

## **Engaging at Risk Populations in Vaccine Preparedness Research**

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I have been asked to talk today about engaging risk populations in vaccine preparedness research and then was later asked to also include a discussion of the role of community in HCV prevention research (instead of Stuart Loveday) but both of these topics are huge topics in themselves. So, due to time restraints I am going to try to broadly cover off both topics by making some general comments about engaging risk populations in research that affects their lives and some specific comments about vaccine preparedness research in particular. When it comes to hep C vaccine preparedness research, there are numerous at risk populations or 'sub-populations' that could be discussed but I am going to focus on the broad category of people who inject/have injected illicit drugs.

In thinking about how to approach this presentation today I have to say that I found myself feeling quite unsure as to where to start and what to say. I know little or nothing about immunology, clinical research studies or vaccine development. In this context it was hard to know what I could really contribute to the discussion today.

From where I stand as someone with chronic hepatitis C infection and as someone who has worked for many years to represent the issues for people affected by hepatitis C, I have to admit that I have actually given very little thought to the issue or prospect of a hepatitis C vaccine. This realisation led me to speak with some of my colleagues at AIVL and some local drug users about their thoughts and reactions to the issue of a hepatitis C vaccine. What I got back was a very interesting level of what can best be called: ambivalence about the whole subject.

The more I thought about this response, the more I realised that it was hardly surprising in that this 'ambivalence' largely reflected the general nature of the clinical relationship between drug users and the health system. That is, a general sense of 'ambivalence' about health and the health system which develops almost as a protective function in response to disempowerment, the impact of stigma and discrimination, poor treatment, a lack of access to appropriate services and a general sense that you have very little control over or say in your health or the way you are treated by the health system at any given time. After all if you are treated badly by your methadone program or by doctors why would you expect anything better from any other part of the health system?

This is the fundamental backdrop to any hepatitis C vaccine initiative. The departure point with the most at risk population in relation to hepatitis C, that is people who inject or have injected drugs, is one of overwhelming disempowerment and disengagement. Drug users are a highly researched group of people and in this context, it is probably fair to say that most people feel at best, research subjects, rather than as active participants in a joint-investigative process. For all the research drug users participate in, unless you happen to work at or are active in a drug user organisation, it is very unlikely that you will ever see the results of any research you participate in.

This is very important in the context of hepatitis C vaccine research because rightly or wrongly, there is a strong impression out there that too often research relating to drug users lives, promises a great deal but rarely seems to deliver. Now, if you are a researcher in this area that may well seem like a harsh comment particularly given the many factors that can intervene on the implementation and impact of research, but at the end of the day, it is not whether the comment is fair or not that I want to focus on, what I want to highlight is that there is a high degree of scepticism and research fatigue among many drug users and this needs to be taken into account if you are seeking to conduct research involving drug users.

Engaging marginalised and socially isolated people as active participants in a research process is very difficult at the best of times. But convincing people who distrust the health system, often for good reason, that it is in their best interests to participate in the development of a hep C vaccine might be best described as an uphill battle. That doesn't mean to say that a process of engagement should not be pursued, but it does mean that there are a number of important factors that need to be properly understood and acknowledged as part of any engagement process in relation to hep C vaccine development and these are:

1. **Understanding the context of people's lives** – many drug users are dealing with multiple complex and competing priorities in their lives at any given time. These issues can greatly affect their ability to engage with services and researchers but can also impact on the priority they give to an issue in their lives such as hepatitis C. For example, it may be quite enough for someone doing a prison term to manage their daily survival and cope with life prison without feeling like they are being 'encouraged' to participate in research about hep C prevention or development of a vaccine lest they be seen as a 'difficult' and non-compliant prisoner. These types of pressures don't have to be 'real' in the sense that they are explicit. It is enough that the person feels the weight of such expectations when they are in an extremely powerless position. As a researcher it is very important to not only understand but genuinely accept that the 'targets' of your research may not be as interested as you are in your research! Just because something is 'theoretically' a priority for a particular group in the community doesn't mean it is 'actually' a priority for that group or that it will be seen as a priority by all members of that group. Indeed, AIVL has at times received quite negative, even hostile responses from researchers if we don't get sufficient participants for their research when they ask or if we are just not as enthusiastic or interested in their research as they are. Sometimes we (AIVL and drug users for that matter) just have different priorities than researchers even if it is perceived as a pressing health issue.
2. **Understanding that some people are very sceptical about large pharmaceutical companies and mega research 'hubs' or initiatives** due to experiences with other clinical research trials and programs in relation to methadone, pain relief, interferon, etc – drug users are used to being given whatever is cheapest, whatever is easiest to deliver on mass and at times (think interferon) virtually whatever is lying around when it comes to 'treatments'. It is not surprising then, that some drug users may not be sure they can trust large vaccine initiatives to look out for their safety. We have seen examples of vaccine development research and trials going very wrong (re: HIV candidate vaccines making people more not less susceptible to HIV infection – they didn't expect it, they still don't really know why it happened, but it did and people, vulnerable people, have been left worse off as a consequence). People hear

