

PROCEEDINGS AND EVALUATION REPORT
Ancillary Session:
PREVENTION TECHNOLOGIES IN THE
BROADER SPECTRUM OF HIV PREVENTION

Canadian Conference on HIV/AIDS Research - CAHR 2010
May 13, 2010 ~ Saskatoon

Prepared for the Interagency Coalition on AIDS and Development
By San Patten on May 30, 2010

TABLE OF CONTENTS

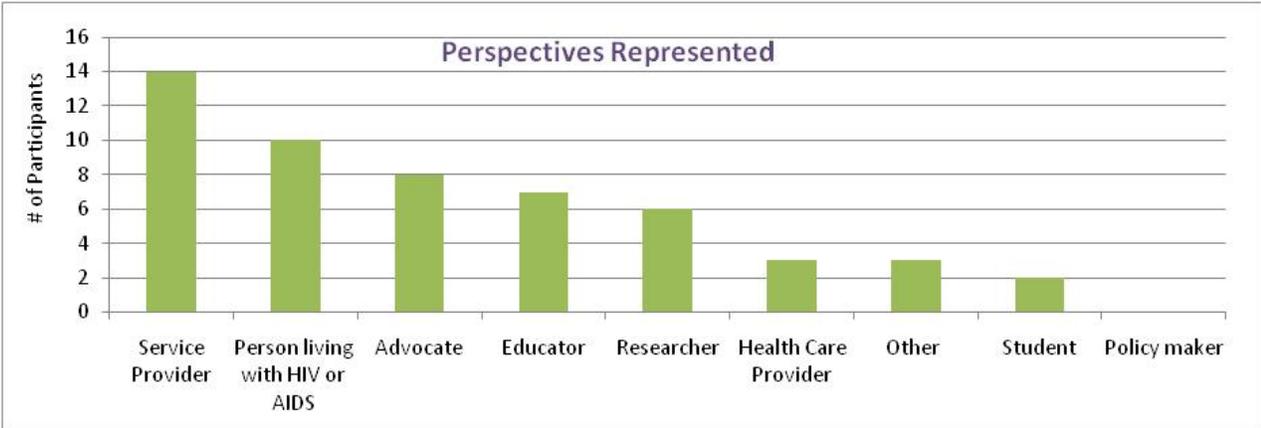
INTRODUCTION.....	1
PURPOSE AND OBJECTIVES.....	1
EVALUATION METHODS.....	2
PREPARATORY WEBINAR.....	2
AGENDA.....	3
SMALL GROUP PRIORITY SETTING.....	4
INDIVIDUAL EXPECTATIONS.....	5
PRESENTATIONS.....	5
WORLD CAFÉ.....	7
NEXT STEPS.....	9
KNOWLEDGE EXCHANGE.....	10
TAKE-HOME MESSAGES.....	11
TOPICS FOR FUTURE MEETINGS.....	12
ACHIEVEMENT OF OBJECTIVES.....	12
PROCESS EVALUATION.....	14
CONCLUSION.....	15
APPENDIX A.....	16
APPENDIX B.....	20

INTRODUCTION

This report provides an overview of the proceedings of the ancillary event called: “Prevention technologies in the broader spectrum of HIV prevention” delivered in conjunction with the 2010 Annual Canadian Conference on HIV/AIDS Research in Saskatoon (May 13, 2010). The event was supported by a grant from the Canadian HIV Vaccines Initiative (CHVI). The report also summarizes the process and outcome evaluation findings from the perspective of the 35 participants and the three host organizations: the Canadian AIDS Society (CAS), the Canadian AIDS Treatment Information Exchange (CATIE) and the Interagency Coalition on AIDS and Development (ICAD).

This day-long ancillary meeting brought together 39 researchers, community and public health workers, community members and government stakeholders to explore how new HIV prevention technologies, including vaccines, microbicides, post-exposure prophylaxis (PEP) and pre-exposure prophylaxis (PrEP), may fit within the broader continuum of HIV prevention strategies already in use. Currently a range of socio-behavioural and structural approaches are employed for HIV prevention. With the potential for new biomedical approaches to HIV prevention on the horizon, and on the direction of the Canadian Microbicides Action Plan (CMAP) Implementation Committee, the three host NGOs recognized the importance of beginning the dialogue of how these new technologies may work within the Canadian HIV prevention landscape.

Below is a figure indicating the various stakeholder perspectives represented at the ancillary event. Individuals may have indicated more than one perspective. Unfortunately, the invited individuals from Health Canada and the Public Health Agency of Canada were not able to participate. However, there was a strong representation of Aboriginal communities.



PURPOSE AND OBJECTIVES

The purpose of the meeting was to provide direction to the three national NGOs (CAS, CATIE, ICAD) on how they each, and in collaboration with one another and with existing networks such as the Canadian Microbicides Action Plan Implementation Committee, can advance NPT policy and program development in order to achieve multi-sectoral preparedness for NPTs in Canada as being discussed currently by stakeholders including the Public Health Agency. Another intended purpose of the

meeting was to generate recommendations which could be forwarded to the CHVI to provide direction for its program areas of Social Research, and Policy and Regulatory Issues, Community and Social Dimensions.

The objectives for the meeting were:

1. To explore how new prevention technologies may fit within the current landscape of HIV prevention strategies in Canada
2. To identify specific stakeholder needs and capacities in the area of NPTs
3. To identify the major issues that are emerging in the following areas, and who needs to be involved in:
 - a) Policy
 - b) Programming
 - c) Research
 - d) Community advocacy

EVALUATION METHODS

The Ancillary Event was evaluated by a consultant (San Patten) who was involved in designing the agenda, facilitating the event, and leading evaluation processes. Evaluation methods included: 1) pre- and post-session participant self-assessment form; 2) post-session participant evaluation form; 3) participant observation and post-session debrief by the organizers; and 4) follow-up interviews with representatives from each of the host organizations. Please refer to Appendix A for a copy of the pre- and post-session assessment forms.

