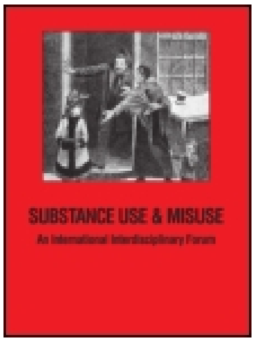

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ORIGINAL ARTICLE

Addiction Research Ethics and the Belmont Principles: Do Drug Users Have a Different Moral Voice?

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This study used semi-structured interviews and content analysis to examine moral principles that street drug users apply to three hypothetical addiction research ethical dilemmas. Participants (n = 90) were ethnically diverse, economically disadvantaged drug users recruited in New York City in 2009. Participants applied a wide range of contextually sensitive moral precepts, including respect, beneficence, justice, relationality, professional obligations, rules, and pragmatic self-interest. Limitations and implications for future research and the responsible conduct of addiction research are discussed.

Keywords ethics, participant perspectives, Belmont Report, confidentiality, moral values, bioethics, drug abuse, justice, autonomy, decision-making

INTRODUCTION

Approximately 20.1 million Americans use illicit drugs, with 3.9 million indicating substance abuse dependency (NSDH, 2008). Although drug abuse and dependency affects all socioeconomic and racial/ethnic categories, individuals living in impoverished neighborhoods and racial/ethnic minorities in the United States disproportionately suffer from social and health impairments associated with drug use, including human immunodeficiency virus (HIV) infection and high mortality rates (Buka & Kington, 2001; Hannon & Cuddy, 2006; National Survey on Drug Use and Health, 2008; Sanders-Phillips & Schoenbaum, 2001; Wenzel et al., 2009).

Today, many societal attitudes, treatments, and policies directed to the reduction of drug use in the United States are informed by knowledge generated and interventions tested by addiction research. Due to shifting trends in use of psychoactive drugs, high rates of medical and mental health comorbidity, the multiple factors and pathways underlying addiction and treatment resistance, the chronic relapsing nature of the disorder among some drug users, and the "natural recovery" observed for others, continued research on contextual factors associated with substance use and studies of treatment efficacy are essential for successful public health efforts to address this epidemic (Amaro, Arevalo, Gonzalez, Szapocznik, & Iguchi, 2006; Dodgen & Shea, 2000; Gorelick, 1992; Leshner, 1997; Lundgren, Amodeo, & Sullivan, 2006; Sobell, Ellingstad, & Sobell, 2002; Stahler et al., 2007). Ethical challenges along with the benefits of a national research agenda on drug use and misuse are associated with the multiple vulnerabilities of persons within these populations. Poverty, lack of education, related health conditions, illegal behaviors to obtain illicit drugs, ethnic minority status, and psychological characteristics such as cravings and impulsivity create ethical challenges for addiction research for which federal regulations and scientific codes of conduct do not provide easy answers.

Ethical Principles Underlying the Conduct of Human Subjects Research

Ethical decision-making in human subjects' research draws upon three basic principles recommended by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in the landmark Belmont Report (National Institutes of Health, 1979). The first principle, respect for persons, requires investigators to treat participants as autonomous agents and provide appropriate protections for persons with diminished autonomy. The second principle, beneficence, refers to scientists' obligation to generate knowledge using scientifically sound methods that maximize potential benefits and minimize risks of research participation. Nonmalfeasance, the obligation to do no harm, is an assumed corollary of this principle (Beauchamp & Childress, 2009). The

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third principle, justice, refers to the obligation to ensure fair distribution of the benefits and burdens of research.

The Belmont principles operationalized in federal regulations on human subjects' protections detail specific responsibilities of investigators and institutional review boards (IRBs) to ensure: (1) a reasonable balance between research risks and anticipated benefits; (2) the informed, rational, and voluntary consent to research participation; (3) appropriate protection of private and confidential information; and (4) equitable and noncoercive recruitment of research participants (DHHS, 2005).

In addition to the Belmont principles, the ethics codes of organizations, whose members conduct research, include principles and standards of conduct specifying general moral norms within their fields (Beauchamp & Childress, 2009; Fisher, 2009). These norms include the duty to clarify their professional roles and obligations, work to ensure the ethical compliance of their colleagues, promote accuracy and honesty in science, keep promises, avoid unclear commitments, establish relationships of trust with those with whom they work, and be aware of their responsibilities to communities and society (American Anthropological Association, 1998; American Medical Association, 2001; American Psychological Association, 2010; American Sociological Association, 1997; Public Health Leadership Society, 2002).

Ethical Contexts of Addiction Research

The National Insurance of Health (NIH, 1979) recognized that in the actual design and implementation of research, foundational principles often conflict. Rather than suggesting a serial ordering of one principle over the other, they recommended that investigators and IRBs take into account the concrete research context in which the principles will be applied. The need for contextually sensitive application of research ethics principles is especially relevant for ethical dilemmas that emerge during addiction research implementation. While experience provides an opportunity for implementation dilemmas to be anticipated in the design of addiction research protocols, the life situations of individuals who use illegal drugs on a regular basis combined with the socio-ecological context in which addiction science is conducted often raise unique and unexpected conflicts between different ethical principles.

For example, ethnographic investigators' first-hand immersion into the lives of street drug users over long periods of time can blur personal and professional boundaries of responsibility. A case in point can occur when participants ask researchers to hold or transport their drugs in order to avoid arrest, especially when the researcher has cast his or her sociological gaze on problem drug use among parents of young children (Barnard, 2005; Singer et al., 1999). Across a broad spectrum of research designs, investigators collecting data on the interrelatedness of drug use and HIV acquisition and transmission often become aware that HIV-infected participants are engaging in HIV risk behaviors with noninfected research participants (Dunlap, Johnson, & Rondolph, 2009; Fisher, 2004; Fisher et al., 2009; Singer et al., 1999). Such awareness can produce a moral quandary when addiction investigators question their roles and responsibilities to each participant. Treatment research can raise additional dilemmas. For example, as marginalized populations increasingly call for involvement in clinical trials as a right (Brody, 1998; Dresser, 2001), addiction investigators conducting research that includes treatments not otherwise available to participants, may be torn between conceptions of justice that seek to equalize treatment access for underserved populations and conceptions of fairness that strive to meet the social need for sound scientific data that will not expose these populations to the risks of untested experimental treatments (Buchanan, Fisher, & Gable, 2009).

