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Ethical and Social Issues in Health Research Involving Incarcerated People

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Abstract

The use of inmates in research in the U.S. was restricted by the recommendations of the National Commission and by federal regulations and guidelines that followed. By the 1980s, many health care officials became concerned about the exclusion of inmates from experimental treatments for human immunodeficiency virus infection (HIV). These developments in ethics occurred in the context of racial/ethnic disparities in health. In this article, ethical considerations in clinical and public health research on HIV in prison and jail settings are considered. Ethical considerations in mental health research are summarized as well as issues pertaining to research involving female inmates. Issues related to oversight of research involving incarcerated people are considered along with the ethics of public health research. The ethics of research involving incarcerated people extends beyond traditional issues in human subjects ethics to include issues within the domains of bioethics and public health ethics.

Keywords

African Americans; bioethics; clinical research; health status disparities; Hispanics; human immunodeficiency virus; human subjects research; public health; research ethics; women

Historically, in the U.S., inmates (often referred to as *prisoners* in the bioethics literature) served as an inexpensive and readily available source of human subjects for medical research.¹ Examples from history include infection with plague, without their knowledge, of inmates sentenced to death and the induction of pellagra by deprivation of niacin in 12 inmates in Mississippi in return for their parole.^{2,3} During World War II, over 400 inmates were infected with malaria to test the safety and efficacy of new drugs for the treatment of the disease.² Shortly after World War II, the Nuremberg Tribunals brought to the attention of

the world the potential for abuse in conducting research on human subjects including inmates. By the 1960s and early 1970s, there was increasing concern about inmates' rights and about the potential for coercion and exploitation in medical research involving incarcerated people. The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research was charged with investigating the use of inmates as research subjects.⁴ Their recommendations, U.S. federal regulations 45 CFR sec. 46, and guidelines that followed, which were intended to protect inmates from the abuses of the past, restricted the use of incarcerated people as research subjects. The federal regulations were amended in 1983 to include special provisions for research on inmates (Subpart C, 45 CFR, sec. 48.301-46.306) and safeguards to address the constraints under which inmates live because their incarceration affects their ability to make a voluntary and un-coerced decision about whether or not to participate in human subjects research. By the mid-1970s, eight states had outlawed the use of inmates as research subjects and, in March 1976, the Bureau of Prison's forbade the use of federal inmates in medical experimentation.³

Following the 1970 declaration of war on illicit drug use, the incarcerated population in the U.S. increased to unprecedented numbers.⁵ Bureau of Justice Statistics data indicate that currently the U.S. has the highest incarceration rate in the world by a large margin.⁶ Over the past several decades, African Americans and Hispanics have been incarcerated at much higher rates than Whites. Over 60% of the U.S. incarcerated population are people of color. African Americans are incarcerated six times more often than Whites, and Hispanics 2.4 times more often than Whites.⁷ The distribution of incarcerated people by both race/ethnicity and age also differs significantly from the general U.S. population. Although men constitute the largest proportion of incarcerated people, incarceration rates among women have increased.

By the 1980s, there was a need to address public health problems in prisons and jails and health care officials became concerned about the exclusion of inmates from experimental treatments for human immunodeficiency virus infection and acquired immune deficiency syndrome (HIV/AIDS). Since that time, ethicists, legal scholars, and expert panels have considered whether the vulnerability of inmates due to their incarceration suffices to prohibit them from participation in clinical trials that offer the possibility of life-saving treatment.^{1,8} In recent decades, several legal cases, expert panel reports, and other developments support the view that inmates should be allowed to participate in clinical trials.⁹ The Institute of Medicine Committee on Ethical Considerations for Revisions to the Department of Health and Human Services Regulations for Protection of Prisoners Involved in Research recommended both further protections and a modified approach to review of research that would provide inmates with greater access to potentially beneficial research.¹⁰ The committee recommended a risk-benefit analysis that would permit clinical studies involving more than minimal risk, provided the research was on practices that have the intent and reasonable probability of improving the health or well-being of the research participants.¹⁰ These important developments in the ethics of human subjects occurred in the context of the substantial racial and ethnic disparities that exist in incarcerated populations in the U.S.