PREPARATORY WEBINAR

The Ancillary Session was designed for participants with at least a basic understanding of NPTs (vaccines, microbicides, PrEP, PEP, treating HIV positive people to prevent transmission). In order to discuss policy, research, advocacy and program issues around NPTs in depth, the hope was that participants would have adequate background information about NPTs so that time in the agenda did not have to be allocated to covering the basics. Factsheets and a webinar to cover basic information about NPTs were made available to participants before the satellite.

Unfortunately, only 6 participants joined the webinar on May 11th, and these participants were individuals who already had some background on NPTs. None of the individuals who most needed the introductory material took advantage of the English version of the webinar. Thus, there were some participants at the ancillary session who were learning about NPTs for the first time. This may have limited the depth of discussion that was possible during the ancillary session.

The webinar was offered in both English and French. As only one individual required the French version, the trainer (Marc-André LeBlanc) provided an individual session in person, while going through the powerpoint slide presentation. The francophone individual expressed appreciation for the webinar and because she had very little background knowledge of NPTs, found the webinar to be very beneficial to her participation in the ancillary event. She also appreciated having the training in French as the content is quite technical.

It may be beneficial for future meeting or workshops to administer a pre-workshop assessment form in advance of the workshop (at least one week prior) and those individuals with the lowest self-ranked knowledge about NPTs should be strongly encouraged to participate in the preparatory webinar.

AGENDA

Time	Agenda Item	Speaker/Facilitator
8:00	Breakfast	
8:30	Registration	
9:00	Welcome, introductions, review objectives	San Patten
9:15	Small Group Priority Setting Small group discussions and plenary report back	San Patten and facilitators at each table
	On the ground experiences	
10:00	Perspectives from community advocates regarding access issues	Louise Binder - Chair, Canadian Treatment Action Council
10:20	Break	
10:35	Community preparedness and acceptance issues or concerns in Canada, as NPT trial results roll out and become available	Marc-André LeBlanc - Consultant
10:55	Early community experiences in use of NPTs	Dr. Réjean Thomas - President and Clinician, Clinique medicale l'Actuel
11:15	Plenary Discussion	San Patten
	Regulatory processes and jurisdictional issues	
11:45	Perspectives from Health Canada regulators	Ian Chisholm - Health Canada
12:05	Plenary Discussion	San Patten
12:15	Lunch	
	Behavioural and social science issues and partial effectiveness	
1:00	Overview of socio-behavioural issues in NPTs as part of the broader spectrum of HIV prevention	Anthony Lombardo - Canadian AIDS Treatment Information Exchange
1:20	Critical social science perspectives on NPTs as part of the broader spectrum of HIV prevention	Barry Adam - University of Windsor, Ontario HIV Treatment Network
1:40	Plenary Discussion	San Patten
2:00	Break	
2:15	World Café – four stations: 1. Policy 2. Programming 3. Research 4. Community advocacy	Facilitators: 1. Ian Chisholm 2. Réjean Thomas 3. Andrew Matjevic 4. Marc-André LeBlanc
3:15	Next steps	San Patten
3:45	Wrap up and evaluations	
4:00	Closing	

Given that the participants included some individuals with extensive background and knowledge of NPTs, and the limited time in the agenda to cover several topics, the facilitator (San Patten) set some ground rules for the day:

- Everyone's input is equally valued. Share "air time."
- Everyone is responsible for keeping the schedule.
- Only one conversation at a time (in plenary).
- Cut to the chase.
- Discussions and criticisms will focus on issues, not people.
- No idea or question is bad.
- Silence cell phones.
- Don't forget the interpreters.

One of the participants also requested that the facilitator keep a "speakers list" to keep track of the order of individuals who put up their hands to participate in the plenary discussions.

SMALL GROUP PRIORITY SETTING

Each round table had at least one member of the organizing committee (staff from CATIE, CAS and ICAD) who acted as facilitators and note-takers. Participants were asked, at their tables in small groups, to go around to each person at the table and briefly introduce themselves (name and affiliation), describe their understanding of NPTs, and identify their priorities for the day's discussions. Their responses were shared in plenary and are included below:

- Gap between community expectations/hopes and trial findings
- Focus on NPTs at community level: treatment as prevention, PrEP, PEP
- Community literacy, messaging & awareness – population- specific messaging
- Jurisdictional issues – advocacy needed at various levels for access
- Equity issues with respect to NPT access
- Off-label use of ARVs – drugs already available, control problems
- Implications for existing prevention methods and education programs
- Media engagement
- NPTs along the timeline of exposure (pre-exposure, at the point of exposure, and post-exposure)
- Scientific and social limitations of NPTs
- Ethics issues in the research and roll-out of NPTs
- Separation between biomedical and social interventions should be eliminated
- Geographic variations to access
- Impacts of NPTs on gay men
- Level of community knowledge
- Historical factors regarding vaccines
- Inclusion of communities in dialogue
- Existing challenges/barriers to prevention
- Meaning of partial efficacy at an individual level
- Comparison with variety of contraceptives available
- PEP already available (in limited contexts) but lack of awareness and advocacy
- Government response to NPTs

INDIVIDUAL EXPECTATIONS

In the pre-session self-assessment form, participants were asked to answer the question: “What is the one thing you want to get out of this symposium?” Their responses are summarized below:

- More general knowledge about NPTs (6)
- Updated information about NPTs and their research status (5)
- Better understanding of community perspectives, community involvement, and strategies for community advocacy (3)
- Learn more about NPTs to inform my agency’s prevention program planning
- Networking, diversity of perspectives
- Policy issues we can assist on at the provincial level
- Learn more about HIV prevention technologies for IDUs and MSM
- Learn new prevention technologies and how my community can benefit from such technologies
- Determine the place of microbicides in Canada
- Current issues in microbicide policy and advocacy in context of anticipating an effective product

PRESENTATIONS

Louise Binder’s presentation was titled “**Community concerns about access to microbicides**” and she discussed the need for community-level awareness, communications and education initiatives, particularly with respect to product marketing and information. She also discussed considerations in access to microbicides and prioritization of populations with first access, who will pay for microbicides, both in developed and developing countries, and the need for post-market surveillance of microbicides for short- and long-term safety and efficacy, and resistance.