Participant Perspectives

When investigators grapple with competing principles for good and rightly practiced addiction science, they draw upon the Belmont principles, professional codes of conduct, institutional guidelines, and their own moral compass. Thus, research ethics procedures are often constructed in isolation from the values and expectations of the participants for whom they are designed to protect (Fisher, 2002, 2004; Fisher & Wallace, 2000; Fisher et al., 2002; Fisher et al., 2008, 2009; Fry, Treloar, & Maher, 2005; Grady et al., 2006; Marshall, 1999; Oransky, Fisher, Mahadevan, & Singer, 2009).

There has been a paucity of research on moral reasoning among street drug users both generally and with respect to addiction research ethics. The few studies available focus on general levels of sociomoral reasoning, community attitudes toward the morality of drug use, the ethics of clinical research, and perceptions of research risk interpreted through the lens of traditional moral development theory or regulations for the protection of human participants (Grady et al., 2006; Rhodes, Zikic, Prodanovic, Kuneski, & Bernays, 2008; Slomka, McCurdy, Ratliff, Timpson, & Williams, 2008; Stevenson, Hall, & Innes, 2004). Applying traditional frameworks to the design of research ethics practices involving drug users and others who may deviate from traditional social norms may be inadequate when they do not reflect the practical ethical challenges confronted by drug use investigators nor inquiry into how these populations view and manage their moral worlds (Klockars and O'Connor, 1979).

There is little evidence of a single path to moral reasoning and moral development. Rather, moral evaluation and action are multiply determined through experience and continually evolving along with an individual's personal resources and social capital. Consequently, research ethics discourse informed by participants' moral perspectives confers contextual legitimacy to ethics-in-science decisions and gives participants the respect due all persons as moral agents in their own right (Dickert & Sugarman, 2005; Fisher, 1999). Failure to understand the moral principles and values applied by participants can result in an overestimation or underestimation of participant risk and personal agency leading to an overexposure to research harms or overprotective limitations on access to beneficial research (Mastroianni & Kahn, 2001; Slomka et al., 2008).

Aim of the Study

The primary aim of this study is to surface the moral precepts that street drug users apply to addiction research ethical dilemmas. The research sought preliminary answers to the following three questions:

- Which ethical precepts do street drug users apply in their moral justifications for resolving specific types of addiction research ethics dilemmas?
- To what extent do these precepts correspond to or deviate from ethical principles embodied in the Belmont Report and codified in regulations and professional ethics codes for human subjects' protections?
- Do street drug users apply these precepts rigidly or on a case-by-case basis sensitive to the contextual nature of each ethical dilemma?

METHODS

Participants

A total of 90 active drug users (51% male), mean age 34 years 7 months (*SD* = 9.98 years; range 18–61 years), participated in individual interviews. Participants self-identified as non-Hispanic black (31%), Hispanic (34%; majority Puerto Rican), non-Hispanic white (31%), and other (1%). Inclusion criteria entailed: (1) use of illegal or nonprescription drugs other than alcohol, marijuana, or prescription methadone within the past 30 days; (2) previous participation in drug use related research study; and (3) proficiency in spoken English. Participants were excluded during recruitment if they showed signs of withdrawal, mental disorder, or cognitive impairment. These inclusion–exclusion criteria are typical of ethnographic and intervention studies involving economically and socially marginalized street drug users. Recruitment was conducted at shelters, harm reduction centers, methadone mobile distribution sites, and other areas frequented by street drug users. Individuals who met inclusion criteria were given an appointment to participate in the research at local offices rented for the purposes of the study. During recruitment, individuals were informed that if at the time of the appointment they exhibited transient drug-related impairments, the appointment would be rescheduled. This did not prove necessary. Additional demographic data are included in the Results section.

Measures

Demographic Questions

Demographic information included data on drug use, employment, education, housing, incarceration, and HIV risk-related information.

Addiction Research Ethics Scenarios

As part of a larger study, three hypothetical addiction research dilemmas were created to reflect contexts in which moral principles might conflict during the conduct of research. The dilemmas were constructed to stimulate moral reasoning about "retrospective" responsibilities (Malone, Yerger, McGrudder, & Froelicher, 2006) operationalized in these scenarios as unanticipated challenges that arise during the implementation of IRB-approved research. In Case 1, Dr. Jones has been conducting participant observation on maternal drug use and parenting for several months. Just prior to an anticipated police raid, Terry, a female participant, asks Dr. Jones to hide her drugs. The researcher must decide whether protecting the participant from imminent arrest and potential loss of child custody is an ethical justification for breaking the law. In Case 2, Dr. Alba learns through ethnographic interviews that one participant, John, is intentionally hiding his seropositive HIV status from and having unprotected sex with another participant, Chris, who the researcher knows to be seronegative (adapted from Fisher et al., 2009). The researcher has promised confidentiality to the participants and must decide whether to disclose this information to the uninfected participant. In Case 3, Dr. Ross, the principal investigator of a placebo-controlled cocaine treatment study, must decide whether to fire the research assistant who has compromised random assignment by overenrolling into the treatment group homeless addicts with no healthcare resources.

For Cases 1–3 respectively, participants were asked to rate how important (1 = definitely not important, 4 = definitely important) it was for the investigator to obey the law by refusing to hide the drugs; keep the promise to protect HIV confidentiality; and to fire the research assistant for violating the randomization protocol. Participants were then asked to provide ethical justification for each of their decisions. The cases and questions are available upon request.

Procedures

The study was approved by the University's IRB and an informed consent was obtained. Participants were told the aim of the study was to "improve the way drug use and related HIV risk research is conducted by learning what community members think about everyday moral dilemmas and specific ethical challenges faced by researchers." They were informed that we would be describing situations that require researchers to make an ethical choice and asking them what they think researchers should do in these situations. They were also informed that we would ask them some general background information including questions about their drug use and health. In addition to explaining the voluntary nature of participation, compensation ($25 + public transportation) and confidentiality protections, the consent form specifically noted that "there are no direct benefits of participating." To minimize the potential effects of low reading levels which are characteristic of many in this population, all questions were read to participants and their answers contemporaneously transcribed by the interviewers. The demographic questionnaire was administered first. Prior to presenting the cases, interviewers defined research as follows: A research study is conducted by a researcher when he or she wants to understand why things happen the way they do, how people think and feel about issues, or what kinds of treatments may or may not work. For example, a researcher who wants to understand why people get addicted will ask participants to fill out surveys or interview drug users about their drug use. Or a researcher who wants to test whether a new treatment to reduce drug use works will recruit individuals, who use drugs, to participate in a study to test the treatment.

