

Good Intentions and Dangerous Assumptions: Research Ethics Committees and Illicit Drug Use Research

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Abstract

Illicit drug users are frequently identified as a 'vulnerable population' requiring 'special protection' and 'additional safeguards' in research. However, without specific guidance on how to enact these special protections and safeguards, research ethics committee (REC) members sometimes fall back on untested assumptions about the ethics of illicit drug use research. In light of growing calls for 'evidence-based research ethics', this commentary examines three common assumptions amongst REC members about what constitutes ethical research with drug users, and whether such assumptions are borne out by a growing body of empirical data. The assumptions that form the focus of this commentary are as follows: 1) drug users do not have the capacity to provide informed consent to research, 2) it is ethically problematic to provide financial incentives to drug users to participate in research and 3) asking drug users about their experiences 're-

traumatizes' and 're-victimizes' them.

Keywords: drug users, addiction, informed consent, financial incentives, monetary payments, trauma

Introduction

People who use illicit drugs are frequently identified as a 'vulnerable population' requiring 'special protection' and 'additional safeguards' in research [1-2]. However, concerns about participant vulnerability have been translated into ambiguous regulatory requirements and guidelines. As Anderson and DuBois [2] note, "vague requirements for 'additional safeguards' for vulnerable participants place a heavy burden on researchers and institutional review board members who may want to protect participants (and minimize institutional liability) but may not know how best to accomplish these goals" (p. 96).

When assessing the ethicality of research proposals, research ethics committees (RECs) must often rely on common sense, prior personal experience, and the imagined perspectives of the study participants [3, 4]. While these strategies play a useful role in decision-making, they may be based upon "biased opinions and untested assumptions" [3, p. 30]. Without an adequate understanding of the realities of illicit drug use, RECs may unwittingly make determinations based on prevailing stereotypes that depict drug users as selfish, irresponsible and unable to make sound judgments [5]. Thus, existing forms of research ethics oversight have not necessarily served to make research with drug users more ethical or respectful. Indeed, there is some evidence to suggest that 'special

protections' for drug users have become synonymous with 'over-protection' [1, 6].

Our prior research [7] suggests that several assumptions about illicit drug users are particularly entrenched: 1) the view that drug users do not have the capacity to provide informed consent to research, 2) ethical concerns about the provision of financial incentives to drug users to participate in research and 3) the belief that asking drug users about their experiences 're-traumatizes' and 're-victimizes' them. These are certainly not the only ethical concerns raised about research with illicit drug users, which includes an array of other complex issues relating to confidentiality and privacy, fair subject selection, the extent of researchers' responsibilities to protect participants from harm, duties to report illegal activities to authorities, etc. However, these three assumptions are arguably the greatest source of contention between addiction researchers and RECs in terms of what constitutes ethical practice.

Our goal in this article is to examine these assumptions in relation to a growing body of empirical data examining the ethics of drug use research. In order to identify relevant literature, a search of Pubmed/Medline was conducted in November 2010 using the search terms "ethics" AND "research" AND "drug users". Searches were also conducted of Google Scholar in June 2011 using the search chains: "research ethics" AND "drug users"; and "research ethics" AND "trauma". Although we have not conducted a systematic review of the literature, we believe we have captured the tenor of key research findings in the three areas we have identified.

Assumption: Drug users have impaired capacity to provide informed consent

A central concern of research ethics committees is drug users' perceived ability to provide informed consent to research participation [8-10]. Capacity issues are generally seen to be a concern in research with drug users for two reasons. First, acute intoxication or withdrawal may lead to temporary impairments in attention, cognition and recall of important information, as well debilitating physical symptoms [11]. Second, the cognitive consequences of long-term drug use, in conjunction with the co-occurring health and psychiatric conditions that frequently accompany and precipitate substance use problems, may also reduce concentration and limit understanding during the informed consent process [11, 12].

Although little empirical research has been conducted, and the available studies are restricted to injecting drug users (IDUs) recruited into HIV vaccine trials, this evidence does indicate that such concerns are likely overstated. For example, Harrison et al. [13] found that IDUs' comprehension of the consent process was comparable to that of non-IDUs enrolled in the study and MacQueen et al. [14] found that comprehension levels amongst IDUs were high at baseline and improved at follow up. Another study [12] of recall and comprehension of consent information amongst drug court clients found that participants failed to recall over 65% of the consent information within two weeks of entering the study; however, such lapses were not dissimilar from those reported among other, non-drug using populations. In light of the fact that less-than-perfect recall of consent information has been consistently found amongst all study populations, the problem may lie more with current conceptualizations of informed consent than the

capacities of drug users to participate in research.

