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Preparing Public Health for New HIV Prevention Technologies:

A Road Map for Comprehensive Action in Canada

Canadian Public Health Association

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CANADIAN PUBLIC HEALTH ASSOCIAITON

The Canadian Public Health Association is a national, independent, not-for-profit, voluntary association representing public health in Canada with links to the international public health community. CPHA's members believe in universal and equitable access to the basic conditions which are necessary to achieve health for all Canadians.

CPHA's mission is to constitute a special national resource in Canada that advocates for the improvement and maintenance of personal and community health according to the public health principles of disease prevention, health promotion and protection and healthy public policy.

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EXECUTIVE SUMMARY

In the absence of a cure for HIV, the development of vaccines and other new prevention technologies (NPTs) to prevent HIV infection offers one of the greatest promises for slowing the epidemic. Throughout 2010-2011, biomedical prevention technologies have begun to show great promise as several large efficacy trials recently demonstrated proof-of-concept or established efficacy for vaccines, oral pre-exposure prophylaxis, microbicides, and treatment-as-prevention.[i] While some of these products (i.e., vaccines, vaginal microbicides) are not currently available anywhere outside of clinical trials, other NPTs (i.e., treatment-as-prevention, pre-exposure prophylaxis) are currently available to Canadians. Though current levels of awareness and access vary greatly, these technologies have the potential to considerably reduce the impact of HIV in Canada and around the world.

Public health has been identified as a central mechanism in the effective and efficient delivery of NPTs nationwide. However, more needs to be done to "mobilize resources and develop the public health guidance, provider training and public health education needed to ensure rapid implementation of new prevention methods".[1] The public health workforce needs not only to build its own preparedness, knowledge and capacity, but also to engage more meaningfully in NPT research, policy and planning. The success of NPTs in Canada will be measured by how they are introduced, communicated and adopted.

This document examines public health's knowledge, information needs, roles, opportunities, challenges and capacity to introduce and deliver NPTs in Canada. The report presents the findings of various data collection methods including consultations, a literature search/review, key informant interviews and a nationwide online survey of public health stakeholders. There was considerable convergence of the data across the information-gathering approaches.

Public health perceptions. Throughout the project consultations, it was widely agreed among public health participants that not only was the introduction and delivery of NPTs the responsibility of public health but also that "public health should be engaged with new HIV prevention technologies at this point" (CPHA consultation). In the CPHA survey, 97.8% of public health unit respondents agreed or strongly agreed that NPTs will play an important role in reducing the spread of HIV in Canada. Interestingly, the perceptions with regard to the urgency of addressing NPTs were mixed and seemed to depend on the informants' beliefs about how soon the technologies would be ready for "real-world" use and on their level of knowledge about NPTs.

Public health experience. Canadian public health is seen by key informants and consultation participants as a credible authority that has extensive experience, understands the demographics, and has the resources and infrastructure in place to deliver NPTs. Many of the systems that are in place for the introduction of other interventions and vaccines were seen as helpful for public health delivery of NPTs. Public health's role in the delivery of other sexual and reproductive health

[i] Please see Table 2 in Chapter 3 for further information on trial design and efficacy

technologies such as the Hepatitis B vaccine, HPV vaccine and condoms makes it uniquely qualified when considering the delivery of NPTs. The value of public health rests in its extensive experience in promoting other prevention and treatment technologies, and its knowledge of how other interventions have been received by communities from the perspectives of education, usability and marketing. Public health can leverage its substantial experience and infrastructure in delivering sexual and reproductive health and infectious disease prevention programs.

Knowledge, education and training. In order to prepare for the roll-out of NPTs, public health needs a clear understanding of existing information and policies, of their effectiveness, and of ongoing research around NPTs. The public health community has identified the need for further knowledge through education and training and for a knowledge transfer and exchange system among federal, provincial and regional levels of public health that will synthesize, translate and distribute information about ongoing HIV prevention clinical trials. Perceptions of the potential impact and importance of NPTs, and the sense of urgency to incorporate them into HIV prevention efforts were closely linked to NPT literacy levels. Making relevant research information available and accessible to stakeholders for use in practice, planning and policy-making is necessary to prompt public health action on NPTs.

Leadership, policy and guidance. Leadership is essential to spur action when discussing a sensitive public health issue like HIV. The public health community has indicated that there is a need to re-energize HIV prevention in Canada, specifically highlighting the importance of leadership around the implementation of NPTs. Increased public health leadership will strengthen government collaboration at the federal, provincial/territorial and regional levels and will ensure a clearer vision and a harmonized approach, and possibly achieve consensus. Public health stakeholders have called on the federal government to demonstrate leadership and commitment to comprehensive HIV prevention by strengthening existing policies and developing new policies relating to NPTs. Public health informants and consultation participants have highlighted the need for timely guidance around NPTs that will maximize their benefits as they are proven to be effective and become available, and minimize the harm that may be caused by improper or off-label use.

Resources, capacity and research. Addressing the procedures, policies, structures and practices of organizations is required to optimize and expand their response to HIV. Public health stakeholders identified the need for increased capacity to deliver both existing and new HIV prevention interventions in a timely and equitable manner. Integrating NPTs into existing HIV prevention, sexual health and clinical care programs will be challenging due to competing priorities and will be ineffective if existing delivery challenges are not addressed first. Public health stakeholders understand the importance of working collaboratively with community partners which are often better situated to reach key populations, and of identifying and taking advantage of opportunities for synergy in order to make efficient use of limited resources and capacity. These partnerships are especially helpful in extending public health's reach to marginalized populations. Understanding the specifics of each NPT is critical for planning how to approach their implementation. Preliminary decisions on the availability of NPTs should largely be based on

research, modeling and planning around the public health impact of specific NPTs, to identify scenarios, plans and recommendations for their use as well as monitoring and evaluation of their impacts.