Coding Procedures

All interviews were transcribed verbatim for coding and analysis. The qualitative process began with extraction of key themes permeating responses to the three cases. In this first iteration, coding emphasis was descriptive and thematic rather than conceptual. As described in detail in the Results section, additional iterations yielded a coding frame that in many respects mapped on to the Belmont principles, principles of trust and fiduciary obligations inherent in professional association ethics codes, and sociomoral stage theory (Gibbs, Bassinger, & Fuller, 1992; Kohlberg, 1981). Once the coding guide was finalized, a trained independent scorer coded 50% (n = 135) of the responses randomly selected and equally distributed across the three cases. Interrater reliability was 94%, 89%, and 96% for Cases 1–3, respectively. The final coded scores, demographic information, and Likert-type decisional scores for each participant were entered into the SPSS (Statistical Package for the Social Sciences) for additional quantitative analyses. The coding guide is available from the author on request.

RESULTS

Study Population

Table 1 provides demographic and drug use information for all participants. The sample had approximately similar numbers of males and females and individuals self-identifying as black/African-American and Caribbean, Hispanic (largely Puerto Rican), and non-Hispanic white. Amphetamines, crack, cocaine, and heroin constituted the drugs of use most frequently reported over the past 30 days: 72% of amphetamine users also reported using crack, cocaine, or heroin, and 42% reported injecting drugs intravenously during this period. Over half of the users were unemployed, most reported income less than $250 a month, had a history of incarceration, had not attended high school, and lived in marginal housing (e.g., homeless, living in shelters).

Addiction Research Ethics Emergent Themes

Across cases, seven themes emerged. In this section, the themes and examples of participants' responses mapped on to each theme are described. Conceptual definitions and exemplars of each theme are provided for each case in Table 2.

TABLE 1. Demographic variables by number and percentage of participants (n = 90)

Demographic variable	n (%)	Demographic variable	n (%)
Gender		*Substance use in past 30 days*	
Male	46 (51)	Alcohol	49 (54)
Female	43 (48)	Marijuana	14 (15)
Transgender	1 (1)	Cocaine	31 (34)
Race/ethnicity		Crack	42 (47)
Black and Caribbean	28 (31)	Heroin	23 (26)
Hispanic/Black Hispanic	32 (36)	Amphetamine	90 (100)
White	29 (32)	Street methadone	13 (14)
Other	1 (1)	Speedball	18 (20)
Education		IDU	38 (42)
No formal education	22 (24)	*Unemployed*	49 (55)
Elementary	12 (13)	*Income in last 30 days*	
Middle school	28 (31)	None	30 (33)
Some high school	18 (20)	$1–$249	35 (39)
High school graduation or GED	6 (7)	$250–$499	12 (13)
Some college	4 (4)	$500–$999	7 (8)
Marginal housing	49 (54)	$1,000–$3,999	2 (2)
History of incarceration	59 (66)	*Income source*	
MSM	22 (24)	Steady work	30 (33)
Caring for a child	19 (21)	Pick up jobs	25 (28)
		Welfare	15 (17
		Disability	10 (11)
		Illegal activities	25 (28)

Note: Missing data or multiple category responses resulted in some percentages not equaling 100.

Respect for Personhood

Comments coded for this theme emerged in response to Cases 1 and 2 in which ethical justifications focused on participants as moral agents responsible for the consequences of their decisions and the investigator's duty to acknowledge participant agency. Justifications drawing on self-determination recommended that Dr. Jones did not hide drugs for Terry because she had failed to live up to her parental responsibilities, e.g., "If Terry cared about her kid, she wouldn't be doing drugs. So Dr. Jones should not help her."

A few responses to Case 2 were similar in spirit to regulatory and professional ethics code applications of the principle of respect to the obligation to protect participant privacy and self-determination. For example, some participants argued for and against disclosing John's HIV status to Chris based on John's "right to privacy" or Chris' "right to know who he is sleeping with." However, as in Case 1, most comments applied this principle to the hypothetical participant's responsibility to disclose HIV status or to protect oneself from HIV infection. In these justifications, moral agency belonged not to the investigator but to John to "let Chris know" or to Chris who should have "found out for himself."

