

“It’s My Life” – Ethical Issues in AOD Research from the Consumer Perspective

INTRODUCTION:

I would like to begin by recognizing the traditional owners and thanking the conference organizers for inviting me to give this presentation today.

Because I always seem to run out of time when doing these types of presentations I am going to jump straight into the topic today which is – *Ethical Issues in AOD Research from the Consumer Perspective*. I have titled my presentation on this broad theme: “It’s My Life” in an attempt to highlight why appropriate and meaningful involvement in AOD research is so important to AOD consumers. And that is because such research *is* about our lives and our health and from this perspective we have a great deal to gain from meaningful engagement and of course a great deal to lose from being excluded.

It was from this ‘gut level’ understanding, that consumer involvement in research that affected us as drug users is really important, that AIVL was motivated to develop and release our National Statement on Ethical Issues for Research Involving Injecting/Illicit Drug Users. This national statement was released in June 2003 after many years of development and work and it is this statement that I am going to focus on today.

To give you a brief overview of my presentation, I will be commencing with:

- A brief explanation on ‘How’ and the perhaps more importantly ‘Why’ AIVL develop the “*AIVL National Statement on Ethical Issues for Research Involving Users*”;
- I will then move on to look in more detail at some of the key issues covered in the *AIVL National Statement* – this will be the main part of the presentation as it will give us a chance to look at some of the specific ethical and practical issues from the consumer perspective in undertaking research in this area and what it means in practice to “meaningfully involve” consumers; and then finally
- I will make some recommendations that I believe would improve consumer participation in AOD research going forward.

HOW DID WE DEVELOP THE AIVL NATIONAL STATEMENT?

Although the AIVL national statement was eventually developed as a “product” (in the new funding speak), of the AIVL National Hepatitis C Policy Program in 2002/2003, there was actually quite a long and interesting development process stretching back many years. I think that it is worthwhile taking you through this history, albeit briefly, because in many ways I believe the difficulties we experienced in developing and gaining recognition for our statement on ethical issues speaks to the difficult history of consumer participation itself in this area of research...

As it says on the slides,

- The AIVL document was built on or grew out of a set of ethical guidelines originally developed in 1997 by AIVL's member organisation in NSW, the *NSW Users & AIDS Association (NUAA)* for use in the NSW context. Looking back now I think that the NUAA document was amazing and very brave in many ways – (refer to ATSI Guidelines and NHMRC & CHF). So to have seen the need for a document to highlight ethical and participation issues for drug users involved in research at this time was significant and indeed highlights the innovative work and thinking that many Australian peer-based drug user organisations do and which is often overlooked
- Once the need for a national document was recognised, AIVL decided to use a modified and updated version of the NUAA document as the basis for a comprehensive consultation process involving all key stakeholders as the first step in developing the new national document.
- Although initially we had started out with the idea of developing a set of national ethical guidelines, it became evident following the consultation process that there would probably be a more positive reception particularly from the research community if we were to develop a ‘national statement’ rather than a ‘set of guidelines’. We also agreed that to address any concerns about “expertise” in relation to ethics and research that we would limit the document to being a statement on the issues from the ‘drug user perspective’ – as this is our area of expertise;
- These developments were important because it took the document away from any perception that AIVL was trying to ‘tell researchers how to do their job’ (God forbid) and allowed AIVL to speak from its area of expertise. In short

AIVL was not trying to develop a general set of guidelines on research ethics but rather a very specific document that spoke about the experience of consumers in illicit drug-related research. In this way the main aim of the AIVL statement became promoting discussion and encouraging further action on ethical issues in illicit drug research – which was in the interests of both consumers and researchers;

- We also recognised during the development process that *if* a set of national ethical guidelines *were* going to be developed then this would need to involve all the stakeholders in the research process and that AIVL did not have the capacity, expertise or interest to lead such a process. We believed that the development of a set of ethical guidelines to guide research in the AOD area (that all parties would agree to implement and be bound by) would need national leadership and the involvement of the relevant committees such as MACASHH and ANCD . This would give ‘authority’ to the guidelines and support a consensus approach to developing them. We believed that guidelines developed with such national leadership would also have more chance of being promoted through the Australian Health Ethics Committee framework and gaining formal NHMRC recognition.

WHY WAS A NATIONAL STATEMENT NEEDED?

For some years now, AIVL, its member organisations and some researchers have been calling for a greater degree of consultation on ethical issues relating to AOD research so that those most affected by the research (and it has to be said, those who have the most to lose from poor research) will have more input into the process, impact and outcomes of such research. In a variety of forums, AIVL and its member organisations have argued for:

- more consultation with consumers in setting the research agenda;
- more involvement of consumers in developing and planning research projects, in deciding where and how research funding is allocated; in carrying out research projects and in the application and impact of the findings.
- We have also called for more support for peer-driven research – which is an issue I will return to later.