Marc-André LeBlanc provided an **overview of community preparedness and acceptance**. He described lessons learned from the promotion and implementation of female condoms, the HPV vaccine, and male circumcision. He also discussed the impact of NPT trials on prevention, particularly the potential for confusion and false claims. Finally, he presented the challenges for community workers and advocates in staying informed about NPTs, anticipating and addressing challenges to access, and communicating results of trials to community members.

Dr. Réjean Thomas provided a presentation called “**Early community experiences in NPT use.**” Dr. Thomas reported the PEP program at l’Actuel Medical Clinic (Montreal) which has been in operation since 2001. He described the PEP protocol at the Clinic, and shared some interesting client statistics:

- 511 consultations in 2009 (up from 199 in 2007)
- Risk evaluation results: 81% considered high risk and treatment indicated
- 87% clients are male, mean age 34, 52% university educated, 95% high risk sexual contact
- Rate of seroconversion: 7/931 PEP receivers (0.7%)

Ian Chisolm provided a presentation called: “**Prevention technologies in the broader spectrum of HIV prevention: perspectives from Health Canada regulators.**” Ian provided an overview of the relevant regulatory frameworks (Canada Food and Drugs Act), the drug authorization process for new drug submission (safety, efficacy and quality requirements), and for expanding the indications of an already authorized product. He also described priority review status for products with significantly better risk-

benefit profile (180 day review vs 300 days), and the implications of NPTs for Canada's Access to Medicines Regime.

Dr. Barry Adam presented on behalf of Dr. Anthony Lombardo (who was unable to attend the event). Anthony's presentation, "**Socio-behavioural issues of new prevention technologies**" described the importance of social science in NPTs, particularly in considering acceptability, access and awareness. The presentation covered key socio-behavioural issues accompanying NPTs such as understandings of risk, risk compensation, gender, agency and empowerment. Overall, the presentation emphasized the need to look beyond the individual, and carefully consider implications for communicating/marketing NPTs.

The final presentation was by Dr. Barry Adam, called "**Prevention technologies in context and practice.**" Barry noted that while we need NPTs, we've had very limited success with biotechnical tools. He discussed treatment as prevention in terms of both biomedical problems (viral load) and problems of population level logic. He noted that all biotech solutions to HIV prevention are in fact social interventions, and therefore there's a need for synergy between prevention technology research and social science. In particular, neglected areas include ethnographies of vulnerable populations and examination of institutional sources of HIV information.

The presentations were followed by plenary discussion. The presenters were asked to provide two or three analytical questions to examine issues introduced in their presentations in more depth. Although the organizing committee compiled these analytical questions, they were not necessary. The plenary discussions after the presentations evolved naturally as the participants asked questions of clarification and raised issues that emerged from the presentations. For future reference, the prepared analytical questions are provided below:

On the Ground Experiences:

1. What messages will we convey to our communities when PrEP efficacy trial results become public this year? If they show that PrEP doesn't reduce risk? If they show PrEP reduces risk?
2. Who should be prioritized in Canada for access to NPTs and who should pay for them?
3. Given the efficacy and cost-effectiveness of PEP, why haven't we demanded broader access to PEP for non-occupational exposure? What does this mean for NPTs?

Regulatory Issues:

4. The regulatory system is designed to control how and which ARVs are used for treatment. Do you think the regulatory system is adequate for regulating ARV use for prevention?

Behavioural and Social Science:

5. How might your organization manage communicating "partial efficacy" to potential users of NPTs?
6. How will NPTs change the social context within which sex and drug behaviours occur? And what does this mean for prevention programming?

WORLD CAFÉ

The World Café is a small group conversational process that allows participants to rotate between various topics. These conversations link and build on each other as people move between groups, cross-pollinate ideas, and discover new insights into the four issues:

1. Policy/Regulatory issues: facilitated by Ian Chisholm
2. Programming: facilitated by Réjean Thomas
3. Research: facilitated by Andrew Matjejc
4. Community advocacy: facilitated by Marc-André LeBlanc

As a process, the World Café evokes the collective intelligence of the group and ensures that all participants are able to contribute. The figure below depicts the principles behind the World Café method (www.theworldcafe.com):



Participants were instructed to choose the three topics most relevant/interesting to them. They rotated between three of the four tables every 20 minutes. The facilitator at each table provided a brief introduction to set the context for the discussion, and then allowed the conversations to take place between the participants. There was a note-taker at each table to record the conversations' key messages. Please see Appendix B for the facilitator worksheets that were provided. The following are summaries of key messages coming from each theme:

Community Advocacy

- Raise awareness about NPTs in various sub-populations as well as in general population, and create general literacy levels about NPTs
- Reach consensus on which communities will be prioritized, and anticipate access barriers

- Anticipate trial results: prepare media, community members and CBOs/ASOs for various efficacy scenarios
- Develop strategic plan for how NPTs would fit within broader prevention agenda: to cover issues of stigma, population-specific strategies, criminalization, drug approval process, and making the case for increased funding for research, access, treatment
- Tailor education on NPTs for how and when people are having sex
- NPTs vis-à-vis trend towards criminalization
- More advocacy is needed around PEP: Clinique medical Actuel's model should be promoted and replicated across Canada so that PEP is more available for those in need
- Need more proactive preparation for PrEP trial results, understanding the difference between failed trials versus negative results (i.e., low efficacy)