In describing some of the opportunities and challenges public health currently is facing, we begin to appreciate some of the issues that will be encountered in delivering NPTs in a timely and equitable manner as they are proven to work, are approved and become available. While Canada's response to HIV has realized great successes in reducing the spread of HIV, public health's unpreparedness to capitalize on the success of recent research is concerning. This report is designed to provide guidance for public health and civil society organizations working in HIV prevention to develop policies, resources and programs that address issues of equity and accessibility of new HIV prevention technologies by identifying clear roles that public health should be assuming in a number of areas of action to prepare for NPTs in Canada.

Areas for Public Health Action

1. Building Awareness: Public Health Knowledge, Information and Education around NPTs

1.1 Develop Appropriate Education and Training Opportunities

i. Develop and deliver an ongoing education and training strategy for public health workers to raise their awareness of the state of NPT science and its implications for Canadian HIV prevention efforts in order to reinforce existing prevention approaches, and to promote combination prevention. This strategy includes:

   - Developing and delivering training opportunities for the public health workforce, offered as professional development through workshops, in-person or online e-learning courses, webinars and making use of existing conferences and training opportunities.
   - Provide public health with ongoing opportunities in their everyday practice to interact with new HIV prevention education materials through information and resource access such as listservs, mailing lists and newsletters.

1.2 Ensure the Application of Information and Evidence

ii. Public health should actively support the development of a knowledge exchange working group for federal, provincial and regional levels of public health. Possible distribution mechanisms include the Canadian Microbicides Action Plan (CMAP) Implementation Committee, or the MAG-Net listserv. This working group would include public health representation and would:

   - Regularly review, translate and distribute relevant trial information, and stimulate dialogue, to improve knowledge exchange around NPTs.
   - Develop knowledge synthesis tools for partners and clients that identify best practices and lessons learned in the roll-out of sexual and reproductive health technologies, identifying sub-topics such as delivery preparedness, messaging, communicating efficacy, and counseling to avoid risk compensation.

2. Creating an Enabling Environment: Public Health Leadership, Policies and Guidance Regarding NPTs

2.1 Provide Leadership for a Harmonized Approach

i. In response to calls from stakeholders for a strengthened national response, and consistent with its mandate, public health at the national level should provide timely leadership around NPT delivery. This includes:
   - Establishing priorities
   - Developing policy and guidance
   - Provincial/Territorial coordination
   - Allocating resources
   - Scenario planning
   - Engaging stakeholders

ii. The F/P/T-AIDS Committee should engage in discussions to understand jurisdictional roles and responsibilities with respect to NPTs, and to support uniform guidance and coordination between jurisdictions.

2.2 Support Necessary Policy Development

iii. The federal government should adjust, update and develop key documents and commitments to more explicitly refer to and integrate NPTs as part of a comprehensive HIV prevention approach (e.g., the Federal Initiative, Leading Together).

iv. Public health stakeholders and other partners should ensure public policy/decision-makers are well informed about HIV and NPTs to facilitate timely development of supportive policy and funding decisions.

2.3 Provide Timely Evidence-Based Guidance

v. Develop and disseminate evidence-based and timely public health guidance for NPT implementation, including interim guidelines in advance of regulatory approval. This guidance should be initiated at federal levels, and subsequently adapted to provincial and regional levels.

vi. Full guidelines should be immediately developed for non-occupational post-exposure prophylaxis and the use of treatment-as-prevention and interim guidelines should be developed for pre-exposure prophylaxis to build inter-jurisdictional consistency in NPT awareness and access.

3. Preparing for Delivery: Public Health Resource Capacity and Planning around NPTs

3.1 Build Organizational and Resource Capacity

i. In anticipation of NPT availability, the public health sector should make a case for dedicated funding, additional infrastructure and human resources to avoid overstretching the existing public health system as NPTs are integrated into comprehensive HIV prevention programs.

ii. Public health should optimize existing public health programs to ensure appropriate resource distribution, and:

- Extend service delivery points (e.g., pharmacies, harm reduction programs, HIV/STI testing clinics, etc.) to key populations at high risk to ensure NPT access.
- Further address stigma, discrimination and issues of criminalization that may impede NPT access.

3.2 Expand and Develop Strategic Collaboration and Partnerships

iii. Public health stakeholders should strengthen existing programs through the development of partnerships with other organizations (community-based organizations, AIDS service organizations, primary care providers, HIV specialists) and with vulnerable communities to extend the breadth and cultural appropriateness of existing HIV prevention interventions and address delivery barriers in a coordinated and comprehensive manner.

iv. Commit to, and build on, formal mechanisms for collaboration and consensus between levels of government to implement NPTs consistently across jurisdictions.

3.3 Support Modeling, Planning and Implementation Research

v. Public health at the national level should support social science research and the development of a multi-sectoral steering committee that will monitor promising HIV technologies and develop modeling, scenarios, plans and recommendations regarding the introduction and delivery of NPTs.

- Develop modeling around a monitoring and evaluation system for prevention programming to measure the impact of existing interventions and to prepare for measuring and comparing the impacts of NPTs.
- Examine how to integrate NPTs into a comprehensive prevention approach and develop HIV prevention messaging to optimize uptake, access and adherence but minimize safety concerns and risk compensation of both existing interventions as well as NPTs.

vi. Engage multiple public health jurisdictions with other partners (researchers, community-based service providers, clinicians) in scenario planning and demonstration projects to develop knowledge about the delivery of NPTs for specific populations, to provide cost-benefit analyses, to gauge their possible impact, and to optimize delivery methods to specific communities.