Drug user organisations are regularly approached to be involved in research projects after the project has been developed and funded, frequently with little or no financial reimbursement on offer and without discussion of formal recognition for involvement or

input into findings and outcomes. In other cases, drug user organisations are regularly expected to participate in relevant research projects as part of their 'core business' without any recognition by researchers or funding bodies of the impact that this involvement has on the workload of the organisation. Gladly very recently some of this has started to change but there is still a long way to go.

It seems that the individual experience of drug users in research varies from one extreme to another. Some groups of drug users regularly speak of feeling 'over-researched', unclear about the objectives of the research that they are participating in, frustrated that they never seem to hear back about the findings of research they participate in and angry about inconsistent approaches to payment of participants within research projects. While other groups of drug users complain that their issues receive very little attention from researchers and that many key health, social and legal issues are either under-researched or not researched at all.

There are many reasons why injecting/illicit drug users need special consideration in relation to the ethical implications of research not the least of which is their status as an extremely isolated and marginalised group within society. This poor health and social status creates a range of significant barriers to conducting ethical research based on trust, respect and human dignity. Those researchers and institutions already working within ethical frameworks will understand the value of such approaches. But for those who are new to these issues I suppose the main reasons 'why' we developed the AIVL statement is to:-

- a) encourage the development of research practice that is of a consistently high ethical standard and is beneficial to injecting/illicit drug users in Australia;
- b) recognise that drug users and their organisations have valuable experience, knowledge and skills to bring to the research process;
- c) propose a set of clear principles for involving and working with AIVL and its member organisations in illicit drug research in Australia;
- d) facilitate a shift from simply 'protecting' individual participants to actively engaging in meaningful partnerships with drug user networks and communities;
- e) encourage researchers and research institutes to honestly review the values and principles that they bring to the research process and to assess them in relation to their ethical implications;

f) encourage discussion about the need for a set of formally recognised ethical standards for research involving injecting/illicit drug users.

KEY ISSUES COVERED IN THE AIVL STATEMENT

The three key areas covered in the statement are:

- Research Ethics Committees;
- Consumer Participation in Research;
- Ethical Issues in Conducting Research.

I am going to look at each of these areas in more detail as a way to unpack some of the key ethical issues in AOD research from the consumer perspective... but

- not much more than 20 minutes
- not going to be able to cover all of the issues (refer to many issues covered in workshop on Monday)
- only going to have time to touch on some of the really major issues
- will use some examples to highlight what I'm saying
- but lots of issues won't be covered – doesn't mean their not important.

Research Ethics Committees:

The main issues I am going to look at under this heading are: consumer involvement in ethics committees, legal issues, free and informed consent and peer-driven research and ethics committees. One of the main reasons why I am going to spend some time on the issue of Ethics Committees is because any changes in the way that ethical issues are addressed within AOD research will need to be driven by the existing research infrastructure. In particular, Human Research Ethics Committees (HRECs) will have a significant role to play in bringing about a renewed emphasis on ethical practice in AOD research.

a) Consumer Involvement in Ethics Committees:

One of the most important issues in relation to HRECs is the need to the incorporate consumer perspectives into decision making. Both Bastian and McNeill et al have questioned the current approach to consumer representation on HRECs. They state that lay persons on ethic committees can be outnumbered in terms of being the single 'consumer' representative on a large committee and may not be supported in their role or have accountability mechanisms back to the specific consumers who are the focus of

the research proposal(s).¹ Frequently consumer representatives on HRECs are 'generalist' health consumer representatives with little or no specialist knowledge and no requirement to consult with those directly affected by the research.

Despite the fact that there is a great deal of research involving illicit drug users being considered by HRECs at any given time, AIVL and its member organisations do not currently have any mechanisms to provide input into the decision making of ethics committees. Further work needs to be undertaken through the appropriate channels to determine how to support and improve existing HREC structures to actively manage ethical issues relating to AOD research including:

- How to improved consumer consultation;
- Potentially creating Illicit Drug Use sub-committees or advisory groups;
- Possibility of expanding committee membership to include additional members with specialised knowledge and experience for specific categories of proposals; and
- A need for guidelines to support the decision making of HRECs in relation to ethical issues in illicit drug research.

b) Legal Issues:

Research into illegal behaviours raises some complex legal and ethical issues. HRECs are increasingly concerned about the legal implications of conducting research into illegal behaviours. These concerns, while justified, must be placed in the context of a realistic appreciation of the law and its practical operation.