TABLE 2. Thematic categories and illustrative statements across cases

Theme	Illustrative statements		
	Case 1	Case 2	Case 3
Beneficence			
Investigators should strive to do good and prevent harm. This principle can be achieved through: (1) maximizing knowledge that will be useful to future vulnerable populations through scientifically valid methods; or (2) maximizing the health and well-being of research participants and others, especially those who are vulnerable to harm.	"I don't care if Dr. Jones is a researcher or not, but the thing is Terry could lose her kid and once ACS takes the kid it is gone. So she should try to help Terry." "[Hiding the drug] would perpetuate a risky situation for the child without necessarily helping Terry."	"Chris could die then [Dr. Alba] will never be able to live with that." "Dr. Alba should tell Chris because that is only the right thing to do, He should make sure Chris doesn't get sick too. That goes beyond the duties of a researcher's promise to keep confidentiality in my opinion."	"This would violate the integrity of the study and would not necessarily help the addicts since the medicine's effects are yet unproven." "Dr. Ross should make an exception every now and then because in this case [Mary] is not just breaking the rules, she is trying to help those people."
Respect			
Investigators respect the rights of all individuals to self-determination by recognizing that participants are responsible for the choices that they make; have the right to knowledge that will affect their safety or healthcare decisions; or have a right to privacy.	"If Terry was so concerned about her kid, she wouldn't be doing drugs and hiding from the cops in the first place if you ask me." "Terry needs to know better than to ask Dr. Jones. That is not Dr. Jones's job." "Because you're grown and know what you're doing. You know the consequences."	"You gotta remember that John is a grown adult who can let Chris know if he wants. So no [Dr. Alba] should not tell Chris." "If Chris had some sense, he would have done some homework of his own and found out for himself. It is not Dr. Alba's job." If your going to do something that will hurt people's lives, confidentiality does not apply anymore." "John has a right to his privacy."	
Justice			
Fairness requires that investigators ensure that all persons have equal opportunity to share the benefits and burdens of research; eliminate bias in subject selection or group assignment; or use group assignment to make up for historic and current health disparities.			"Everyone should be treated the same which is why the guidelines were that way." "By firing Mary Dr. Ross did the right thing because he is saying that he does not support preferential treatment." "When you make exceptions like that you are not giving everyone an equal chance."
Relationality			
As human beings, researchers and participants are in relationships that obligate investigators to: (1) obtain and maintain the trust of participants and (2) honor the reciprocity of relationships in which both investigator and participant "get and give."	"Just because she is a researcher doesn't mean she stops being a friend." "How can you trust a researcher if the researcher is going around hiding drugs in their bags?" "You gotta help the person that's helping her get the data for her research."	"John trusted him with something personal, so he should not let him down I feel." "Because when you agree to participate in a study, you trust the researcher with something very personal. So it is all about trust."	
Professional obligations			
Researchers have responsibilities to participants and society defined by their training and membership in a profession. Investigators must serve as a model of right conduct;	"Dr. Jones should just do her job and not get involved in all of Terry's stuff. That is just getting too personal with your subjects and to me that feels wrong somehow.	"All that is not Dr. Alba's business if you ask me. He should just stay out of it and not get involved. Informing Chris is not his responsibility."	"[Mary] should have checked with [Dr. Ross] first. How can she take the decision into her own hands like that? She deserves [to be fired]."

(Continued on next page)

TABLE 2. Thematic categories and illustrative statements across cases *(Continued)*

Theme	Illustrative statements		
	Case 1	Case 2	Case 3
maintain professional–personal boundaries with participants; preserve the good reputation of the profession; and ensure the good conduct of other members of the profession.	"[Dr. Jones] should set an example for Terry, not the other way around." "If Dr. Jones gets busted then the research organization she works for ends up looking bad too."		"People need to know boundaries especially when it comes to work. Otherwise they do not learn." "This may not be that bad that she needed to be fired but if she gets away with it, next time another one of his staff will. So it is important to set examples."
Rules			
Rules have intrinsic moral value and are important for preserving social order. Investigators are morally obligated to obey the law, adhere to informed consent agreements with participants, and follow research guidelines.	"You should obey the law . . . no matter what it is. It is what keeps society going." "As a researcher [Dr. Jones] has a higher responsibility to obey the law at all times." "As a human being [Dr. Jones] should help out Terry, but since she is at a job she should obey the law."	"I don't care, but if you promise me to keep my info safe, then you should not go back on it. It is a basic expectation you know." "As a professional researcher, Dr. Alba has a responsibility to both Chris and John. But still, because he promised John he should keep that end of his professional obligation."	"Everybody should follow rules because otherwise there will be no order. So yes, [Mary] should be punished for that." "Dr. Ross should have considered that Mary was trying to help, but since she did break the rules she should be fired I feel."
Pragmatic self-interest			
The moral priority in a given situation is to maximize satisfaction of the researcher's own needs and to minimize negative consequences to the self.	"I don't think that [Dr. Jones] should break the law. . ..that would end up with her in jail." "Why am I [Dr. Jones] going to take something when I could go to jail? My family and everything I studied could go down the drain."	"[Dr. Alba] has to follow the rules because he could lose his license."	"What if they, the people who gave him the money for the study, come after Dr. Ross? So he is doing the right thing—he is protecting his job." "If they find out, then it will look bad on Dr. Ross. He is the main researcher and he will be held accountable for Mary's stupidity. So its good that he fired her."

Beneficence

Statements coded for this theme emphasized the investigator's obligation to do good and minimize harm. Only a handful of statements reflected the Belmont Report's application of this principle to researchers' obligation to generate scientifically valid research to promote public welfare: Five respondents justified firing Mary because she had jeopardized the scientific validity of the randomized controlled trial (RCT) study by violating the scientific norms. As one respondent noted, "She's ruining the whole study. The results will not be accurate."

For most respondents, the application of this principle went beyond the Belmont Report's focus on research risks and benefits to include an obligation to protect the health and well-being of participants and others beyond the research context: a valuing more consistent with a conception of beneficence based on human beings as in need of goods and vulnerable to harm (Dubois, 2008). For example, in Case 1, the moral imperative for or against hiding Terry's drugs was protecting Terry from losing her children or protecting the children from "a risky situation." A few were concerned that if Dr. Jones "gets caught then who is going to help all the Terry's in the world."

In response to Case 2, almost a quarter of respondents believed that Dr. Alba should disclose John's HIV status because he had a moral "duty to protect" Chris from getting "a deadly disease" or to "save a life." Some thought that this obligation stemmed from Dr. Alba's expertise as a researcher. Others referred to Dr. Alba's potential complicity in exposing Chris to danger if the researcher maintained confidentiality. In many instances, respondents specifically gave beneficence privileged moral status, noting, e.g., that "Chris's health is more important than John's privacy." Similarly, in Case 3, many respondents believed that “Mary should not be fired for trying to help people.” Some, as illustrated in the following statements, explicitly prioritized helping participants over the obligation to follow rules: “Dr. Ross should make an exception every now and then because in this case she is not just breaking the rules, she is trying to help those people”; “Dr. Ross is being too harsh. [Mary] is trying to help them, she didn’t steal or anything.”

Justice

Statements coded for this category emerged primarily in response to Case 3. Consistent with the National Commission, comments emphasized that fairness and justice entitles all participants to equal access to the potential benefits and burdens of research. As illustrated by the following quote, the majority of comments coded for this theme justified a decision by Dr. Ross to fire Mary for overenrolling those who were homeless, based on a researcher’s obligation to eliminate “bias” or “preference” in subject selection and RCT group assignment, i.e., “I think when you make exceptions like that you are not giving everyone an equal chance.” Some linked fairness in RCT group assignment to achieving scientific goals, i.e., “Because that’s doing research. You’re not going to get the results you need. She’s having favoritism.” Only one of the 90 respondents applied a distributive justice argument in favor of Mary’s actions, “Because nobody ever does anything for people that are homeless. They deserve exceptions.”