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LIST OF ACRONYMS

AIDS	Acquired Immune Deficiency Syndrome
ARV	Anti-Retroviral Treatment
ASO	AIDS Service Organization
CAHR	Canadian Association for HIV Research
CBO	Community Based Organization
CHVI	Canadian HIV Vaccine Initiative
CIHR	Canadian Institutes of Health Research
CPHA	Canadian Public Health Association
HIV	Human Immunodeficiency Virus
HPV	Human Papilloma Virus
HSV-2	Herpes Simplex Virus 2
IDU	Injecting Drug User
KAP	Knowledge, Attitude and Practice
MSM	Men Who Have Sex With Men
NACI	National Advisory Committee on Immunization
NGO	Non Governmental Organization
NPT	New HIV Prevention Technology
PLWHA	People Living With HIV and AIDS
PHAC	Public Health Agency of Canada
RCT	Randomized Control led Trials
PEP	Post Exposure Prophylaxis
nPEP	Non-Occupational Post Exposure Prophylaxis
PMTCT	Prevention of Mother to Child Transmission
PrEP	Pre Exposure Prophylaxis
STI	Sexually Transmitted Infections
UNAIDS	United Nations Joint Programme on HIV/AIDS
UNGASS	United Nations General Assembly Special Session on HIV/AIDS
VCCT	Voluntary Confidential Counseling and Testing
WHO	World Health Organization

CHAPTER 1: INTRODUCTION & BACKGROUND

HIV and AIDS represent one of the greatest public health threats in the last few centuries. Worldwide almost 60 million have been infected with HIV and 25 million people have been killed by this deadly disease. Globally in 2010, there were an estimated 33.3 million people living with HIV; in Canada, the number of people living with HIV continues to rise, with an estimated total of 54,000 to 76,000 cases.[2] "Scientists and public health experts believe that only through a combination of prevention, treatment and care plus broad global access to a preventative vaccine can the epidemic be ended".[3] In the absence of a cure for HIV infection, the development of vaccines and other new prevention technologies (NPTs) to prevent HIV infection offers the greatest promise for slowing the epidemic.

Trials for vaccines have been taking place since 1987; a growing number of potential vaccine candidates have progressed through clinical trial phases. Since 1999, the results of 21 randomized placebo-controlled trials (RCTs) of HIV vaccines and new HIV prevention technologies have been released. In the past year (2010-2011), vaccines and other prevention technologies have begun to show great promise. Several large efficacy trials recently demonstrated proof-of-concept or established efficacy for vaccines, oral pre-exposure prophylaxis, microbicides, and treatment-as-prevention.[ii] A very real change is taking place in "public perception and the opinion of policy makers. The discourse on HIV prevention now includes the possibility that the epidemic can be stopped".[4] These technologies have the potential to considerably reduce the impact of HIV in Canada and around the world.

However, the Global HIV Prevention Working Group in their 2006 report noted that "the world is unprepared to capitalize on the potential success of prevention research currently underway. Very little has been done to mobilize resources and develop the public health guidance, provider training and public health education needed to ensure rapid implementation of new prevention methods".[5] Increasingly scarce resources and an overburdened health system are challenges being faced by public health in the response to HIV. In order to avoid preventable infections caused by the delay and unforeseen challenges of NPT implementation, anticipatory preparations must be made to ensure timely and equitable delivery. Priorities are quickly shifting from scientific research to issues of implementation. The success of NPTs will be measured by how well they are introduced, communicated and adopted. Public health has been a central mechanism in the delivery of other sexual and reproductive health technologies and will play a crucial role in the effective and efficient delivery of NPTs[6]. The public health workforce needs not only to build its own preparedness, knowledge and capacity, but to more meaningfully engage in NPT research, policy and planning.

History has taught us that there are important public health reasons to begin planning strategies now to ensure future access to NPTs as part of a larger comprehensive prevention package. Lessons learned from previous vaccination programs are particularly valuable when examining the challenges encountered and

[ii] Please see Table 2 in Chapter 3 for further information on trial design and efficacy

best practices used to ensure timely and equitable introduction and delivery. This report will discuss this further in Chapter 4. Success will require a greater understanding of existing HIV prevention delivery, and comprehensive public health preparations for new approaches.

This report seeks to develop a better understanding of public health's current knowledge, information needs, roles, opportunities, challenges, and capacity to introduce and deliver NPTs in Canada. The report presents the findings resulting from various data collection methods including consultations, a literature search/review, key informant interviews and a nationwide online survey of public health stakeholders. It is designed to provide a further understanding for public health and civil society organizations working in HIV prevention to develop policies, guidance, resources and programs that address issues of equity and accessibility of new HIV prevention technologies.

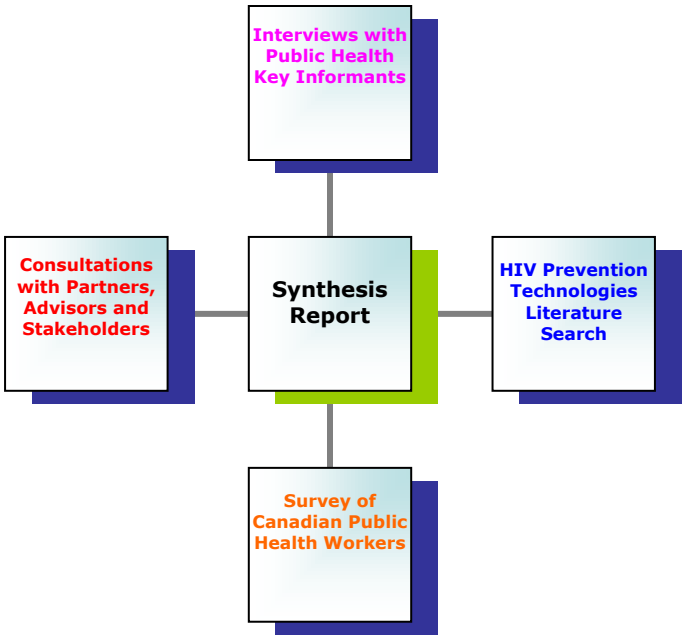
The report is structured as follows:

- Chapter 2 provides an overview of the *New HIV Prevention Technologies* project and sub-components.
- Chapter 3 provides an overview of current HIV prevention and the potential role of NPTs and looks at recent HIV NPT development.
- Chapter 4 provides an overview of public health's work in HIV prevention, and the context for public health action on NPTs.
- Chapter 5 synthesizes the data collected and provides an overview of the findings.
- Chapter 6 provides an analysis of the data and areas for action on the delivery of NPTs.
- Chapter 7 provides the report's conclusions.

CHAPTER 2: METHODOLOGY

This Chapter provides a brief overview of the data collection methods used to inform this document.

