Title

Positive and negative aspects of participation in illicit drug research: Implications for recruitment and ethical conduct.

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ABSTRACT

Improved understanding of incentives and barriers to drug user research participation may improve study recruitment, retention and outcomes and enhance the ethical acceptability of illicit drug research. In Melbourne, Australia during 2001–2004, 507 injecting drug users were recruited from Needle and Syringe Programs and asked to nominate the 'best' and 'worst' things about research. Commonly reported positive aspects of drug research were its capacity to provide valid information about drug use (39%), the potential to improve drug-related policies and practices (20%) and benefits to the community (14%). Reported negative aspects of drug research included concerns about lack of, or negative impact of research findings (31%), personal dislikes about research projects such as discomfort (27%), inconvenience (21%) and risk (9%). IDU may participate in non-intervention research because of expected benefits for themselves and others, and may be discouraged from involvement by personal discomfort, inconvenience and risk, or a perceived lack of impact or benefit. To enhance recruitment to non-intervention research and fulfil ethical obligations investigators should (1) actively consider how best to minimise the IDU-defined negative aspects of research, and (2) clarify for prospective participants the intended impact of the research on policy and practice.

Keywords: Research participation, ethics, drugs, incentives, barriers, injecting drug use

INTRODUCTION

In public health and clinical research that targets 'hidden' populations such as illicit drug users, project success depends on adequate participant recruitment and retention. The challenge of recruiting illicit drug users to research may be addressed through a greater understanding of participation incentives and barriers.

Previous studies of clinical intervention and cohort research populations show that research participation is motivated by a variety of incentives, such as: information access (Smith et al., 1998); economic gain (Cunny & Miller, 1994); desire to help others and contribute to science (Wright, Klee, & Reid, 1998; Hayman, Taylor, Peart, Galland, & Sayers, 2001; Roberts, Warner, & Brody, 2000); expected therapeutic benefits (Brody & Waldron, 2000; Cunny & Miller, 1994); and interest in the research topic (Farre, Lamas, & Cami, 1995). There are also negative factors such as inconvenience, risk and discomfort from study procedures that may serve as barriers to participation or reduce retention and protocol adherence in intervention and cohort studies (Cunny & Miller, 1994; Hayman et al., 2001; Ammassari et al., 2002). These findings have informed the development of strategies to enhance drug user recruitment, retention and adherence in clinical research (see Cottler, Compton, Ben-Abdallah, Horne, & Claverie, 1996; Simoni, Frick, Pantalone, & Turner, 2003; Meyers, Webb, Frantz, & Randall, 2003).

In contrast, there has been little consideration of factors that influence drug user participation in 'non-intervention' research (e.g. community-based epidemiological research, descriptive surveillance studies, attitudes surveys/polls etc). These types of studies, often conducted with non-clinical populations of drug users, are common in the drug and alcohol field and are important for drug policy and program development. Recruitment to these studies is particularly challenging where the target population is not in routine contact with

treatment or other institutions (Braunstein, 1993), and thus may be less willing or used to discussing sensitive personal information (Lee, 1993).

The only published study in this area has shown that injecting drug users (IDU) participate in non-intervention research for a variety of reasons such as: economic gain; citizenship; altruism; personal satisfaction; drug user activism; receipt of information and other assistance (see Fry & Dwyer, 2001). The current paper continues our Centre's ongoing work on this topic by investigating the self-reported positive *and* negative aspects of research participation for the IDU participants of a national drug trend surveillance study.

METHODS

Study eligibility criteria were at least monthly injection during the previous six months, and Melbourne residence for at least the preceding 12 months. Participants were recruited and interviewed onsite at five Needle and Syringe Program (NSP) sites across Melbourne between June and August 2001 to 2004 as part of the serial cross-sectional Melbourne Illicit Drug Reporting System (IDRS) study. Recruitment was supported by NSP staff, however they were not directly involved in recruiting potential participants. To minimise the possibility of participant/response duplication participants were excluded if: (a) they had participated in the annual study in one of the years where data was already included; (b) they did not know whether they had participated in the study before; or (c) they had participated before but could not recall which year/s. Of 605 valid cases in the sample merged across 2001 to 2004, 98 were excluded, leaving 507.

