

Article

Ethical Challenges in Conducting Psychiatric or Mental Health Research in Correctional Settings

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Background: We explored ethical challenges in conducting psychiatric or mental health research with incarcerated people. **Methods:** Semistructured interviews were conducted with 87 people who were researchers; institutional review board (IRB) chairs, members, and prisoner representatives; research ethicists; and prison administrators with experience in and knowledge about the conduct of research in correctional settings. NVivo 9.0 was used to conduct grounded theory analysis of responses to the question: “What would you say are the top three ethical challenges to conducting psychiatric or mental health research with incarcerated people?” **Results:** Key informants identified autonomy and consent, balancing the potential for direct benefit with the risk for harm, and access to and standards of psychiatric care in correctional facilities as the three most important ethical challenges. The characteristics of incarcerated individuals, the nature of correctional systems, and federal regulations for oversight of prisoner research provided the contextual framework for these challenges. **Conclusions:** Findings from this study provide insights into ethical challenges affecting the conduct of psychiatric and mental health research with incarcerated individuals. Given the potential benefit to incarcerated people from access to participation in research, these ethical challenges should be addressed.

Keywords: bioethics, interview, policy analysis, qualitative research

The United States has the highest incarceration rate in the world, with more than 2.3 million individuals housed in federal or state prisons and local jails (West and Sabol 2009) and 5 million under parole or probation supervision (Glaze Bonczar and Zhang 2010). Due to deinstitutionalization, lack of access to community mental health services (Markowitz 2006), and criminalization of the mentally ill (Lamb and Weinberger 2005), prisons and jails have become “America’s new mental hospitals” (Torrey 1995, 1612). Rates of psychiatric disorders in U.S. prisons and jails dramatically exceed general population rates, with 49.2% of individuals in state prisons, 39.8% of individuals in federal prisons, and 60.5% of individuals in local jails meeting criteria for major depression, mania, or psychotic disorders (James and Glaze 2006). Unfortunately, most individuals with psychiatric disorders do not receive adequate care during incarceration (Fazel and Danesh 2002), with only 33.8% in state prisons, 24.0% in federal prisons, and 17.5% in local jails obtaining treatment (James and Glaze 2006).

The growing number of individuals with mental health disorders highlights the need for research on mental ill-

ness and treatment delivery in correctional settings. However, correctional settings, with their constraints on autonomy and privacy and limitations on access to health care and other resources, pose ethical challenges and responsibilities for researchers and for individuals charged with ethical oversight of research (Institute of Medicine 2006). Ethical challenges due to the nature of the research setting interact with ethical challenges due to the nature of psychiatric illness (Roberts 2002a), yielding a complex set of vulnerabilities for participants in psychiatric or mental health research in correctional settings.

The field of psychiatric research ethics has grown dramatically in recent years (Dunn, Candilis, and Roberts 2006); however, there has been little, if any, empirical investigation of the ethical challenges in conducting psychiatric or mental health research in correctional settings. Thus, exploring the nature of ethical challenges and the interpretation and application of ethical safeguards in psychiatric and mental health research in correctional environments is timely and important.

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Table 1. Demographic characteristics of key informants (n = 87)

Demographic variable	Number	Percent
Professional group		
Correctional administrators	15	17.2%
IRB prisoner representatives	16	18.4%
IRB chairs and members	16	18.4%
HIV/AIDS researchers	25	28.8%
Research ethicists	15	17.2%
Gender		
Males	45	51.7%
Females	42	48.3%
Race/ethnicity		
African American	7	8.0%
Asian/Pacific Islander	1	1.2%
Caucasian	75	86.2%
Hispanic	2	2.2%
Native American	1	1.2%
Other	1	1.2%
Highest level of education		
Less than master's degree	6	6.9%
Master's degree	16	18.4%
Doctoral degree	46	52.9%
Medical degree	19	21.8%
Work setting		
Academic	42	48.3%
Correctional	16	18.4%
Medical	13	14.9%
Public health	6	6.9%
Other	10	11.5%
Age		
Years	50.7 (Mean)	9.3 (SD)

METHODS

Interview Protocol

The question "What would you say are the top three ethical challenges to conducting psychiatric or mental health research with incarcerated people?" was added to a semistructured interview that addressed a range of ethical, institutional, and regulatory issues affecting the conduct of HIV/AIDS research in correctional settings. Responses to the mental health research question were analyzed for the current study.

