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Conducting Health Disparities Research with Criminal Justice Populations: Examining Research, Ethics, and Participation

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Conducting Health Disparities Research with Criminal Justice Populations: Examining Research, Ethics, and Participation

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This study explored the challenges of informed consent and understanding of the research process among Black and Latino men under community supervision (e.g., parole and/or probation). Between February and October 2012, we conducted cognitive face-to-face interviews using open-ended questions on the significant areas of research participation (i.e., the informed consent process, confidentiality, compensation, what is meant by human subject and clinical trials) among 259 men aged 35 to 67 under community supervision in Bronx, New York. Content analysis of the open-ended questions revealed limited knowledge concerning the understanding of research participation. The study participants appeared to generally understand concepts such as compensation after research participation and confidentiality. Participants demonstrated a lack of understanding of certain aspects of the research process—*informed consent, human subject, Institutional Review Board, and clinical trials.* These findings are informative to researchers conducting studies with criminal justice populations and Institutional Review Boards reviewing research studies.

Keywords: trust, responsible conduct of research, medical ethics, research participants

INTRODUCTION

Every year across the United States, approximately 650,000 people are released from prison and several million individuals are released from local jails (Pew Center on States, 2008). Black Americans represent 900,000 of the 2.3 million people incarcerated in the United States, and Latinos comprise 20% of the correctional system population, a drastic increase of 43% since 1990 (Fullilove, 2006; Pew Center on States, 2009; West & Sabol, 2009). Due to lifestyle and risky behaviors (Fullilove, 2006; Hammett, Roberts, & Kennedy, 2001; Petersilia, 2003), Black Americans and Latino men under community supervision (e.g., parole or probation) also appear to have a disproportionately greater burden of viral infections (e.g., HIV, Hepatitis C (HCV), and chronic health disparities; Binswanger, Nowels, Corsi, Long, & Booth, 2011; National Commission on Correctional Health Care, 2002; Williams et al., 2010). Black Americans and Latino men under community supervision and returning to the community face numerous hurdles upon release. These challenges include, but are not limited to, unemployment, unstable housing, history of substance use, access to health care, and mental health problems, including anti-social personality disorder (Binswanger, Nowels, Corsi, Long, & Booth, 2011; Brown et al., 2010; Chiu, 2010; Fazel & Danesh, 2002; Freudenberg, Daniels, Crum, Perkins, & Richie, 2005; Greifinger, 2007; Marlow & Chesla, 2009; Petersilia, 2003). Many healthcare providers, researchers, and clinicians view community supervision as an important opportunity to provide linkage to health care services, prevention, and treatment through access to biomedical research and clinical trials for people who have failed to continue treatment initiated during their incarceration (Eldridge, Robinson, Corey, Brems, & Johnson, 2012; Rich et al., 2001).

Although these individuals clearly do not fit the definition of “prisoner(s)” under current federal regulations, Subpart C of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research currently expands the definition of “prisoner” to encompass individuals in community correctional settings (e.g., halfway houses, residential treatment programs) or under community supervision. Emanuel, Crouch, Arras, Moreno, and Grady (2003) and Thomas (2010) have suggested that existing regulations and oversight should be revised to reflect the new challenges to biomedical research and clinical studies. At present, the 2006 Institute of Medicine has provided recommendations for conducting research in correctional settings with incarcerated individuals; however, the individuals under community supervision are no longer incarcerated, and the ethical issues and challenges in conducting clinical trials and biomedical research remain overlooked. A feature of both the 2006 Institute of Medicine report and the existing federal regulations designed to provide protection for prison populations is the absence of empirical data to guide deliberation about the role and conduct of biomedical and clinical research in community supervision settings (U.S. Department of Health & Human Services, 2009). Our study aims to understand the ethical challenges in conducting health research studies with men under community supervision.

METHOD

This article is based on data collected for a study that examined health outcomes among men under community supervision between the ages of 35 and 67 in Bronx, New York. The aim of the parent study was to understand cancer risk and health outcomes among Black Americans

and Latino men under community supervision. The goal of the present study was to assess whether the study participants comprehended key terms used in obtaining informed consent and to evaluate their understanding of participating in health research studies. Albert Einstein College of Medicine's Institutional Review Board approved the study, and we obtained a Federal Certificate of Confidentiality.

Participants

Recruitment took place over 8 months between February 2012 and October 2012. Using a venue-based sampling approach (Muhib, Lin, Stueve, Miller, & Ford, 2011), men were primarily recruited via fliers placed in the criminal court, parole and probation offices, addiction treatment centers, and reentry agencies in Bronx County. Participants underwent an informed consent process and completed an individual cognitive questionnaire with a trained interviewer. We surveyed 259 Black Americans and Latino men released from prison or city jail. Table 1 provides demographic information about the respondents.

