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An Empirical Ethics Agenda for Psychiatric Research Involving Prisoners

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Abstract

In the past 30 years, the incarcerated population in the United States has more than quadrupled to 2.3 million adults. With an alarmingly high prevalence of mental illness, substance use, and other serious health conditions compounding their curtailed autonomy, prisoners constitute perhaps the nation's most disadvantaged group. Scientifically rigorous research involving prisoners holds the potential to inform and enlighten correctional policy and to improve their treatment. At the same time, prisoner research presents significant ethical challenges to investigators and institutional review boards (IRBs) alike, by subjecting participants to conditions that potentially undermine the validity of their informed consent. In 2006, the Institute of Medicine Committee on Ethical Considerations for Revisions to the Department of Health and Human Services (DHHS) Regulations for Protection of Prisoners Involved in Research recommended both further protections and a more permissive approach to research review that would allow inmates greater access to potentially beneficial research. These recommendations have sparked renewed debate about the ethical trade-offs inherent to prisoner research. In this article, the authors review the major justifications for research with prisoner subjects and the associated ethical concerns, and argue that the field of empirical ethics has much to offer to the debate. They then propose a framework for prioritizing future empirical ethics inquiry on this understudied topic.

Keywords

informed consent; mental disorders; prisoners; research ethics; research ethics committees; substance use disorders

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As participants in scientific research, prisoners (which, for the purposes of this article, include all individuals confined or detained in a penal institution) constitute a particularly vulnerable population. They experience severely limited autonomy (i.e., self-rule, freedom to follow one's own will), privacy, and access to many kinds of medical care, exposing them to a variety of forms of exploitation (i.e., use for unfair and selfish purposes). Prisoners are therefore afforded special protections under federal regulations, and federally funded research involving prisoners is largely limited to minimal-risk studies (U.S. Department of Health and Human Services [DHHS] 2005). Yet prisoners share disproportionate burdens of mental illness, substance use, and infectious disease, among other serious illnesses. Corrections-based clinical research holds the potential to improve the current health care of prisoners, and thereby to address the public health problems that are intimately bound to the correctional system, from addiction and trauma to HIV/AIDS. At the same time, such research must strike an appropriate balance between safeguarding inmates and permitting their participation.

In 2006, as described in detail later, the Institute of Medicine (IOM) was charged by the DHHS to evaluate existing federal regulations on prisoner research. The IOM made five recommendations offering greater oversight of prisoner research while permitting potentially more beneficial but higher risk research. As of this writing, however, none of these recommendations have been implemented. The reasons for this, although not entirely clear, may include the associated costs.

"Empirical ethics," which involves the use of empirical methodologies from the social and behavioral sciences to examine ethical issues, can sharpen our understanding of the potential ethical threats in prison research, help determine whether and how the IOM's proposed changes would alleviate or add to these threats, and guide investigators, policymakers, and institutional review boards (IRBs) in their collective efforts to ensure ethical research practice. This article describes the common justifications for conducting prisoner research, considers the key ethical concerns that arise, and proposes a research agenda for psychiatry to ensure that clinical research with prisoners advances in an ethically sound manner.

JUSTIFICATIONS FOR CONDUCTING PRISONER RESEARCH

Prisoners Constitute a Large, High-Risk Population

In 2009, roughly 2.3 million adults were incarcerated in jails and prisons in the United States (Glaze 2010), representing a more than fourfold increase over the preceding 30 years (Mumola 1999). Compared with the general public, inmates bear an alarmingly disproportionate burden of serious mental illness, substance use disorders, infectious diseases, and other major medical conditions (Baillargeon et al. 2000; Greifinger 2007; Okie 2007). Specifically, an estimated 70 to 80% of inmates are diagnosed with a substance use disorder (Karberg and James 2005; NCASA 1998) and 10 to 20% with a serious mental illness (Beck and Maruschak 2001; Steadman et al. 2009). Of those with serious mental illness, 75% also have a co-occurring substance use disorder (Karberg and Mumola 2006). Meanwhile, the prevalence of HIV is five times higher in state and federal correctional systems than in the general population (Maruschak 2008; Spaulding et al. 2002). Moreover, while inmates comprise only 0.8% of the U.S. population, an estimated 22 to 31% of