When the opinion of drug users themselves is solicited, they generally affirm their capacity to provide consent for research. For example, female drug users in our previous study [7] categorically rejected the assertion that their capacity to provide informed consent to participate in research was permanently impaired, suggesting that this assumption was stereotypical, discriminatory and misunderstood the central features of addiction. Participants were particularly critical of the assumption that being ‘under the influence’ of an illicit drug was in itself evidence that a drug user’s decision-making capacity was impaired. Instead, they highlighted that the ability to provide informed consent was potentially more impaired during periods of withdrawal than during periods when they had drugs in their system. This coheres with the findings of neurological research, which indicates that acute drug withdrawal interferes with inhibitory control and decision-making abilities, increasing the risk of making impulsive decisions and ones focused on short-term gains [15].

Assumption: Paying drug users to participate in research is coercive

Although paying drug users to participate in research is a common practice, it is one viewed with a considerable degree of trepidation by many research ethics committees. Key issues identified to date include the idea that such payments exploit the economic vulnerability and marginalization of illicit drug users, thereby acting as an undue inducement, and that paying drug users encourages and rewards illicit drug use [5, 16, 17].

Empirical research into this topic has found financial motivations do play an important role in drug users' decisions to take part in research [7, 18-20]. However, this does not negate the possibility of other influential motivations guiding decisions to participate (or not participate) [18]. Why should drug users' motivations be any less complex than those of the broader population? As studies with other populations have shown, people generally take part in research for a variety of reasons that include personal gain as well as a desire to do 'good' [22]. Empirical research suggests that drug users' reasons for taking part in research are also multifaceted, and entail perceived benefits for others as well as themselves [7, 18].

Participants in these studies have pointed out that money alone is not incentive enough to take part in research [7, 18]. Specifically, while drug users acknowledged that payments for research participation might be spent on drugs, they emphasized that this was not their sole motivation for becoming research subjects, because they could always access resources to obtain drugs through other means. Further support is provided by research into the impact of payments on research participation amongst drug users [2]. The researchers found that cash payments did not have a significant impact on participants' drug use or their perceptions of the coerciveness of the research, although, in keeping with studies of other populations, larger cash honoraria did improve study retention.

Coalescing amongst addictions researchers writing about the ethics of financial incentives is the view that paying drug users for research participation constitutes 'fair

reimbursement’: an ethical and respectful acknowledgement of their time and expertise [7, 19, 20]. This research suggests that research participation becomes enmeshed in the informal economies of economically disadvantaged communities and provides drug users with an important additional source of income [7, 19, 24, 25]. In this respect, research participation may actually keep drug users out of ‘harm’s way’ by temporarily negating the necessity of engaging in other potentially more hazardous ways of earning money, such as survival sex or crime [7, 19].

Assumption: Asking drug users about their experiences re-traumatizes them

Many people whose lives include problematic substance use or addiction have experiences marked by challenging circumstances that include both individual and structural violence and abuse [24, 26]. The idea that many people turn to drugs to ‘self-medicate’ against the stress of unresolved loss and trauma is common [26], although commentators suggest that the pleasurable dimensions of drug use are under-acknowledged, especially in research conducted with under-privileged users [27]. For these reasons, it is often assumed that interview or survey research with drug users and other ‘vulnerable populations’ that probes their personal history is unethical because it may ‘rip open old wounds’ and thereby serves to ‘re-traumatize’ them [28]. However, as Dryegrov [28] notes, this is an assumption rather than a phenomenon that has been empirically documented.

Studies with populations who have experienced trauma uniformly suggest that only a small proportion of participants who become upset during the research process regret

taking part or characterize the experience as a negative one [29-30]. Moreover, it is unclear whether the distress experienced by this minority of participants exceeds the level of harm or discomfort they encounter in the ordinary course of their everyday lives [31]. Yet, RECs generally assume that emotional distress in interviews is evidence of ‘harm’ rather than a consequence of living through difficult experiences, requiring investigators to frame such distress as a potential ‘harm’ of research participation on their study information and consent forms.