Procedure

Participants were drawn from five professional groups: prison administrators, IRB prisoner representatives, ethicists, IRB members, and researchers. Prison administrators included wardens, prison/jail medical directors, and correctional administrators with experience in HIV/AIDS research in correctional settings. IRB prisoner representatives were chosen based on experience reviewing HIV/AIDS

and/or stigmatizing disease research in correctional settings. Ethicists were included if they had special knowledge of the ethical issues pertaining to research with correctional populations. IRB members included IRB chairs, members, directors, and managers who had reviewed HIV/AIDS and/or stigmatizing disease research in correctional settings. Researchers were selected for their experience with conducting HIV/AIDS research in correctional settings. Initial recruits were identified through project members, national project consultants, literature reviews, and Internet searches. For literature and Internet searches, keywords included HIV/AIDS, stigma, prison, ethics, research, and corrections. Additional participants were recruited using snowball sampling; that is, interviewers asked participants to recommend other individuals for interviews.

Semistructured telephone interviews took 45 to 90 minutes and interviewees were compensated \$100 for participation. All procedures were approved by the institutional review board at the University of Alaska, Anchorage.

Data Analysis

Interviews were audiotaped, transcribed, and imported into NVivo 9.0 for qualitative data analysis. The initial analytic step was independent open coding of five interviews (one per group of respondents) by three trained research staff members to identify a pool of free nodes (or themes). Coders and principal investigators met regularly to define and refine emerging themes. Through this process, 78 free nodes were identified and defined. In the second step, all interviews were coded independently by two coders. NVivo files were merged daily, allowing the coding team to identify and resolve disagreements. The coding process was iterative; all previously coded interviews were recoded following changes in node definitions. Kappa coefficients between coders averaged .92, ranging from .91 to .96.

RESULTS

Participants

Using a nationwide sample, interviews were conducted with 87 experts with experience in and knowledge about challenges in conducting research with correctional populations. Participants included 15 correctional administrators; 32 chairs, members, and prisoner representatives from institutional review boards (IRBs); 15 research ethicists; and 25 researchers. Table 1 provides demographic information for all 87 participants.

Respondents were asked for the top three ethical challenges in conducting psychiatric or mental health research with incarcerated people. Table 2 provides the three most frequently mentioned ethical challenges and the three factors that provide the contextual framework for those ethical challenges. Grounded theory formed the basis for identifying the top ethical challenges; the contextual factors were identified a priori by the researchers based on a review

Table 2. Top contextual framework and top ethical challenges across all respondents

	Contextual framework						Top ethical challenges					
	Nature of incarcerated population		Nature of correctional setting		Federal research regulations		Autonomy and consent		Balance between benefit and harm		Access to and standards of care	
	<i>n</i>	%	<i>n</i>	%	<i>n</i>	%	<i>n</i>	%	<i>n</i>	%	<i>n</i>	%
Administrators (<i>n</i> = 15)	7	48%	5	33%	1	7%	9	60%	6	40%	5	33%
IRB prisoner representatives (<i>n</i> = 16)	8	50%	7	44%	2	25%	8	50%	13	81%	3	19%
IRB chairs and members (<i>n</i> = 16)	4	25%	5	31%	0	0	10	63%	10	63%	9	56%
Research ethicists (<i>n</i> = 15)	6	40%	4	27%	1	7%	9	60%	11	74%	4	27%
Researchers (<i>n</i> = 25)	6	24%	2	8%	0	0	14	56%	10	40%	10	40%
Total (<i>n</i> = 87)	31	36%	23	24%	4	5%	50	58%	50	58%	31	36%

of the literature on the ethics of research in correctional settings. The top ethical challenges were autonomy and consent (mentioned by 58% of respondents), balancing the potential for benefits with the risk for harm from research participation (58% of respondents), and access to and standards of psychiatric care in correctional institutions (36% of respondents). With respect to the factors providing the contextual framework for these ethical challenges, 36% of respondents mentioned the nature of the incarcerated population, 24% mentioned characteristics of the correctional setting, and 5% mentioned federal regulations governing research with incarcerated people. We begin by discussing the contextual framework for ethical challenges in the conduct and oversight of psychiatric and mental health research in correctional settings.