Relationality

This theme reflected belief that researchers and participants are in relationships based on expectations of trust and reciprocal exchange. The theme is closely linked to principles of social responsibility found in association ethics codes and to Dubois’ (2008) principle of relationality, which assumes that good and rightly practiced research requires appreciation of participants and investigators as members of a community intrinsically related to one another. Statements coded for Relationality emerged primarily in response to Case 2 and to a lesser extent to Case 1. For example, in response to Case 1, justifications for Dr. Jones to hide the drugs for Terry were based on friendship, i.e., “Just because she is a researcher doesn’t mean she stops being a friend,” or on reciprocal exchange, i.e., “[Terry] helped [Dr. Jones] get the data for her research.” One respondent thought that Dr. Jones would jeopardize the trust of other participants if she hid the drugs. For Case 2, most ethical justifications coded for this theme argued against disclosing John’s HIV status to Chris because “keeping your participant’s trust has to be the number one job of a researcher.”

Professional Responsibility

Comments scored for this theme interpreted moral actions in terms of researchers’ responsibilities to participants and society based on their distinct training and membership in a profession. Beauchamp and Childress (2009) suggest that such norms comprise a “professional morality.” Across scenarios, moral justifications appealed to researchers’ obligation to serve as a model of right conduct, maintain the boundary between professional and personal relationships with participants, preserve the good reputation of the profession, or ensure the good conduct of those with whom they work. This theme is consistent with principles of professional responsibility articulated in the ethics codes of several professional organizations (American Anthropological Association, 1998; American Medical Association, 2001; American Psychological Association, 2010; American Sociological Association, 1997).

For Case 1, many expressed the belief that hiding the drugs for Terry would create an unethical blurring of professional and personal boundaries that “crossed a line” or gave an inappropriate “mixed message.” Other justifications for Dr. Jones to refrain from hiding the drugs reflected an expectation that investigators have a professional obligation to “set an example” of appropriate behavior in their relationships with participants and to protect the reputation of their profession. Case 2 statements coded for this theme focused on Dr. Alba’s fiduciary responsibility to maintain professional–personal boundaries by not interfering in John and Chris’ “business.” For Case 3, some justifications for firing Mary emphasized that she had overstepped her role responsibilities noting that “it was not her study” or “her decision to make.” Others stressed Dr. Ross’ responsibility to ensure that his employees complied with standards of conduct by “teaching them a lesson” or the importance of disciplining Mary to set an example for his other staff members.

Rules

Across the three scenarios, justifications coded for this theme conceptualized moral action in terms of the investigator’s obligation to obey the law, uphold contracts and promises, or adhere to standards of research design. Rule justifications are more specific in content and restrictive in scope than other moral principles (Beauchamp & Childress, 2009). Responses in this category most closely resembled Kohlberg’s description of conventional moral reasoning in the application of rules whose moral authority is not to be questioned (Gibbs et al., 1992; Kohlberg, 1981). While most responses did not go beyond following rules as a moral good in and of itself, others expressed the importance of rules in sustaining a functioning society or profession.

Not surprisingly, all participants applying a Rules justification for Case 1 believed that Dr. Jones should not break the law to hide drugs for Terry. One-third of these comments framed lawful behavior as a universal precept independent of the investigator status as illustrated in this response, “No one is above the law.” Many statements expressed the belief that Dr. Jones’ status as a researcher conferred a greater responsibility to be law-abiding than might be true for nonprofessionals. As noted by one respondent, “You don’t expect people like that—doctors and researchers to break the law.”

For Case 2, Rule justifications for Dr. Alba to maintain the confidentiality of John’s HIV status stressed the universal importance of promise-keeping. As one respondent put it, "When you make a promise, you must keep it." Some respondents assumed that researchers take an oath to maintain confidentiality as part of their professional duties, and thus, if they were "dedicated to their career," they had to "follow [their] oath." Other respondents attempted to reconcile prioritizing promise-keeping over other ethical precepts by suggesting ways that Dr. Alba could protect John's HIV status and help Chris by recommending that John discloses to his partner or by making a general suggestion to Chris to be tested for HIV.

In Case 3, justifications for firing Mary centered around her breaking the rules by overenrolling homeless persons. Some emphasized the general precept that "rules are rules." Others specifically mentioned "going against the [research] guidelines." Many statements noted that anyone who breaks the rules "deserves" or should "know" that there will be consequences. Some respondents noted the moral conflict Mary faced but thought that breaking the rules should supersede "doing something great for that particular group of people."

Pragmatic Self-Interest

Ethical justifications scored for this theme were based on maximizing satisfaction of the researcher's own needs and avoiding sanctions. Beauchamp and Childress (2009) suggest that conflicts between moral requirements and self-interest should be interpreted as practical rather than moral approaches to such dilemmas. Such reasoning is most closely tied to the Stage 1 level of sociomoral reasoning described by Kohlberg (1981) and Gibbs et al. (1992). Case 1 elicited the most frequent use of statements in this category focusing exclusively on the negative consequences to Dr. Jones if she agreed to hide the drugs for Terry, including the risk of getting "caught," "arrested," going to "jail," or "losing her 'career and freedom."' In contrast, this theme appeared much less frequently in response to Cases 2 and 3. Only one participant mentioned a rationale for protecting Dr. Alba's self-interest, stating that "He has to follow the rules because he could lose his license." Only four comments indicated that Dr. Ross should fire Mary out of self-interest to "protect his job," "not to lose money" from funders, or to avoid "looking bad" or "sued."

Unscored Responses

Responses scored as uncodable fell into the following categories: pronoun ambiguity, respondent's inability to draw a conclusion, justifications that fell equally into more than one category, or refusal to answer the question.

Coding Categories by Participant Characteristics

A 2 (gender) × 3 (ethnicity) multivariate analysis of variance was conducted, with the frequency of each of the seven themes across the three cases as dependent variables. Neither main effects nor a gender–ethnicity interaction yielded significance in the multivariate analysis. Applying a Bonferonni correction ($p < .007$), 2 × 3 univariate analyses on each theme similarly did not yield significance. Point-biserial correlations explored individual participant consistency in application of moral themes to the three distinct cases. With one exception, no significant correlations emerged: participants who applied a rule-governed justification to Case 2 were also likely to apply it to Case 3 ($r = .24$, $p = .024$).

