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Perceptions of Risk in Research Participation Among Underserved Minority Drug Users

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Abstract

Research with underserved minority drug users is essential to quality health care and prevention. Understanding how participants perceive risk in research is necessary to inform research regulators so that research protections are neither lax, exposing participants to harm, nor overly stringent, thereby denying access to beneficial research. Data from 37 semistructured interviews of underserved, African-American crack cocaine users, collected from February to May 2006 in a large, urban setting, were analyzed using content analysis. In three hypothetical studies, participants recognized risks as relative and articulated and evaluated specific risks. Research regulators may enhance the accuracy of risk assessment in research by incorporating the views of participants. Study implications and limitations are noted. Future research on risk perception in research participation is suggested.

Keywords

risk perception; drug use; HIV/AIDS; research ethics; underserved minorities; research participation; research risk

Access to preventive health measures and treatment is essential for drug users with or who are at risk for HIV/AIDS. But simply ensuring access is not enough: Prevention and treatment must be high quality, based on rigorous research evidence. Weighing the risks and benefits of research participation is standard practice in all research, but especially so in research with "vulnerable" participants such as drug users and minority populations. Understanding how participants perceive risk in research is necessary to inform research regulators so that research protections are neither lax, exposing participants to harm, nor overly stringent, thereby denying access to beneficial research (Mastroianni and Kahn, 2001). Although all health research conducted in the United States is assessed for proportional risks and benefits by Institutional Review Boards (IRBs), little is known about whether and/or how underserved minority drug users at risk for HIV perceive risks associated with research participation. The question of risk in research is important because minority populations are underrepresented in research and may have difficulty gaining access to experimental treatments for HIV infection (Gifford et al., 2002). If IRBs and other research regulators require protections based on an assumption of risk disproportional to the actual situation, they may inadvertently work to deny underserved minorities the benefits of access to HIV and substance abuse research.

The use of illicit drugs exposes users to a variety of risks related to harm. How such risks are recognized and defined is pertinent to individual, research, and policy efforts to decrease risk.

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Epidemiologists view risk as an objective and quantifiable phenomenon. On the other hand, social scientists have argued that risk cannot be measured as an absolute value. Rather, perceptions of risk are formulated through social processes in which individuals and communities engage. The definition and/or assessment of risk, therefore, are subject to value judgments, psychological biases, cultural influences, and power relationships (Douglas and Wildavsky, 1983; Redelmeier, Rozin, and Kahneman, 1993; Slovic, 1999).

A traditional approach to decreasing HIV risk in high-risk populations such as drug users has focused on changing individual behaviors. This approach has been informed by research on the *context* of individual behaviors. That is, researchers have attempted to understand how social constraints and contexts shape individual high-risk behaviors (Bloor, 1995; Rhodes, 1997). Understanding the social context of risk may help to explain the logic of drug users failing to choose the “rational” behavior of decreasing HIV risk. For example, Connors (1992) notes that drug users perceive risks related to drug use as hierarchically ordered. That is, if drug users engage in needle sharing because their primary fear is a lethal overdose, then the risk of HIV infection through needle sharing becomes subordinated to the more feared risk of death from an overdose that is prevented by needle sharing (Connors).

Drug users may also experience risk as a result of their socioeconomic and political environment: Violence, crime, and drug use are often part of the everyday existence for residents of impoverished urban neighborhoods, although the location of environmental risk in a hierarchy of risk as perceived by drug users is not clear. The stresses of poverty, racism, and harsh and discriminatory legal sanctions may affect HIV risk by providing the structures for enhancing the means of disease transmission or by unintentionally producing barriers to effective prevention (Kalichman, Simbayi, Jooste, Cherry, and Cain, 2005; Rhodes, Singer, Bourgois, Friedman, and Strathdee, 2005).