Programming

- Challenges that have prevented programming in regards to non-occupational PEP: lack of data on efficacy, cost, and lack of sympathy for those who expose themselves non-occupationally
- Concerns about the medicalisation of prevention: NPTs are mostly biomedical and their programming is mostly limited to clinics, and excludes ASOs
- Need for programming to connect this bridge between ASOs and clinics. The successful PEP program at Clinique L'Actuel may explained by their strong community-oriented services. ASOs and clinics will need to co-ordinate to provide the same messages regarding NPTs.
- Need for ASO programming in NPTs to focus on awareness about NPTs (lack of PEP use is associated with poor awareness in at-risk communities), develop clear guidelines and budget for integration into prevention programs
- Need for programming to be backed up by clear guidelines from the government, advocacy from ASOs will be important
- Programming around NPTs needs to focus on linking those using biomedical technologies with other services, need strong integration with other supports (e.g., mental health, addictions)
 - Example: frequent users are often depressed and should be linked with mental health services. Also these frequent PEP users would be good candidates for PrEP
- ASO programming may involve linking these people to the appropriate services and following up.
- For many ASOs, NPTs are not a priority because there are many other prevention programs to focus on. Lack of priority is also the result of lack of knowledge about NPTs such as PEP. NPTs are also more complicated, difficult to understand biomedical technologies.
- Learn from successes and challenges in PEP and advocate for its expansion

Research

- Need resources for NPT-related research, e.g., to build and support necessary human resources
 - Q to CIHR: "Why aren't you funding more NPT research?"

- Q from CIHR: “Why aren’t you applying more for NPT research?”
- Plan for raising awareness: need more research about how to communicate and educate on NPTs
- Need a joint research program: combining biomedical science with social-behavioural science

Policy

- Many questions about how the regulatory process works, and how community can provide input and be more engaged
- Concern: regulatory system is not proactive. Although the Therapeutic Products Division is aware of NPT products in the pipeline, it can’t initiate approval processes until a manufacturer applies for review
- Black market concerns, especially across US border if Canada’s approval system lags behind other foreign jurisdictions
- Difficult to get community engagement at Federal or provincial level of policy-making. Community has more input into regional public health policy – e.g., updating PEP guidelines. Thus, participants recommended that the best place to start policy discussions around NPTs is with local public health units.
- Good policy development should rely on community realities and end users need to be meaningfully involved. For example, there is a perception in the general population that vaccines are 100% effective, so the education to health care providers and community members needs to be very clear about partial efficacy.
- Regulatory processes only focus on safety and efficacy of products. PHAC is a separate agency that deals with public health policy. Once a drug is approved, it can be marketed. PHAC can determine if further guidelines are needed about how it is marketed; separate process from regulatory review/approval.
- Need to have clear process for monitoring adverse effects: what if behavior change (i.e., risk compensation) wipes out efficacy? Will this be monitored?
 - The Marketed Health Products Directorate should monitor drug efficacy in real world, could pull drugs off for lack of efficacy.
- Need a lobbying strategy around cost-benefit that includes a sliding scale for individual drug costs – use public health emergency measures to produce low-cost drugs for micro-epidemics; need to be careful that we don’t create a reason for patent extensions on existing ARVs.
- What are the links with the criminalization issue?

NEXT STEPS

- POLICY: create a document that outlines issues for each NPT, and creates a community position - cost-benefit and risk-benefit analyses, regulatory and formulary implications, lobbying strategy, provincial reimbursement. One of the host organizations proposed that a consultant be hired to draft the document, and then host a meeting of relevant stakeholders to review and validate it.

- COMMUNITY ADVOCACY: develop “cheat sheets” for various efficacy scenarios of PrEP trial results; develop targeted education outreach program for Aboriginal communities
- RESEARCH: the CMAP Implementation Committee can apply to CIHR for a meeting grant to bring together community stakeholders, biomedical researchers and social science researchers
- PROGRAMMING: advocate for and engage in updating of PEP guidelines

Several individual participants also identified ways in which they could take steps to raise awareness within their communities (e.g., Aboriginal communities, African and Caribbean black communities) or within their professional or scholarly roles to advance dialogue and advocacy on NPTs.

KNOWLEDGE EXCHANGE

In the pre- and post-session self-assessment forms, participants were asked to rate their own level of experience, skills or knowledge in various content areas. They were asked to use the following five-point Likert scale to rate themselves:

1 = Novice/
Little or None 2 = Beginner/
Limited 3 = Competent
Somewhat 4 = Proficient/
Considerable 5 = Expert/
Extensive

The following table is a summary of the average pre- and post-session scores and average change in knowledge from 29 participants who completed the evaluation forms. Of the 29 completed forms, 18 could be matched for pre- and post-session scores.

Table 1: Pre- and Post-Session Self-Assessment Scores

How would you rate <u>your current</u> level of experience, skills or knowledge in each of these content areas?	Average Pre-Session Scores	Average Post-Session Scores	Average Post-Pre Difference
Understanding of how new prevention technologies (NPTs) fit within the current landscape of HIV prevention strategies in Canada	3.15	3.48	0.39
Understanding of community advocacy issues regarding NPTs in Canada	3.04	3.52	0.56
Understanding of community preparedness and acceptance issues relevant to NPTs in the Canadian context	2.85	3.48	0.56
Ability to describe early community experiences in use of NPTs	2.44	3.29	1.06
Understanding of NPT regulatory processes and jurisdictional issues	2.52	3.24	0.72
Understanding of socio-behavioural issues associated with NPTs	3.19	3.67	0.50
Ability to identify social research questions arising from NPTs	2.96	3.52	0.67

As indicated in the table, the greatest change in self-assessed knowledge was in the area “ability to describe early community experiences in use of NPTs.” The least amount of improvement in

knowledge was in the area “understanding of how NPTs fit within the current landscape of HIV prevention strategies in Canada.” Thus, this is an area for further dialogue and discussion, between policy makers, community members and ASOs.