Study Setting

Bronx, New York, is one of the poorest counties in the United States; 41% of all Bronx residents live below the federal poverty level (New York City Department of Health, 2009). The Bronx also has an unemployment rate of 13.9% (New York State Department of Labor, 2012) and a disproportionate incidence of chronic health disparities, including HIV/AIDS, cancer, asthma, and diabetes (University of Wisconsin Population Health Institute, 2012). Bronx, New York, has a total population of 128,313 former prisoners, of which 35% are foreign born (Mellow, 2008). Black Americans comprise more than half of all former inmates residing in the Bronx, and the borough has largest number of former prisoners of Latino descent in New York City (Mellow, 2008; New York State Division of Corrections and Community Supervision, 2012).

Cognitive Questionnaire Interviews and Procedures

As part of the individual cognitive questionnaires, study participants were asked to assess and evaluate the consent form and their comprehension of health research (Belson, 1981). These questions examined aspects of research participation (i.e., informed consent, confidentiality, compensation, and what is meant by human subject and clinical trials). Responses to the open-ended questions were analyzed for this study. The cognitive questionnaire interviews lasted approximately 2 hr, and participants were compensated \$30 for their time.

Data Analysis

Content analysis was used to code men's responses to the open-ended questions regarding research participation and knowledge. The open-ended questions were as follows: (a) What is informed consent? (b) What is confidentiality? (c) What is an Institutional Review Board? (d) What is compensation for your participation? (e) What is a human subject? (f) What are clinical trials? Space was provided for answers to these open-ended questions, wide enough for

TABLE 1
Participant Characteristics

<i>Characteristics</i>	<i>N = 259</i>
Age in years, <i>M</i> (range)	47 (35–67)
Race/ethnicity, <i>n</i> (%)	
Black	120 (46%)
Latino	127 (49%)
Other	12 (6%)
Marital status	
Single	159 (61%)
Married	44 (17%)
Divorced	46 (17%)
Widow	10 (5%)
Education	
Less than high school/ No GED	161 (62%)
High school/ GED	65 (25%)
Trade school/Some college	27 (10%)
College degree	5 (2%)
Employment	
Yes	137 (53%)
No	122 (47%)
Length of incarceration	
Less than 1 year	110 (43%)
1–2 years	32 (12%)
2–5 years	59 (23%)
More than 5 years	57 (22%)
Type of facility	
Jail	102 (40%)
Prison	157 (60%)
HIV status	
Yes	45 (17%)
No	213 (82%)
HCV status	
Yes	71 (34%)
No	138 (65%)
Don't know	1 (1%)
Chronic condition (reported 1 or more)	
Asthma	70 (27%)
Arthritis	57 (22%)
Chronic pain	72 (28%)
Mental illness	75 (29%)
Health insurance type	
Medicaid	229 (91%)
Employee-based Insurance	19 (6%)
Other	8 (2%)

the respondent to articulate his opinions to the interviewer. There were 1,295 comments—after excising the irrelevant statements (e.g., Q: *What is informed consent?* R: *Counting someone.*), participants who answered the wrong question (Q: *What are clinical trials?* R: *I forgot.*) and confusing participant answers (Q: *What is compensation for your participation?* R: *No nobody needs to know.*), we were left with 1,020 comments. The responses were originally entered in an SPSS file, along with the rest of the data taken from the questionnaire. We transferred the comments to a Microsoft Excel file because SPSS is designed to handle only numerical and coded data and has no way of handling open-ended text.

Our analysis focused on open-ended questions to assess participants' reaction to the consent form and to evaluate their comprehension of participating in a health research study. We also used Ryan and Bernard's (2003) repetitions, cutting and sorting approach to content analysis to facilitate themes through examining the recurrence of words and phrases in the comments that were salient. When a question was answered correctly, we put 1 for Yes for that question. If the answer was No, we put 0; if the answer was unclear, we entered 2. When the preliminary coding was completed, the coders met to deliberate on the statements that were coded as 2. When there was a discrepancy between the coders, the first author decided how a 2 would be entered as 0 or 1. The aim was to convert all 2's into 0's or 1's. When the coding review was completed, we summed each column to obtain one sum score for each category. We then totaled each category to create a sum of scores on the open-ended research participation questions. Descriptive statistical analyses were conducted.

RESULTS

We surveyed 259 Black Americans and Latino men released from prison or the local jail in Bronx, New York. The sample characteristics, including means and frequencies for all study variables, can be found in Table 1. Participants ranged in age from 35 and 67 ($M = 47$, $SD = 6.63$). Forty-six percent of participants identified as Latino, 49% identified as Black, and 5% selected other race/ethnicity. Sixty-two percent of the participants did not complete high school, 25% completed high school/GED, 10% obtained trade or some college, and 2% completed college. Forty-seven percent of the sample reported being unemployed.