Questions that have been raised about whether drug use encourages risk-taking and whether drug users' routine risk-taking diminishes perceptions of harm (Connors, 1992) have not been considered in the context of the risks presumed to stem from a research protocol. The Code of Federal Regulations, which includes the legal requirements for conducting research in the United States, offers no clarity on how risk assessments should be undertaken in the IRB review of research protocols. In practice, risk assessment by IRB reviewers has been described as impressionistic (Coleman, 2004) and, in the case of social science research, focused primarily on risks related to violation of confidentiality (Gordon, 2003). Kimmelman (2004) explains that an underlying assumption of IRBs is that risk is objective and measurable. This view, he notes, may neglect other values that influence risk assessments and may disregard concerns of research participants who may not share the same premises. Understanding research participants' views of research risk in the context of other risks encountered in everyday life is necessary for “negotiating” the meaning of risk (Rhodes, 1997) with research regulators so that participants will have appropriate protections from research risk as well as access to the benefits of research. This study provides preliminary data on the perception of research risk by participants who are drug users, with or at risk for HIV infection. The research question we ask is “How do economically disadvantaged African-American crack cocaine smokers' perceive risk in research?”

Methods

Design, Setting, and Population

Using standard qualitative interview techniques (Patton, 2002), we conducted 41 semistructured, open-ended, in-depth interviews as a pilot study of economically disadvantaged African-American crack cocaine smokers' motivations to participate in research (Slomka, McCurdy, Ratliff, Timpson, & Williams, 2007; Slomka, Ratliff, McCurdy, Timpson,

& Williams, 2008). Data were obtained from 37 usable interviews. Participants were recruited from among those taking part in three large, concurrent public health studies who had given prior consent to future contact. Two of the parent studies involved behavioral interventions to prevent HIV/AIDS, and the third was a hepatitis B model vaccine study. Interviews were conducted from February to May 2006, at a research field office established for the parent projects in two underserved urban communities in Houston, Texas. Participant characteristics are reported elsewhere (Slomka et al., 2007) and summarized in Table 1. This study was approved by the University of Texas Health Science Center's Committee for the Protection of Human Subjects. An informational letter was read with and given to participants in lieu of a written consent form. Participants were paid $20 for their time and to defray travel costs.

Procedures, Data Collection, and Analysis

Three scenarios depicting hypothetical clinical research studies were used to prompt discussion of attitudes, perceptions, and beliefs about research in general and about risks, inconveniences, benefits, financial compensation, and desired information that might affect participants' decisions to take part in the kind of study presented in each scenario. These scenarios were typical of research studies in which individuals with or at risk for HIV might be asked to participate. As a means of eliciting differences in participants' perception of risk and benefit between and among clinical studies, the scenarios described elsewhere (Slomka et al., 2007) and described in Table 2, were designed to represent different levels of risk. The scenarios included a survey study relating sleep disturbances and stress (minimal risk); a randomized, controlled trial of a new medication (more than minimal risk); and a test of a vaccine for HIV (more than minimal risk).

Scenarios were presented in both oral and written form. The order of presentation was random. Depending on participants' time constraints, either two or three scenarios were presented. Of the 37 interviews, 19 included discussion of all 3 scenarios; 33 included the sleep disturbances study scenario; 34 included the medication trial scenario; and 23 included the HIV vaccine trial scenario. In each category, the number of scenarios discussed, 19, 33, 34, and 23, respectively, were sufficient to obtain theme saturation.

Interviews were approximately 30–45 minutes in length and were audio-recorded and transcribed verbatim. A single investigator (JS) conducted the interviews and coded them for thematic content. Data were analyzed using both conventional content analysis, in which coded data were grouped under categories derived from themes that emerged during analysis, and directed content analysis, in which data categories were derived from pre-existing theory that informs the analysis (Hsieh and Shannon, 2005). Because interviews involved the elicitation of perceptions relating to individuals' experiences, as well as views of current research practices, both methods were cogent to the analysis. All authors contributed to the analysis and interpretation of data. Interpretive differences among authors were rare and were discussed to achieve consensus. This paper reports on participants' perceptions of risks of participation in three different hypothetical research scenarios.