Since July 2010, a number of activities have been undertaken to inform this document, including several consultations, a literature search/review, key informant interviews and a nationwide online survey. The methods used focused on gaining a better understanding of the knowledge, experiences and practices of public health and civil society organizations in HIV prevention as well as attitudes towards and capacity to deliver new HIV prevention technologies in Canada.



2.1 Literature Search/Review of New HIV Prevention Technologies

An initial unstructured review of scientific literature and published reports was conducted in 2010 to scope out relevant issues and topics for public health and civil society organizations in the context of HIV prevention and new HIV prevention technologies. The searches were focused on Canadian literature and resources, but also included key international resources. Various general 'explorative' searches were conducted from the fall of 2010 through early spring 2011 in order to better understand the public health landscape on the issues of HIV vaccine, HIV treatment and prevention best practices, new HIV prevention technologies, and other related technologies. In addition, through working with experts and knowledgeable stakeholders, numerous key reports and policy documents were identified for inclusion. In addition, several specific 'targeted' searches were conducted. These targeted searches sought to find the HIV-related literature on 'lessons learned', and literature by particular authors identified as key.

2.2 Online Survey of Public Health Workers

Based on the evidence collected from the literature reviews, CPHA conducted a survey called "New HIV Prevention Technologies and the Potential Role of Public Health" between April and June 2011 in order to measure the Knowledge, Attitude and Practices (KAP) of public health workers from across Canada. The survey was distributed electronically though mailing lists, membership lists, and electronic

digests, and targeted those with experience working in HIV prevention. The survey resulted in 473 responses and provided a better understanding of the knowledge, information needs, capacity, challenges and potential role of public health workers and civil society in delivering both existing and new HIV prevention technologies. The data were separated into three categories:1) *Public Health Unit respondents* includes the responses of only those who specified "Public Health Unit (Health Authority)" as the organization they work for; 2) *Other respondents* includes the responses of workers who specified another type of organization (AIDS service organization, community-based organization, community health centre, infectious disease clinic, ministry of health (provincial), other non-governmental organization, professional associations); 3) *All respondents* includes *Public Health Unit respondents* and *Other respondents* together. The survey provides an understanding of policy, programs, education, information and practice related to public health and civil society preparedness for NPTs in Canada.

Appendix 1: New HIV Prevention Technologies and the Potential Role of Public Health Survey Questions (Survey responses are available from CPHA)

2.3 Consultations with Partners and Stakeholders

2.3.1 Webinars

A series of open webinar sessions on new HIV prevention technologies involving participants from public health units, civil society groups, government, research and consultancy groups took place in December 2010 and between July and August 2011. The webinar sessions were held in partnership with the Canadian AIDS Society, Interagency Coalition on AIDS and Development, CATIE and CPHA, they provided overviews of the concept of NPTs and focused on the broader implications of NPTs in the Canadian context, in light of recently released trial results. The webinar sessions allowed barriers and enablers to be identified concerning the implementation of NPTs.

Appendix 2: List of Summer Webinar Series Session Topics

2.3.2 Canadian Conference on HIV/AIDS Research

In April 2011 at the Canadian Conference on HIV/AIDS Research (hosted by the Canadian Association for HIV Research), the Canadian AIDS Society, Interagency Coalition on AIDS and Development, CATIE and CPHA convened an ancillary event entitled "Emerging New HIV Prevention Technologies: Community and Public Health Preparedness in Canada". In light of recent encouraging NPT trial results, the event aimed to foster dialogue among researchers, community and public health workers, healthcare providers/physicians, community members and government stakeholders. Participants discussed how to effectively implement an HIV vaccine and other NPTs in Canada, looking at mandates, resources, timelines, information and capacity building for health and social support professionals.

Appendix 3: CAHR Ancillary Event Overview (Full report available from CPHA)

2.3.3 CPHA Pre-Conference Session

A second consultation was held at CPHA's annual conference in June 2011. Entitled "Preparing the Canadian Public Health Community for New HIV Prevention Technologies", delegates' perspectives on public health's role and capacity to deliver an HIV vaccine and other NPTs. Focusing on public health perspectives, this consultation was informed by the literature review and April 2011 CAHR ancillary event consultation and centered on discussions related to the preliminary results from the survey. The session drew on the experiences of the public health community on the topic of delivery of HIV vaccines and other new prevention technologies projects, examining strengths, enablers, resources, limitations, needs and constraints of public health with regard to NPT implementation.

Appendix 4: CPHA Pre-Conference Session Overview (Full report available from CPHA)

2.4 Key Informant Interviews of Public Health and HIV Experts

Using preliminary findings from the survey and consultation data, a series of key informant interviews were conducted during July and August 2011 to better understand the role and capacity of public health in HIV prevention, and in the implementation of NPTs. The five key informants included individuals with experience and expertise in HIV prevention from Public Health Units, and representatives from a provincial Ministry of Health and a provincial government health agency. Interviews were semi-structured, conducted by phone and guided by the research question: What should public health practitioners be doing regarding the introduction of an HIV vaccine and other new prevention technologies, and what needs to be done to enable them to do so? The interviews focused on the role and capacity of public health regarding the implementation of a putative NPT, and in particular what public health experts see as their role, enablers and barriers, and as required guidance.

Appendix 5: Key Informant Interview Guide (Full report available from CPHA)

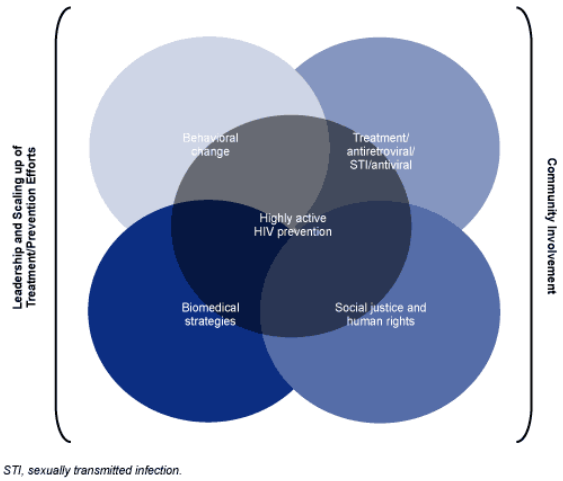
CHAPTER 3: HIV PREVENTION AND NEW HIV PREVENTION TECHNOLOGIES

This chapter provides an overview of current HIV prevention, the role of new technologies and the "state of the science" looking at recent NPT research efforts.

