Clayton, Australia.

Incarcerated individuals, over 95% of whom are eventually released, experience high burdens of chronic disease and behavioral health and social risk factors. Understanding the health needs of this population is critical to ensuring that general medicine physicians in prisons and in the community are adequately prepared to meet those needs. However, people in prison are significantly underrepresented in health research. In response to historical exploitation of prisoners in medical experimentation, federal guidelines appropriately require additional oversight for, and limit the scope of, research in prisons. Yet, according to a 2006 Institute of Medicine report, these requirements have produced inconsistent local regulations that often limit opportunities for incarcerated individuals to participate in research, and can slow the development of innovative medical interventions to improve their health. In this article, we describe the historical context surrounding regulations on research involving individuals in prison, the harms that can arise from excessive limitations to research in such settings, and the benefits of greater access to ethically conducted research in prison. We conclude with recommended actions that can be taken by general medicine researchers, correctional leaders, and policymakers to achieve consistent access to health research for incarcerated populations.

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Incarceration has affected tens of millions of Americans in recent decades,^{1, 2} particularly black and Latino men in communities with poor access to health care.³ The impact of health disparities among the incarcerated, and the quality of

the health care they receive, extends into the community, with implications for general medicine practitioners. For example, individuals who experience incarceration have disproportionately high rates of chronic disease, mental illness, and substance use disorders,^{4, 5} which directly affect community health systems, since over 95% of prisoners are eventually released.^{6, 7} Poor health among incarcerated individuals also adversely affects the health of their families: their children, spouses, and parents.^{8, 9} For these reasons, experts and policymakers consider mass incarceration a public health crisis.^{10, 11} Yet people in prison are profoundly underrepresented in health research, limiting the development of evidence-based health interventions for this population.^{12, 13}

With a growing criminal justice reform movement at state and local levels, correctional health research has become even more urgent. This is because many criminal justice reform measures have an impact on health care delivery, including, for example, policies to reduce the use of incarceration in response to substance use disorders and mental illness, and others (e.g., sentencing, parole, and bail reforms) aimed at shifting large populations from correctional health care systems to the care of general medicine practitioners in community health care systems. Patients transitioning from incarceration to community settings are at high risk for adverse health outcomes, including poor chronic disease management, inadvertent discontinuation of medications for serious mental illness, substance use relapse, and death.^{14–16} As a result, criminal justice reforms should be informed by knowledge about the health and social needs of the incarcerated; however, that evidence is markedly underdeveloped.^{12, 17, 18}

The research gap in correctional settings exists in the context of appropriately stringent safeguards protecting incarcerated people from exploitation. Following a history of degrading and harmful research in U.S. prisons, the federal government responded by classifying prisoners as a “vulnerable population” in need of additional protections in order to participate in research.¹⁹ However, the federal guidelines that followed resulted in some local regulations that restricted the right of incarcerated individuals to participate voluntarily in ethical research designed to benefit them.²⁰ This manuscript offers

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recommendations for steps that can be taken by general medicine researchers and clinicians, correctional leaders, and policymakers to support expanded access to ethically conducted correctional health research designed to improve the health of currently and formerly incarcerated patients.

BACKGROUND TO CORRECTIONAL HEALTH RESEARCH IN THE U.S.

Stringent protections for incarcerated individuals participating in research are well-founded, rooted in a history of exploitation.²¹ Following World War II, attorneys defending Nazis asserted equivalence between Nazi medical experiments on prisoners and common practice in U.S. correctional facilities. This unexpected line of defense led to an independent review of health research conducted in U.S. prisons. The results, published in the *Journal of the American Medical Association*,²² described dangerous drug experimentation in an Illinois state prison as “ideal,”²³ establishing a low bar for ethical correctional health research.

A boom in poorly regulated, risky, and exploitative medical research with prisoners followed.²⁴ But reform was ultimately spurred by revelations regarding the unethical Tuskegee syphilis study—conducted with 600 non-incarcerated African Americans to study the devastating effects of untreated syphilis.²⁵ In response, Congress established a national commission to develop guidelines for research with vulnerable subjects, including prisoners.²⁶ Three years later, under the sponsorship of the Department of Health, Education, and Welfare (DHEW Report), the commission issued DHEW Report Publication No. 76-131, *Report and Recommendations: Research Involving Prisoners* (the DHEW Report).²⁷

The DHEW Report distinguished three types of medical research being conducted with prisoners (Box 1), and raised concerns about the first, which the authors termed “biomedical research.” The commission recommended that prisoners “receive a fair share of the benefits of research,” and supported, with additional ethical safeguards, research designed to improve prisoners’ health and/or investigate the causes and effects of incarceration. These recommendations were integrated into the 1979 Belmont Report, ultimately leading to the 1991 Federal Policy for the Protection of Human Subjects. Today, this “Common Rule” is codified into law providing ethical guidelines for research on human subjects and requiring additional protections for research involving prisoners.^{28, 29}

Box 1 The Three Types of Research Conducted in Prisons According to the DHEW Report Report

1. “Biomedical research” including the development of new treatments via phase 1 drug testing.
2. Research with the “intent and reasonable probability” of improving prisoner health.
3. Research investigating the causes, effects, and processes of incarceration.