Results

Sleep Disturbance Study Scenario

Of the three hypothetical study scenarios, participants viewed the sleep disturbance study scenario as having little or no risk of harm. Thirty-three participants were questioned about this scenario. Only six declined or did not clearly accept hypothetical participation, citing lack of interest or concern about the study itself causing stress.

In several instances, participants remarked on the difference in level of possible harm between the medication and/or vaccine trials and the sleep disturbance study. After noting that no “pills” were involved in the sleep study, one participant remarked, “So this is a totally different type of research. That means the side effects and all, there's none, so I would really take this one (i.e., choose to participate) and be confident.” Some participants viewed the study as low risk only after verifying that the study was not one that involved taking a medication.

From the perspective of an IRB, the blood test result for drug screening obtained by the hypothetical investigators from a participant's medical record might be considered a confidentiality risk in this study scenario. However, participants either did not mention it as a concern, or when asked about it, did not consider it problematic. An exception was one participant who asked whether the drug screening test result was part of the study itself or whether it would be used to exclude participants:

> I mean, as far as me it would (concern me) because I don't see where they're going with it. I need to know would be the reason for that. Like is it to help them understand … why a person can't sleep? Or is to say that they don't need that type of person (as a participant)? I'd inquire about that.

This participant's question was related to the inclusion and exclusion criteria for some research studies, as well as to a desire for more information about the study.

Participants tended to view this study as beneficial, especially if they experienced stress or sleep disturbances. Many believed participation in it would help them in dealing with stress or sleep. Most accepted the idea, when presented, that the study probably would not provide individual benefit, but a few were not dissuaded.

Medication Study Scenario

A clear “yes” or “no” regarding participants' hypothetical willingness to participate in the medication study scenario was difficult to elicit because most participants qualified their answers. Participants stated their willingness to take part would depend on such factors as type of drug being tested; amount of money offered; kinds of side effects expected of the study drug; and whether the drug was specific to their situation (e.g., participating in a test of a blood pressure medication if one has hypertension). Many participants were willing to participate in the hypothetical medication study only if they themselves or a family member had the condition for which a drug was being tested.

Participants often misunderstood aspects of the study design. In addition, the term “sugar pill” as a nontechnical term for “placebo” was interpreted by some as a pill to treat diabetes. Some participants had concerns about study drugs reacting in a manner opposite to their expected effect. Most concerns, however, focused on side effects, often characterized as “allergic” reactions or allergies. Participants also voiced worries that certain drugs might be too “strong” for an individual, especially if the participant did not have a disease condition congruent with the drug's treatment target. One participant related the danger of taking a study drug for paranoid schizophrenia when one was not ill. When asked what the risks or harms of such a study might be, he replied,

> Well, it's a bad risk if you're not paranoid schizophrenic and you're acting or you are just friendly, and you take medicine that you're not medicated to take. Oh, yeah, it's going to mess you up. You know, they're going to mess you up because your system can't immune to that … So you got to know what you're doing but you can't go there and play with it because of the money that you'll get. You really be messed up. Just like you have seen people play crazy and they end up being crazy because of the medication that they're taking is too strong for them. I done seen that happen.

Other participants also mentioned concerns about taking part in medication trials of psychotropic drugs. When asked if he would participate in a study of a psychotropic medication, this participant responded that “Some psychotropic drugs have adverse effects” and that some people are “not capable of handling certain chemicals.” He stated he would be concerned about taking part in study of a new psychotropic drug because

> I mean, there again, you're basing it on the success on a animal. I mean, were there any—they don't have any human test subjects that you can base that analysis on. So yeah, that would concern me.

When asked if he would take part in a study of the drug if it had been tested in a smaller group of people prior to doing a larger study, he replied:

> Well, then, if they had that fact, if they could prove that fact, I mean, that would make me feel a little more comfortable about it than if they never had (tested it on humans).

Participants viewed the effect of the drug and knowledge of possible side effects as important information for decision making. Some stated they would only participate in studies in which the side effects of the drug were already known.

A few participants said they had taken part in pharmaceutical company trials. Most had heard of such studies but stated they had not actually participated in them. While some said they would be willing to take part in a well-paid drug trial, they again often qualified their responses as being dependent on other factors, such as potential side effects. Others would not participate in drug trials even for relatively large amounts of money because of their awareness of potential serious consequences, such as liver damage.