TAKE-HOME MESSAGES

Participants were asked: **“Please name your top three take-home messages from this symposium.”** Their responses are summarized below. In cases where more than one individual stated a take-home message, the number of responses are indicated in brackets:

- Need to increase education/awareness of NPTs in communities (4)
- A comprehensive advocacy framework, marketing campaign and common communication strategy which prioritizes actions is essential (4)
- We need to educate the general public and disseminate information about NPTs – too much misinformation (3)
- More networking needs to be done across disciplines (between researchers, community, funders) on NPTs (3)
- Better understanding of PrEP (2)
- The importance of and more need for community involvement (2)
- Need for basic biomedical researchers, social researchers to work together (2)
- Dr. Thomas has created a great PEP model for the country, needs to be replicated in other provinces (2)
- NPTs are not “absolute” prevention tools but part of a prevention approach: how do we educate people?
- Microbicides will be used by women and men – how educate on safe use?
- NPTs require education/support on socio-behavioural issues as well as biomedical application
- Explore with ASOs and health clinics regarding knowledge sharing re: NPTs
- Community-based research
- I found there was a big disconnect between community workers/organization and the researchers (scientist). Especially their expectation of the scientist.
- We need to access the “invisible” populations
- We need to engage in more translational research
- Many new faces – a lot of repeat / re-education
- Progress?
- People wait for the “quick-fix”? Biomedical
- Prevention is still the key
- Condoms may be an old invention but they work
- Confused
- Tap into funding opportunities mentioned
- Lots of questions about NPTs – ethics, legalities, efficacy – lots of work to do!
- Importance of looking at / factoring in socio-economic, political, etc impact of NPT use and individual, community and societal levels
- Need for equal access for all to NPTs
- Need for community advocacy, need for document listing roll out of NPTs in regards to policy and regulatory guidelines

- There is a significant amount of information that I need to absorb
- How difficult it is to develop an effective vaccine
- Committing to NPTs
- A better understanding of the diverse perspectives will help enhance preparedness and programming
- Regulatory involvement needed at an early stage
- Overall plan for NPTs necessary
- Treatment as prevention?

TOPICS FOR FUTURE MEETINGS

The participants were asked: “**What topics would you recommend for future workshops or symposiums?**” Their responses are listed below:

- Bridging disciplines (clinical, basic research, community members/groups, etc.)
- Biomedical / community research meeting on NPTs
- Focus on PrEP and advocacy, programming, regulatory
- HIV-1 replication dynamic review (basic science)
- Social science review
- Perspectives of research participants
- The same topics on advocacy, programming, research
- HIV/AIDS trials in North American context
- NPTs in the North American context
- Prison population and access to NPTs
- At the appropriate time: rolling out, scaling up, prioritization of target populations, impacting cost/benefit analysis
- Taking position for/against NPTs – is it necessary? If yes, is there an ideal “ideal” timing to do so?
- Intended beneficiaries of NPTs: people in high prevalence zones in and outside Canada
- Further meetings are necessary to delve into more details.

ACHIEVEMENT OF OBJECTIVES

This section assesses the extent to which the objectives were achieved, based on participant evaluation, participant observation, and feedback from the organizers.

Objective 1: To explore how new prevention technologies may fit within the current landscape of HIV prevention strategies in Canada

Although discussed, the event did not result in any definite conclusions about how to integrate NPTs into the current prevention strategies in Canada as seen in Table 1. At an earlier meeting of the CMAP Implementation Committee, government stakeholders identified a gap in understanding about how NPTs may fit within the broader prevention strategy in Canada. It was beneficial to have a representative of CHVI at the session, but unfortunately, PHAC was not able to send a representative to the meeting so policy discussions lacked sufficient government input.

Further work is necessary to clarify how each NPT would fit within the current prevention landscape in Canada. On the introductory webinar the continuum of prevention was clearly articulated and in

retrospect it would have been useful to emphasize the continuum again at the beginning of the ancillary event. PEP and PrEP were discussed in more depth than were microbicides and male circumcision. It was useful to examine PEP more closely and understand its current status, and raise advocacy issues as they might relate to other NPTs. It would have been useful to also discuss limitations of condom use and harm reduction programs in specific populations as a way of making the case for expansion of HIV prevention strategies in Canada beyond the interventions which are already known to be efficacious.

Objective 2: To identify specific stakeholder needs and capacities in the area of NPTs

This objective was only partially met because there was representation from some stakeholders was minimal (basic, clinical and social science researchers; policy makers). Therefore most of the discussions focused on the needs of ASOs and national NGOs. Participants did learn a lot about the regulatory process and the role of Health Canada as a stakeholder; this was new information to most of the participants.

“Maybe we’re just not at the point that we can identify specific stakeholder needs/capacities, and at this point we can just talk about it on an ad-hoc basis.”

More detailed discussion is needed on the needs and capacities of some stakeholder and some population groups (e.g., IDU, heterosexuals, MSM). We also still need detailed discussion of what is needed in Canada in terms of research (basic, clinical and social research) and more discussion of population-specific needs. CIHR’s observations that researchers and NGOs are not submitting many research proposals indicates that we don’t have strong ideas of what research needs to happen. A one-day meeting does not provide adequate time to flesh out research priorities, particularly since there were only a few researchers in attendance.

Objective 3: To identify the major issues that are emerging in the following areas, and who needs to be involved in:

- a) Policy
- b) Programming
- c) Research
- d) Community advocacy

While the World Café discussions helped to raise these issues, the discussions may have been more in depth if a greater diversity of stakeholders were in attendance. For example, for the programming issue, the ASO perspective was well-represented, but there was little discussion of programming from a clinicians perspective, such as how NPTs might be prescribed and the HIV testing that would be necessary. The host organizations recognize that these are complex issues, and it is unreasonable to expect that major progress is made in building consensus within a one-day meeting. The most in-depth discussions were around PrEP and PEP. One issue that was briefly introduced by Barry Adam was access to male circumcision in Canada, as many provinces have delisted circumcision of male infants from their health coverage. This may be an area for further discussion, research and perhaps advocacy.