Americans with HIV, 40% with tuberculosis, and 29% to 43% with chronic hepatitis C pass through the correctional system each year (Hammett et al. 2002; Weinbaum et al. 2005). Thus, the sheer size and concentration of inmates with serious illnesses constitute a unique research opportunity for addressing the preventive and treatment needs of a large at-risk population.

Prison-Based Treatment Is Often Inadequate

Despite prisoners' constitutional right to health care recognized under the 8th Amendment because of their inability to pursue treatment on their own (Estelle v. Gamble 1976), correctional settings often fail to provide adequate care for mental health, substance use disorders, and other medical illnesses (Belenko and Peugh 2005; Clemmitt 2007; Human Rights Watch 2003; Wilper et al. 2009). Several scholars have pointed out that certain types of prisoner research would be unnecessary if correctional authorities provided access to treatments already accepted and widely available in the community (Gostin et al. 2007; Obasogie and Reiter 2011). Nevertheless, a number of factors collectively stymie the much-needed improvements to correctional health care. Some courts, for example, have ruled that prisons need only provide minimally acceptable treatments rather than the range of options accessible to the public (Lazzarini 2000).Moreover, providing medical services to a large, stigmatized, and ill population is both costly and unpopular (Fiscella et al. 2004).

One particularly alarming example that serves to highlight this issue is the treatment for opioid addiction. Continuing methadone during incarceration is rarely practiced (Nunn et al. 2009), despite the considerable suffering that follows its abrupt discontinuation and strong evidence that community-based methadone maintenance reduces HIV transmission, mortality, and criminal recidivism (Capelhorn and Ross 1995; Metzge et al. 1993; Newman et al. 1973). Instead, correctional facilities favor the "abstinence model," viewing methadone as the substitution of one addiction for another, and worrying that giving inmates access to opiates leads to behavioral and security problems (Nunn et al. 2009; Rich et al. 2005). However, emerging scientific research, such as a recent study demonstrating that continuing methadone during incarceration improves postrelease outcomes, including criminal recidivism (Magura et al. 2009), may help shift these restrictive practices.

Engagement and Retention in Treatment Are Often Poor

Persons with a history of involvement with the criminal justice system are a particularly difficult population to engage in care, and can demonstrate poor adherence to community-based treatment both before and after incarceration (Czuchry et al. 2006; Farabee and Leukefeld 2001). Indeed, many individuals have their first adult contact with health care while incarcerated (Hammett et al. 1998). In one study of more than 6,000 inmates in Massachusetts, 82% had never had a primary care provider (Conklin et al. 1998). Research on improving treatment engagement and adherence could consequently lead to better outcomes for the millions of underserved Americans in jails and prisons who might not otherwise receive services (Boutwell and Rich 2005; Boutwell et al. 2007). However, strategies used to engage patients in the community frequently fail when applied to inmates because of both external factors and internal ones (e.g., behavioral disinhibition or low internal motivation) (Andrews and Bonta 2006; Fishbein et al. 2009), suggesting that

alternative practices for incarcerated populations need to be developed and tested (Czuchry et al. 2006; Ko et al. 2010; Serin 2005).