In this article, ethical issues in health research involving incarcerated people are discussed. First, ethical considerations in clinical and public health research on HIV/AIDS in prison

and jail settings are considered. Ethical considerations in mental health research are summarized, and issues pertaining to research involving female inmates are covered. Issues related to institutional review board (IRB) oversight of research involving incarcerated people are discussed and, the ethics of public health research in correctional systems is considered. An argument is made that the ethics of research involving incarcerated people extends beyond traditional issues in human subjects ethics to include issues within the domains of bioethics and public health ethics. Finally, key topics are summarized and recommendations are offered.

Research on HIV/AIDS in Prison and Jail Settings

The progression of the HIV epidemic increased the importance of people from underserved populations to have the opportunity to participate in clinical trials.³ A substantial proportion of people living with HIV or at risk for the infection, including those with substance use and mental health disorders are incarcerated. Because the prevalence of HIV/AIDS is higher among incarcerated people than in the general population, correctional facilities can be sites for conducting HIV/AIDS epidemiological and intervention research.⁹ However, the ethical and regulatory challenges that exist in correctional settings have sometimes limited the extent and scope of research.^{3,11} The conditions necessary to conduct ethical research in prisons include updated state policies, refined IRB guidelines, and cooperation between prison systems and researchers to expand access to clinical trials.^{8,9} Potential obstacles to enrolling prisoners in HIV clinical trials include the need for accurate and complete medical records, the need for dispensing investigational drugs and avoiding sharing of medications, adequate record keeping and documentation requirements, and the need for follow-up appointments.³ There may be difficulties in identifying the primary care provider at a prison to facilitate care of patients on study and inter-institutional transfers or parole may affect continuity of care. Restrictions in research participation can also occur due to security issues (e.g., transportation, officer escorts, etc.) or protocol requirements (e.g., laboratory work).

In view of the overlapping epidemics of incarceration and HIV, there is a need for academic medical centers to collaborate with the criminal justice system to improve the health of incarcerated populations.⁹ With coordinated collaboration and new programmatic initiatives, it is possible to reduce HIV-associated risk behaviors and the likelihood of acquisition and transmission of HIV in prison settings. The Centers for AIDS Research (CFAR), funded by the National Institutes of Health, responded to this need through a program, Collaboration on HIV in Corrections (CHIC), which has a goal of improving the diagnosis, treatment, linkage to care, and prevention of HIV. This collaboration serves as a model for aligning academic expertise with criminal justice to address HIV among inmates and formerly incarcerated people. In the US, prisoners are entitled to receive health care by constitutional mandate. In *Estelle v. Gamble*, 429 U.S. 97 (1976), the U.S. Supreme Court ruled that to place people in prison or jail, where they could not secure their own care, and then to fail to provide that care, could result in pain and suffering prohibited by the Eighth Amendment to the Constitution.

Collins et al.¹² conducted a telephone survey of medical directors of departments of corrections in 32 states in order to identify their policies concerning inmate participation in

research studies and state policies and practices relating to inmate access to HIV-related clinical studies and experimental therapies. The results indicated that state policies governing inmate participation in clinical trials and access to new therapies varied widely. States with high HIV/AIDS incidence rates, a large number of AIDS-related deaths in prison, and high concentrations of minorities in the correctional system were more likely to allow inmates to enroll in clinical studies and to receive experimental medications. Overall, however, a relatively small number of inmates in state prisons had enrolled in clinical studies. The authors identified participation of a prison representative on the board reviewing a clinical study as an important factor in allowing inmate participation in studies.¹²