Commentators have pointed to several conceptual flaws in the ways that RECs generally conceptualize emotional distress. First, as Newman [31] has argued, to assume that retelling one’s story in a research context ‘re-traumatizes’ the participant, “equates recounting a traumatic experience with the actual occurrence of traumatic exposure... [and] ignores the distinction that emanates from recall of an event versus the ‘intense fear, helplessness, or horror’ that emanates from direct experience of trauma”. Second, such conceptions of emotional distress seem to assume that life can be risk-free, in effect requiring researchers to meet conditions that cannot actually be achieved in the course of participants’ everyday lives [32].

There is considerable evidence to suggest that the emotional ‘distress’ research participants may experience when talking about past traumas is generally experienced as beneficial and cathartic, rather than harmful [29-31]. McIntosh [33] concludes that: “It is a gross simplification, therefore, to conceptualize emotional distress as a mere component, by-product or adverse effect of unstructured interviews” (p. 42). Instead,

emotional distress can be viewed as evidence of emotional engagement rather than a de facto indicator of harm, or as a harm itself [28, 33].

For these reasons, Fendrich et al. [34] suggest that standard consent form wordings “convey an exaggerated sense of a drug survey’s risk” (p. 34). They object to the sorts of disclaimers drug researchers are generally required to put on their consent forms about the emotional risks of discussing drug use and point out that such wordings may give the false (and unethical) impression that withdrawal from a study is only appropriate if such responses occur. Although voluntary participation is a non-contingent right, standard wordings about drug users’ right to withdraw if they find the subject matter of the study upsetting, seem to “link the right of refusal and the voluntary nature of participation to this exaggerated risk” [34].

Rethinking vulnerability

These findings suggest that current notions of ‘vulnerability’ require reconsideration. As several observers have noted, the concept is both too broad and too narrow to be of practical assistance to RECs’ evaluations. It stereotypes whole categories of individuals and diverts attention away from features of research projects and their environments that might positively or negatively affect participants [35-36]. This is particularly true of illicit drug users, who have generally been treated as a generic category despite important differences in people’s experiences based on factors such as gender, class and ethnicity [37]. For example, a white male advertising executive who regularly uses cocaine and an indigenous, street-involved woman who regularly uses heroin are both technically classed

as ‘illicit drug users’, but they have little in common beyond this label. That assumptions are sometimes automatically made about the demographic characteristics of illicit drug users may tell us more about the ways RECs tend to perceive people who use illicit drugs than the actual individuals participating in such research.

As Fry et al. [16] have previously stated, “Research participants who use and who may be dependent on drugs deserve the same ethical protections *and* choices during research as other participant groups” (p. 32). History has shown us that blanket research exclusions of ‘vulnerable’ populations, such as children and pregnant women, have often resulted in further harms to these groups [38]. It is therefore imperative that illicit drug users’ rights to ‘protection’ are not emphasized at the expense of their rights to be included in research that reflects their concerns, interests and priorities, as well as their rights to benefit from the results of such research.

Conclusion

If we are to take drug users’ rights to participate in research seriously, along with our responsibility to facilitate such inclusion in an appropriate manner, it is important to recognize that there are no easy answers in ensuring that research with drug users is ethical and respectful. As Fisher [39] notes, resolving ethical dilemmas in addictions research is “a reflective, contextually and relationally based endeavour, with no cookie cutter answers” (p. 737). However, it is important that REC members do not start from a *prima facie* assumption that drug users’ capacity to participate in research is, by definition, compromised. Instead, they should consider whether researchers’ informed

consent processes reflect adequate familiarity with the participants: in particular, the potential impact of withdrawal and the accessibility and comprehensiveness of informed consent processes. Second, instead of concerning themselves with whether subject payments are *warranted*, REC members' focus should instead shift to whether the amounts are *appropriate* and commensurate with other sources of income drug users have access to. Finally, RECs should recognize that asking drug users about their drug use involves potential benefits that generally outweigh the potential for 're-traumatizing' them. Moreover, evidence of emotional engagement is not, in itself, a 'risk' and researchers should not be forced to frame it as such on consent forms.

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