Nearly all participants (91%) reported obtaining Medicaid upon release. Sixty-five percent reported being HCV negative, 34% reported being HCV positive, and only 1% did not know their status. As for HIV status, 82% were HIV negative and 17% were HIV positive, whereas 1% did not know their HIV status. The primary health concerns were mental health problems (29%), asthma (27%), arthritis (22%), and chronic pain (27%), with the majority of the men reporting one or more chronic medical conditions.

During participants' last incarceration, 43% reported being in custody less than 1 year, 12% reported being in incarcerated 1 to 2 years, 23% of the sample reported being in custody 2 to 5 years, and 22% were incarcerated more than 5 years. Forty percent of participants were released from jail, whereas 60% were released from prison. On the research participation knowledge test, participants, on average, answered about four questions correct out of six total questions.

What Is Informed Consent?

Fifty-nine percent of the respondents produced an appropriate response to the question, “What is informed consent?” Several participants responded by stating that “consent is when I [participant] give the researcher permission; I sign a form to authorize someone to do something to me, and that the study is voluntary.” However, 41% of the sample had no previous understanding of the informed consent process, even though all participants were provided adequate information about the study, and the researcher described the potential risks and benefits in Spanish or in English. A signed consent form was required to participate in the study. Because many of the study participants self-reported low education, and poor health and mental health outcomes, these factors may have interfered with fully understanding the informed consent process.

What Is a Human Subject?

When asked about participants’ understanding of a human subject, 68% understood it as “someone involved in a research study.” Thirty-two percent did not know what a human subject was. The majority of the participants tended to describe a “human subject as guinea pigs,” and several participants described themselves as “being experimented on.” There were more negative terms associated with the question “What is a human subject?”

What Is Confidentiality?

In response to the question, “What is confidentiality?” 88% of the participants used words such as “privacy” and “secret” to describe confidentiality. Respondents noted the “importance of having information shared and that it needs to be kept in private between the researcher and the participant.” Others reported that confidentiality is when “my personal information is only accessible to certain people.”

What Is an Institutional Review Board?

Slightly more than half of the participants answered the question, “What is an Institutional Review Board?” Participants tended to use “parole board” to refer to an Institutional Review Board. Several men noted that “an Institutional Review Board is like going to a parole hearing where they go over your history in jail and review your case.” Others stated that “it is a place where someone decides whether he will be institutionalized.” Numerous respondents expressed concern that “I do not know anything about it [Institutional Review Boards] but would like to know more about it.”

What Are Clinical Trials?

In response to the open-ended question, “What are clinical trials?” only 45% were able to state with some certainty that “clinical trials are studies where they test new drugs in a clinical setting before using them onto the whole population.” Others noted that “it is where medication or treatment is introduced to a person or a thing.” Participants also described clinical trials “as

experiments and that these were studies that they do on you or trials for new medication that have not yet been approved by the FDA.” However, 55% “did not know what clinical trials were” or simply stated “that these are places where they check your health condition.” Participants admitted having limited understanding of clinical trials, and some men suggested that there is not enough information about trials targeted to them.

What Is Compensation for Your Participation?

Eighty percent of the participants were particularly aware that research participation involved “receiving payment or a reward for their time and effort.” A majority noted that financial compensation increased their willingness to participate in the research study. Concerns about the role of compensation for effectively recruiting marginalized populations have been widely cited (Grady, 2005; Macklin, 1981; Slomka, McCurdy, Ratliff, Timpson, & Williams, 2007; Tishler & Bartholomae, 2002), but very little is known about how individuals under community supervision view payment for participating in research. Our data suggest that participants were unlikely to participate in research if there were no financial compensation in place, as some participants searched for money to meet daily living expenses and viewed the reward or payment as “extra income” (Festinger et al., 2005).

DISCUSSION

Despite being an important opportunity for addressing chronic medical conditions including viral infections, community supervision presents unique challenges for conducting health disparities research (Solomon, 2006). Our study adds to the limited body of knowledge concerning the understanding of research participation by men under community supervision. It is important to note that the majority of the participants appeared to generally understand concepts such as compensation for participation and confidentiality. Participants demonstrated a lack of understanding of certain aspects of the research process—*informed consent, human subject, Institutional Review Board, and clinical trials*. The next section provides an overview of these ethical issues.