In terms of community advocacy, the meeting resulted in some clear next steps for the CMAP Implementation Committee. However, there is still confusion about the roles of MAG-Net and the

CMAP Implementation Committee: should they continue to focus solely on microbicides or should their focus expand more broadly to NPTs? Is another network necessary for NPTs or would it be redundant with existing structures?

PROCESS EVALUATION

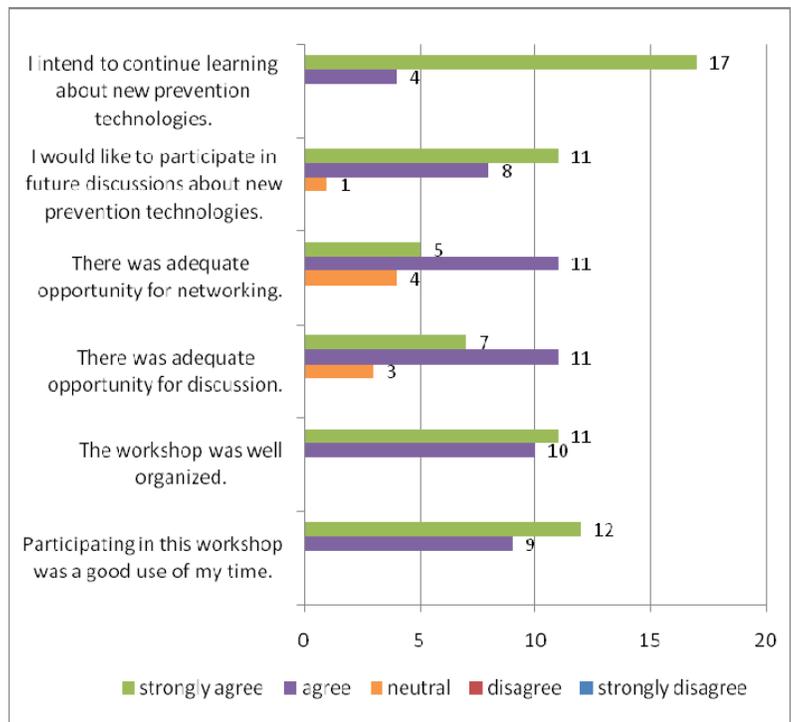
Participant Evaluation:

The following graph indicates the level of agreement from the event participants on various elements of the event’s process and delivery. According to the results, the participants felt that the workshop was well organized and worthwhile, and there is strong intention to continue learning about NPTs. For future events, there is room for improvement with respect to allowing time for networking and discussion.

Overall, the participants and organizers expressed satisfaction with the facilitation – there was a good level of participation during group discussions and participants weren’t cut off: *“The facilitator did a good job of managing potentially dominant people in the room.”* The use of ground rules was considered to be an effective way to ensure that all participants had equal opportunity to join discussions. A very positive indicator of a successful program is that almost all of the participants remained until the end of the day.

With the exception perhaps of the presentations by Anthony Lombardo and Barry Adam, all of the presentations were diverse and relevant to the objectives, and the presenters were generally effective in covering interesting and informative content.

Especially effective parts of the agenda were the morning priority setting activity and the World Café activity. The one exception was the policy table during the World Café which turned out to be an opportunity for participants to ask Ian Chisolm questions of clarification about regulatory processes. It was also noted that while the World Café structure is very conducive to participation and diversity of perspectives, the one-day event only allowed discussion of the issues in generalities or superficially. It was suggested by one of the organizers that we may need an entire workshop focused on each issue area: programming, research, community advocacy and policy.



Additional comments from participants:

- I find the youth (including university undergrads) and talking about youth issues in the context of prevention issues are under-represented
- Thanks for putting workshop together
- Facilitation went extremely well
- Need to keep momentum going with staple participants
- Well-organized, many thanks
- Well planned. Great discussions – leading to lots of questions needing to be addressed
- Thank you
- The whole workshop was worth attending. I am grateful to all the organizers and for the great opportunity to learn. I will take back this information/knowledge to my community/agency and hope to continue this conversation in future.
- Great work
- Great Canadian initiative!
- Fabulous job!

CONCLUSION

The CAHR ancillary session called “Prevention technologies in the broader spectrum of HIV prevention” was overall a successful collaboration between ICAD, CAS, and CATIE. Overall, the session achieved its objectives, with relevant and informative speakers, and content delivered in an engaging and interactive program. The participants largely were representative of ASO and NGO stakeholders, but lacked representation from policy makers (particularly the Public Health Agency of Canada and Health Canada) and researchers. There were some challenges in the planning process, in large part due to the short time frame between funding being granted and the event date. The event resulted in some clear and tangible next steps for follow-up actions to continue to build multi-stakeholder interest, awareness and preparedness for NPTs in Canada. The discussion does not end here, of course. There are many issues around integration of NPTs into Canada’s HIV prevention strategy that still need further consideration and analysis. The three NGOs should continue to collaborate and communicate to build on their respective strengths and roles in the Canadian response to HIV NPTs.

APPENDIX A

Pre-Workshop Questionnaire

Prevention Technologies in the Broader Spectrum of HIV Prevention

Please complete this questionnaire before the beginning of the workshop. It should take you no longer than 5 minutes to complete.

Your feedback will help us evaluate the workshop and inform future planning to advance ICAD's work on new prevention technologies. Your responses will be anonymous and confidential.

In order for us to match your pre- and post-questionnaire, please provide us with a code word that you will remember to use after the workshop.