(continued on next page)

Box 1. (continued)

The DHEW Report recommended excluding category 1 research from correctional settings. Categories 2 and 3 were used in the development of federal guidelines to describe permissible research with people in prison.

As the Common Rule emerged, researchers were also acknowledging that restrictions on research participation for specific populations could produce unintended health inequities.³⁰ The AIDS epidemic, for example, brought renewed attention to the DHEW Report Report’s “fair share of the benefits of research.”³¹ Politicized patients and advocates asserted their right to participate in early-stage trials for potentially life-saving—but experimental and high-risk—drugs.^{32, 33} Women’s health advocates also argued that women were unfairly excluded from clinical trials, and successfully pressed the National Institutes of Health (NIH) to adopt new rules for the inclusion of women and minorities in research.³⁴ Today, researchers prioritize participatory research to improve the health of vulnerable populations³⁵ and recognize voluntary and informed participation in research as a right, even when it poses some risk to health or confidentiality.³²

Federal protections for prisoners are narrow. They define “prisoners,” mandate a special institutional review board composition for prisoner research, and require that correctional research potentially benefit prisoners as a class. These additional safeguards are appropriate and essential to protecting prisoners from exploitation and harm. However, additional regulations aiming to meet this higher standard of protection have proliferated in some states and institutions. These local regulations, though well-intended, can infringe on incarcerated individuals’ right to voluntarily participate in research, limiting the growth and spread of knowledge needed to improve medical practice and policy for this population.^{12, 13, 18}

IMPLICATIONS OF STATE AND INSTITUTIONAL VARIATION IN CORRECTIONAL HEALTH RESEARCH REGULATION

In 2006, the Institute of Medicine (IOM) issued a landmark report describing the dearth of correctional health research and calling for more research “to facilitate prisoners’ successful reentry into society... and inform policy makers about the most humane and effective strategies for the operation of correctional systems.”²⁰ The report attributed some of the research gap to varying regulations, either in state law or Department of Corrections (DOC) policy, concluding that such “policies may preclude potential remedies ... to ensure equitable research participation by prisoners.”²⁰

In this context, many DOCs rely on their own expertise, research infrastructure, and funding to conduct quality improvement research, adapt community-based innovative health care models to the correctional setting, and evaluate whether they are meeting their constitutional obligation to provide community standard care. Asking that DOCs alone

perform these critical duties alongside their core responsibilities as correctional agencies may represent a conflict of interest and could produce biased results. Yet in our 2015 review of all criminal justice-related health research funding awarded by the NIH from 2008 to 2012, we reported that just 90 health research grants were awarded to projects undertaken by independent researchers in partnership with state DOCs or local jails.¹⁸ The lack of such partnerships prevents whatever knowledge is generated within DOCs from reaching physicians in the community who will ultimately care for the more than 95% of these patients who are released.

In unpublished analyses from our 2015 review, we also found that no NIH funding over this 5-year time frame was granted to research conducted in partnership with California prisons, which house nearly 10% of all U.S. prisoners. In contrast, the Rhode Island DOC, with a prison population approximately 1% of California's, partnered with outside researchers for 13 NIH grants totaling more than \$16 million. This funding disparity reflects a significant difference in regulation between the two states. In California, correctional research is restricted by provisions of the penal code passed in 1977 following the DHEW Report Report. The code defines "biomedical research" as any "research relating to or involving biological, medical, or physical science," encompassing most if not all health research, and states that "biomedical research shall not be conducted on any prisoner in this state." Conversely, Rhode Island has no state laws limiting research with people in prison. Its DOC requires strict adherence to federal guidelines for ethical research with prisoners without imposing categorical research exclusions. Their extramural research approval policy is publically available, transparent, and streamlined.³⁶ Rhode Island's approach has produced partnerships with independent researchers that have led, for example, to the development of correctional care models that link patients in prison to community health care upon release, and evidence-based strategies to interrupt the costly cycle of repeat incarceration for medically vulnerable populations.³⁷⁻³⁹ In the process, they have developed innovative programming to combat the opioid crisis.⁴⁰⁻⁴²