Contextual Factors

Characteristics of the incarcerated population. The nature of the incarcerated population was the contextual factor that was mentioned most frequently by respondents. Slightly more than one-third (36%) of respondents discussed the nature of psychiatric illness in the incarcerated population. First, respondents noted the high prevalence of psychiatric disorders in correctional populations:

“There’s a ton of mental health pathology in here first of all. So when you’re talking about [psychiatric illness] you’re talking about a very large proportion of the inmates.” (Correctional administrator)

“A really significant portion of the folk who are locked up really are there because they have an untreated mental health condition.” (IRB member)

Second, respondents described the impact of deinstitutionalization in shifting the burden of care from psychiatric institutions in the community to the criminal justice system:

“What we’ve done in this country is we’ve dismantled what little mental health system we had twenty plus, thirty years ago and now our mental health treatment programs are really our jails and prisons.” (Researcher)

Third, respondents noted that psychiatric illness makes incarcerated people more vulnerable to the impact of incarceration and to harm from research participation:

“If you were to find a group of people who were overrepresented in prisons, it would be people with mental health problems and who are subject to all kinds of discrimination and are incredibly vulnerable in the research context.” (Research ethicist)

“They’re another vulnerable population because they can be manipulated, they are more vulnerable and they can be manipulated because they have vulnerabilities.” (Correctional administrator)

Fourth, the high prevalence of psychiatric illness has implications not only for psychiatric or mental health research in correctional settings, but also for other types of research in correctional settings. Because of the high prevalence of psychiatric illness, participants or potential participants in other areas of research (e.g., HIV, infectious and chronic disease, vocational training and rehabilitation, drug treatment, etc.) are likely to have psychiatric symptoms that require additional safeguards for recruitment, consent, and research activities. Two researchers who do not conduct psychiatric research noted the impact of the high prevalence of psychiatric disorders on their research:

"We're not looking specifically at mental health and psychiatric treatment; we're doing behavioral HIV prevention, treatment. But we do obviously. Because there are so many people who are incarcerated who are experiencing mental health issues and psychiatric issues, we do encounter that a lot." (Researcher)

"We have a number of people with psychiatric problems that are in our studies, but they are not psychiatric studies per se." (Researcher)

Fifth, incarcerated people with psychiatric disorders are not a homogeneous group. Respondents noted that psychiatric symptoms range from mild and transient symptoms of anxiety or depression to severe and debilitating psychoses. Individuals with mild psychiatric symptoms may require only limited protections, whereas individuals with severe and debilitating psychoses may require substantial additional safeguards to protect their rights as research participants or potential participants.

"When people are mentally ill, you know their ability to cope with the correctional setting and understand what they're being asked to do is greatly compromised. Now some inmates have mental health diagnoses that are not related to their ability to comprehend what they're being asked to do. They might have an anxiety disorder or mild depression, but there are a lot of people in institutions who are schizophrenic or bipolar etcetera where you've got to clearly distinguish who is capable of giving consent." (Prison administrator)

In addition, by their nature, psychiatric symptoms change over time and with treatment and are affected by the conditions of incarceration.

"You are dealing with populations who are minimally, if at all, treated. Or the other extreme may be over-treated. In other words, over-medicated and sedated." (Researcher)

According to one IRB member, a significant ethical challenge is:

"[the] appropriate assessment or diagnosis of the condition that one has and whether that is more likely to change in a prison system as opposed to outside of a prison system due to the pressures of being incarcerated and how long someone's been incarcerated."

Finally, incarcerated individuals in general, and incarcerated individuals with psychiatric disorders in particular, have fewer social and personal resources than people who are not incarcerated.

"You may have folks who are not as high functioning on average as a general community sample. You have a bunch of people who may be a little more damaged than a regular community sample and so I think that your responsibility to them is going to be higher." (Research ethicist)

Characteristics of the correctional environment. One-quarter (24%) of respondents described characteristics of the correctional environment that provide the context for ethical

challenges in conducting psychiatric or mental health research in that environment. The correctional environment was described as antithetical to the foundations for ethical research—maximizing autonomy and respect for the individual. In contrast, correctional settings are designed explicitly to strip individuals of autonomy, individuality, and control over their lives or decisions.

"We are trying to protect those basic research participant rights within a contextual environment that, by nature, doesn't support them." (Researcher)

Respondents noted that correctional settings differ philosophically from therapeutic settings, which can create ethical dilemmas for researchers.

"Consider the culture that even though we have lots of mentally ill inmates, we are organized according to different principles. Mental health settings are considered therapeutic and we're considered punitive. Inmates are here for punishment, not to be punished, but punishment is the model. In the course of research, the researcher might see things and be troubled by them thinking that this inmate is being treated abusively. But from the standards of sound correctional practice, we're doing what we have to do. Cultural awareness of a correctional setting is important for somebody who comes in to do psychiatric research." (Correctional administrator)

Finally, conditions of confinement may exacerbate psychiatric illness and increase the vulnerability of people who are mentally ill.