about such outcomes and are naturally very scared and distrustful of a health system that has done little to win their trust over the years with less harmful medications let alone vaccines. There also examples in Asia with HIV vaccine trials where highly vulnerable groups of drug users have been exploited by poor research standards and controls. Where drug users rightly or wrongly got the 'message' that their participation in the methadone program was contingent upon their participation in the vaccine trial. Concerns about a lack of informed consent are very real in this context.

3. **Researchers need to be mindful that it can be very hard for people to get interested in a vaccine** for a disease they can't see, is not making them ill or where they can see their friends with hep C doing OK. Researchers involved in hep C preparedness studies need to understand why people might opt out of such a study or at the very least be ambivalent or disinterested. For some people it will be a question of "why take the risk of being involved in development of a hep C vaccine that could go horribly wrong or just go nowhere when there are so many other issues that I need to address in my life, right here, right now or even just so many other issues that I would like to see researched or action taken on such as more pharmacotherapy options, heroin trials, etc.

But I need to stress here, despite having outlined a number of reasons why people might not engage in hep C vaccine preparedness research, it is also very important to talk about those drug users who will be interested in such engagement because some drug users will be genuinely interested in research that affects their lives:

4. **Researchers need to be extremely careful about setting up unrealistic expectations of vaccine development or just the danger of misinformation** and how that can impact on a person's or even a whole network's protective behaviours. Many years of work has gone into strategies for getting accurate information to drug users about hep C and supporting people to engage in safer practices and blood awareness. Information in relation to hep C vaccine development is very complex and there is a very real risk of misinformation – people thinking a vaccine is just around the corner when it is not, changing their practices based on incorrect assessments about what a hep C vaccine might do if and when such a vaccine is developed and available, etc. This a major research ethics and responsibility issue for any researcher involved in or seeking to engage at risk communities/populations on the issue of hep C vaccine preparedness and one which a great deal of thought and work needs to go into before researchers even think about talking with active drug users about the possibility of hep C vaccines. Damage can so easily be done but very difficult to undo once misinformation and/or unsafe practices take hold.
5. **Linked to the issue of raising false hopes are questions about the role of people who already have hep C in any hep C vaccine preparedness research.** Now of course the answer to this question depends on whether the candidate vaccine is a preventative or therapeutic vaccine and many other questions besides but, the fact is, that in developing this presentation, a number of drug users with hep C stated to me that they weren't interested in the hep C vaccine issue because it would be "no good for them" even if a vaccine was to be developed. A number of people expressed sentiments along the lines of "being thrown on the health system scrapheap" if an effective hep C vaccine was ever available and that

they expected they would experience even higher levels of stigma and discrimination than they do now. I think this is a really important issue for researchers in Hep C vaccine preparedness as it will be an 'unspoken' reason why people will withdraw from engagement in the research as they will simply see it as another way for them to be seen as at best irrelevant and at worst, the 'problem' that everyone needs to be vaccinated against.