The major issue is that of access to information collected in the course of research. At the moment, data collected by researchers on illegal behaviour, including injecting/illicit drug use, do not have legally protected status to protect them from either, a search of premises by police officers or a court order to provide information and data. This raises issues in relation to the welfare of both research participants and researchers and may have implications for others involved in the research process.

Information about illegal behaviours obtained by researchers may incriminate research participants, resulting in direct harm as result

¹ Bastian H (1994) The Power of Sharing Knowledge, The Cochrane Collaboration, www.cochrane.org.au and McNeill et al, (1994) How Much Influence do Various Members have with Research Ethics Committees?, Cambridge Quarterly Journal of Healthcare Ethics, Special Section: Research Ethics 3, pp.522-32.

of their participation in research. **(eg. Ethnographic research giving great deal of detail about closed scoring and using scenes and rituals can expose user dealer networks to police scrutiny – so the information provided by users in research can end up being used against them – hard for individuals to see the whole picture of the research data until its too late.)**

Consequently, it may be no longer ethical to provide participants with absolute assurances of confidentiality even though this may undermine the capacity of researchers to recruit participants.

It is very important, however to say that these concerns need to be placed in context. Experience suggests that the likelihood of the authorities seeking access to research material is relatively small. There is no indication, for example, that police are likely to regard material as a significant source for investigative purposes although this does depend on the focus of the research and there could be significantly more law enforcement interest in ethnographic data.

In the past few years increasing levels of concern have been expressed within the sector in relation to the potential criminal liability of researchers. The potential for legal action against researchers tends to have been generally overstated, in advice which is often both legally inaccurate and practically unrealistic. Criminal liability is only extended under the doctrine of complicity (e.g. to those who 'aid and abet' offences) if the complicitor is actively involved in the offence in a blameworthy manner. A researcher would only fall into this category if he or she encouraged or facilitated the commission of an offence.

The issues in relation to criminal liability become far more complex, however, when applied to peer-based or peer-driven research. Increasingly, drug user organisations are conducting research and the precise legal position of the individual drug users employed as peer researchers is, at best, unclear. The boundaries and distinctions that may be used in a legal case involving a recognised research institution will not necessarily apply in the case of a peer researcher. This is a particular issue if the peer researcher is a 'known drug user' or someone who is 'known' to the police.

Drug user organisations engaged in peer-driven research projects have heard numerous claims of legal problems encountered by peer researchers including; police surveillance and harassment peer researchers and participants, confiscation of research data and participant's details, search warrants, etc. Not surprisingly, drug users tell each other about poor treatment from police and other service providers, which can act as a deterrent to other drug users considering participation in future research projects. This

'grey' area of criminal liability needs further discussion and resolution so that valuable peer-driven research practices can continue and develop.

c) Free and Informed Consent:

The issue of gaining written consent for research involving illicit drug users is both complex and difficult. The overwhelming need to protect the identity and confidentiality of participants within the area of research often leaves researchers in direct conflict with HREC guidelines on gaining written consent. While the requirement that all participants sign consent forms prior to HREC approval may be a realistic and important accountability measure for some research projects, additional options for meeting consent requirements need to be developed to accommodate projects where protecting the identity and confidentiality of participants is paramount.

The illegal nature of most drug use also means that the very act of signing a consent form may be considered dangerous and far too risky for many illicit drug users. For many drug users, written consent does not necessarily mean 'free and informed consent', and it does not necessarily guarantee equitable treatment. This being the case, it is necessary for HRECs to work with researchers and drug user organisations to develop ways of ensuring that research participants in the area give their free and informed consent in a way that satisfies ethical protocols, but does not place drug users in danger.

Lisa Power a Health Advocacy Manager from the Terrance Higgins Trust in London in her letter to the BMJ on this issue argues that informed consent is fundamentally about much broader issues than a signature on a piece of paper or even a well designed consent process. She states that by viewing informed consent as a process of participation and respect, we can begin to look at the overall issue rather than getting caught up in whether the single act of gaining written consent constitutes informed consent.² Issues such as confidentiality, the potential dangers associated with disclosing an illegal behaviour, the ethical issues associated with gaining informed consent from highly intoxicated people and/or drug users with mental health problems, have all lead to the view that current requirements need to be revised in favour of a more comprehensive and flexible approach. **(Example of peers use to communicating with each other when out of it and we are not intimidated by this – it is our preferred state of being, can look out of it but we know that they know what's going on)**

² Power L (1998) Trial subjects must be fully involved in design and approval of trials, BMJ, 316:1000-01.