HIV Vaccine Study Scenario

Almost all participants perceived the HIV vaccine study scenario as high risk and as greater risk than the medication study scenario. Of the 23 participants presented with this scenario; 2 indicated willingness to participate; 4 viewed their decision to participate as contingent on more information; 12 declined; and 5 were unsure, grossly misunderstood, or gave no definitive response. The HIV vaccine study was the most technically difficult of the three scenarios. Participants identified major reasons for declining participation as the possibility of a false-positive HIV test with its medical and social consequences, and fear of infection with HIV or other diseases due to decreased immunity.

The understanding of concepts such as testing “positive” or “negative” for HIV did not appear problematic, nor did the concept of being “at risk” for HIV infection because participants had fairly sophisticated ideas about complex medical concepts. However, they also had misconceptions and difficulty in grasping meanings and procedures in the scenario. Some participants seemed unclear as to the purpose and meaning of “vaccine,” referring to it as a cure for HIV. Participants also had difficulty with the idea that the vaccine could cause a positive HIV test when the person was not infected with the virus. Long-term risks and a false sense of protection from an ineffective vaccine were also noted as risks. In addition, the study design was frequently misunderstood. Features such as use of a placebo (“dummy vaccine”) and randomization were viewed as unfair by some participants.

Participants tended to view a positive HIV test caused by response to a vaccine as the same as being HIV positive due to infection and/or having the same detrimental medical and social consequences. One participant expressed her concerns about the vaccine scenario:

> Because what if I don't have it (the infection), and I keep going to clinics and everything, and they're saying that I am HIV-positive and they really want to start giving me medication for it and everything. And I really don't have it. That's something

> I don't want to happen, because then you really couldn't even have a malpractice lawsuit because it's really showing up that you're HIV-positive and there's no way to prove it. So that's why I wouldn't do it. And if it so happened like after the study was over and I got pregnant and had a baby, that means that that will lead to my baby having HIV. Do you know what I'm saying?

This same participant acknowledged that there were reasons why she might choose to take part in the vaccine study, to help HIV-positive family members and to "find a cure." But these reasons were not convincing enough for her to participate:

> … But if it doesn't work and I have to live with it the rest of my life with just a record saying that I'm HIV-positive, I mean, I know it's not in my bloodstream. I couldn't live like that for the rest of my life. That would drive me crazy.

Another participant gave his view of the potential social consequences of testing positive for HIV as a result of a vaccine:

> … Say, for instance, you go on a job interview and you have to be tested for HIV. And you come up positive, and even though you're not positive, that's going to go around the United States. Even though it's supposed to be confidential, it might cause you not to get the job. You know, things of that nature. So that's one reason that I wouldn't (take part in the study).

Finally, some participants said they valued their health more than money, so financial compensation would not be an inducement for them. For example, when asked if she would take part in the vaccine study for $10,000, one participant replied, "No price … No, this is risky. This is pertaining to the rest of your life. You have to deal with that, so no." And in regard to whether other people would do the study for that amount, she opined,

> Some people would. And some people will probably–God forbid, this never happened, but get the dummy pill. And you think you're covered, and you're still having unprotected sex, and you're going to–there's nothing you can do after you did this study. You come back HIV-positive.… it should be a criteria thing where you qualify, and the researchers should let you know what it is and what it's not. And they should give everybody the real vaccine, instead of having some dummies out there. That's not fair.

This response typifies the discomfort, as well as the misunderstanding, many participants had with various aspects of the HIV vaccine study scenario.