CODE WORD:

1. Which perspective(s) are you representing? (please check all that apply)

- | | | |
|---|---|---------------------------------------|
| <input type="checkbox"/> Person living with HIV or AIDS | <input type="checkbox"/> Service Provider | <input type="checkbox"/> Student |
| <input type="checkbox"/> Researcher | <input type="checkbox"/> Advocate | <input type="checkbox"/> Educator |
| <input type="checkbox"/> Health Care Provider | <input type="checkbox"/> Policy maker | <input type="checkbox"/> Other: _____ |

2. What is one thing you want to get out of this workshop? _____

4. How would you rate <u>your current</u> level of experience, skills or knowledge in each of these content areas?	Novice / Little or None	Beginner / Limited	Competent Somewhat	Proficient /Considerable	Expert / Extensive
Understanding of how new prevention technologies (NPTs) fit within the current landscape of HIV prevention strategies in Canada	1	2	3	4	5
Understanding of community advocacy issues regarding NPTs in Canada	1	2	3	4	5
Understanding of community preparedness and acceptance issues relevant to NPTs in the Canadian context	1	2	3	4	5
Ability to describe early community experiences in use of NPTs	1	2	3	4	5
Understanding of NPT regulatory processes and jurisdictional issues	1	2	3	4	5
Understanding of socio-behavioural issues associated with NPTs	1	2	3	4	5
Ability to identify social research questions arising from NPTs	1	2	3	4	5

Post-Workshop Questionnaire

Prevention Technologies in the Broader Spectrum of HIV Prevention

Please complete this questionnaire before the beginning of the workshop. It should take you no longer than 5 minutes to complete. Your feedback will help us evaluate the workshop and inform future planning to advance ICAD’s work on new prevention technologies. Your responses will be anonymous and confidential.

In order for us to match your pre- and post-questionnaire, please provide us with the same code word that you used before the workshop.

CODE WORD:

1. Please name your top three take-home messages from this workshop:

- a) _____
- b) _____
- c) _____

2. How would you rate your current level of experience, skills or knowledge in each of these content areas?	Novice / Little or None	Beginner / Limited	Competent Somewhat	Proficient /Considerable	Expert / Extensive
Understanding of how new prevention technologies (NPTs) fit within the current landscape of HIV prevention strategies in Canada	1	2	3	4	5
Understanding of community advocacy issues regarding NPTs in Canada	1	2	3	4	5
Understanding of community preparedness and acceptance issues relevant to NPTs in the Canadian context	1	2	3	4	5
Ability to describe early community experiences in use of NPTs	1	2	3	4	5
Understanding of NPT regulatory processes and jurisdictional issues	1	2	3	4	5
Understanding of socio-behavioural issues associated with NPTs	1	2	3	4	5
Ability to identify social research questions arising from NPTs	1	2	3	4	5

3. Please indicate your agreement with the following statements:	Please circle one				
	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
Participating in this workshop was a good use of my time.	5	4	3	2	1
The workshop was well organized.	5	4	3	2	1
There was adequate opportunity for discussion.	5	4	3	2	1
There was adequate opportunity for networking.	5	4	3	2	1
I would like to participate in future discussions about new prevention technologies.	5	4	3	2	1
I intend to continue learning about new prevention technologies.	5	4	3	2	1

Rate each of the following presentations using the following scale (please circle one): 1 = Poor 2 = Fair 3 = Good 4 = Very Good 5 = Excellent			
4. Please provide us with some feedback on each of the presentations:	Clear explanations	Interesting presentation	Useful information
Perspectives from community advocates regarding access issues (Louise Binder) <u>Comments:</u>	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
Community preparedness and acceptance issues (Marc-André LeBlanc) <u>Comments:</u>	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
Early community experiences in use of NPTs (Dr. Réjean Thomas) <u>Comments:</u>	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5

Rate each of the following presentations using the following scale (please circle one): 1 = Poor 2 = Fair 3 = Good 4 = Very Good 5 = Excellent			
4. Please provide us with some feedback on each of the presentations:	Clear explanations	Interesting presentation	Useful information
Perspectives from Health Canada regulators (Ian Chisholm) <u>Comments:</u>	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
Socio-behavioural issues in NPTs (Anthony Lombardo) <u>Comments:</u>	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
Critical social science perspectives on NPTs (Barry Adam) <u>Comments:</u>	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5

4. What topics would you recommend for future workshops?

5. Any other comments?

Thank you very much for completing this questionnaire, and thanks for your participation in the Workshop.

APPENDIX B
World Café and Small Group discussions
Facilitators Guide

Session Description:

Four facilitators and four note-takers will be seated at tables with 8 chairs at each table. Participants will be asked to choose the 3 topics most relevant/interesting to them. The hour will be divided into 3 x 20 minute sections, and participants will visit the tables they are most interested in. No more than 8 people will be allowed at each table to make sure there are people at every table. After 20 minutes, a bell will sound and people will move on to the next table. In the 20-minute sessions: table facilitator will do a brief (2 minute) introduction to the issue and then facilitate discussion at the table and record the information. The facilitators will have worksheets which provide background information, potential discussion questions to stimulate discussion, and space for note-taking. The remaining time in the session will be an open discussion with note-taking.

The objective for this session is: to identify the major issues that are emerging in the following areas, and who needs to be involved in:

- a) Policy
- b) Programming
- c) Research
- d) Community advocacy

The following worksheets provide background information for facilitators, as well as potential discussion questions to stimulate discussion. Please note that the narrative is only for information and facilitators do not have to cover all of it.

Policy

Promoting action to plan for availability and accessibility—in particular, policy dialogue with decision makers—needs to happen well in advance of a product being proven effective. Encouraging the appropriate uptake and use of HIV NPTs will create complex policy and education issues for all jurisdictions. For example, in the case of ARV-based NPTs, pricing of drug products is a provincial jurisdiction and each individual province/territory will determine policy details around age eligibility, available by prescription, over the counter or behind the counter of pharmacies. In Canada, NPT uptake may be affected by the fact that some NPTs may only be appropriate for some people. The Canadian HIV Vaccines Plan and Canadian Microbicides Action Plan calls on HIV-affected communities, public health, health care providers, manufacturers and governments to anticipate and proactively develop appropriate policies. This could involve, for example, working with the National Advisory Committee on Immunization to develop recommendations to public health authorities on how to administer HIV vaccines in Canada.

