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The Attitudes of Females in Drug Court Toward Additional Safeguards in HIV Prevention Research

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Abstract

This article examines the attitudes of 97 women from the St. Louis City Drug Court who previously participated in an HIV prevention study. Data from the previous study indicated that the women met multiple criteria for vulnerability in research. Federal regulations require that such participants be provided with "additional safeguards." The survey explored the following questions: (1) What are participants' attitudes toward commonly proposed additional safeguards for vulnerable participants in research, and (2) Are attitudes toward safeguards related to participants' previous compliance with an HIV prevention protocol? Preferences regarding safeguards in research were not significantly related to participants' compliance in the previous study. Most participants wanted researchers to take extra measures not only to provide consent information, but to ensure that they are not high on drugs, that they understand relevant information, and that they retain consent information at each visit. Most participants wanted researchers themselves, and not a third party, to assume this responsibility.

Keywords

Research ethics; Research protections; HIV prevention; Community attitudes; Drug court; Longitudinal study; Qualitative study

Additional Safeguards in Research: The Preferences of Vulnerable Participants

A recent study, "Prevention of HIV and STDs in Drug Using Women" (DA11622), used a longitudinal experimental design to examine the effects of Well Woman Examination (WWE) and peer-delivered education sessions in the prevention of HIV and STDs. The study relied primarily upon community-based recruitment methods to enroll drug-using women; however, a subset of women from the St. Louis City Female Drug Court was recruited as well. The female

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offenders appeared to be at the highest risk for HIV and STDs. However, since the initial study was not focused specifically on female offenders, the study aims did not allow for a complete analysis of the factors that differentiated female offenders from other participants or factors that impacted participation and behavior change among female offenders. A follow up project, "Deconstructing HIV Interventions for Female Offenders" (DA 019199), aimed to understand attitudes about research as well as to explore variables that would facilitate the development of adaptive treatment measures for female offenders in future studies (Murphy et al. 2007). The present article examines attitudinal data from 97 women from the St. Louis City Drug Court who participated in both the initial HIV prevention study and the "Deconstructing" study.

By the standards of many institutional review boards (IRBs) or research ethicists, demographic data from the initial study indicated that the women from Drug Court met multiple criteria for vulnerability in research: 60% were unemployed; 89% reported lifetime sex trading; 80% were opiate dependent; and 92% were cocaine dependent. Sixty-nine percent of the women were African-American. These demographic traits may be translated into research vulnerabilities in the following ways: Given rates of cocaine and opiate dependence, the participants were at risk of diminished cognitive capacity (Gorelick et al. 1999); the voluntariness of their participation could be compromised by their involvement in the court system (Appelbaum 1995; Duval and Salmon 2004); the combination of unemployment and drug dependence increased the risk that any payment could be perceived as unduly influential (Charland 2002; Koocher 1991); the sensitive nature of their data (on sex trading, drug abuse, and HIV status) created a risk of social stigmatization and other harms if confidentiality were breached (Buchanan et al. 2002; Fitzgerald and Hamilton 1997); and the racial demographics of the population risked contributing to negative stereotyping (Anderson and DuBois 2007; Corbie-Smith et al. 2004; National Bioethics Advisory Commission 2001).

While there are many forms of vulnerability in research, they all share one thing in common: a reduction in the participants' ability to protect themselves (DuBois 2005; Levine 1988). Accordingly, it is universally agreed that vulnerable research participants deserve additional protections. However, widespread disagreement exists over who counts as vulnerable and what specific protections should be provided (Anderson and DuBois 2007).

Within federal regulations, specific additional protections exist for research participants who belong to only three broad groups: (1) pregnant women, human fetuses and neonates; (2) prisoners; and (3) children (Department of Health and Human Services 2005, subparts B–D). However, guidance is vague regarding the protections appropriate for other vulnerable research participants. The federal regulations simply state that "when some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons" then IRBs should ensure "that additional safeguards have been included in the study…" (Department of Health and Human Services 2005, at 46.111(b)). The present study explored the following question: *What are participants' attitudes toward commonly proposed additional safeguards in research?*

The following are some of the "additional safeguards" commonly proposed for research involving participants with drug dependence or cognitive impairments, followed by brief descriptions of why they may be controversial.

1. *Read consent forms to facilitate understanding in populations at risk of low literacy*. While this is a low burden safeguard that may facilitate comprehension, one might speculate that some participants would not welcome it because it could increase inconvenience by lengthening the consent process and could rest upon a stigmatizing assumption of low literacy.