HIV in Canada remains a serious public health challenge. Canada's HIV prevention efforts have achieved some encouraging results: harm reduction programs, and the virtual elimination of maternal-child transmission and of the spread of HIV through the blood collection system. However, there continues to be challenges with regards to the changing nature of the epidemic and the ability to reach vulnerable and marginalized populations. The national annual incidence rate has remained largely unchanged for the past decade, with an estimated range of between 2,300-4,300 new infections every year.[2] From one perspective, this can be seen as a success: the rate of new infections has stabilized. From another, these numbers emphasize the limitations of our current prevention efforts-while the number of new infections has stabilized, it is not decreasing.

3.1 Comprehensive HIV Prevention

Comprehensive HIV prevention is an evidence-based approach to HIV prevention that includes a focus on structural issues, efforts to ensure access to proven interventions, and the development of new or tailored prevention options that can meet a variety of user needs and preferences. Advocates, public health workers, policy-makers and researchers promote a comprehensive approach that combines a range of prevention options, particularly for vulnerable populations and those populations most at risk, as a way to improve HIV prevention efforts both in Canada and globally. Advances in biomedical HIV prevention, "provide substantial opportunities to re-invigorate behavioural approaches to HIV prevention and challenge us to advance structural approaches".[7] NPTs have the potential to be effective HIV prevention tools but will need to be used in combination with existing proven HIV interventions and strategies. This comprehensive HIV prevention approach is understood to include several components.



Lancet, Thomas J Coates, August 6, 2008

First, interventions that have been proven to reduce the risk of HIV are made readily available to populations most at risk. These behavioural and biomedical interventions include HIV education, risk reduction counselling, provision of male and female condoms, needle exchange programs, post-exposure prophylaxis, prevention of mother-to-child transmission, and promotion of and access to HIV testing. Testing and treatment of sexually

transmitted infections is often included as part of this prevention package,[iii] and in high-prevalence settings, medical male circumcision can reduce HIV-negative men's risk of acquiring HIV through unprotected vaginal intercourse. Recent studies have added treatment-as-prevention and pre-exposure prophylaxis (PrEP) to this list of effective HIV prevention strategies.[8,9,10, 11,12] Unfortunately, even some of the most long-standing and non-biomedical prevention strategies do not reach all of the most vulnerable populations due to personal, social and structural barriers.

Second, an expanded range of HIV prevention options are used to meet a variety of needs. Some of the most effective tools currently at our disposal have some important limitations for many people most at risk of HIV. For example, male and female condoms prevent conception, but they also represent a barrier to trust and intimacy for many people, particularly those in long-term relationships, and they require the active consent and cooperation of the insertive partner. Developing HIV prevention tools that would allow conception while still reducing the risk of HIV infection, and that would be within the control of the receptive partner, would provide critical new options that are largely missing from current interventions. The experience of contraception shows us that the more options you provide to people, the more sex acts are protected since people are more likely to find an option that best suits their environment, needs and preferences.[13]

Third, addressing structural factors that exacerbate HIV risk for certain populations is paramount. This includes a range of interventions that address: social determinants of health (e.g., housing, socio-economic status, sexism, racism, homophobia); human rights, stigma and discrimination; and, systemic conditions such as the criminal justice system and healthcare infrastructure.

3.2 HIV Prevention Research

3.2.1 Preventive HIV vaccines

The search for a preventive HIV vaccine began as soon as HIV was discovered to be the cause of AIDS, and global HIV vaccine research efforts still receive the lion's share of HIV prevention research funding.[iv] As of September 2011, there are over 30 clinical trials of experimental HIV vaccines currently underway in nearly 25 countries, involving thousands of participants.

In 2003, the results of the world's first two large-scale preventive vaccine efficacy trials were released. AIDSVAX was tested among men who have sex with men in the U.S., Canada and the Netherlands in one trial, and among injection drug users

[iii] STI testing and treatment is generally considered a staple of effective HIV prevention programs. There are immunologic responses common to many STIs that are thought to facilitate both the transmission and acquisition of HIV. However, despite one randomized placebo-controlled trial (RCT) in the early 1990s demonstrating the effectiveness of STI management as an HIV risk-reduction strategy, 8 subsequent RCTs have failed to replicate these findings. (Padian N, et al. "Weighing the gold in the gold standard: challenges in HIV prevention research", *AIDS*. 2010, 24:621–635)

[iv] In *Capitalizing on Scientific Progress: Investment in HIV Prevention R&D in 2010,* the HIV Vaccines & Microbicides Resource Tracking Working Group reports that HIV preventive vaccine R&D funding in 2010 was US$859 million. Microbicides R&D was US$247 million; pre-exposure prophylaxis = US$58.3 million; Adult male circumcision = US$21.7 million; treatment-as-prevention = US$19.6 million.

in Thailand in another. Both trials had flat results, meaning that there was no sign of reduced risk of HIV but the products were not harmful to the trial participants.

In 2007, two trials testing an adeno-virus-based vaccine by Merck were halted when preliminary results showed an increased susceptibility to acquiring HIV among some trial participants who received the product compared to those who received the placebo. There were trial sites in various parts of the world, including in Canada.

In 2009, the results of a trial conducted in Thailand were released. A prime-boost combination of AIDSVAX and another vaccine candidate called ALVAC were tested among over 16,000 men and women, and reduced their risk of acquiring HIV by about 31%.