Better Community Reintegration Is Needed

Inmates face a host of challenges upon reentry into society. Many of these, from obtaining housing, to reintegrating into families and communities and finding employment, compete with or take priority over seeking medical care (Petersilia 2003; Travis 2002). Indeed, in the two weeks after release, prisoners are at high risk for death from drug overdose, cardiovascular disease, homicide, and suicide (Binswanger et al. 2007). Furthermore, correctional systems typically fail to arrange for appropriate community services (Petersilia 2003). In many cases, this directly contributes to recidivism (Coviello et al. 2010). Evaluating prison-based efforts aimed at successful transition, treatment, and reintegration into the community are consequently a vital focus for correctional research (Bourgon and Armstrong 2005; Fredenberg et al. 2010; Scheyett et al. 2010; Wexler and Fletcher 2007).

ETHICAL ISSUES IN RESEARCH INVOLVING INCARCERATED SUBJECTS

Inmates constitute a vulnerable group with respect to research participation not only because of their health care vulnerabilities, but also because of restrictions on their liberty, autonomy, and privacy (Gostin et al. 2007). These limitations understandably threaten the validity of inmates' informed consent. It is worth reviewing briefly the history of how these concerns have been addressed over time.

A long history of research abuses against prisoners casts a shadow over any discussion of correctional research (Harkness 1996; Hornblum 1997; Lederer 1995; Welsome 1999). For many years, little consideration was given to prisoners' rights or research safeguards, but for many observers, from the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (hereafter, the National Commission) to civil rights groups, inmates involved in these studies were being coerced, exploited, or both (Mitford 1973; National Commission 1976). Prior to the 1970s, more than 80% of clinical trials of pharmaceutical drugs were conducted on prisoners, with financial support largely provided by the companies developing the drugs (Schroeder 1983). There was no established practice for the attenuation of investigator conflicts or even recognizable consent processes as practiced today. Risks and benefits were minimally if ever discussed, capacity and voluntariness were generally not assessed, and ongoing research review was almost nonexistent. According to the National Commission's research, most drug studies involving prisoners would qualify as phase I trials today (Levine 1986, 285). Prisoners were also subjects in nonclinical studies testing a range of toxins, from cosmetics, perfumes, and soaps, to dioxin, radioactive isotopes, and chemical warfare agents (National Commission 1976).

Against the backdrop of such exploitation and in the context of evolving ethical principles for human subjects research in general (e.g., the National Commission's Belmont Report) (Office of the Secretary 1979; Lerner 2007), the Department of Health and Human Services in 1976 enacted regulations that severely restricted federal funding of studies involving prisoners (National Commission 1976). These limitations—including the provision that such

research could pose no more than minimal risk—were driven in part by the belief that informed consent could not be provided by individuals whose autonomy was limited by their incarceration (Gostin et al. 2007). The strict DHHS guidelines, and a related landmark case against the Michigan Department of Mental Health (Kaimowitz v Michigan DMH 1973), had the effect of dramatically curtailing the amount of publicly funded clinical research conducted with incarcerated populations (Gostin et al. 2007; Hoffman 2000). For some diseases such as HIV, the new restrictions were responsible for nearly eliminating research altogether (Dubler and Sidel 1989). By the late 1990s, only 15% of institutions engaging in clinical research in the United States included prisoners in any of their research protocols (Hoffman 2000).

Within the past 10 years, a number of issues converged to prompt a review of the 1976 restrictions. First, the public health problems in correctional settings could no longer be ignored: Both the size of the incarcerated population and the concentration of serious illness within correctional settings demanded attention (Czuchry et al. 2006). Second, prisoners and prison advocacy groups began contesting restrictions on research participation, arguing that inmates wanted “access to, not protection from” protocols offering otherwise unavailable treatments (Gostin et al. 2007). Similarly, some scholars argued that prisoners have a right to participate in potentially advantageous or even lifesaving research—an extension of their constitutional right to health care (Gostin et al. 2007; Hoffman 2000; Thomas 2010). Nevertheless, as recently as 2000, prison research at four academic centers was suspended for further institutional review board (IRB) review after an unsubstantiated complaint was raised (during a site visit) at a conference on the ethical conduct of clinical trials involving prisoners (De Groot et al. 2001).