To facilitate self-report and capture information about positive and negative aspects of participation, the following plain language open-ended questions were asked: 'In your view what is the best thing about drug research projects such as these?' and 'In your view what is the worst thing about drug research projects such as these?' Up to three themes per comment were initially coded (JSN) for responses, with responses assigned categories such as 'Personal

Benefit' or 'Community'. Where multiple themes were mentioned, responses were assigned up to three categories. Ambiguous responses were coded 'Unclear' and up to two categories then suggested. Inter-rater reliability was assessed by a second person (MJB) coding a random sub-sample (n=25 from each year), and then comparing codes. Coders discussed and resolved disagreements in meaning (10% of cases), and recoded ambiguous responses. SPSS 11.5 was used to collate and analyse the data. The Victorian Department of Human Services Human Research Ethics Committee granted ethics approval.

RESULTS

Demographics and research experience

The sample had a median age of 29 years (range 16 to 55) and over half (58%) were male. Response patterns did not vary as a function of participant age or sex. Over one third (37%) of the total sample reported being first-time research participants, with a further third (30%) participating in their second project ever, and the remaining sample (32%) having participated in three or more projects over their lifetime. Two thirds (67%) stated this was the only drug research project they had participated in over the last 12 months.

Positive aspects of research

Table 1 shows respondents' views on the 'best' and 'worst' things about drug research projects. The majority (85%) nominated benefits to others, and 19% identified benefits to self. The most commonly reported positive aspects about drug research projects include: the potential to provide real or true information about drug use (39%), their capacity to improve drug-related policies and practices (20%), benefits for drug user community (14%), and general awareness raising (13%). Although drug research project experience was unrelated to the number of positive aspects reported, respondents who had participated in more than one research project were more likely to identify the potential for policy improvements (24%), compared to first-time participants (14%) (χ^2=7.2, p=.007).

[insert Table 1 here]

Negative aspects of research

Less than half (41%) of the sample identified any 'worst thing' about drug research projects. Although many respondents answered 'nothing' or 'none', it was not possible to retrospectively distinguish these responses from missing responses, so they were excluded. The majority (56%) of those who commented reported personal dislikes about research projects such as discomfort (27%), inconvenience (21%) and risk (9%) (See Table 1). A further third (31%) identified research outcomes as a potential negative aspect, particularly in the case of negative impacts or if research findings and recommendations are not implemented. Of those who responded, 11% identified research validity issues.

The reporting of any type of negative aspect of research varied as a function of participant research experience, with first-time participants significantly less likely to identify negative aspects of research (27%), compared to participants who had been involved in more than one previous study (49%) (χ^2=23.8, p=.000).

DISCUSSION

Consistent with the small amount of prior research on drug user participation (Fry & Dwyer, 2001; Sherman & Latkin, 1999; Wright et al., 1998), this brief descriptive study has highlighted a range of positive factors ('best things') that may be understood as potential incentives for IDU research involvement. The most common of these included benefits to others (e.g. provision of information, policy contribution, assisting fellow drug users) and personal benefits (e.g. cash payment, information, opportunity to talk). These findings indicate that a study's potential and actual benefits to both individual drug users, and to the wider drug user and general community, are important considerations for prospective participants.

This study extends previous research in this area by identifying a number of negative factors that may serve as barriers to drug user involvement in non-intervention research, including personal discomfort, inconvenience and risk. These are similar to the participation barriers identified for clinical trial participants (Cunny & Miller, 1994; Hayman et al., 2001), and highlight the need for careful evaluation of potential risks and harms (and indeed benefits) for participants of all research types and settings. Furthermore, many participants nominated perceived lack of impact of research findings as one of the 'worst things' about drug research projects.

In light of these findings, and recent examples of drug user representative groups withdrawing support for research due to concerns about negative impact (Fry, Madden, Brogan, & Loff, 2006), successful recruitment of IDU to non-intervention studies may require investigators better communicate how a study aims to influence policies and practices to the benefit of drug users and the wider community, in addition to clarification of any benefits to individual participants. There is an ethical mandate for this in the guise of informed consent guidelines and the principle of beneficence underpinning many peak human research ethics policies (see National Health and Medical Research Council, 1999; Beauchamp & Childress, 2001). However, the current findings may suggest grounds for a more active approach to informing participants of results and wider research impact than is currently the norm (MacNeil & Fernandez, 2006).

The generalisability of these findings is limited by the non-random cross-sectional design, in which participants primarily injected heroin and attended NSPs. It is also possible that responses were influenced by social desirability. Future research could address the issue of generalisability of these themes, in other jurisdictions or by recruiting IDU who do not attend NSPs, or by attempting to access IDU who do not participate in research. Further, the

strength of the social desirability bias in such studies might be addressed with the use of peer researchers to examine user-defined incentives and barriers.

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