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Is there a problem with the status quo? Debating the need for standalone ethical guidelines for research with people who use alcohol and other drugs

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Abstract

In 2011, the Australian National Health and Medical Research Council (NHMRC) initiated an inquiry to determine whether there is a need for expanded ethical guidance in the form of a discrete guidance document for alcohol and other drug (AOD) research. An issues paper was developed to frame the inquiry. AOD researchers, Human Research Ethics Committees and others were invited to discuss whether there are distinctive ethical issues facing researchers and Human Research Ethics Committees in the AOD setting. Based on the public submissions, the NHMRC recommended that no AOD research-specific guidance is required. The inquiry and the NHMRC decision were not widely publicized, and we feel there is a need for further discussion. In order to do so, we have analysed the public inquiry submissions and described the central themes. Few submissions in the inquiry explicitly agreed AOD research warrants a specific guidance framework. Most were concerned that the NHMRC issues paper unfairly targeted people who use drugs as complex research participants. The inquiry highlights tensions around research governance and ethics review boards dealing with illicit and stigmatised behaviours. While we agree that a specific guidance framework for AOD research is not needed and could potentially be harmful and restrictive, we are concerned that the wholesale rejection of a guidance framework has closed the door to much needed debate. There remains, we argue, a need for alternative strategies and tools to support ethical research, inform and streamline institutional ethics approval, and engage and protect participants.

Keywords: ethics; research; guideline; drug; Human Research Ethics Committee

Introduction

In addition to Australia's national framework of principles for ethical research, the National Statement on Ethical Conduct in Human Research [1], the National Health and Medical Research Council (NHMRC) has developed a number of accompanying guidelines that cover activities associated with specific fields (e.g. 'Ethical guidelines on the use of Assisted Reproduction technology in clinical practice and research' and 'Values and ethics: guidelines for ethical conduct in Aboriginal and Torres Strait Islander health research'). In 2011, the NHMRC initiated an inquiry to determine whether expanded ethical guidance in the form of a discrete guidance document is required for alcohol and other drug (AOD) research. Assisted by an expert Advisory Group—members of the Australian Health Ethics Committee and two senior Australian researchers—the NHMRC developed an issues paper: Ethical Issues in Research into Alcohol and Other Drugs: An

issues paper exploring the need for a guidance framework (Issues Paper) [2]. The issues paper argued for the distinctiveness of AOD research: 'it deals with highly stigmatised forms of behaviour', can 'involve criminal behaviour', 'may involve the collection of sensitive personal information' that could cause 'direct harm to research participants', deals with a behaviour topic (drug use) that 'often has adverse effects on family members and the wider community', and finally, involves a behaviour where there is disagreement about whether it is 'a medical disorder, a personal choice, or a combination of the two' [2].

AOD researchers, Human Research Ethics Committees (HREC) and others were invited to respond to the issues paper and comment on: 'a) the distinctive ethical issues facing researchers and HRECs in the AOD setting; b) whether the Issues Paper identifies the most important new and emerging forms of AOD research; c) whether the values and principles put forward by the Issues Paper are adequate as a basis for ethical decision making in AOD research; and d) which issues need to be addressed in the proposed guidance framework, and whether any issues identified in the Issues Paper should be excluded from, such a guidance framework' [2]. Six specific ethical issues affecting AOD research were identified for discussion: participant payment; consent in minors and parental consent; dependants of participants; online methods in recruitment and data collection; contingency management payments; legal risks of research for participants and researchers; and protection of researchers [2]. In 2012, after consideration of the public submissions, the NHMRC recommended that no AOD research-specific guidance is required but that some general issues would be considered for the development in the National Statement on Ethical Conduct in Human Research [1]

The NHMRC received 27 submissions; the 21 publically available submissions were from HRECs, individual researchers, research groups, professional associations and non-government organisations (see http://consultations.nhmrc.gov.au/public_consultations/submissions/alcohol_drugs). Only five of the 21 public submissions explicitly agreed AOD research warrants a discrete guideline. These authors argue that participant payment, consent, legal risks for participants and researchers, and risks to researchers (but not the remaining discussion points) are issues significant to AOD research and that specific guidance is needed. In four submissions, authors did not explicitly state their preference for a guideline. Within the remaining 12 submissions, authors argued that the ethical issues raised by the issues paper are not sufficiently different to other human research to support discrete guidelines.