Discussion

Although participants' hypothetical responses may differ from their responses in real situations, many, but not all, of our participants' perceptions of kinds and levels of risk in the different research study scenarios coincided with what an IRB would likely identify as potentially harmful. None of our participants fit the stereotypical image of drug users as challenged in their ability to perceive and evaluate risks of research and willing to ignore those risks because of their drug use or desire for money. Even those individuals who stated they would participate in a risky study for money viewed their participation as contingent on the amount of money and kinds of risk. On the other hand, misunderstanding of the research process and study design was common, a phenomenon that has been noted in a variety of clinical research settings (Lidz, Appelbaum, Grisso, and Renaud, 2004). Part of a lack of understanding of the research scenarios may have also been due to their brevity and to time constraints in the interviews. It is possible that more time spent in explanation would have improved understanding for some participants. Participants viewed research risks in a relative sense, differentiating, for example,

among the three scenarios, and among the different levels of risk in clinical trials of drugs with known or unknown side effects.

In the sleep disturbance study, researchers' obtaining confidential drug-screening results from a participant's medical record was not viewed as threatening. But a positive test result for HIV, even a false-positive derived from participation in a vaccine study, was seen as a serious risk. Participants viewed taking part in the medication study scenario as contingent on numerous qualifiers, in contrast to the HIV vaccine study where most participants declined participation because of medical and social concerns. Perceptions of risks associated with medication side effects varied among participants. At times they both underestimated and overestimated the risks of medication studies.

The “therapeutic misconception” was prevalent in participants' responses. Lidz and Appelbaum (2002) have described the therapeutic misconception as a participant's belief that the goals of research and treatment are the same, and that research will benefit the individual. These authors have also referred to the therapeutic misconception as the “failure to appreciate that elements of research design [e.g., use of placebo controls and randomization, parentheses added] may limit the degree of individualized care” (Lidz, Appelbaum, Grisso, and Renaud, 2004, 1691). We observed that participants often claimed both direct benefit to themselves and benefit to others through research participation. Such benefit is not entirely a misconception: in nonplacebo clinical trials of similar medications, participants could benefit directly from medications to which they might otherwise not have access. Furthermore, the contention that the design of a research study limits the individualization of health care may have little meaning as a risk factor for our participants, most of whom lacked access to ordinary health care and who were exposed to the multiple risks of poverty in their everyday lives. Participants did appreciate risk in research design in their view of randomization and placebo use as unfair, with the risk implicitly situated in lack of access to the active intervention. Although these observations are preliminary, they speak to a need for further investigations of the meanings of risk associated with research participation in economically-disadvantaged populations.

Study's Limitations

Our study has several limitations. Our sample of respondents may have been self-selected for those who were more willing and able to think and talk about the research processes in which they were asked to consider participation. In some instances, those who had participated in other studies may have learned appropriate responses to interviewers' questions. The use of a convenience sample limits generalizability of our results. In addition, we were not able to assess, within the scope of our study, what effect participants' HIV status might have on their perceptions of risk in participating in research.

Although the capacity of economically disadvantaged drug users to provide informed consent or to make good decisions about research participation is often questioned, we did not see a need to specifically assess participants' decisional capacity. We believe that all of our participants were capacitated to consent to the interview study and to assess the research scenarios for several reasons. First, decisional capacity generally is presumed in community-dwelling individuals and the fact of substance use itself does not necessarily imply altered capacity for decision making in other non-research contexts. Second, participants' interactions and conversations with us gave no reason to doubt their decisional capacity. If an individual manifested behaviors that might suggest that s/he was currently under the influence of drugs, our protocol and consent form instructed the researcher to exclude the individual from participating or stop the interview. Third, in the course of the interviews, participants demonstrated accepted criteria for competency: They were able to make choices; their choices

and outcomes were “reasonable” and based on “rational” reasons; and they demonstrated both the ability to understand and actual understanding (Roth, Meisel, and Lidz, 1977).

In contrast to the view of many IRBs that economically disadvantaged, minority drug users are in need of additional protections because they will dismiss, disregard, or fail to recognize risks of research, the majority of our participants were able to perceive, articulate, and evaluate risks that might be present in a research study. Although based on hypothetical scenarios, our results did not demonstrate a propensity for participants to take “irrational” or unknowing risks in research participation. The risks of the socioeconomic and political environment—that is, the “risks of everyday life”—in relation to risks in the research study scenarios were not assessed and are a topic for future investigation.