Understanding of Informed Consent and Human Subjects

Participants appeared to have limited understanding of the consent form and confusion about the phrase “human subjects.” Although researchers are required by regulatory guidelines and academic Institutional Review Boards to provide adequate information about the research study that is understandable to their subjects (Code of Federal Regulations Title 45 Public Welfare Department of Health and Human Services Part 46 Protection of Human Subjects §46.116, 2009), populations under community supervision present an ethical challenge to researchers. Prior literature and research on these populations indicate that they are economically disadvantaged, have lower educational levels, and have higher rates of illiteracy and health problems than the general population (Durose & Mumola, 2004; Greifinger, 2007; Harlow, 2003; Marlow & Chesla, 2009; Nyamathi et al., 2012).

Limited understanding of the informed consent process may contribute to increased coercion and exploitation and may decrease retention in a clinical trial or a biomedical research study (Mann, 1994; Ogloff & Otto, 1991; Tamariz, Palacio, Robert, & Marcus, 2013). Because of restrictions in the U.S. Code of Federal Regulations 45 Subpart C on the involvement of prisoners in research, individuals under community supervision have had limited access to the different types of clinical research and experimental trials that might otherwise have been available to them (Thomas, 2010). In addition, lack of understanding of the risks, benefits, and protections of human subjects could also create unnecessary barriers to research participation.

As noted earlier, the majority of the participants tended to describe a “human subject as guinea pigs,” and several participants described themselves as “being experimented on.” There were more negative terms associated with the question, “What is a human subject?” This is not surprising, especially among the Black men who participated in this study, because of the legacy of Tuskegee. Previous studies have documented the suspicion, mistrust, and negative attitudes among Black Americans toward biomedical research (Buser, 2009; Shaya, Gbarayor, Yang, Agyeman-Duah & Saunders, 2007). It is likely, therefore, that the negative attitude expressed by these participants is similar to that of the Black American community in general. There are significant barriers including, but not limited to; personal factors (distrust, language), social factors (transportation, childcare), and procedural factors (insufficient outreach; Yancey, Ortega, & Kumanyika, 2006). A criminal justice background poses additional burdens to recruitment and research retention (Magruder, Ouyang, Miller, & Tilley, 2009).

Understanding of Institutional Review Boards

The majority of the participants did not know what an Institutional Review Board was and they tended to use “parole board” to refer to an Institutional Review Board. This misunderstanding is not surprising, considering that the term “Institutional Review Board” is vague and could apply to any board or committee that reviews anything. The term is used only in the United States, whereas other countries use a descriptive term such as Ethical Review Committee or Research Ethics Committee. In Canada, these committees are called Research Ethics Boards. Even some people in the United States who are knowledgeable about research think that IRB stands for “Internal Review Board.” Our study findings raise critical questions about the role of academic researchers in helping study participants understand academic Institutional Review Boards and the importance of human subject research. Researchers who conduct studies with hard-to-reach and marginalized populations must first build participants’ research literacy, so that subjects are truly informed of the potential risks and benefits of clinical, biomedical research or trials (Grady et al., 2006; Schüklenk, 2000).

Understanding of Clinical Trials

Some of our participants’ confusion of clinical trials reflects a lack of understanding about clinical trials. Participants must be made aware of clinical trials available to them and be informed of the potential benefits and risks to participation. Studies have shown that inclusion of ethnically and diverse populations into clinical trials is a challenge for researchers (Buchanan et al., 2010; Burlew et al., 2012; Dancy et al. 2004; Durant, Davis, St. George, Williams, & Blumental, 2007).

Because little information is available regarding clinical trial participation among populations under community supervision, strategies to increase their knowledge, effective recruitment, and access to clinical trials are needed.

Limitations

Our findings from this study have several limitations. Although our study participants were racially and ethnically diverse, it included only Black and Latino men who are under community supervision and is not representative of other populations (e.g., women, White men) involved in the criminal justice system, therefore limiting our ability to generalize our findings. The small scale qualitative findings from this study of Black and Latino men under community supervision is the first step in assessing the research understanding of this target population in the conduct of biomedical research and clinical trials. Future research should also study these issues quantitatively. Despite the limitations of the study, we believe the findings here have shed light on the critical challenge of recruiting and involving individuals under community supervision into clinical research. Guidelines and recommendations are needed by stakeholders—individual Institutional Review Boards, criminal justice populations, researchers, and parole and probation officials—to determine how to enhance the current knowledge about clinical research and trials among criminal justice populations.

Summary

To our knowledge, this is the first time in the literature of ethical research in criminal justice settings that researchers have assessed knowledge and attitudes concerning research participation among individuals under community supervision. Our study participants expressed interest in becoming a human subject but had low research literacy of certain research participation areas (i.e., understanding of human subject, informed consent clinical trials, and Institutional Review Board). Interventions to modify the content of the consent form could be addressed by using words in ordinary language instead of the terms used in regulations and in the literature of bioethics research.

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