2. *Assess decision-making capacity*. Assessing capacity is meant to ensure that participants are capable of understanding, appreciating, and reasoning with information that is relevant to making a good decision whether to participate in a research project (Berg and Appelbaum 1999). The National Bioethics Advisory Committee (NBAC) recommended that capacity be assessed whenever research is conducted with populations that are at risk of cognitive deficits and risks are greater than minimal (National Bioethics Advisory Commission 1998). While various drugs may interfere with cognitive functioning, the few studies of intravenous drug users conducted to date have not indicated lower than normal performance on measures of decisional capacity (Anderson and DuBois 2007). Moreover, some have expressed concerns that this will add to the burden of participation for researchers and participants, it unfairly stigmatizes certain populations of participants, and could diminish some participants' access to potentially beneficial research (Appelbaum 2001).

3. *Include a consent auditor, participant advocate, or independent professional advisor in the consent process*. The National Commission, which was established by Congress following the Tuskegee syphilis study to produce guidelines for research protections, recommended the use of consent auditors (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research 1978). Years later, the NBAC recommended the involvement of independent professional advisors during the consent process whenever risks are greater than minimal (National Bioethics Advisory Commission 1998). However, such processes add cost and time burdens to research, and may unnecessarily introduce an additional party into a private discussion.

4. *Keep payments for research participation to a minimum* and/or *provide gift certificates rather than cash*. Some have argued that due to economic hardship many drug users cannot say "no" to research that offers cash incentives (Grady 2001; Koocher 1991); others have argued that researchers may be complicit with illegal drug use when participants use cash to purchase drugs (Ritter et al. 2003). However, several ethicists and researchers have argued that it is only fair to pay participants for their time, and that unusually low payments risk disproportionately targeting lower-income individuals (Lemmons and Elliot 1999; Levine 1988). Moreover, in two recent studies Festinger et al (2005; Festinger et al. 2008) found that high payments increased retention without increasing drug use or perceived coercion. Similar arguments are put forward both for and against "payments in-kind"; that is, payments using gift cards rather than cash. On the one hand, they are alleged to reduce the likelihood that participants will spend them on illicit drugs; on the other hand, they are paternalistic and treat certain populations of participants differently, they may be unwanted by participants, and those who sell them for cash lose a percentage of their payment (Cottler et al. 1995; Gordon et al. 2002).

5. *When data are sensitive and a signed consent form is the only identifier, allow verbal consent without a signed consent form*. Federal regulations allow IRBs to waive the requirement to obtain participants' signatures on a consent form whenever the form would be the only means of identifying participants' within a study (Department of Health and Human Services 2005, at 117c). Additionally, some participants may feel uncomfortable signing a document that appears to be a contract; some may fear that they are signing away their rights (Appelbaum et al. 1987; Sieber 2001; Wendler and Rackoff 2001).

6. *Exclude from research unless the research will provide direct benefits or knowledge directly relevant to serving the needs of the participant population*. McCarthy (1998) observes that following the Tuskegee syphilis trial, the primary concern about

justice in research was the over-inclusion of vulnerable participants who were unlikely to benefit from research (National Commission 1979). However, particularly during the 1980's society witnessed a push for greater therapeutic research of particular interest to vulnerable groups, particularly in the areas of breast cancer and HIV/AIDS. Increasingly, it is observed that justice requires one to avoid unfair exclusion from potentially beneficial research (King 2005).

Consistent with the values of community-based participatory research (Israel et al. 1998), the authors decided to ask participants what their preferences are regarding these possible additional safeguards, which may be controversial, may fail to achieve their desired aims, or may increase burdens on researchers or participants.

A second research question was formulated in response to data from studies that examined barriers to research participation: *Are attitudes toward research safeguards related to participants' previous compliance or noncompliance with an HIV prevention protocol?* Corbie-Smith et al. (1999) and Giuliano et al. (2000) found that minority group members generally favor medical research but have concerns regarding burden, risk, dishonest researchers, and fear that they are used as guinea pigs. Fouad et al. (2000) found that barriers include mistrust of the research community, mistrust of informed consent information, and inappropriate use of incentives. Accordingly, we hypothesized that participants' preferences regarding additional safeguards in research—particularly those surrounding the consent process and the use of financial incentives—might be related to their retention and compliance in the previous HIV prevention study.