Research on Mental Health in Prison and Jail Settings

Health disparities in the U.S., including racial and ethnic differences in mental illness, are driven by complex societal problems, such as alcohol and drug abuse, lack of access to health services, poverty, racism, and stigma. Although estimates range widely, the prevalence of mental illness and substance abuse disorders is higher among incarcerated people than in the general population.¹³ A sizeable percentage of inmates are diagnosed with a substance use disorder.¹⁴ Many inmates have both a substance abuse disorder and a comorbid mental health disorder, although prevalence estimates have ranged widely.¹⁴ Inmates have a suicide rate much higher than the general population.¹⁵

Clinical and public health research addressing these topics must strike an appropriate balance between safeguarding inmates (e.g., by protecting their privacy and confidentiality, minimizing potential harms and risks, providing potential benefits, and obtaining their informed consent) and permitting their participation. Christopher et al.¹⁶ provided an agenda that should be undertaken for empirical studies to understand ethical issues in mental health research involving inmates, including studies of the decisional capacity of incarcerated research participants who may be mentally ill or suffering from medical illnesses that affect decision making; possible coercive influences (e.g., financial compensation or favorable treatment from prison authorities in return for taking part in a study); therapeutic misconception (i.e., viewing research as treatment despite the important difference between medical care and clinical research); and IRB oversight.

Research on the Health of Incarcerated Women

Although incarcerated women often have important and gender-specific health issues and concerns, relatively little clinical or public health research has focused on female inmates. Conducting research on the health concerns of incarcerated women can pose unique challenges and ethical dilemmas.¹⁷ One potential approach for addressing such challenges is community-based participatory research, in which members of the target population, organizational representatives, and academic researchers participate in all phases of the research process including assessment and definition of the problem; selection of research methods; data collection, analysis, and interpretation; and dissemination of findings. Community-based participatory research helps to minimize problems, such as the stigmatization of communities due to the release of sensitive data by researchers without prior consultation, communities feeling further marginalized by research, or researchers

advancing their academic careers at the expense of community members who may be left feeling over-researched or misled.¹⁸ The inclusion of community members in the research team as partners helps to protect the target population from harm and exploitation.¹⁹ Martin et al.²⁰ engaged incarcerated women in a study involving community-based participatory research. Female inmates, correctional center staff, and academic researchers participated collaboratively. The study, in Canada, was accomplished in a short-sentence (two years or less), minimum/medium-security women's correctional center. In-depth interviews were conducted with 16 incarcerated women and, in-depth group interviews were facilitated with 16 correctional center staff.²⁰ In an extension of the study, up to 15 women worked each day as prison research team members; between November 2005 and August 2007, a total of 190 women participated at some time in the project.²¹ The researchers used an ethnographic multi-method approach for data collection and analysis. Quantitative data were collected by in-depth interviews, audio recordings, written archives of research team discussions, forums, debriefings, and presentations. These data and ethnographic observations were transcribed and analyzed using NVivo 7 software for interpreting qualitative data.²¹ The themes that emerged from content analysis of the data converged into five major categories: addiction and mental health; HIV, hepatitis, and other infections; health care in prison; life skills and re-entry into society (including homelessness and housing); and children, family, and relationships.²¹ In this way, ideas for health interventions and participatory projects, each relating to one of the five major themes were derived. The study provided incarcerated peer researchers (incarcerated women) with opportunities to develop leadership and technical skills.

Public Health Research, Practice, and Ethics

Those who enter and leave prisons and jails in the U.S. are increasingly African American, Hispanic, poorly educated, lacking in vocational skills, and struggling with drugs and alcohol or with mental health problems.^{22,23} Incarceration rates are much higher for minorities than for Whites.⁵ These trends have consequences for public health, especially for communities that have racial and ethnic disparities in health. Prisons and jails include relatively high numbers of people who are living with HIV/AIDS and/or hepatitis C and individuals who are at risk for these infections.⁹ These disparities affect both prisoners and the communities into which they are released.²² There is a need for additional multidisciplinary research on the health effects of incarceration and on ways to improve the health and well-being of incarcerated people before and after release. Several pathways by which jails and prisons affect health have been identified, including increased risk of infection, physical and sexual assault, and the quality and availability of medical and psychiatric care.²³ Correctional systems can indirectly affect health by influencing family structure; economic opportunities; and normative community values on sex, drugs, and interpersonal violence.¹⁵ Upon release, many formerly incarcerated people return to communities affected by inadequate housing and employment opportunities, poverty, and other structural problems, which can lead to economic dependence, social isolation, substance abuse, and other physical and mental health difficulties.²³