Thus, in 2004, DHHS appointed the Institute of Medicine (IOM) to revisit the ethical issues surrounding prisoner research. Mindful of past abuses and the continuing potential for exploitation, the committee nonetheless recognized the critical health problems within correctional settings and the potential benefits of scientific research. They recommended five broad changes to the 1976 regulations: (1) broadening the definition of “prisoner” to include anyone whose liberty is restricted by criminal justice involvement; (2) establishing universal guidelines for prisoner research and creating a public database of prison research studies to ensure consistently applied standards of protection; (3) updating the ethical framework to include collaborative responsibility whereby investigators seek input from prisoners and other stakeholders on the protocol design; (4) enhancing systematic oversight of all prison research; and (5) shifting from a categorical approach for determining study risk level, to a risk–benefit analysis. Under this final recommendation, clinical studies that involved more than minimal risk would be permitted, as long as such research was “on practices which have the intent and reasonable probability of improving the health or well-being of the subject” (Gostin et al. 2007, 80).

Notwithstanding these recommendations, the IOM committee cautioned against ignoring the barriers to “the prerequisites of ethical research, namely the acquisition of voluntary informed consent, protection of privacy, and access to adequate health care,” and warned that many prisoners may “still choose research participation as a desperate act to obtain treatment” (Gostin et al. 2007, 21).

AN EMPIRICAL ETHICS AGENDA FOR PRISONER RESEARCH

Although none of the recommendations of the IOM committee have yet been implemented, they have reinvigorated debate on prisoner research (Chwang 2010; Obasogie 2010; Obasogie and Reiter 2011; Thomas 2010). At present, this discussion is largely theoretical. This section outlines an agenda by which empirical ethics may further contribute to our understanding of these issues. We outline five specific areas of inquiry, review existing empirical data with prisoners for each, and suggest strategies for future study.

Decisional Capacity

Incarcerated participants in research studies may demonstrate mental illness, substance use disorders, or both, poor literacy, and other comorbid medical illnesses that affect decision making. Unique contextual issues from correctional settings may also affect decisional capacity, including the acute stress associated with incarceration, trauma during incarceration, desperation, substance intoxication or withdrawal, and stress associated with reentry into the community. Applying brief, established instruments like the MacArthur Competence Assessment Tool for Clinical Research (MacCAT-CR), a semistructured interview assessing four domains of decision-making capacity (Appelbaum et al. 1999), could determine the degree to which capacity is affected by these common stressors, and serve to exclude those incarcerated subjects who lack sufficient capacity from enrolling in studies.

In seminal work, Moser and colleagues (Moser et al. 2004) evaluated the decisional capacity among prison research subjects by comparing 30 mentally ill prisoners and 30 non-incarcerated healthy controls on their ability to provide informed consent to a hypothetical drug trial. Using the MacCAT-CR, they found that the mentally ill prisoners scored significantly lower than controls on the Understanding and Appreciation subscales, but not on Reasoning or Choice. However, as the authors point out, poor neuropsychological functioning was significantly associated with lower MacCAT-CR performance across the board; thus, it is not known whether non-mentally ill prisoners would demonstrate similar impairments. Further research in this area might clarify this matter by evaluating decisional capacity among inmates who are actively participating in different types of research studies, and comparing decision-making capacity between mentally ill and non-mentally ill prisoners.

Potentially Coercive Influences

Because of constraints on liberty and a history of past abuses, coercion is the most well-publicized and most discussed ethical issue in prisoner research (Gostin et al. 2007). In a strict sense, coercion exists when “one party intentionally and successfully influences another by presenting a credible threat of unwanted and avoidable harm so severe that the person is unable to resist acting to avoid it” (Faden et al. 1987, 339). However, various influences can motivate prisoners to participate in research: some directly coercive, others arising from undue influence or an inducement that may be inappropriate in an environment of restricted autonomy. Each merits attention. These influences include financial compensation (which in prison settings can yield significant benefits from small sums), the

hope of favorable treatment from prison authorities, insulation from prison violence, and the attraction of risk (McCarthy 1989).