Methods

Sample, Eligibility, Replicates and Recruitment

Potentially eligible participants were the 129 women from the St. Louis City Female Drug Court who participated in our prior NIDA-funded study, "Prevention of HIV and STDs in Drug Using Women" (WTW; DA 11622), between May 2000 and September 2003. Data were collected for this study between September 2005 and March 2007. This data time point was the 4th with the women.

All eligible women were sorted into five replicates for recruitment and interviewing, which are described in Table 1. Women in replicates 1–3 had completed all tasks associated with their randomization as well as all three interviews in the prior study. These women were considered "highly compliant" (HC) for these analyses. Data from women in replicates 4 and 5 provided the "low compliant" (LC) data for statistical analyses. All women were offered the same level of payment for their participation.

The research team was blinded to the meaning of the replicates when tracking and locating respondents. We utilized contact information provided by the respondent during the prior study, and because the respondents had given our team permission to re-contact them for future studies we were able to achieve a high relocation rate (91%). Since many of the women completed their participation in the former study nearly 3 years prior to participation in the current study, many of the contact addresses and telephone numbers had changed. We utilized standard methods, including Internet and field-based tracking, to locate potentially eligible women.

Instrument Development

Survey questions were developed in three stages prior to pilot testing. First, questions were drafted in response to a review of the research ethics literature, which was conducted by the first author in connection with two other publications (Anderson and DuBois 2007; DuBois 2008). Second, questions were circulated among four research ethicists in the Department of

Health Care Ethics at and the National Institute on Drug Abuse for comments. Third, question phrasings were revised after cognitive interviewing with staff in the Epidemiology and Prevention Research Group at Washington University, including interviewers and methodologists (authors CCO and LBC) (Willis 2005).

Item responses were “yes” or “no” because the data IRBs need is decisional not simply attitudinal (i.e., should we read consent forms, should we test comprehension, etc). For each item, “do not know,” “undecided,” and “refused to answer” were hidden responses; that is, they were not offered to participants as response choices, but such responses were recorded in the few instances when a participant was unable to provide a “yes” or “no” response.

Screening

Once we located a respondent, we probed for general information (full name, date of birth, etc.) to verify that we were talking to the correct woman. With confirmation of the respondent’s identity, we were able to screen the respondent for eligibility in the Deconstructing study. Because we were interested in understanding the helpful and salient characteristics of our former HIV prevention intervention, it was important to assess whether the potential respondents remembered participating in the prior study. To do so, we administered an eight-question open-ended telephone script aimed at assessing each respondent’s memory of general information related to the prior study. We asked women to remember details such as the site where they participated, what kinds of questions were asked in the interview, and how they found out about the study. Women who had no memory were prompted one time. Women who passed an identification threshold were told that they were eligible for a follow-up study aimed at helping us understand what they liked and did not like about the prior HIV prevention intervention study. They were told that the study would involve one interview that would last approximately 1 h, and they would be reimbursed $25 for their time and inconvenience. The Deconstructing Study Interview was conducted at a location separate from the prior study, so respondent memories were not biased by the location. Additionally, staff employed to conduct the locating, telephone screening, and the interview procedure had not performed those tasks in the prior study.

Interview

Prior to beginning the interview, a Washington University School of Medicine Human Research Protection Office approved informed consent document was read and discussed with participants.

The items presented in this paper were administered at the end of a face-to-face interview that lasted approximately 1 h. Prior to asking questions about preferences regarding “additional safeguards” in research, the Deconstructing Interview inquired into risk behaviors including alcohol and drug use and high-risk sex behaviors over the past 12 months, and explored a series of qualitative questions on their attitudes toward the previous study, the barriers they perceive to full research participation, and the benefits they seek by participating in research.

Results

Of the 129 women who were originally eligible for participation, 2 had died, 6 had moved out of the area, and 1 was considered ineligible because she had already enrolled in another, similar HIV prevention trial. Of the remaining 120, 2 were scheduled but did not show up for the interview, 4 refused, and 5 could not remember the former study. We were unable to locate 12 using the information provided at the final interview for the WTW study. Thus, 97 (81%) of the 120 eligible women were enrolled in this study. The 12 women who did not participate did

not differ significantly from the women who did participate in terms of their compliance in the previous protocol.

In general, preferences regarding additional safeguards in research (i.e., modifications to the consent process, financial incentives, or inclusion criteria) were not significantly related to participants' compliance in the previous HIV prevention study. Of the 16 items reported, only 1 item was significantly related to compliance: 88% of highly compliant versus 69% of low compliant participants wanted the informed consent form read aloud to them during the consent process (X^2=0.02). However, this difference is not "clinically significant" as a supermajority of both groups preferred that the consent form be read aloud.