TABLE 3. Number and percentage of responses ($n = 90$) coded for each theme across three cases

Thematic category	Cases			
	Case 1	Case 2	Case 3	Total
Respect	6 (7%)	9 (10%)	0 (0%)	15 (6%)
Beneficence	23 (26%)	22 (24%)	19 (21%)	64 (24%)
Justice	0 (0%)	1 (1%)	19 (21%)	20 (7%)
Relationality	3 (3%)	16 (18%)	0 (0%)	19 (7%)
Professional obligations	18 (20%)	8 (9%)	23 (26%)	49 (18%)
Rules	15 (17%)	23 (26%)	20 (22%)	58 (21%)
Pragmatic self-interest	20 (22%)	2 (2%)	4 (4%)	26 (10%)
Uncodable	5 (6%)	9 (10%)	5 (6%)	19 (7%)

Frequency of Themes and Resolutions

Table 3 provides the frequency and proportion of comments scored for each theme across all three cases. On the basis of the absence of individual difference effects described above, the table represents the participant sample as a whole. Dominant themes in response to Case 1 included beneficence, professional obligations, rules, and pragmatic self-interest. The majority (79%) of respondents concluded that it was important for Dr. Jones to obey the law and refuse to hide the drugs for Terry. Ethical justifications for hiding the drugs for Terry only emerged in responses coded for beneficence and relationality. The most frequently coded themes for Case 2 were beneficence, rules, and professionalism. With the exception of those whose ethical justification was rooted in the principle of beneficence, most respondents (72%) recommended that Dr. Alba should keep his promise to not disclose John's HIV status to Chris. Justifications based on beneficence, justice, professional obligations, and rules dominated responses to Case 3. Most (78%) thought that Mary should be fired, with only beneficence ("she was trying to help those people") emerging as a primary justification for not firing Mary. Dependent *t* tests were conducted to evaluate the contextual dependence of themes across cases. As illustrated in Table 3, cases differed significantly in justifications reflecting respect, justice, relationality, professionalism, and pragmatic self-interest.

DISCUSSION

An evolving perspective in public health research suggests that expert-driven ethical decision-making may be limited in its ability to anticipate ethical problems and generate solutions appropriate to the publicly charged and contextual nature of socially sensitive research (Barnard, 2005;

Buchanan, 2008; Childress et al., 2002). While ethical engagement with members of prospective participant communities is increasingly discussed in the field of addiction research (Fisher, 2004; Fisher et al., 2008, 2009; Fry et al., 2005), empirically generated knowledge illuminating the moral lens through which street drug users view investigators' ethical decisions is rare. This preliminary investigation provides an insight into ethical precepts applied by street drug users to addiction research dilemmas.

The data answered the three questions posed in the introduction of this article. First, analysis of participant ethical justifications indicated that they use the following moral precepts in resolving research ethics dilemmas: respect for personhood, beneficence, justice, relational obligations, professional responsibility and adherence to social rules, and pragmatic self-interest. Second, the first three of these precepts correspond to ethical principles embodied in the Belmont Report and codified into federal regulations for human subjects' protections, and the precepts involving relational obligations, professional responsibility, and adherence to social norms correspond to standards governing research in professional association codes of conduct. However, as detailed below, while regulations and professional codes restrict obligations imposed by these principles to investigators, street drug users applied these precepts to both investigators and participants. Finally, the data provided insight into whether street drug users applied these precepts rigidly or on a contextually sensitive case-by-case basis. Individually, and as a group, participants prioritized different moral precepts to justify resolution of each dilemma, demonstrating moral sensitivity to the contextual requirements of each case. This section highlights the implications of these findings for addiction research.

Respect for Personhood

As articulated in regulations and professional guidelines for research participant protections, the principle of respect is typically perceived as investigators' obligation to ensure that participation is informed, rational, and voluntary, and that participant privacy is protected. Unexpectedly, the majority of ethical justifications based on the principle of respect for personhood were applied to drug users' own role as moral agents responsible for the consequences of their actions. For example, Mary's failure to consider the consequences of her drug use to the welfare of her children was believed to be an ethical justification for Dr. Jones to refuse to hide Mary's drugs from the police. Only a few comments in response to Case 2 emphasized John's "right to privacy." Rather, some respondents concluded that John's irresponsible behavior justified Dr. Alba disclosing John's HIV status to Chris. For others, Dr. Alba was justified in maintaining John's confidentiality because Chris should take responsibility for being aware of and protecting oneself against sexually transmitted diseases.

This pattern of results illuminates a potentially striking distinction between participant and investigator perceptions of moral agency and self-reflection among drug users that deserves future exploration. Compulsive thoughts and impulsive behaviors associated with addiction have often led to more general claims of drug users' compromised autonomy. While decisional capacity may be impaired during periods of intoxication or cravings, the emphasis on moral agency and personal responsibility expressed by some of our respondents adds to a growing body of ethics scholarship calling for appreciation and cultivation of autonomy in illicit drug using and other vulnerable research populations (Buchanan, 2008; Foddy & Savulescu, 2006; Slomka et al., 2008).

Beneficence, Relationality, and the Scientist–Citizen Dilemma

Participants whose ethical justifications were motivated by themes of beneficence often applied this principle to obligations to do good and avoid harm that extended beyond those traditionally associated with the responsible conduct of research. For example, respondents who recommended that Dr. Jones should hide Mary's drugs, justified the decision in terms of an obligation to help ensure that children are able to be raised by their mothers. In the Dr. Alba case, many respondents believed that "saving a life" held moral precedence over investigator promises of participant confidentiality. Similarly, participants who believed that Mary should not be fired for overenrolling homeless addicts into an RCT, prioritized "helping" over deviating from research guidelines and other arguments for firing her, i.e., "It's not like she murdered anyone." Only a handful of participants advocated that Mary should be fired because her actions had undermined research methods that could determine treatment effectiveness.

Justifications coded for relationality similarly emphasized personal rather than professional obligations. For example, in Case 1, Dr. Jones' months of participant observation was seen as creating relationships of trust that extended obligations beyond those of researcher and participant, to friendship and responsibilities based on reciprocity. In Case 2, justifications for maintaining confidentiality or disclosing potentially dangerous information were sometimes framed within the context of the trusting relationship established between Dr. Alba and John or Chris.