Several instruments are available to measure perceptions of coercion in different contexts (Gardner et al. 1993; Iversen et al 2002; Klag et al. 2006), yet there is no standardized instrument for evaluating coercion among incarcerated research subjects. The MacArthur Perceived Coercion Scale (PCS) (Gardner et al. 1993), initially developed to assess coercion among individuals admitted to psychiatric hospitals, has been used in various clinical settings (Cusack et al 2010; Hiday et al. 1997; Poythress et al. 2002; Rain et al. 2003; Wild et al. 1998). To our knowledge, however, it has not been validated to measure perceptions among prisoners participating in research.

Nonetheless, the Moser study described earlier did measure prisoners' perceptions of coercion in a hypothetical study using the Iowa Coercion Questionnaire (ICQ) (Moser et al. 2004), a 20-item instrument adapted from the PCS. ICQ domains include whether subjects perceived having a choice, felt controlled, threatened, or forced into participating, or were motivated by other factors such as desire to appear cooperative, to avoid boredom, to obtain financial compensation, and to meet someone new. The incarcerated subjects were significantly more likely than non-incarcerated subjects to report their participation was motivated by a desire to appear cooperative, avoid boredom, meet someone new, and help others. The study authors identified these as "benign influences," compared with the survey items addressing more direct coercion (e.g., "Someone tried to force me to be in this study") for which no significant differences were found. Unfortunately, it is not known whether those who expressed a desire to appear cooperative also expected favorable treatment as a result of participating, or feared negative repercussions from not participating.

Another study examined three types of perceived coercion among 84 misdemeanor offenders participating in research on a drug court program: (1) concerns about the repercussions of refusing to participate; (2) pressures related to financial compensation; and (3) other pressures to participate (Dugosh et al. 2010). Subjects rated their level of agreement with eight survey items. Fewer than 5% of subjects rated the following items true or somewhat true: "I felt like I was talked into entering the study," "It was entirely my choice to enter the study" (reverse scored), and "I entered the study even though I did not want to." However, 14% agreed with the statement "I felt that I could not say no to entering the study." Moreover, 51% of subjects agreed with the statements "I felt the judge would like it if I entered the study" and "I felt that entering the study would help my court case," suggesting that some possibly coercive influences were present.

Ideally, an instrument to measure coercion among prisoner subjects would be able to distinguish between overt, clearly identifiable external sources of coercion and more contextual forms that might arise from the prison's "constraining influences" (i.e., fewer available treatment options) (Appelbaum et al. 2009a; Beauchamp 2005; Miller et al. 2011). Like other vulnerable groups for whom there is limited availability of effective medical treatment—for example, certain cancer patients or those with rare illnesses—inmates may seek to enroll in clinical research simply to access otherwise unavailable care. Indeed, this point has been used to argue for offering prisoners greater access to clinical trials (Gostin et

al. 2007). Measuring the extent to which prisoners weigh such factors when making enrollment decisions would provide useful guidance for determining whether their choices are coerced. However, such factors are not generally captured by current measures (Appelbaum et al. 2009a), though a few relevant scales under development seek to address this shortcoming (Appelbaum et al. 2009b; Miller et al. 2011).

Therapeutic Misconception and Trust

Prisoners might also view research as treatment, despite the fundamental differences between medical care and clinical research. Clinical treatment aims to provide individual patients with what the provider believes is optimal care for the individual patient; clinical research, on the other hand, primarily seeks to answer scientific questions to advance knowledge (Miller et al. 2003). The failure of research subjects to appreciate this distinction is now established under the term “therapeutic misconception” (Appelbaum et al. 1982). Numerous studies have demonstrated the high prevalence of this phenomenon (on average 60–70%) among subjects in various clinical trial contexts (Appelbaum et al. 2004; Dunn et al. 2006; Henderson et al. 2006; King et al. 2005; Lidz and Appelbaum 2002; Lidz et al. 2004). The wide range of clinical populations and study scenarios in which therapeutic misconception has been identified suggests it is a diffuse and serious problem in clinical research. Moreover, its persistence over the past 30 years suggests that efforts to address it within the informed consent process have yet to achieve widespread success.