AIVL believes that peers are the key to ensuring more ethical standards in relation to informed consent in AOD research. By and large, drug users are more comfortable with other drug users and, other users often know when someone is uncomfortable or doesn't understand the process. Developing more ethical and effective consent processes will also depend on researchers gaining a better understanding of both the real and perceived concerns that many drug users have in relation to health research. For example, one of the major concerns that some drug users have is that they will be denied treatment or services if they do not consent to participate in certain research. Such concerns need to be taken seriously, whether they are perception or reality and addressed in a way that instils confidence in drug users. The issue also of payment for participants and how this can get in the way of free and informed consent is another issue that needs to be discussed carefully particularly when what's being researched is so far away from what drug users really need to be researched. There needs to be a commitment to true partnership and collaboration with drug user organisations to address these issues.

d) Peer-Driven Research and Ethics Committees:

Given that peer-driven research by its nature is largely conducted by peer-based non-government organisations with no direct relationships with HRECs, it has never been entirely clear on how such organisations should proceed in relation to ethics clearance. Unfortunately, rather than there being any move to resolve this issue, those undertaking peer-driven research have simply found themselves isolated in terms of the process and ignored in terms of the important research they are doing. AIVL has recently experienced a range of difficulties and barriers within the existing HREC structure and process in relation to gaining ethics clearance for peer-driven research including:

- A general lack of clarity about requirements for NGOs in relation to ethics approval;
- Difficulties in accessing information about the process;
- It was an extremely onerous process that was unrealistic for a small NGO with limited resources;
- The application required sign-off from a very senior level in the health bureaucracy which was simply unrealistic for a peer-based drug user organisation initiating its first major peer-driven research project;
- An existing ethics approval process that is based on demonstrating a long-track record in research or demonstrating the involvement of individual researchers with such a record – this served to undermine the peer-driven nature of the proposal;

- Lack of expertise on the HREC in relation to peer-driven research involving /illicit drug users – this resulted in little or no understanding of AIVL or the organisation's expertise in peer-based approaches;
- Our experience as drug users was viewed more as a 'disadvantage' rather than an essential requirement for a peer-driven project.
- A lack of recognition of the training and skills development needs of peer-based NGOs – AIVL had no previous experience with gaining ethics approval but there seemed to be no support available to assist us in developing the required skills other than handing over control of the project to non-peers;

AIVL supports the development of a flexible and appropriate ethics clearance process for peer-driven proposals. Given that research conducted *by* drug using peers raises very different ethical issues to research conduct *on* or *with* drug users, consideration would need to be given to how this distinction is recognised within any peer-based ethics process.

CONSUMER PARTICIPATION IN RESEARCH:

There is actually a whole, large section in the AIVL national statement on the issue of Consumer participation, consultation and involvement in research as it is of course a major component of the whole issue of ethics and research from the consumer perspective. The problem is that I am almost out of time and to be honest I could do an entire presentation just on the issue of consumer participation so I am just going to very quickly focus on one aspect of this section of the document which is the set of principles for consumers participation and involvement in research. The section covers a lot of other issues including discussions on "who is a consumer?" and the different levels of consumer participation and involvement in research so I recommend people get the document from the AIVL website for further discussion of these issues.

I am just going to make some very brief comments on each of these key principles for consumer participation in research:

- Collaboration and Partnership – flexible collaborations between researchers and consumer organisations – informal and formal, discussions over coffee to consultancies to full partnerships;
- Consumer Participation - consumers supported to participate in **all** aspects of the research process including setting research priorities, developing proposals and

methodologies, conducting research, analyzing the data, report writing, disseminating the findings and assessing research outcomes for future action;

- Consumer Consultation - researchers should consult with consumer orgs in the development of research proposals to identify issues and concerns, to discuss the potential costs and benefits of the proposed research and to check the appropriateness of the planned approach from the consumer perspective;
- Supporting Consumer Research - consumer/peer-driven research is recognised and supported as an important and valuable component of consumer participation in research;
- Supporting Consumer Researchers - to use consumer/peer researchers wherever possible in research projects;
- Recognition of Consumer Expertise - the expertise and credibility of consumers and consumer organisations needs to be recognised and treated in the same way as the expertise of other key stakeholders, that is, it is respected, properly remunerated, taken seriously, listen to and acknowledged;
- Resourcing to Support Consumer Participation – adequate resources to support the full and ongoing participation of consumers and consumer organisations in research is planned into project budgets including sitting fees other expenses for consumer reps, funding for participation of consumer orgs, payment for consumer focus groups and research participants, funding for dissemination of information for consumers, etc.
- Communicating with Consumers - researchers need to develop their skills in relation to engaging and working with consumers and consumer representatives. If you want consumers and consumer orgs involved in your research then you need to make it your business to understand the issues and priorities of consumers;
- Respecting Consumer Rights - researchers need to respect the fact that consumers have a *right* but not an *obligation* to participate in research that affects or involves them. The issue that you think is important or is important to where you want to take your career may not be important to us.