The Scientist–Citizen Dilemma

Endorsement of the extra-experimental obligations conferred by respondents' application of principles of beneficence and relationality may reflect the "scientist–citizen dilemma" (Fisher & Goodman, 2009; Fisher & Rosendahl, 1990; Veatch, 1987). This dilemma arises from investigators' dual identity as a professional scientist and as a citizen of the larger moral community. As professional scientists, investigators and IRBs emphasize the obligation to produce scientifically valid knowledge in a manner that minimizes risks and maximizes benefits directly related to the research design. As citizens, researchers conducting socially sensitive research are confronted with questions of interpersonal moral responsibility that transcend the investigator role. Although participant populations and members of the research establishment may differ in their prioritization of these responsibilities, the mutual recognition that such dilemmas are inherent in the conduct of science may be a productive starting point for scientists' ethical engagement with members of communities struggling with addiction.

Justice

The principle of justice dominated participants' decisions to fire Mary for overenrolling homeless addicts into a randomized placebo-controlled addiction treatment trial (Case 3). Respondents viewed such actions as biased and unfair. These findings suggest that investigators and IRBs should be sensitive to how members of vulnerable populations view group membership. Although half of the participants were themselves homeless or living in marginal housing, they perceived an investigator's preferential treatment for members of this group as unethical. Only one of 90 participants provided a distributive justice rationale for overenrolling members of this group as compensation for health disparities suffered by homeless drug users. Additional research is needed to examine the extent to which these perceptions of fairness reflect a cohesive or fragmented sense of group identity among impoverished drug users, belief in the potential benefits of carefully controlled experimental treatments, or a privileging of justice over other principles.

Professional Obligations and Rules

Ethical justifications drawing upon professional obligations or rules indicate that respondents placed a great deal of faith in and expected that investigators should be held to a higher standard of moral responsibility than nonprofessionals. While some comments framed rule-following as universally required, many specifically related this duty to a belief that as professionals, researchers were expected to "know better." Statements drawing on this precept emphasized investigators' obligations to serve as models of right behavior for participants and to ensure that others conduct research responsibly. In contrast to comments reflecting the dual obligations associated with the scientist–citizen dilemma, in statements coded for beneficence or relationality, most justifications reflecting professional obligations called for definitive boundaries between professional and personal roles. Underlying many of these statements was the recognition that good and rightly practiced research may not always result in decisions meeting all participants' interests.

Pragmatic Self-Interest and Sociomoral Maturity

Only 10% of responses reflected justifications for moral action based on maximizing satisfaction of the researcher's own needs and avoiding sanctions. Sociocognitive theorists consider such responses as "immature," with greater maturity marked by a progression through empathic concern and social perspective-taking, an understanding of trust and mutuality, to appreciation of interdependencies underlying society (Gibbs et al., 1992; Kohlberg, 1981).

There has been a paucity of research on moral reasoning among street drug users. The few theoretical and empirical studies examining moral reasoning among criminal populations, some of whom used drugs, are inconclusive regarding the attainment of mature levels of moral reasoning (Stevenson et al., 2004). Taken as a whole, the diversity of moral precepts expressed by participants, including sensitivity to the welfare of others, consideration of moral agency, fairness, interpersonal responsibilities, and appreciation of role obligations, suggests that socially and economically marginalized street drug users with minimal levels of education are nonetheless capable of mature sociomoral reflection.

Moral Sensitivity and Context

Engagement in illegal behaviors, social stigma, and the social, economic, and health risks associated with substance abuse exacerbated by disparities in education, housing, and health services highlight the need for contextually sensitive interpretations of federal regulations for the protection of participants involved in addiction research (Farmers, Connors, & Simmons, 1996; Singer, 1994). When working with populations with known health, social, legal, and economic vulnerabilities, addiction researchers often confront problems for which different moral precepts suggest different moral actions. Resolving such dilemmas is a reflective, contextually and relationally based endeavor, with no cookie cutter answers. Scientists and IRBs do not expect nondeliberative, categorical, or decontextualized answers from their colleagues on such complex issues.

The present study confirms a similar diversity among street drug users in applying different moral precepts to addiction research ethics dilemmas. Moreover, individual participants did not uniformly apply the same precepts to the three different cases but rather took into account the specific research context in which the dilemma arose. For example, the Case 1 dilemma involving breaking the law to protect a mother of young children from arrest primarily elicited ethical justifications based on beneficence or rules (laws). The Case 2 dilemma pitting breaking confidentiality against warning a participant about HIV risk raised justifications based on relationships of trust and participant autonomy. Justifications based on the principle of justice only emerged in response to the Case 3 dilemma concerned with oversampling of homeless persons in a treatment efficacy study. These results suggest that investigators engaging drug-using populations in an ethical dialogue should anticipate and encourage participants' multiple and contextually sensitive views of the moral rightness of specific human subjects' protections.

Limitations

This study provides preliminary data on the moral precepts that a sample of marginalized street drug users apply to addiction research ethical dilemmas. Some limitations should be noted. First, the sample, while racially and ethnically diverse, was drawn from New York City, Bronx, and Brooklyn, all densely populated urban environments with their own unique drug cultures, extensive network of research institutions, and social services for active drug users. Second, while interrater agreement on coded themes was high, the preliminary nature of the coding scheme calls for replicability with different samples and across different hypothetical cases. Third, the thematic findings emerged in response to hypothetical scenarios. Ethical evaluation might be different if participants were speaking about an actual experience. However, such is also true for investigators and IRBs attempting to establish a priori protocols for addressing ethical dilemmas that emerge during the course of research. In addition, the moral development literature consistently demonstrates that scores on moral reasoning tasks are only moderately correlated with actual moral behavior (Smetana & Killan, 2005). Future research is needed to examine whether drug users' moral judgments are related to their willingness to participate in addiction research and how actual research participants evaluate the moral conduct of investigators.