These latest trial results and the recent discovery of several broadly neutralizing antibodies-generally considered a prerequisite to preventing an infection-have led to renewed optimism for HIV vaccine research.[14]

3.2.2 Other new HIV prevention technologies

Since the 1990s, HIV prevention research efforts have expanded beyond preventive vaccines. First, vaginal microbicides research began to receive attention. By the early-to-mid-2000s, global HIV prevention research also included PrEP, treatment-as-prevention, rectal microbicides, diaphragms and treatment of herpes simplex virus 2 (HSV-2).

What are "new" HIV prevention technologies?

The term *new prevention technologies* (NPTs) can be ambiguous.

First, the word *technologies* is sometimes replaced with *interventions*, *tools, approaches* or *options*. Second, alternate phrases are sometimes used, such as *biomedical interventions*. Third, the exact meaning of *new* is not always clearly explained.

One of the reasons for this is that the list of technologies included as NPTs evolves over time. For example, up until 2007-2008, there were efficacy trials testing whether treatment of HSV-2 could reduce the risk of HIV infection, and whether a diaphragm could reduce the risk of acquiring HIV among women. Today, these interventions are no longer included in the list of potential NPTs since the trials demonstrated no prevention benefit.

The term *new prevention technologies* generally refers to HIV prevention options that are still in clinical trials. Their efficacy might not yet be established, or some trials may have recently demonstrated proof-of-concept, but efficacy still needs to be confirmed through further study.

Therefore in late 2011, NPTs typically refer to preventive vaccines, vaginal and rectal microbicides, pre-exposure prophylaxis and treatment-as-prevention. Occasionally, medical male circumcision is still included in discussions of NPTs, since its HIV prevention efficacy was only proven in trials in 2007.

Since 1999, the results of 21 randomized placebo-controlled trials (RCTs) of new HIV prevention technologies (NPTs) have been released. All of these are late-stage trials: either phase IIB proof-of-concept trials or phase III efficacy trials. Until very recently (2010-2011), most of these trials yielded either flat results (safe product, no reduction in HIV risk, no indication of increased risk) or negative results (trend towards increased risk of HIV using the product). Table 1 provides an abbreviated overview of the general results from these 21 trials. In some cases, trials testing similar intervention types yielded different results. For example, a total of nine trials testing vaccines, pre-exposure prophylaxis or vaginal microbicides failed to demonstrate a reduction in HIV risk, while five other trials testing those interventions (usually testing different candidate products) did demonstrate such a reduction.

Table 1. Categories of results for late-stage trials testing new HIV prevention technologies.

	Signs of efficacy/effectiveness[v]	No efficacy/effectiveness
Safe	Medical male circumcision (3 trials) Pre-exposure prophylaxis (3 trials) Treatment-as-prevention (1 trial) Vaccine (1 trial) Vaginal microbicide (1 trial)	Diaphragm (1 trial) HSV-2 treatment (2 trials) Pre-exposure prophylaxis (1 trial) Vaccine (1 trial) Vaginal microbicides (3 trials)
Trend towards harm	N/A	Vaccine (1 trial) Vaginal microbicides (3 trials)

In the past year (2010-2011), NPTs have begun to show great promise. Several large efficacy trials recently demonstrated proof-of-concept[vi] or established efficacy[6] for oral pre-exposure prophylaxis, microbicides, vaccines and treatment-as-prevention. In fact, five of the nine positive trial results shown in Table 1 (vaginal microbicides, PrEP (3), treatment-as-prevention) were released in the last year (2010-2011). Table 2 provides more detailed information of the nine trials that have demonstrated a reduction in HIV risk.

Table 2. Late-stage NPT trials demonstrating proof-of-concept or efficacy/effectiveness.

NPT/intervention	Efficacy/effectiveness	Trial population	Trial countries
Medical male circumcision	60%	3,274 men	South Africa
Medical male circumcision	48%	5,000 men	Uganda
Medical male circumcision	53%	2,784 men	Kenya
Pre-exposure prophylaxis (Truvada pill) *[iPrEx]*	43.8% overall 73% among consistent users	2,499 gay men and other men who have sex with men (MSM); transgender women	Brazil, Ecuador, India, Peru, South Africa, Thailand, U.S.
Pre-exposure prophylaxis (Truvada pill) *[TDF2 or CDC 4940]*	63% overall 78% among consistent users	1,219 heterosexual men and women	Botswana
Pre-exposure	62% overall for	4,758 serodiscordant	Kenya, Uganda

[v] *Efficacy* refers to how well a product works under ideal conditions. *Effectiveness* refers to how well a product works in practice. For example, when used consistently and correctly condom efficacy is 80-95%. Condom effectiveness is 69% because some people don't always use them correctly or consistently.

[vi] Proof that a certain method or approach with regard to HIV prevention can reduce risk. Proof-of-concept trials do not always have the statistical power to determine the level of efficacy; only to determine whether or not a new intervention can in reality reduce HIV risk.

prophylaxis (Truvada or tenofovir pill) *[Partners PrEP]*	tenofovir 73% overall for Truvada	couples, where one partner is HIV+ and the other is HIV- (heterosexual men and women)	
Treatment-as-prevention (Combination of antiretrovirals) *[HPTN 052]*	96%	1,763 serodiscordant couples, where one partner is HIV+ and the other is HIV- (97% of couples were male-female)	Botswana, Brazil, India, Kenya, Malawi, South Africa, Thailand, U.S., Zimbabwe
Vaccine regimen (AIDSVAX and ALVAC) *[RV 144]*	31.2%	16,000 men and women	Thailand
Vaginal microbicide (Tenofovir gel) *[CAPRISA 004]*	39%[vii] overall 54% among consistent users	889 women	South Africa

As of September 2011, a few late-stage NPT trials are still underway around the world. By 2013, these trials will provide information on the effectiveness of PrEP among injection drug users, and will provide further information on the effectiveness of PrEP and vaginal microbicides among women. There are also a few studies exploring the potential prevention benefits of treatment-as-prevention at a population level, including one trial in BC called *Seek and Treat to Optimize Prevention of HIV/AIDS* (STOP HIV/AIDS).

Table 3. Late-stage NPT clinical trials which have yet to release results.