Descriptive data on participants' preferences for informed consent safeguards are presented in Table 2. As noted, a high percentage of women (96%) stated that they wanted researchers to test their understanding of consent information, and wanted to be reminded of consent information at each visit (80%).

Descriptive data on participants' attitudes toward differential payment and inclusion of people who use illegal substances are presented in Table 3. Most participants considered payments for their time to be fair (94% HC, 89% LC) and believed that payments do influence decisions to participate in research (88% HC, 91% LC). Very few agreed that large payments would lead them to ignore the risks of a study (8% HC, 16% LC). Most participants were against policies that excluded prisoners or people who use drugs from participation in clinical trials. Overall, participants were divided on questions pertaining to the reduction of undue influence (i.e., whether it is acceptable to avoid large payments to drug users or to offer only in kind payments such as gift cards).

Additionally, participants were asked what they considered to be a "fair payment" and a "large payment" for participation in a study that involved a blood draw and a 90-min interview. The median amount described as "fair" was $30; the median amount described as "a lot" or "large" was $100. In subsequent items that referred to "fair" or "large" payments, the researchers inserted the participants' actual amounts into the question. For example, the item in Table 3 that asks, "Would offering a large payment make most people sign up for a study they normally would not sign up for?" actually replaced the term "large payment" with the dollar amount a participant described as "large."

During the interviews, we offered open-ended follow up questions to two of the items pertaining to the consent process. We asked women why they would or would not prefer to have someone with them during the consent process and why they would or would not prefer giving consent verbally without a signed form. Many of those who did not want a person outside the research team to assist during the consent process indicated that that their consent agreement was between the interviewer and the participant and, as such, another person was not necessary. Others thought it would be an intrusion into their private affairs with one respondent stating, "it's none of their business." When probed, those who indicated a preference for having a family member, friend or outside person to assist during the consent process generally indicated that having an additional person present might result in a more clear, neutral explanation of the process or, alternately, that a friend or family member could help them remember what was agreed to. As shown in Table 3, almost all women reported a preference for signing the consent form instead of verbally consenting. When probed, these women indicated that their signature provided proof that they agreed to participate and documented the conditions of their participation for future reference.

Discussion

This is one of the first studies to examine the preferences of vulnerable participants toward a variety of additional safeguards that are commonly proposed, and further, to explore the relationship of these attitudes to compliance.

We found that compliance in the previous HIV prevention study was not significantly correlated with attitudes toward additional safeguards. We do not believe this suggests that additional safeguards have nothing to do with compliance or that research ethics is of little consequence to participant satisfaction. We did not assess, for example, whether the women were satisfied with the protections offered in the previous study, nor whether they adequately understood the protections offered (such as a certificate of confidentiality). Our questions only allowed us to assess whether the significance the women attach to additional safeguards correlates with past compliance. It is also possible that the 19% of eligible women who chose not to enroll in this follow-up study have significantly different attitudes toward research protections; however, our sample was fairly representative across compliance groups, so it is unlikely that additional variation in attitudes would have correlated with compliance. Further study is needed to understand what variables predict compliance (e.g., age, active drug use, or motivation for participation).

One could summarize the results from our informed consent items by saying that our participants want researchers to take extra measures not only to inform them, but to ensure that they are not drunk or high, that they understand the relevant information, and that they retain the information at each visit. However, most participants want researchers and not a third party —friends, family, or an advocate—to assume this responsibility.

Our major consent findings—both positive and negative—are interesting. On the one hand, our participants clearly take the informed consent process very seriously. It is not merely a hurdle to get over before enrolling and receiving a payment. Questions about ensuring they were not high and ensuring understanding received more support than items inquiring whether payments for time are fair. The women in our study did not consider such measures to be overly invasive or overly burdensome to them, as some might fear. On the other hand, a majority of our participants did not want a third party present during the consent process. This finding is particularly interesting because the use of consent auditors in greater than minimal risk research was a recommendation of both the National Commission (1978) and theNational Bioethics Advisory Committee (1998) as they addressed additional safeguards in research with vulnerable participants. When asked to give comments about the inclusion of a third party in the consent process, comments included “its none of their business”—suggesting that concerns about privacy may exist at least in this type of sensitive research. Our finding may also suggest a certain level of trust in the researchers. That being said, only 10% of women would prefer to give consent orally without signing a consent form. This contradicts some data with elderly participants (Brod and Feinbloom 1990) as well as the hypotheses of some research ethicists (e.g., Sieber 2001). It may be that signing a consent form is reassuring to participants insofar as it might appear to constitute a contract (one that promises confidentiality, payment, and the right to leave the study at anytime).