Regardless of their stance on the proposed guideline, authors of submissions were generally concerned by the inclusion of generic research methods (e.g. recruitment of minors and online research) in the issues paper, and several suggested that AOD research was being unfairly targeted. For example, the General Ethical Issues Sub-Committee of Alfred Hospital wrote:

> *There is little guidance available on the ethical issues raised by online research processes; this is an area of need for HRECs and researchers … however, the issues are not restricted to AOD research and are just as significant for other kinds of research*.

Following on from the resistance to labelling AOD research as more ethically fraught than other areas of research, many authors were also concerned that separate guidelines would discriminate against people who use AOD:

> *[N]one of this leads us to think that a national framework, specific to AOD research, is sensible or appropriate. It is stigmatising, and has the potential to create more harm than good—marginalising both AOD research participants and researchers.* (Drug Policy Modelling Program)

The terms 'stigma' and 'marginalisation' were used frequently in the submissions, and particular sections within the issues paper, such as the discussion of potential harm to dependants of

participants, were deemed stigmatising of people who use drugs. Further, the terminology used throughout the issues paper was criticised for being poorly defined or drawing on stigmatising, outdated and overly medicalised language:

> *We note that some of the concerns raised in the discussion document (e.g. Section 6.1) are based on stereotypical and simplistic understandings of drug users as lacking control over their use.* (National Drug Research Institute)

In a broader statement by the Centre for Research Excellence into Injecting Drug Use,

> *Throughout the consultation document there is a lack of recognition of the continuum of attitudes and behaviours regarding AOD use in Australia, with terms such as 'dependence' and 'addiction' used interchangeably in various sections. While this is in part reflective of the differences of opinion about how problem AOD use should be framed (as per 2.1.1e), this is not unique to the AOD field meaning that imprecision such as this does not warrant the development of a separate guidance document. Rather, stakeholders in the ethics review process need to be cognisant of these issues as they apply to AOD research.*

Both the issues paper and inquiry submissions include a number of key ethical concerns that will be familiar to AOD researchers. Further, we briefly summarise some of the literature that deals with these concerns, discuss why specific guidelines are contentious and go on to discuss alternatives.

Informed consent and participant payment

The ability of individuals with drug dependence to give adequate informed consent has been investigated and debated [3]. As discussed in the issues paper, differing viewpoints on vulnerability and capacity to consent are largely founded in whether 'addiction' is perceived as a medical disorder or an autonomous choice. Discussions of autonomy and self in biomedical literature identify philosophical and scientific tensions but tend to conclude that it is dangerous and unhelpful to label all people who are dependent on drugs as being unable to consent [4,5]. This issue is less clear with respect to intoxication where it has been argued that obviously intoxicated people should be deemed ineligible participants [6,7]. On the other hand, researchers employing observational methods defend the ethics of engaging in the lived experiences, and thus drug use, of people who use AOD [8–10].

Concerns about the decision-making capacity of people who use AOD are not supported by empirical data. Testing of consent comprehension and recall suggests people who use AOD possess adequate understanding of the consent process [11–14]. Research participants have been shown to possess clear views on research responsibility when it comes to consent [15] and share with researchers concerns about loss of confidentiality [16] and a common appreciation for the foundational moral principles guiding research regulation and scientific codes of conduct [17]. Participants who use drugs do not view reimbursements or incentives as coercive, and payments are not correlated with increased substance use in the short term [18–21]. This body of research has limitations and would benefit from application to broader populations beyond people who inject drugs. However, it does demonstrate that people who use AOD possess better comprehension of ethical issues than HRECs may anticipate, and overly protectionist ethical protocols in the AOD field may not be warranted [11]. Indeed, Bell and Salmon [22] note 'additional safeguards' regularly applied by HREC when assessing projects involving 'vulnerable populations' are applied with little specific guidance, meaning committee members resort to assumptions about the vulnerable group. HRECs need education, access to these debates and summaries of relevant empirical evidence.