NPT/intervention ***[Common trial name]***	**Trial population**	**Trial countries**	**Date of expected results**
Pre-exposure prophylaxis (Tenofovir pill) *[CDC 4370]* Phase II/III	2,400 injection drug users	Thailand	2012
Pre-exposure prophylaxis (Tenofovir or Truvada pill) Vaginal microbicide (Tenofovir gel) *[VOICE]* Phase IIB	5,000 women	Malawi, South Africa, Uganda, Zimbabwe	2012
Vaccine (DNA prime – Ad5 boost) *[HVTN 505]* Phase II	1,350 men who have sex with men	U.S.	2012

[vii] The product tested in this trial also reduced the risk of acquiring genital herpes by 51%.

3.3 Implications of research results for Canada

The recent successes of large scale-trials in 2010-2011 have increasingly pushed the HIV prevention community to look beyond the scientific research and begin to examine issues of implementation, guidance, access and delivery. These recent trials create an urgency to deal with NPT implementation issues in the Canadian context. While we now have proof-of-concept for vaginal microbicides and vaccines, these products are not currently available anywhere outside of clinical trials. However, other NPTs are currently available to Canadians and the level of awareness and access varies greatly. Antiretroviral treatment (ARV) is widely available to persons living with HIV, but the prevention benefits and use of effective antiretroviral treatment for pre-exposure prophylaxis is not yet well integrated into HIV prevention policy, programming and messaging. On the other hand, PrEP is not very widely available. There are reports that off-label[viii] prescriptions for Truvada are being provided for those who are aware of the prevention potential of PrEP.[15]

Past experiences with the delivery of other sexual and reproductive health technologies identify and highlight the important role public health has played in implementing new biomedical technologies, which we explore further in Chapter 4. The introduction and delivery of NPTs in a safe and equitable manner is paramount in order to create meaningful impact. The public health benefits of NPTs could be significant in reducing HIV incidence within key populations at high risk, but this will only be possible if the Canadian public health community begins to prepare itself for this impending role. Sufficient research into the possible benefits of NPTs for specific populations is needed to ensure appropriate planning and implementation as part of a comprehensive HIV prevention strategy.

[viii] Off-label use is the practice of prescribing pharmaceuticals for an unapproved indication or in an unapproved age group, unapproved dose or unapproved form of administration. Truvada is approved by Health Canada to treat HIV infection. Prescribing it for HIV prevention is using it "off-label".

CHAPTER 4: CONTEXT FOR PUBLIC HEALTH ACTION ON NEW HIV PREVENTION TECHNOLOGIES

This section provides a brief overview of the public health system with regard to HIV prevention, including public health functions, core programs, policies and principles.

Understanding public health and the health care system, functions, core programs and principles with regard to the current response to HIV is necessary to appreciate the capacity and roles that public health will need to fulfill to ensure the timely and equitable delivery of NPTs in Canada.

4.1 Public Health and HIV Prevention

The structure of public health in Canada varies across jurisdictions[16] but the core mission of public health is consistent – to protect and promote the health of all people and prevent disease and injury. The essential functions of public health in Canada have been divided into 6 areas by the Federal/Provincial/Territorial Public Health Working Group of the Advisory Committee on Population Health,[17] namely:

1. Population Health Assessment
2. Health Surveillance
3. Health Promotion
4. Disease and Injury Prevention
5. Health Protection
6. Public Health Emergency Preparedness and Response

The public health response to HIV in Canada is shared across federal, provincial/territorial, and local/regional governments. Most jurisdictions "have articulated a comprehensive, sound and well-considered strategy that provides direction to stakeholders".[18] Provincial and territorial governments are responsible for the delivery of public health and health care programs/services, while the federal government retains lead responsibility for ensuring health services availability for specific populations, including First Nations and Inuit, armed forces, and federal prisoners. Because of this structure and shared responsibility for public health, coordination is required across each level to achieve a comprehensive approach to HIV prevention and treatment.[19]

Public health jurisdictions across Canada have a strong base for addressing HIV. While not considered part of the formal health care system, non-governmental and community organizations have played a key role in mounting a strong and sustained response to HIV since its emergence. Because of their important public health role in HIV prevention, access to treatment, care and support, they are included in this document's description of public health structure, responsibilities and funding.

4.1.1 Public Health Structure, Responsibilities, Activities and Funding

At the federal level in Canada, Health Canada and the Public Health Agency of Canada have a range of public health responsibilities for the protection and promotion of all Canadians' health, including with regard to HIV.[20] PHAC has lead responsibility for HIV prevention overall. PHAC's Centre for Communicable Diseases and Infection Control works with other federal departments and agencies on activities related to the Federal Initiative to Address HIV/AIDS in Canada.[21] Its mandate includes monitoring and evaluation of the Federal initiative, as well as HIV/AIDS communications, national-level program and policy development, and providing advice and assistance internationally.[22]

Health Canada has jurisdiction over providing health services to First Nations on-reserve communities across Canada and Inuit communities in the north. Health Canada funds public health programs and services through a distinct health system administered through its First Nations and Inuit Health Branch, which transfers lead responsibility for the formal public health system in First Nations and Inuit communities to the communities' governments. The *First Nations and Inuit Health Program Compendium* is maintained by Health Canada and specifically highlights the details and objectives of the First Nations and Inuit HIV/AIDS program.[23]

Provincial and Territorial governments have primary responsibility for the provision of health care and public health services and programs. Each province and territory has its own public health act, and the majority have adopted or developed strategies to address HIV. Several provinces/territories have taken an integrated approach to HIV within broader sexually transmitted infection initiatives (Quebec, Alberta and Northwest Territories), while others have developed HIV-specific initiatives (British Columbia, Manitoba, Saskatchewan, Ontario, Nova Scotia, Newfoundland and Labrador, Nunavut and the Yukon).[19]

Provincial/territorial public health structures vary across jurisdictions, though the Provinces/Territories are generally divided up into a number of smaller regions and/or service delivery areas. For example, in Ontario health services are planned, funded and managed through a number of Local Health Integration Networks (LHINs) that have jurisdiction over many public health units. In Alberta, health services management and delivery was recently reorganized into five 'zones'. Québec is unique in that health has been integrated with social services and is organized, managed and delivered by 18 local/regional agencies.