The responses to most items pertaining to payments are somewhat less surprising. The vast majority considered payments for their time to be fair; they believe that payments do influence decisions to participate in research; and they do not believe that payments lead them to ignore the risks of a study. While participants may be poor judges of the influence payments might have on risk perception, their responses are consistent with the high value they appeared to place on the informed consent process.

Regarding differential treatment, one could say the following: If the different treatment involved exclusion from participation, they were against it; if the differential treatment appeared aimed at avoiding undue influence on decisions to participate, then they were ambivalent as a group. That is, the vast majority (75–90%) were against excluding prisoners and substance users from participation, but 46% of the overall group thought it was acceptable to prohibit researchers from paying drug users cash, and 40% of the overall group thought researchers should not be allowed to offer large payments to get people to enroll in a study they would not otherwise enroll in. These items were the only items that polarized the participants.

We do not believe the responses we received were due to social desirability. For example, some women supported additional protections we did not offer (e.g., testing for understanding of consent information) and the amount of payment they considered fair on average was higher than what we paid.

We believe that this study was valuable insofar as it assisted researchers in the EPRG to better understand the preferences their participant population has toward additional safeguards. The study provided the women with a voice that should be heard, and that may shape future protections offered. For example, researchers in the EPRG are now considering adopting a more formal approach to ensuring participant understanding. EPRG faculty and staff also feel vindicated in their efforts to advocate for the fair inclusion of these women in research studies (Cottler et al. 1996). These two examples—the decision to formally assess understanding of consent information and the decision to advocate for inclusive rather than exclusionary policies—illustrate the fact that while IRBs must approve all safeguards, they and researchers often have considerable discretion in determining which specific safeguards should be offered. Participant attitudes and preferences may inform and influence how this discretion is used.

We encourage others to engage in similar research ethics “quality improvement” research on a regular basis within their own local research communities to understand the needs and thoughts of their own populations. As we have found, others may also find that adding a few additional yes/no questions on research safeguards, within the context of an already planned study, can yield information whose value exceeds its costs.

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Table 1

Description of the participant replicates

Original Study Intervention	Replicate				
	1	**2**	**3**	**4**	**5**
Standard intervention	C	C	C	1 or more NC	C or NA
Well-woman exam	NA	C	C		C or NA
Educational intervention	NA	NA	C		C or NA
Baseline interview	C	C	C	C	1 or more NC
4-month interview	C	C	C	C	
12-month interview	C	C	C	C	

NA not assigned, *C* completed, *NC* not completed

Table 2

Responses to consent questions among 97 female participants from drug court

Do you want …	High compliance % Yes (*n*)	Low compliance % Yes	X^2
Researchers to read consent forms out loud to you?	88 (46)	69 (31)	0.02
Researchers to test your understanding of consent information?	96 (50)	96 (43)	NS
Researchers to verify you are not high during the consent process?	96 (50)	89 (40)	NS
A friend present during the consent process?	31 (16)	16 (7)	NS
A family member present during the informed consent process?	40 (21)	27 (12)	NS
A stranger present during the consent process—someone who is not part of the research team, but is trained to help you understand the study?	40 (21)	31 (14)	NS
Researchers to remind you of consent information at each visit?	79 (41)	80 (36)	NS
To give consent verbally, without signing a form?	10 (5)	9 (4)	NS

Table 3

Responses to financial incentives and differential treatment questions among 97 female participants from drug court

Question	High compliance % Yes (*n*)	Low compliance % Yes (*n*)	X^2
Should participants be paid for their time?	94 (49)	89 (40)	NS
Would you be willing to participate in a study if you were paid using a gift card rather than cash—in an amount you consider fair?	88 (46)	84 (38)	NS
Would offering large payments make most people sign up for a study they normally would not sign up for?	88 (46)	91 (41)	NS
Do you think you would ignore the risks of a study if you were offered a large payment to participate?	8 (4)	16 (7)	NS
Should researchers be allowed to offer large payments to encourage participation?	58 (30)	56 (25)	NS
Is it fair to forbid researchers to pay drug users cash?	42 (22)	51 (23)	NS
Should researchers be allowed to exclude drug users from ordinary clinical studies?	25 (13)	16 (7)	NS
Is it right that government regulations exclude prisoners from participating in ordinary clinical trials?	10 (5)	18 (8)	NS