Legal risks for participants and researchers

There has also been an ongoing discussion in Australia about the possibility of uncovering illicit offences in research, including in AOD research. The National Statement [1] directs that it is not the role of a HREC to provide legal advice but notes the possible legal implications of some research.

Chapter 4.6 [1] reviews the ethical and legal implications of research that may uncover illegal activity by participants or others, or may discover information indicating future illegal activity. A variety of strategies is suggested to protect research participants in these circumstances. Regardless, legal obligations to disclose research data to government agencies or courts may be imposed on researchers who acquire knowledge of criminal activity in AOD research, thus potentially exposing research participants to legal risks [2]. Researchers outside Australia have received requests from legal authorities to disclose confidential information, and several have faced legal action when they refused [23,24]. We are not aware of similar cases in Australia. However, Fitzgerald and Hamilton [25] described facing pressure from criminal justice agencies to hand over confidential information and suspended fieldwork while they clarified their legal position. More recently, Clough and Conigrave [26] described the risks of prosecution for researchers and participants in the Northern Territory should illicit offences be revealed during interviews. We have heard anecdotally about HRECs advising researchers to avoid specific questions that may generate information about potentially illegal activities.

The lack of clear guidelines for HRECs when reviewing ethics applications for research that may expose illicit activity was noted in several submissions:

> *The most challenging area is that of legal risks—where the research collects information (including human samples) that could be seen as evidence of illegal activities. On the one hand, participants need to be informed about, and protected from, potential legal risks of participation; on the other hand, giving undue weight to these risks might make it difficult to recruit participants. An over-emphasis on possible legal consequences could potentially make it impossible to continue conducting valuable and much-needed research in any field where 'legally sensitive' information might be collected.* (General Ethical Issues Sub-committee of Alfred Hospital Executive Committee)

The Centre for Research Excellence into Injecting Drug Use's submission called for consideration of legal reform to protect the confidentiality of the research findings. Currently, laws vary across jurisdictions. Some researchers may receive statutory protection for data as certain acts [Epidemiological Studies (Confidentiality) Act 1981 (Cwlth); Epidemiological Studies (Confidentiality) Act 1992 (ACT)] impose a statutory duty to maintain confidentiality of any information concerning the affairs of another person where that information was gathered as part of a 'prescribed study' [27]. The status of the researcher is also relevant as practitioner–researchers are subject to mandatory reporting legislation and professional codes of conduct. The legal obligations for researchers are complex and unclear to AOD researchers and HRECs. Further discussion of several legal issues would be useful: researchers' legal obligations; minimisation of legal risk in research; definition of unethical legal situations; and consent processes which adequately communicate complex legal risks to participants [2].

Community engagement

Within inquiry submissions, there was a widespread support for consumer consultation and community participation in research: 'What is required is practical guidance, of the sort that might be provided by stakeholder input, rather than a new set of guidelines' (Deakin University). Several authors noted drug user organisations already working to further the debate on human rights and research ethics through peer ethical review processes and collaborative methodologies [28,29]. Australian AOD researchers have also recently argued for an engaged, communitarian approach to ethics focusing on core values, such as reciprocity, advocacy and participation within a view of ethics as an ongoing and negotiated process [9,30,31]. Although a number of submissions argued against formalising (mandating) community-based ethical approval, there was a general consensus that community engagement in research is an essential part of ethical research practice. We are not aware of any consumer representation on the expert advisory group assigned to developing the issues paper and note the absence of drug user organisation in the public submissions. AOD

consumers groups and community organisations should be directly engaged in any changes to ethical frameworks or development of tools to support ethical practice.

Where to from here?

Although the outcome of the inquiry was not, as perhaps intended, endorsement of the need for a guidance document for AOD research, the inquiry did demonstrate a number of ethical issues concerning researchers and HRECs. As indicated above, many of these topics are 'live' ethical issues within the AOD sector. This leaves the question of how—without establishing guidelines—we might increase the understanding and knowledge of HRECs and researchers about these ethical issues. Three key areas strike us as requiring action.