Public health studies of these complex issues can lead to the development of new interventions and policies that promote health and disease prevention. Identifying evidence-

based programs and interventions for improving the health of prisoners and developing effective partnerships between the criminal justice and public health systems are desirable goals.¹⁵ Rigorous studies are needed to identify programs that are most effective in linking inmates to services, reducing risk behaviors, and reintegrating former inmates into their communities.

Research on the impact of incarceration tends to focus on the sentenced individual and only occasionally on the children of incarcerated parents. The health consequences of incarceration may extend to other family members and friends left behind in the community. Krueger and De Loney⁵ used a community-based public health survey to assess how incarceration of a friend or family member was associated with physical and mental health status. The participants provided information in a county-wide telephone health interview. Controlling for demographic factors and health-related behaviors, individuals who knew someone who was recently incarcerated reported worse mental and physical health. African Americans were more likely to report knowing someone who was incarcerated and also felt closer to the incarcerated individuals.⁵ The degree of closeness felt with someone incarcerated correlated positively with worse physical health (Pearson $r = 0.14$; $p < .01$) and mental health (Pearson $r = 0.09$; $p < .05$). Thus, public health studies can provide information about the potential effects of incarceration on the people closest to those incarcerated.

Although the literature on ethical issues in research involving inmates focuses almost exclusively on the ethics of clinical research and human experimentation, it is necessary to consider public health ethics in assessing ethical and social aspects of research and evaluation projects focused on the health of prisoners, before or after their release, and on their family members.^{24–26} The relevance of public health ethics is discussed further later in this article.

Institutional Review Board Review

The purpose of IRBs is to ensure that studies involving human research participants are designed to conform to relevant ethical standards and that the rights and welfare of participants are protected.²⁶ Review by such committees ensures that studies have a favorable balance of potential benefits and risks, participants are selected equitably, and procedures for obtaining informed consent are adequate. In the U.S., federal regulations to protect human research subjects (45 CFR 46) have resulted in a complex IRB system. According to the United States federal regulations that govern all human subjects research supported by grants from Department of Health and Human Services, all IRBs that evaluate research involving prisoners must include in their membership at least one representative from the prison population with an appropriate background and experience to serve in that capacity (45 CFR sec. 46.304b).

Elderidge et al.²⁷ explored ethical challenges in the conduct and oversight of HIV/AIDS research in correctional settings by asking 92 researchers; IRB chairs, members, and inmate representatives; research ethicists; and prison administrators the following question: “If you had to pick the single most important ethical challenge to HIV/AIDS research with

incarcerated people, what would it be?" The key concerns included confidentiality and privacy; autonomy and informed consent; and justice and access when reviewing prison-related research protocols. Characteristics of people who are incarcerated, the nature of correctional institutions, and state and federal regulatory issues contributed to these challenges.²⁷ Kondo et al.²⁸ surveyed 760 HIV/AIDS researchers and IRB chairs, members, and inmate representatives to identify areas in which additional training might ameliorate these challenges. The most commonly identified training needs related to federal regulations, ethics (confidentiality, protection for participants/researchers, coercion, privacy, informed consent, and general ethics), and issues related to the environment. The latter included the culture of the correctional setting; general knowledge of correctional systems; and correctional environments, policies, and procedures. The authors noted that improving the availability of training on the challenges of conducting HIV/AIDS research in correctional settings is a step toward increasing research that could yield significant benefits to incarcerated individuals and to society as a whole.²⁸