"The psychiatric situation may be compounded because of the fact that they are incarcerated." (IRB prisoner representative)

"Prison environments are really toxic to people with mental illness. They are just everything wrong about them generally for a person who is mentally ill. And what ends up happening is a lot of people with mental illness end up being disciplined essentially because they are ill. And so it's a real challenge for psychiatric researchers to figure out how to have an effective intervention in that very toxic environment." (IRB prisoner representative)

Federal regulation of research with prisoners. Although few respondents (5%) addressed the impact of federal regulations, their comments warrant inclusion because federal regulations to protect incarcerated people as research participants form part of the context for conducting psychiatric research in correctional settings. One subset of federal regulations were designed to protect an especially vulnerable class of individuals—prisoners—from harm due to participation in research. The most common perception among the few respondents who discussed this issue is that incarcerated individuals as a class are so vulnerable that, even with additional protections, psychiatric research in correctional facilities should not be conducted.

"Except in very, very narrow circumstances it is probably best not to use incarcerated people for psychiatric studies at all." (IRB prisoner representative)

"These are really difficult things to research. I think we have to find a way to do it, but I don't think prison is the place to do it. We could do it with people who are out on probation but not within the prison because at least you might be able to refer them for help." (IRB member)

A second perception by this small group of respondents is that meaningful research with direct benefits for incarcerated populations has been hampered by federal regulations. Respondents noted that research with the greatest potential for benefit, including high-risk protocols and medical research, was most likely to be hampered by federal regulations and oversight.

"I would be very skeptical about even attempting any research like that, even when [facility name] gives their O.K. On our IRB for just prisoners in general, it still goes up to the Human Research Protections Office at NIH. They have to bless it too, with this type of population. So it is a lot of gatekeepers and not just an IRB and then we also require the local IRB, especially if we're using a university, they have to bless it too." (IRB prisoner representative)

"Because of the way the prisoner regulation was written, what happens is we now have a fair amount of very low risk research that goes on. And that includes a lot whole lot of psychological evaluations and stuff. It is almost impossible the way the current regs are to do anything at all medically related. So it's much, much harder to do that. But right now psychological research in prison is, I think is, I don't want to say a dime a dozen, but there's a lot of them going on." (Correctional administrator)

Because of the difficulty in gaining approval for high-risk studies, low-risk behavioral and epidemiologic studies that produce data but little, if any, direct benefit for research participants, are more common.

"We assess needs for services, but we don't provide them. So for us I think a difficult moral issue is that we get a lot of information from people on what services they need but we don't do anything to help; because an epidemiologic study is all about describing, not about helping." (Researcher)

With this summary of the context of psychiatric and mental health research in correctional settings, we now turn to descriptions of the top three ethical challenges identified by respondents: autonomy and consent; balancing the potential for benefits against the risk for harm; and access to and standards of psychiatric care in correctional settings.

Top Ethical Challenges in Psychiatric Research with Correctional Populations

Autonomy and consent. The combination of psychiatric illness and incarceration led respondents to characterize incarcerated people with psychiatric disorders as "doubly vulnerable."

"These populations fall under what I'm talking about as double vulnerable populations, people with mental illness, because they have impairment that's separate and above their impair-

ment that comes about just being in a prison environment." (IRB prisoner representative)

That double vulnerability contributed to the perspective that the threat to voluntarism was the paramount ethical challenge for psychiatric research in correctional settings.

First, respondents weighed whether individuals who are incarcerated possess the autonomy to consent or refuse to participate in research. The correctional environment was described as inherently coercive; autonomy is deliberately constrained in the interests of punishment, rehabilitation, and public safety. Incarcerated individuals are given little opportunity to refuse to participate in prison activities and programs, and that "habit" of acquiescence may extend to decisions about participating in research activities.

"An individual that is in a restricted setting where their rights, many of their rights, are taken away from them, and so under those conditions, can informed consent actually be provided? Meaning is there always some coercion or perceived coercion that's involved in that dynamic, whether they'll get better treatment, whether they'll get consequences for refusing to participate. The issue is that in an incarcerated setting, the consequences of slight or potential coercion could be much greater." (Researcher)

As one IRB member described:

"Inmates will sign, you can sit down with an incarcerated individual, give them a consent form that's a page long, look at them and briefly explain to them the consent form in a way that really does not mirror what's on the consent form, and they'll sign it. It's unethical but it happens all the time. Then you put on top of that a vulnerable population that's mentally ill and I think that's a major ethical issue."