6. **Where researchers seek to access people to participate in their research, particularly in clinical research like vaccine studies is also very important.** It is critical to recognise the diversity of people who inject drugs and don't simply seek to access participants in the 'usual' places and services such as NSPs, drug treatment services, etc. This is particularly when discussing hep C vaccine research that is looking to recruit a rolling cohort of hundreds of hep C negative people. Participants will need to be recruited from a diversity of venues and places to ensure a broad cross-section of drug users who are hep C negative. It is also important to ensure the space is safe for the participant both in terms of privacy and confidentiality and in relation to enough 'space' and appropriate support to make an informed decision about something as important as going on a clinical trial for a new vaccine. The role of trained and supported peers is crucial to assist with the education and informed consent process for such research.
7. **It is also important to consider whether the development of a hep C vaccine or even talk of a possible hep C vaccine can erode support for critical harm reduction programs like NSP?** These programs are difficult to gain and retain political support for in the best of political circumstances – they are extremely vulnerable programs and any researcher working in the area of hep C vaccine preparedness needs to take very seriously the potential negative impact that talk of a hep c vaccine could have on access to these critical programs for those who need them. The main concern is whether even possible availability of a hep C vaccine could lead to funding being pulled from NSP in favour of funding for a more palatable 'technological fix' such as a vaccine. While I know that some think it is too early to be even raising issues such as these given that an actual vaccine will be many years away (if ever) but I believe it is never too early to begin thinking about the potential policy impacts of any research initiative. If you are talking to people about the vaccine initiative then it is not too early.
8. **I couldn't conclude a discussion about engaging IDU in hep C vaccine preparedness research without reflecting on the issue of hepatitis B vaccination.** We know that drug users are not really engaged on the issue of vaccination. We have a perfectly acceptable vaccine for hep B but still many drug users are not vaccinated – why? There are numerous reasons that mostly relate to lack of access to primary health care, distrust of the health system, poor experiences of the health system, lack of access to information about hep B and hep B vaccination and the competing priorities in people's lives that prevent them from engaging on many issues. In relation to hep C vaccine preparedness research there is much we can learn from the hep B vaccination experience with IDU including:
  - a. **The need to engage people in the development process from day one** – which is why involvement of drug user organisations in workshops like this one is so important. It is also why the social research arm of the vaccine initiative is so

important because it is where the views of ordinary drug users and their attitudes to hep C vaccination can be identified.

- b. **Providing better access to information on hepatitis C and the possibilities for a hep C vaccine.** People are not stupid, not everyone will be interested but for those who are there needs to be easy to access, accurate, credible, balanced and accessible information on hep C vaccine developments to prevent misinformation and to empower people to decide for themselves what level or sort of engagement they want to have on this issue – if any.
- c. **We also need to learn from the delivery problems associated with the hep B vaccination schedule involving 3 injections over a long period of time.** Long and complex vaccination schedules will never work for a group of people who have very poor access to health services. Any hep C vaccine will need to address this problem with preferably a one injection schedule. Issues of protection over time and whether people will need booster vaccines will also need to be addressed effectively if barriers to a hep C vaccine are to be removed.
- d. **But finally, we need to get serious about addressing the fundamental reasons why drug users do not access hep B vaccinations,** other available treatments and are often reluctant to engage with research and that is because they have appalling access to good quality, non-judgemental primary health care. Drug users carry a fundamental distrust of the health system based on routine discrimination and poor quality treatment. Until we address this we will never increase access or engagement. After all, as hep B vaccination has shown, there is no point in putting all the work into developing an effective and safe vaccine if those who could most benefit, do not benefit because there are structural inequities that prevent access.

Having said all of that however, this does not mean that AIVL is anti-vaccine or anti-vaccine preparedness research per se. I am saying however, that it is really important that those engaged in vaccine research don't get so caught up that you forget that at the end of the day all of this is about people. I can imagine that it is tempting when you are working on the edge of scientific discovery that it could be very easy to just to closet yourself with other clinical researchers who understand you, who 'get you' and what you are trying to achieve. But sooner or later it has to come back to people – people for clinical trials, people to take the vaccine. And when we are talking about a vaccine for hepatitis C we are talking about some extremely vulnerable people who are relying on all of you to do the right thing by them, to ensure what you do is done ethically.

In the end I am left quite unsure about the hep C vaccine issue. Investing multi-million dollar budgets into hep C vaccine research when we don't have enough funding to undertake hepatitis C prevention properly, when we aren't funding NSP adequately to ensure there is a new fit available for every injection that happens – when we can do this, maybe the issue of hep C vaccine will be more of a priority. At the end of the day I keep coming back to the fact that we need to get hep C prevention right – because even without a vaccine hepatitis C is a preventable virus.