In an effort to expand evidence-based correctional health care in their state, California policymakers recently passed a law specifying that the ban on biomedical research in prisons does not include the use of "statistical data in the assessment of the effectiveness of non-experimental public health programs or treatment programs in which inmates routinely participate."⁴³ This law opens up a wealth of secondary health data for researchers. However, California continues to prohibit the enrollment of individuals in clinical and outcomes research, effectively excluding patient perspectives from research and undermining efforts to improve patient-centered care for these medically vulnerable Californians. For example, California medical parole laws allow for the early release of incarcerated individuals with serious health care needs, yet such releases are rare.⁴⁴ Research describing the prevalence of

serious illness, advance care planning needs, and trajectories of cognitive and functional decline among incarcerated older adults could be used to help the state make better use of its existing laws. Such research would benefit California taxpayers, who bear the costs of care for incarcerated patients with serious illness that would be lower in community settings, while optimizing care for seriously ill people in prison who are not released. Such research cannot be conducted using secondary data alone.

A NATIONAL REMEDY

Protecting people in prison from exploitation and harm is critical from a medical ethics perspective. But failure to include this population in ethically conducted research designed to address the health risks that disproportionately affect them also has ethical implications. For example, a recent report by the Massachusetts state legislature found that the risk of opioid overdose death among recently incarcerated adults was 120-fold that among the general population, and that the majority of such deaths occurred in the first month following release from jail or prison.⁴⁵ Participatory research with incarcerated people is needed if community-based health practitioners are to understand and respond to the unique factors underlying this extreme disparity in behavioral health-related mortality risk. The relative lack of such research recalls the circumstances that led to the ethically motivated movement to expand access to research for people living with HIV in the early years of the AIDS epidemic.³³ Today, participatory research is standard practice in the community, as patient perspectives are recognized as essential to developing efficient and effective health policies, programs, and strategies of care. Ensuring that people in prison have similar access to research should be regarded as an ethical imperative by health researchers, practitioners, and policymakers.

Consistent access to ethically conducted health research for incarcerated individuals would provide general medicine practitioners with the knowledge needed to implement evidence-based transitional care interventions and to provide effective chronic disease management, mental health care, and substance use disorder treatment to this unique, high-risk patient population. The expansion of such research could also yield measurable public benefits, including reduced recidivism,⁴⁶ improved family and community health,⁴⁷ and a more judicious use of public funds,¹⁷ \$12.3 billion of which is currently spent on prison health care each year.⁴⁸

There are specific steps that general medicine researchers and practitioners, correctional leaders, and policymakers could take to address the research gap in U.S. jails and prisons (Box 2). For example, researchers could engage with correctional institutions to address their research needs, correctional leaders could adapt their policies to reflect the 2006 IOM report guidelines, and policymakers could convene

multidisciplinary stakeholder reviews of correctional research regulations. As the nation grapples with its failed experiment in mass incarceration and that experiment's complex public health legacy, ethically conducted research across our nation's many diverse systems of justice will be essential to improving the health and health-related outcomes of current and former prisoners, their families, and their communities. We should not deny willing individuals the right to participate in that effort.

Box 2 Recommendations to Expand Access to Participation in Research for Incarcerated Individuals

Health Researchers

- Engage correctional institutions and agencies to understand research needs.
- Consider incorporating criminal justice-involved individuals and/or questions about criminal justice history in current research.
- Engage individuals who are recently released from jail or prison in existing and new community-based research projects to better understand the needs of this population.
- Understand IOM guidelines for ethical research with people in prison.

Correctional Leaders

- Eliminate restrictions on ethically conducted primary research that falls within the scope of permissible research under Subpart C of the federal guidelines.
- Develop a list of research priorities and areas of need for outside expertise.
- Partner with outside researchers to develop and fund quality improvement research.
- Understand IOM guidelines for ethical research with people in prison.

Policy makers

- Review existing laws and state government regulations to identify legal restrictions on incarcerated individuals' right to participate in research.
- Convene stakeholders for a policy review (e.g. health researchers, correctional leaders, affected individuals, and community members) and research agenda setting, including agencies that provide services to individuals following release from jail or prison.
- Consider administrative and legislative remedies as needed.

Corresponding Author: Brie Williams, MD, MS; Department of Medicine, Division of Geriatrics/University of California, San Francisco, San Francisco, CA, USA (e-mail: brie.williams@ucsf.edu).

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