Another IRB member stated:

"Indirect coercion, you know that if you take this medicine and you're doing good you'll get promoted [to less restrictive custody] or you'll get better treatment, you've got to guard against that. Because it's quite likely that if a prisoner's mental health improves, they're going to move up to less restrictive custody."

Second, researchers, IRBs, and correctional administrators face significant challenges in ensuring adequate understanding of a study and its potential risks and benefits because incarcerated individuals are more likely to be poorly educated, to be limited in their ability to read or write, to have learning disabilities, and to have language and cultural barriers (cf. Western 2006) that may interfere with their ability to comprehend.

"That is a population that may not have an understanding of what exactly is going on and why they're participating in this type of research, or even have a clue that that's what they are doing." (IRB prisoner representative)

Third, respondents weighed the impact of psychiatric illness on decisional capacity. Respondents noted that

decisional capacity or the capacity for voluntarism is not necessarily compromised by psychiatric symptoms. As one correctional administrator noted:

“Now some inmates have mental health diagnoses that do not, are not related to their ability to comprehend what they’re being asked to do.”

Similarly, an IRB member said:

“Psychiatric illness does not necessarily mean that one is decisionally impaired, but there certainly is the possibility that there could be decisional impairment.”

However, severe psychiatric symptoms, delusions, cognitive incapacity, vulnerability to coercion, and desperation for treatment may impair an individual’s decisional capacity.

“Their mental illness makes it difficult to interact with them and to really know that you’ve obtained voluntary informed consent—they’re not just consenting because they think you’re a religious leader or something that speaks to their psychotic delusions.” (IRB prisoner representative)

“When people are mentally ill, their ability to cope with the correctional setting and understand what they’re being asked to do is greatly compromised.” (Correctional administrator)

“You may be dealing with populations of people who are not cognitively capable of understanding the risks and benefits of research and the nature of what’s voluntary and what’s not.” (Researcher)

Finally, consent to participate may vary over the course of the study with changes in a participant’s mental status.

“Simply because you’ve signed an informed consent, you have the right to verbally withdraw at any time, in any study. People who are unbalanced and made sane—are they rescinding the consent because they don’t want to be involved in the study or have they slipped back into a state that doesn’t permit them to rationally make a decision?” (IRB prisoner representative)

Respondents differed on whether these challenges to informed consent can be overcome. Some respondents took the position that the challenges are so severe that incarcerated individuals with psychiatric illness should never participate in research. Others believed that the challenges could be overcome by careful adherence to recruitment and consent procedures developed to protect people with psychiatric illnesses in other settings. According to one research ethicist, the challenge is to find “the methodology for recruiting people in and then assuring their ongoing authentic consent and authentic willingness to remain or authentic decisions to disenroll.”

Respondents made suggestions for improving the recruitment and informed consent process to protect voluntarism and autonomy. One suggestion was to spend sufficient time with potential participants to ensure comprehension and to present the elements of consent in an

understandable form for individuals to assess the study and its potential for benefit and harm and determine whether they want to participate or not.

“To insure that this population is given the attention that they need, which is going to be more than the general population as far as understanding their participation, making sure that it is voluntary.” (Correctional administrator)

A second suggestion was for researchers to assess comprehension of the elements of the study and its associated harms and benefits as part of the process of obtaining consent. A third suggestion was to use mental health advocates to ensure that potential participants understand research processes and are able to weigh potential harms and benefits from participation.

“That person’s [the advocate] got to have the interest of the prisoner in mind and decide about the risks and benefits to the prisoner. Some of them will be able to make their own decision but some won’t.” (IRB member)

A fourth suggestion was to train research staff to recognize psychiatric symptoms and their impact on the consent process.

“The informed consent issues are obviously paramount. I think the people who are doing research in this setting really need to train their recruiters and their interviewers to recognize severe mental illness and to recognize when people are not able to give consent.” (Researcher)

A final suggestion was to avoid recruiting participants for studies at times of particular vulnerability, for example, immediately after an individual’s entry into the correctional system or immediately after sentencing.

Balancing the potential for benefit with the risk for harm. Respondents discussed the balance between protecting individuals from harm while providing the opportunity to benefit from participating in research.