Discussion

Scientifically rigorous clinical and public health research involving incarcerated people can potentially improve their health and well-being and inform correctional policy.¹⁶ Such research also has the potential to provide community benefits. Researchers undertaking studies of incarcerated people must navigate ethical issues in consultation with IRBs and correctional system officials. Health research involving incarcerated people raise ethical issues because of their vulnerability. Inmates are a particularly vulnerable population because of their limited autonomy, privacy, and access to many forms of medical care.¹⁰ Because of the potential for exploitation, they are afforded special protections under federal regulations. Most human subjects research involving inmates is limited to minimal-risk studies.¹⁶ The ethics of the research should extend to a consideration of sensitivity to how the lives of incarcerated people and those connected with them are affected for good or for ill. It should go beyond what is traditionally known as clinical research ethics and human subjects research ethics.

While it has long been recognized that the ethics of research involving incarcerated people include issues within the domains of bioethics and human subjects ethics, an increasing number of research and evaluation projects having to do with inmate health and well-being also lie within the domain of public health. Public health is primarily concerned with the health of the entire population, rather than the health of individuals, and emphasizes the promotion of health and the prevention of disease and disability and the collection of qualitative and quantitative health data.^{24,25} Public health also recognizes the multidimensional nature of health determinants and the complex interactions of biological, behavioral, social, and environmental factors in developing effective interventions.²⁴ Although the literature on ethical issues in research involving prisoners focuses almost exclusively on clinical research ethics and the ethics of human experimentation, it is appropriate to consider public health ethics in assessing the ethics of research and evaluation projects focused on the health of inmate, before or after their release, and their family members. Public health ethics, which can be defined as the identification, analysis, and resolution of ethical problems arising in public health practice and research, has domains

different from those of medical ethics.²⁸ Ethical concerns in public health often relate to the dual obligations of public health professionals to acquire and apply scientific knowledge aimed at restoring and protecting the public's health while respecting individual autonomy.^{26,28} Ethics in public health involves an interplay between protecting the welfare of the individual, as in medicine, and the public health goal of protecting the public welfare. Other ethical concerns in public health relate to the need to ensure a just distribution of public health resources.^{24,25} Public health ethics has a broad scope that includes ethical and social issues arising in health promotion and disease prevention, epidemiologic research, and public health practice.²⁶

A problem is that few national health datasets include information about incarcerated populations.²⁹ In view of the dramatic growth in the population of the criminal justice system and associated health care costs, the inclusion of questions related to incarceration in additional national health datasets could provide substantial data to researchers and policy makers. Ahalt et al.²⁹ reviewed 36 publically available national health datasets for their relevance to study the health of currently or formerly incarcerated people. The datasets were included in the Society of General Internal Medicine Dataset Compendium related to individual health. Although 12 (33%) datasets returned keyword matches, none could be used to study incarcerated people. Three (8%) could be used to evaluate the health of formerly incarcerated individuals, but only one dataset included multiple questions such as length of incarceration and age at incarceration. As identified by Ahalt et al.,²⁹ missed opportunities consisted of datasets that included current inmates but did not record their status; datasets that asked questions related to incarceration but did not specifically record a subject's status as formerly incarcerated; and longitudinal studies that dropped and/or failed to record people who became incarcerated during the study. Thus, changes to existing national health datasets could substantially expand the available data, including the recording of status for study participants who are incarcerated; recording subjects' history of incarceration when these data are already being collected; and expanding incarceration-related questions in studies that already record incarceration history.²⁹

In summary, ethical issues arise in health research involving incarcerated people. The ethics of such research extends beyond traditional issues in clinical research ethics and human subjects ethics to include issues within the domains of bioethics and public health ethics. Bioethics and public health ethics are well suited for analyzing ethical issues in research and practice activities involving vulnerable populations, especially when there are concerns about justice and the well-being of entire communities. In prison and jail settings, there is a need to consider ethical considerations in clinical and public health research on HIV/AIDS, mental health, substance abuse, and women's health. Institutional review boards (IRBs) help researchers to reach an appropriate balance between safeguarding inmates (e.g., by obtaining informed consent, minimizing potential harms and risks, and providing potential benefits) and permitting their participation.

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