A fourth limitation is the absence of data on the complexity of each participant's personal and social resources to his or her moral evaluations of research. The percentage of responses illustrated in Table 3 underscores the individual variability in moral precepts applied to research ethics dilemmas. The moral precepts of street drug users, like all individuals, are continuously shaped by a variety of roles, environmental contexts and social networks, social networks, a range of personal qualities, the challenges of street drug life, and, in the case of research ethics, their experience with health scientists and practitioners. Finally, the brief response format calling for justifications for a linear ethical judgment and categorical coding system also limited exploration of the nonlinear dynamic and multidimensional nature of ethical decision-making. A more in-depth study of the complex processes underlying moral judgment applied by drug users across a variety of contexts is needed.

CONCLUSION

Research is a moral enterprise requiring contextually sensitive and principle-guided reflection on the nature of the good and how scientists should pursue it. Including the perspectives of participant communities in this enterprise lends a moral authority to research that would otherwise be lacking (Dubois, 2008). Consideration of participant perspectives on addiction research ethics dilemmas can inform but not dictate how investigators and their IRBs resolve such dilemmas. Rather, the purpose of this type of empirical investigation is to challenge current ways of thinking about addiction research ethics and point to new directions of moral awareness and scientific inquiry (Fisher & Wallace, 2000; Fisher et al., 2008; Grady et al., 2006).

Although limited by the preliminary nature of this study, several insights can be gleaned from the current research. First, while the combination of poverty, poor education, and addiction can create decisional vulnerabilities leading to illegal behaviors, this study demonstrates that street drug users have the ability and willingness to grapple with core dimensions of morality. They share with investigators an appreciation for foundational moral principles guiding research regulation and scientific codes of conduct. Like members of the research community, their ethical justifications reflect individual diversity and sensitivity to the research context. Second, they see themselves and addiction researchers as moral agents responsible for the consequences of their actions. Third, they value the expertise and professional obligations conferred on scientists by virtue of their education and status. They look to researchers as role models, hold them to a higher standard of moral excellence, and expect them to treat all participants fairly and equally. While they are not comfortable when scientists blur certain professional and personal boundaries, they do value participant–scientist relationships based on trust and reciprocity. Fourth, while they recognize and respect scientists' professional obligations, they believe that some moral ideals supersede these obligations, including protecting children, saving a life, and helping the needy.

Research involving impoverished and marginalized groups disproportionately burdened by illicit drug use and related HIV risk is essential if treatment, prevention, and harm reduction programs are to adequately address the unique challenges of addiction in these populations (Adrian, 2006; Deren et al., 2003). However, as drug use investigators have long noted, such research efforts are stymied by how difficult it is to recruit these "hidden populations" (Ompad et al., 2008; Scott, 2008; Vernon, 2007; Watters & Biernacki, 1989). There is a growing consensus that breaking down recruitment barriers requires an understanding of local beliefs about research practices within the context of community norms (Fisher, 2004; Fry, Madden, Brogan, & Loff, 2006; Grady et al., 2006; Oransky et al., 2009; Plumridge & Chetwynd, 1998; Rhodes et al., 2008; Slomka et al., 2008; Velleman et al., 1993). This preliminary investigation adds to the growing literature by highlighting the moral lens through which street drug users view ethical dilemmas encountered by addiction researchers and illuminates new areas meriting investigation. Engaging active drug users as moral agents and integrating prospective participant opinions in ethical decision-making will help investigators and IRBs actualize the moral ideals guiding research.

Declaration of Interest

The author reports no conflict of interest. The author alone are responsible for the content and writing of this paper.

RÉSUMÉ

La ética en la investigación sobre adicciones y los principios de Belmont: ¿los consumidores de drogas tienen una conciencia moral diferente?

Este estudio utilizó entrevistas semi dirigidas y análisis de contenidos a fin de examinar los principios morales que aplican los consumidores de drogas de la calle a las 3 hipótesis de dilemas éticos de la investigación sobre adicciones. Los participantes eran 90 consumidores de drogas de diferentes etnias y de escasos recursos económicos que se reclutaron en la ciudad de Nueva York en 2009. Estos participantes aplicaron una amplia variedad de preceptos morales que dependían del contexto, por ejemplo, el respeto, la beneficencia, la justicia, la interacción personal, las obligaciones profesionales, las normas y el interés personal pragmático. Se debate sobre las limitaciones y las consecuencias de la investigación futura y la conducta responsable en la investigación sobre adicciones. Esta investigación se financió con la subvención número RO1 DA015649–01A2 del NIDA (National Institute on Drug Abuse, Instituto Nacional sobre el Abuso de Drogas).

RESUMEN

Éthique de la recherche sur les addictions et Principes de Belmont: les consommateurs de drogues ont-ils une ligne de conduite morale différente ?

Cette étude se basait sur des entretiens semi-structurés et l’analyse de leurs contenus pour examiner les principes moraux que les consommateurs de drogues illicites appliquent à 3 dilemmes éthiques hypothétiques en matière de recherche sur les addictions. Les 90 participants étaient des consommateurs de drogue économiquement défavorisés et issus de 90 ethnies différentes, recrutés dans la ville de New York en 2009. Ces derniers ont appliqué une large gamme de préceptes moraux dictés par des contextes précis, parmi lesquels le respect, la bienfaisance, la justice, la relationalité, les obligations professionnelles, les règles et l’intérêt personnel motivé par le pragmatisme. Les limites et les implications pour des recherches futures ainsi que la conduite responsable des recherches sur les addictions sont examinées. Cette recherche était soutenue par le NIDA, subvention N° RO1 DA015649–01A2.

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GLOSSARY

Belmont principles: This refers to the moral principles of respect, beneficence, and justice proposed by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in the landmark Belmont Report (NIH, 1979).

Beneficence: In federal regulations, this ethical principle requires investigators to minimize research risk, maximize potential research benefits, and attain a reasonable balance between research risks and potential benefits.

Justice: In federal regulations, this ethical principle pertains to fair distribution of the burdens and benefits of research.

Professional obligations: In ethics codes for professional organizations, this term applies to the duty to clarify professional roles, ensure the ethical compliance of colleagues, promote honesty in science, keep promises, maintain trust, and fulfill obligations to community.

Relationality: In this article, this term refers to researchers’ obligation to maintain the trust of participants and honor the reciprocity of participant–investigator relationships.

Respect: In federal regulations, this ethical principle requires protection of research participant autonomy usually attained through informed consent and protection of private and confidential information.

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