“Being sure that the research that you are going to do did not exacerbate the mental health condition that you are looking at, given the setting, and alternatively that it offered some benefit for that condition.” (Researcher)

The most commonly mentioned risk for harm was breach of confidentiality or violation of privacy arising from the physical environment and from the policies and procedures in correctional institutions. Respondents tended to use “confidentiality” and “privacy” interchangeably to refer to protections for data and records and to the potential for individuals to be seen participating in potentially stigmatizing research. For example, respondents referred to violations of confidentiality because the physical arrangement of the correctional facility made it possible for other individuals to see that participants were attending research sessions.

"Maintaining the confidentiality is tough because these are also stigmatizing illnesses. You don't want to be seen as that researcher that only talks to crazy people, you know what I mean? Being sensitive to that and really making sure that you're not outing people because it is so stigmatizing." (Researcher)

Breach of privacy or confidentiality has potential for harm because of stigma about mental illness in the correctional environment.

"We have plenty of people who are diagnosed with or are in treatment for major mental health disorders but they're functioning well with their treatment and medication and I don't think it serves their interests well to have their business put out on the street, in the institutions. Confidentiality becomes another real important piece." (Correctional administrator)

"Protect confidentiality because mental illness in prison is also stigmatized, stigmatized just as it is out in the free world." (IRB prisoner representative)

"The biggest problem has to do with the stigma that's associated with mental health problems among inmates. If you're doing a study of psychopathology inside an institutional context and people find out about you, a particular inmate has been involved in that study, that's going to be problematic. Inmates who really do have mental health problems don't want to let on to anyone because they are more vulnerable and there is a great deal of stigma associated with it." (Research ethicist)

A related issue is mandatory reporting (e.g., of illegal behavior or threats of harm), which may pose ethical challenges in correctional settings that they do not pose in other research settings. In other settings, researchers may feel comfortable reporting threats against participants or suicidal ideation to authorities; however, in a correctional environment, researchers may fear that reporting would lead to punitive or other harmful consequences for the participant.

"There can be concerns about whether what you're telling someone in that facility could ultimately put that inmate at additional or even more risk than what they were already under." (Researcher)

The second risk for harm was the potential for exacerbation of psychiatric symptoms due to participation in research.

"[Need a] good understanding of the risks, for example, of suicide, the risks of depression and so forth as a result of the research." (Research ethicist)

A specific risk for harm is the potential for retraumatization.

"You could take people down roads where they are remembering traumatic events. You might not always think of that as a harm to the patient, but retraumatization is an ethical concern and a risk that just might not be emphasized enough or that the patient recognizes before they give their consent to participate in the study." (Researcher)

The potential for an escalation of symptoms is problematic because responsibility for dealing with behavioral and psychiatric problems falls to the correctional system.

"A lot of these folks have a level of emotional distress that once you tap into it, it may be more than you anticipated. Somebody is going to have to deal with it." (Researcher)

"First, do no harm. Please remember that whatever you're asking in the course of your research, when you leave, the subject, inmate remains here; and that if something is stirred up in the course of that research we need to deal with the consequences. Say, you know, trauma, posttraumatic stress, something like that, don't conduct your research in a way that leaves the person kind of cranked up or traumatized. Because that's not fair to them and it makes life hard for us." (Correctional administrator)

Respondents noted that when crises arise in the course of research, researchers rely on the resources available in the correctional system, including referrals to mental health providers within the system. Crisis response protocols should be sensitive to the relative lack of services within correctional settings.

"There would have to be some safeguards to make sure that if discussion or therapy leads to stirring up a traumatic event et cetera that could be dealt with effectively by the study staff within the context of the prison, which I suspect would be very, very challenging." (Researcher)

"You need to be able to refer inmates to services if something comes up. If you're talking to people about experiences with child sexual abuse and things start to come out, you need to be able to refer them, if there's not a good mental health professional that they could talk to, you're doing more harm than good. So I think that just the availability of services, the lack of services is really an issue." (Researcher)

Respondents made little mention of specific benefits that could accrue to research participants, but did discuss the issue of distributive justice. Respondents made reference to the history of prison research in which incarcerated people were a convenient population for research where the benefits accrued to others and the harms accrued to the research participants. A consistent perspective among respondents was that psychiatric research in a correctional setting must provide direct, meaningful benefit to the participants themselves and not merely benefit to other incarcerated individuals or society at large.