Policy recommendations will need to be built on evidence-based criteria for determining:

- who will receive NPTs;
- how they will be distributed and promoted, based on scenarios (e.g., ARV-based NPTs or not, various levels of vaccine efficacy);
- the settings in which NPTs will be delivered;
- how adverse events (e.g., reactions, side effects) will be monitored;
- how to regulate safety, purity, formulation of any HIV NPT that reaches the production stage;
- how liability will be managed; and
- how the immunization or prescription program will be evaluated.

Stakeholders should also collaborate to ensure that all NPT activities are strategically aligned with existing HIV/AIDS policies and strategies, including Canada's International Policy Statement, *Leading Together: Canada Takes Action on HIV/AIDS*, the Federal Initiative to Address HIV/AIDS in Canada, the AIDS Community Action Program (ACAP), and the HIV/AIDS strategies of CIDA, CIHR and DFAIT.

Discussion Questions:

1. How would the potential cost effectiveness of NPTs be measured and factored into their distribution amongst various Canadian populations?
2. What policies or practice guidelines do you anticipate would be needed around education, delivery and access to NPTs?
3. What process can we begin to undertake to proactively develop policies around NPTs? Who should be involved in this process?

Programming

Canada's community-based HIV/AIDS organizations serve a very wide range of communities and are seen to be leaders in meaningful involvement of communities, so that people affected by HIV/AIDS can have an impact in shaping the distribution and access of NPTs. Community-based organizations have an important role to play in developing and implementing an education program that would raise awareness of NPTs, and promote them as part of a comprehensive approach to HIV prevention and treatment. CBOs also will need to lead in reinforcing the message that we need other prevention/education initiatives and in countering risk compensation.

Some possible ways that community-based programming can contribute to the education, delivery and access of NPTs are:

- developing community competence and preparedness for NPTs, based on scenarios (e.g., ARV-based NPTs or not, various levels of vaccine efficacy);
- developing community-based strategies to maintain behavioural prevention;
- developing public education strategies
- providing education, presentations, communications, to members and clients, customizing information for specific vulnerable populations
- documenting lessons learned from other prevention and treatment technologies (e.g., ARVs, pre-exposure prophylaxis (PREP), the HPV vaccine, male circumcision, female condoms, and emergency contraception)

Important questions remain around NPT preparedness and communications at the community level

- WHAT: should be in place before NPTs are rolled out in various Canadian populations
- WHO: should be targeted by NPT strategies, which populations should be prioritised
- WHERE: these NPTs should be offered
- HOW: NPT programs should be delivered and managed vis-à-vis other socio-behavioural interventions

Discussion Questions

1. How do you think AIDS service organizations should integrate NPTs into their current prevention programs? How would this vary for ARV-based versus non-ARV-based NPTs?
2. What do you anticipate to be some of the challenges in integrating NPTs into community-based HIV programming?
3. What process can we begin to undertake to proactively prepare community-based organizations for NPTs? Who should be involved in this process?

Research

Greater understanding is needed about the socio-behavioural issues involved with NPTs, including issues of community readiness and awareness, acceptability, access and adherence. There is a need for social and behavioural research that:

- works alongside epidemiologists and regulators to prioritize populations for access to various NPTs
- assesses the acceptability of various NPTs
- identifies any misperceptions that people living with or at risk of HIV may have
- assesses the impact of trial results on risk behaviour in the communities affected by HIV
- seeks to understand how NPTs make personal calculations of risk more complex, and could influence personal agency
- explores and tests Innovative multiple combination strategies
- conducts relevant operations research around NPT preparedness and communications at the community level
- assesses the gender implications of NPTs in terms of autonomy, covert use, partner negotiation and risk compensation
- finds ways to prevent or reduce risk compensation, and
- develops and evaluates community-level interventions and structural interventions that will roll out NPTs once they are available.

Social research could also help to document lessons learned from other prevention and treatment technologies (e.g., ARVs, pre-exposure prophylaxis (PREP), the HPV vaccine, male circumcision, female condoms, and emergency contraception) – and how they have been received by communities from education, usability and marketing perspectives. Specific research efforts should include studies to take stock of lessons learned from these other prevention and contraception technologies, and translate those lessons to NPT promotion and delivery.

Discussion Questions:

1. What are the big unknowns regarding NPT use in the Canadian context, and therefore your priority social research topics?
2. What process can we begin to undertake to proactively address some of these research priorities? Who should be involved in this process?

Community Advocacy

Community involvement is crucial in generating funding, raising awareness and putting NPTs on the political agenda. Raising NPT awareness, particularly among vulnerable populations, will prepare communities for participation in trials, and will ensure effective NPT delivery and use. Given that public sector support is required to fund NPT research, it is important for the governments to hear that all Canadians will benefit significantly from the availability of NPTs.

In the Canadian context, the availability of NPTs could have a positive impact on many populations. However, there are certain populations in Canada that are marginalized by economic ability to pay for the drugs on their own and should be able to receive NPTs free of charge (or for very minimal cost), such as through drug formularies for Aboriginal people. Thus, stakeholders across all sectors should advocate for availability, access and use at three levels: individual/community; service delivery; and policies. Advocacy efforts could include:

- supporting the development of a national HIV prevention plan or strategy that includes NPTs as well as voluntary counseling and testing, education, harm reduction, condom distribution, and efforts to address stigma, discrimination and gender vulnerability
- working to remove barriers to informed choice as a result of social factors, laws, policies, service-delivery practices, resource constraints and service providers' attitudes.
- endorsing and advocating for NPT research
- providing education, presentations, communications, to members and clients, customizing information for specific vulnerable populations
- engaging political leaders to understand the value of NPTs and commit the resources needed to advance NPT R&D.

Discussion Questions

1. What are some specific ways that community members and organizations can become more engaged in NPT advocacy?
2. What are some population-specific advocacy messages that may be necessary with respect to access to NPTs?
3. What process can we begin to undertake to proactively develop and promote community advocacy messages? Who should be involved in this process?

The following figures indicate the level of satisfaction with each presentation on the basis of how clearly the presenter explained the content, how interesting the presentations were, and how useful the information was.