Inclusion and exclusion have both risks and benefits for research participants, but empirical evidence to support decisions about the best level of protections for participants is limited (Anderson and DuBois, 2007; Sieber, 2004). To exclude underserved minority participants from research because they have been ill-used in the past risks compounding the error and exacerbating existing disparities in research and health care (Wojtasiewicz, 2006). Attention to the views of participants may enhance the accuracy of research risk assessment in disadvantaged minority or marginal populations and ultimately provide them a better service.

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Glossary

Underserved populations	Populations are considered underserved if they lack access to societal resources, such as adequate health care, or are disadvantaged due to socioeconomic and/or historical circumstances
Institutional Review Board (IRB)	An Institutional Review Board is a multidisciplinary committee mandated by the U.S. government to review an institution's research studies for compliance with legal and ethical standards
False-positive HIV test	A false-positive HIV is a test result that appears positive even though the individual is not infected with HIV
Code of Federal Regulations	The Code of Federal Regulations is a listing of the rules and regulations of the U.S. government covering a variety of areas that are subject to federal regulation
Minimal risk	According to the U.S. Code of Federal Regulations, Title 45, Part 46.102i, a research study is defined as “minimal risk” when “the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.” (http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm (Accessed May 9, 2007)

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Biographies

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Table 1

Characteristics of participants*

Sex		Age (years)	
Males = 20		Range = 22–53	
Females = 17		Median = 40	
Years of schooling	N %	Living arrangements	N %
7 to 11	15 (42%)	Own home/apartment	13 (36%)
12	17 (47%)	Someone else's home	20 (56%)
13 to 16	4 (11%)	Transient housing or “on streets”	3 (8%)
Employment	N %	HIV status	N %
Unemployed	27 (75%)	Positive and aware of status	6 (17%)
Regular, full-time job	2 (6%)	Negative and aware of status	14 (39%)
Part-time or other	7 (19%)	Unknown/unverified status	16 (44%)
Monthly income	N %	Major source of income	N %
None	5 (14%)	Jobs	6 (17%)
<$200	7 (19%)	Disability/other public assist	9 (25%)
$200–399	10 (28%)	Money from family, friends	7 (19%)
$400–599	7 (19%)	Other	9 (25%)
$600 and above	7 (19%)	No source	5 (14%)

*Data, except for age and sex, were missing for one participant. Percentages are rounded.

Table 2

Descriptions of hypothetical research scenarios

Sleep disturbances and stress
This scenario was adapted from a study by Vosvick and colleagues (2004). Participants would complete 4 questionnaires on the kinds of stress they are experiencing; the availability of social supports; the amount of pain they may be having; and any difficulties in falling asleep or staying asleep. Researchers would obtain blood test results for screening for drug use from the medical records of participants. The study would involve a one-time visit to the clinic and would take 90 minutes to complete.
Randomized, double-blind, controlled trial of a new medication
Features of this scenario included information that a new drug plus an older, approved drug would be tested against a placebo or "sugar pill" plus the older approved drug. Details about randomization and blinding procedures were described in lay terms. The drug to be tested was not named, but referred to only as "the new medication." Examples of specific kinds of study drugs specific to different diseases were introduced later in the discussion. Other information included the requirement of an hour-long visit with the study assistant every week for 3 months; and a medical examination, chest x-ray, electrocardiogram (EKG) and blood tests at the beginning and end of the 3-month period.
Randomized, controlled trial of a new vaccine to prevent HIV-infection
This scenario was based on a study published by Coletti and colleagues (2003). Procedures included initial screening for HIV infection and risk factors (e.g., sexual history; drug use). Persons who were both HIV negative and at risk for HIV infection would be invited to continue participation. Details about randomization and blinding procedures were described in lay terms. The participant would undergo a medical examination, chest x-ray, EKG and blood tests at the beginning and end of this 12-month study and would be required to have a clinic visit and blood test once a month. Other information included the possibility of decreased immunity, false positive HIV tests and protection from HIV infection if the vaccine should work, for those who receive the vaccine.