"If this isn't likely to benefit the individual, but will benefit perhaps other individuals, then those questions of distributive justice that we shouldn't be disadvantaging one group of people to benefit others." (Research ethicist)

"The aspect of justice, allowing those individuals access to research which could be of direct benefit to them." (Research ethicist)

"We're always asking them for information about themselves and their experiences but we really do not give back to those individuals and giving back is not 'give me your name and I'll send you the research report when it's all done.' Because that is not going to help them." (IRB member)

Of particular concern was ensuring that incarcerated people do not assume risks for harm while benefits accrue to people outside the correctional system.

"Making sure that the research is relevant to the lives of the prisoners and not again something that can just as easily be conducted outside of prison." (Researcher)

"They need not be exposed to any medication or treatment that would not be common to a free world psychiatric research subject." (IRB prisoner representative)

Access to and standards of care in the institution. The third most frequently mentioned challenge was the adequacy of and access to psychiatric care in correctional institutions. Because incarcerated individuals are dependent solely on the correctional system for care and services, access to adequate medical and psychiatric care for everyone in the institution was viewed as a prerequisite for the ethical conduct of psychiatric research in correctional settings. Respondents noted that correctional budgets are increasingly strained and providing medical and psychiatric services for incarcerated people is not a social priority.

First, respondents noted that standards of care and access are not the same in a correctional institution as in the community outside the facility.

"This is a population that may not be getting all of the help that they need. What you or I might get in the free world might not be the same level of treatment that an incarcerated individual might get. So the first ethical challenge is for the researchers to reconcile with themselves that the level of treatment that is adequate and acceptable in a prison population may not rise to the same level that they may be accustomed to in their personal life. This is a prison with a prison budget; this is not a free world person with insurance." (Correctional administrator)

"One of the biggest ethical challenges in conducting psychiatric research and mental health research is the equality of the care that's provided. One of the requirements to ethical conduct of clinical studies is that these studies take place in a setting where people have access to the same kind of care that they would have, good quality medical care. I think it would be very difficult to do a psychiatric study without running into the comparison between people's access to mental and psychiatric help on the outside versus on the inside. Dramatically different. I don't think that you could conduct psychiatric studies in correctional facilities and be ethical." (Research ethicist)

Second, in the absence of access to adequate psychiatric care or other services, incarcerated individuals may feel compelled to participate in research because that is the only means to get care that is otherwise unavailable.

"[The issue is] balancing the needs for inmates to get a hold of some of these new drugs which they can't get from their current formulary with the desire to actually participate in research." (IRB member)

"Is the standard of care for people in prisons at least the community standard? If it is, it is much easier to design and conduct an ethical study because if it's not, then you're talking about a deprived population for whom a study may look like the only way to get good care." (Research ethicist)

Third, respondents were concerned that problems created by research participation could not be adequately addressed with the resources available in a correctional setting.

"Are the resources available in the facility or in the system to deal with any issues that are raised by the research? The difference between what's ideal and the reality is just huge sometimes, so that ability to deal with whatever research might pull up. You may have correctional officers who have great hearts, but they don't have the skills to deal with somebody who might be disturbed by something in the research process." (Researcher)

Fourth, respondents noted that research designs might limit an individual's access to care.

"That's always the challenge in dealing with prisoner populations, ensuring people get the treatment that they need and not creating research designs whereby some do not get the treatment that they need." (Correctional administrator)

Fifth, respondents raised concern about participants' access to care in the correctional institution after a study ends or in the community after they are released.

"If we were to start somebody on a psychiatric medication we think they could benefit from, however after they go out into the community, which 99% of our people do, they're not able to continue that medication. Is that ethical?" (Correctional administrator)

Finally, participation in research may uncover a need that cannot be addressed within the context of the correctional system.

"We've done work in jails and prisons that are remote or rural or understaffed or under-resourced and getting someone who poses a risk to themselves, finding the necessary mental health services, the psychological treatment that they need which you could uncover or discover in the context of mental health-related research could pose a real ethical or moral challenge." (Researcher)

DISCUSSION

This study examined the perspectives of researchers; IRB members, chairs, and prisoner representatives; research ethicists; and correctional administrators about the ethical challenges in conducting psychiatric or mental health research with correctional populations. Three factors—the nature of the incarcerated population, the nature of the

correctional setting, and federal oversight of research with incarcerated people—provided the context for the ethical challenges identified by respondents. The top three ethical challenges were preserving autonomy and ensuring voluntary and informed consent; balancing the potential for benefit with the risk for harm; and ensuring that the lack of access to adequate psychiatric care in correctional settings does not compromise voluntarism or introduce risk for harm.