Given this past research, incarcerated subjects may be susceptible to viewing research as primarily intended to help them, believing the study doctors (who are not employed by the correctional system) will personalize their treatment, and overestimating the extent to which they are likely to benefit (Stone 2000). These are the core features of therapeutic misconception. On the other hand, a lack of trust is among the most prominent reasons that prisoners do not seek help from health professionals (Howerton et al. 2007). Indeed, the abuses in past correctional research have engendered deep distrust among prisoners and prisoner advocates as well (Byrne 2005; Gostin et al. 2007) Therefore, inmates may be less susceptible to therapeutic misconception than non-incarcerated research subjects. To our knowledge, there are no empirical studies on the extent to which prisoners may experience therapeutic misconception. This would be an important area for scientific inquiry since it may expose the unique ways in which research participants may be vulnerable or resistant to such misconceptions.

Investigators’ Perspectives on Research

There is also a small but growing empirical literature describing how investigators view research and research participants. A recent study (Lidz et al. 2009) in which investigators and research coordinators of clinical trials were asked how they behaved when faced with competing clinical and research commitments found that 69% of researchers agreed that “researchers should deviate from the protocol if doing so would improve the subject’smedical care.” Among those who had ever faced deciding whether to permit an ineligible subject to enter a trial, 22% reported having recruited the ineligible person. Similarly, among researchers who were faced with deciding whether to prescribe a medication that would benefit the subject but was prohibited by the protocol, 28% reported

having prescribed the medication. In these instances, the researchers appeared to follow the best interests of their subjects, potentially violating the scientific integrity of the study. How investigators might conduct prisoner research—which is fraught historically with these tensions—is unknown. However, this would be an interesting area of inquiry since, arguably, investigators may need to consider a third ethical commitment: the pressure to maintain safety and order in the correctional setting.

IRB Oversight

The IOM committee deflected much of the new oversight responsibility to IRBs, the review bodies already assessing protections of vulnerable participants within research protocols. Under the recommended risk–benefit analysis, "It will be up to IRBs to determine whether there is a convincing affirmative reason for conducting research in a prison setting" (Gostin et al. 2007, 124) by evaluating the potential benefits and harms of any research protocol while considering the relevant ethical issues that each protocol raises. Whether this additional responsibility is appropriate for the overburdened and under-resourced research review system remains open to question. Indeed, IRBs are already under severe criticism for the inability to keep up with increasing numbers of studies and shrinking times for review (Emanuel et al. 2004). Moreover, a recent study of IRB decision making identified minimizing risk, a key component of risk–benefit analysis, as a particular weakness of IRBs (Lidz 2010). Studying whether and how IRBs address regulatory requirements in their deliberations on prisoner research would be an important first step toward assessing whether they might successfully manage any additional new responsibilities.

CONCLUSIONS

While clinical research with prisoners holds the potential to improve both public health and public safety, there are a number of outstanding ethical issues remaining to be explored. Indeed, ironically, empirical studies exploring these issues may themselves face the challenges of conducting research within a vulnerable population. Considering what is at stake on both sides of the argument, it is surprising how few empirical studies have explored these ethical issues. Yet if the field of prisoner research is to contribute to public health and safety, these concerns need to be rigorously examined. At the very least, research on decision-making capacity, coercion, therapeutic misconception and trust, investigator perspectives on research participation, and IRB review can help guide investigators, clinicians, policymakers, and regulators in their efforts to ensure that much needed scientific research improves treatment while conforming to appropriate ethical standards.

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