First, a major theme in the NHMRC inquiry was that many concerns might be well intended, but the limited empirical data suggest they are unfounded; informed consent and recruitment payments are good examples here [11]. In short, despite the evidence, the inquiry reflects ongoing concern and uncertainty about ethical decision making on these issues suggesting the need for education materials or training.

Second, it also is clear that the laws around participant protection and researcher requirements when dealing with illicit behaviours, or potentially illicit behaviours, are generally not well understood or defined. This is tied into a core ethical principle, participant confidentiality. Researchers and HRECs are concerned by the unclear legal situation that a researcher may find themselves in if confronted by an illegal behaviour or if asked to reveal information about a participant to a law enforcement authority. This is an area ripe for attention; if it is not the role of a HREC to provide legal advice to researchers, then where does the legal expertise lie and how can it be made available to researchers and HREC? As previously suggested, legal reform in this area should be considered.

Finally, on the surface, much of the antipathy pitched at the issues paper appears focused on the concepts and language. The inclusion of matters impacting on research beyond the AOD sector also produced consternation. However, the criticisms are no doubt also bound up in ongoing concern about the governance of research via ethical review. Indeed, in our discussions with AOD researchers, we often hear frustration with an ethical approval process characterised by misconceptions of people who use AOD, a lengthy review process and, at times, unreasonable conditions.

Internationally, academics have argued that the regulatory structure of ethics review is clinically focused and therefore not always relevant to other types of research [32]; overly bureaucratic [33]; and is expanding its institutionalised dominance over all types of research practice [34]. Most fiercely, academics argue that the imposition of ethical review boards stalls careers blunts the 'essence of many intellectual traditions' all without evidence that participants' rights or welfare has benefited [35]. Further, unlike our national ethical framework, in which core principles tend to be broad and somewhat adaptable to context, guidelines have the potential to specifically direct the actions of researchers.

Despite resistance to overly protectionist guidelines, a call for some kind of consensus in approach across HRECs also emerged from the inquiry. In several submissions, for example, authors called for tools to assist HRECs in interpreting the existing NHMRC framework with respect to AOD research:

> *In the absence of obvious gaps in the National Statement, or a clear ethical requirement to deviate from the principles articulated in it, there does not appear to be any reason to look for new principles or values. Rather, assistance in interpreting the principles and values already articulated seems most useful.'* (Deakin University)

> *ACT-HREC does not believe the National Statement requires expansion for the sake of addressing any AOD specific research quandary; however, supplementary guidelines would be appropriate and beneficial.* (ACT Health Directorate HREC)

One option is to encourage further production of evidence around ethics and AOD research as well as harness the knowledge within the AOD research sector to generate case studies. Through both evidence and anecdote, case studies help to highlight the limitations of general ethical frameworks and improve professionals' capacity for practical reasoning when designing and reviewing research [22,27,36]. Case studies of fieldwork dilemmas, for example, expand the range of ethical issues beyond our foundational codes of conduct and provide space for practitioners to raise concerns. Such studies 'typically rise out of a researcher's own reflections on fine nuances of judgment in circumstances he or she faced' [37]. Case studies have the potential not only to provide training materials or guides for researchers and HRECs but also to encourage us to more formally engage with our day-to-day ethical dilemmas in research practice thereby keeping the channels open for discussion without creating further rules and restrictions. Critical reviews or fact sheets may be equally helpful.

It is clear from the NHMRC inquiry that researchers and HRECs encounter ethical and legal challenges related to AOD research. Some of these issues may not be distinctive of AOD research; this should not preclude discussion of these issues and how they play out in the context of AOD research. People involved in the ethics review process, whether as researchers, HRECs or community members, want to be better prepared for issues involved in AOD research. Researchers should be encouraged to engage in thinking through the practice of ethics in AOD research by publishing empirical and theoretical accounts or critiques of ethical practice or working on peer ethical review processes. The development of strategies and tools to support ethical research, inform and streamline institutional ethics approval, and engage and protect participants is an alternative to guidelines that should be considered.

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