Incarcerated people were described as “dually vulnerable” or “doubly vulnerable” because of the intersection of vulnerability related to psychiatric symptoms and vulnerability related to their status as incarcerated people. Vulnerability can be conceptualized as “centering on the philosophical and legal doctrine of informed consent” (Roberts 2002a, 529). This conceptualization of vulnerability is based on the nature of the relationship between the investigator and the participant, a relationship that is characterized by trust and professional integrity and that sets conditions for the individual to truly understand and freely agree to take part in research. Vulnerable individuals are those for whom this ideal is threatened and for whom voluntarism is compromised. Roberts (2002b) proposed a framework for understanding voluntarism in consent decisions. She focused on four domains of potential influence on consent decisions: developmental factors, illness-related considerations, psychological issues and cultural and religious values, and external features and pressures. Her work provides a framework for understanding the dual vulnerability of incarcerated individuals and for contextualizing the ethical challenges identified by respondents in this study.

First, as noted by respondents, incarcerated individuals are disadvantaged as a class, with lower socioeconomic status (SES) and lower educational levels and higher rates of illiteracy than the general population, potentially affecting cognitive abilities. This, in turn, has the potential to affect the incarcerated individual’s ability to comprehend the details of a study, to discern the difference between participation in research and participation in therapeutic activities (therapeutic misconception), and to appraise the potential for benefit and the risk for harm. Second, psychiatric illness in and of itself has the potential to affect the individual’s ability to make an autonomous decision to participate or not participate in research (Dunn, Candilis, and Roberts 2006). Third, psychological issues and values have the potential to interfere with voluntarism and autonomy. In this context, the values of the criminal justice system, with its emphasis on constraining autonomy and substituting obedience and deference to authority, may be particularly salient. Fourth, the external features and pressures of the correctional environment greatly affect voluntarism.

Correctional systems are inherently coercive (Kalmbach and Lyons 2003; Peternelj-Taylor 2005) and designed to constrain autonomy in service to the values of punishment, rehabilitation, and public safety (Rich, Wakeman, and

Dickman 2011). The dehumanization and power dynamics within correctional settings affect the development of the respectful, trusting, and equal relationship between researcher and participant that is the foundation for informed consent (Roberts 2002a; Seal, Eldridge, Zack, and Sosman 2010). In addition, the well-documented lack of access to adequate care and services in correctional settings may further erode autonomy in that incarcerated individuals may see research participation as their only option for receiving otherwise unavailable care. (The lack of access to services may also introduce the potential for unanticipated harm, in that participants whose symptoms are exacerbated by participation may not receive adequate care within the correctional system.)

The history of research with incarcerated people is rife with examples of abuse, including violations of prisoner rights, drug testing without consent, and using inducements, such as food and medical care, that are coercive for individuals living in conditions of severe deprivation (Institute of Medicine 2006; Lazzarrini and Altice 2000). This history of abuse led to designating prisoners as a vulnerable class and the implementation of federal regulations to protect their autonomy as research participants (Institute of Medicine 2006). However, the structure of federal regulations to protect prisoners as research participants may have had the paradoxical effect of hampering important research that might have direct benefits for incarcerated individuals with mental illness (Gostin 2007).

The current study has three primary limitations. First, qualitative data were collected from a nationwide sample of researchers; IRB members, chairs, and prisoner representatives; and research ethicists; however, the findings may not generalize beyond this group. Second, although respondents were chosen for their experience in or expertise with research in correctional settings, the sample was not specifically recruited for involvement in the conduct and oversight of psychiatric research in correctional settings. Third, interviews did not include the perspectives of incarcerated individuals who may have participated in or been eligible to participate in research.

Limitations notwithstanding, this study revealed significant barriers and challenges that may serve to restrict psychiatric research in correctional settings. Given the prevalence of psychiatric disorders in correctional settings, addressing and resolving these barriers and increasing the amount and quality of research have the potential to yield significant benefits to potential participants and society overall. This study represents a starting point in collecting empirical data on the ethical challenges in psychiatric research with correctional populations. Future research needs to gather additional perspectives from professionals directly involved in such research and from research participants. This line of research can facilitate a discussion amongst researchers, policymakers, correctional staff, and other stakeholders about addressing ethical

barriers and challenges and facilitating psychiatric research in correctional settings. ■

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