- Informing Consumers - researchers need to provide information in forms that are accessible to all consumers and are able to be readily understood by them. The purpose of the research, how the research will be conducted, how data will be used, how reports will be published and disseminated and how the research outcomes will be used. It should also list any potential costs to consumers or consumer orgs as well as potential benefits. Most poorly done – participant information/consent forms just cut and paste from project grant proposal;
- Training for Consumers – we need training so that we can be effective consumer reps. Consumer orgs given no training and no funding but expected to carry the responsibility of all consumers for the project – wonder why it is hard to get new faces into consumer positions????

ETHICAL ISSUES IN CONDUCTING RESEARCH:

The final section of the AIVL national statement looks at each stage in the research process (as you can see on the slide) and identifies key ethical issues in each of these areas. Now I have actually touched on some of these as I have gone through the presentation so in the interests of time I am just going to identify one or two major issues in each of these areas before I move on to my conclusions and recommendations.

a) Planning and conducting research:

All of these issues were broadly picked up (not surprisingly in the consumer participation principles above but I cannot stress enough the importance of involving consumers in ALL stages of the research process not just to get your ethics clearance, not coming to us once the project proposal is written or worse still, already funded and not deciding for us what stages of the project we are capable of being involved in or understanding. With the right support and funding we can participate meaningfully in all stage of the process.

b) Storing, managing and analysing data:

Something that rarely happens in my experience is the involvement of consumer reps in the data analysis phase of the research. It is so important because so often researchers misinterpret data, take data out of context or trivialize really important issues. Whether people admit it or not – researchers interpret the data and consumers are critical to this process. They can also ensure that the rights and needs of consumers are protected during the report writing phase.

c) Dissemination of research findings:

This is a huge issue that I discuss with researchers all the time in terms of how to improve dissemination. It would be rare to meet a consumer in this area who says that they specifically received the findings of the research they were involved in. This is simply not good enough and there are many strategies including user magazines, forums, web and video based resources that can be used.

d) Uses of research data:

I said at the workshop on these issues on Monday that I thought that we had an increasing problem in relation to the negative impact of research data on the lives and health of consumers. I know there are people who will disagree with me but I believe that it is absolutely the responsibility of the researcher to ensure that their data is not used to the detriment of consumers and researchers need to be putting a great deal more effort into that end rather than simply accepting the inevitable or acting like disempowered observers. Enough said!

CONCLUSIONS AND RECOMMENDATIONS:

Despite my negative assessment of some aspects of research practice in relation to ethical issues, I do want to finish by saying that things are changing in some ways and some areas. AIVL and its members are having more dialogue about consumer participation in research more often (there was a good workshop held at this conference and there are plans I believe to continue that workshop at future conferences.) We are involved in numerous research projects (steering committees, associate investigators and partnerships). The NCHSR has developed a consumer liaison position, invited AIVL on to their Scientific Advisory Committee and are working in a full partnership with AIVL on a new peer-driven research project (we have the funding & we engaged them on our terms).

So there are some good things happening but, we need more discussion among researchers on ethics and consumer involvement; Ethics needs to be seen as a "whole of research" concern – not just about HRECs or gaining ethics approval but an issue from before the ethics application to long after the research has been done; and we need to see ethics as an issue for all research disciplines – not just an issue for social research or a stretch epidemiology.

Future issues include the establishment of a Consumer Ethics Advisory Group and a clear process for consumer endorsement or rejection of research proposals that affect our lives. Pleasingly at the IHRC being held in Vancouver early next year, the IHRA is holding a meeting of the recently formed International Research Ethics Committee to look at many of the issues I have raised and; of course from AIVL's perspective we believe we need to continue to lobby for a National Code of Ethics for AOD Research.

I wanted to finish with some thoughts on "why" we should be concerned about ethics and research and the main reasons I believe are:

- Because it makes for better research;
- It is about treating people with dignity and respect;
- It creates better evidence-based practice and highlights when the evidence is missing and action is needed; and
- It leads to improved health benefits and outcomes for all.

But to finish where I began, the main reason to involve consumers in your research is because *your* work affects *our* lives and we have a *right* to be involved in that.