A few provinces have documents explicitly describing core public health programs and HIV prevention, varying in their linkage to legislation (BC, SK, ON, QC). While these documents promote provincial uniformity, they simultaneously recognize the need to tailor approaches to community contexts - a recognition made explicit in several provinces' documents, including Ontario's Public Health Standards,[24] British Columbia's Core Public Health Functions and Québec's Public Health Program 2003-2012.[25]

At the local/regional level, public health programs and services are delivered through over 140 public health units and regional health authorities across Canada.

In terms of HIV, local/regional public health plays key roles in surveillance and monitoring; case management; community collaboration, support, education and awareness-raising (Key Informant Report).

Non-governmental and community organizations have played a key role in mounting a strong and sustained response to HIV since its emergence, frequently at the local/regional level alongside public health units and regional health authorities. Non-governmental and community organizations doing work to promote public health and HIV treatment, prevention and care are occasionally supported through resources from each level of government, and they often work closely with government and the formal public health system by participating in planning committees, policy and program development, and the front-line delivery of programs.[19]

Non-governmental and community organizations receive funding from four national funds through the *Federal Initiative to Address HIV/AIDS in Canada*, as well as a number of other funding programs. The AIDS Community Action Programme (ACAP) is a regionally managed fund under the *Federal Initiative*, which often funds non-governmental and community organizations and supports community-based organizations in provinces and territories, and larger regions. Federal funding objectives include supporting increased community capacity, responsiveness, and engagement of HIV-affected people, as well as policy and program development and the establishment of strategic collaborative partnerships.[19]

4.1.2 HIV and the Social Determinants of Health

Public health action on the social determinants of health (SDOH) is important in addressing the vulnerabilities and risks associated with HIV transmission.[26] The social determinants include the following factors that could potentially influence HIV risk.

1. Income and Social Status
2. Social Support Networks
3. Education and Literacy
4. Employment/Working Conditions
5. Social Environments
6. Physical Environments
7. Personal Health Practices and Coping Skills
8. Healthy Child Development
9. Biology and Genetic Endowment
10. Health Services
11. Gender
12. Culture

Public health at the highest levels in Canada have taken steps to address social determinants and HIV-related inequalities through a number of initiatives, including partnerships across government agencies and programs that directly attempt to reduce HIV vulnerability (e.g., initiatives addressing vulnerability in Aboriginal persons).[19] In 2009, under the Government of Canada Assistant Deputy Minister

Committee on HIV/AIDS, the first Interdepartmental Policy Forum on the Determinants of Health and HIV/AIDS was held.[27]

Public health can play a role in mitigating inequalities in health and HIV/AIDS through the following:

- documenting inequalities, reporting on them so as to draw public attention to them, and analyzing the factors that contribute to these inequalities;
- working with communities to change the conditions that contribute to inequalities in health in their community;
- advocating for healthier public policies and changes in social, economic, cultural, and environmental conditions that will reduce inequalities in health;
- directing programs to high-risk/disadvantaged groups;
- improving access/removing barriers to public health programs;
- forging partnerships with other organizations to address multiple barriers and/or issues in a coordinated and comprehensive manner;
- using community development as a means to support self-advocacy and self-reliance; and,
- ensuring that the core programs provided by the health authorities reflect the priorities of the people at greatest need.[28]

4.2 Formal Expectations for Public Health Action on NPTs

The role of public health in the delivery of HIV prevention strategies in Canada is one that is continually evolving as the epidemic progresses, but is rooted in well-articulated policy. The promotion and implementation of NPTs is guided by key documents and commitments: the *Federal Initiative to Address HIV/AIDS in Canada*, *Leading Together: Canada Takes Action on HIV/AIDS (2005-2010);* the *Canadian HIV Vaccines Plan* and the *Canadian HIV Vaccines Initiative*; and the *Canadian Microbicides Action Plan.* These documents and commitments identify both the role and importance of public health (along with other stakeholder groups) in NPT development and delivery to ensure timely and equitable access as NPTs become available.

4.2.1 *The Federal Initiative to Address HIV/AIDS in Canada*

The Public Health Agency of Canada (PHAC) is responsible for the overall coordination of the *Federal Initiative to Address HIV/AIDS in Canada*. The *Federal Initiative* – a partnership between the Public Health Agency of Canada, Health Canada, the Canadian Institutes of Health Research, and Correctional Service Canada – has the goal of a Canada free from HIV and the underlying conditions that make Canadians vulnerable to the epidemic. Through the *Federal Initiative*, federal government departments, provincial and territorial governments, non-governmental organizations, researchers, health care professionals and people living with and vulnerable to HIV collaborate in five areas of federal action: program and policy interventions; knowledge development; communications and social marketing; coordination, planning, evaluation and reporting; and global engagement. The *Federal Initiative* makes reference to NPTs in terms of "development of policies, programs and interventions, such as new prevention technologies and therapies"

and also in terms of providing "technical support and policy guidance on global issues…such as microbicides and vaccines".[21]

4.2.2 *Leading Together*: *Canada Takes Action on HIV/AIDS (2005-2010)*

Leading Together: Canada Takes Action on HIV/AIDS (2005-2010) is a blueprint for Canada-wide action on HIV/AIDS. It calls for consolidated action on all fronts, including governments, community, researchers, individuals and others involved in Canada's response to HIV/AIDS. *Leading Together* was developed collaboratively by a wide spectrum of stakeholders involved in the Canadian response to HIV/AIDS and frames HIV first and foremost as a preventable disease. It emphasizes that communities most vulnerable to HIV need targeted programs and that access to new prevention tools, such as preventive vaccines and microbicides will significantly enhance their ability to protect themselves. This call for NPTs is framed in terms of a comprehensive prevention package. *Leading Together* conceptualizes NPTs as making an important contribution to HIV prevention from a gendered perspective and calls on all stakeholders to develop plans to support the development of NPTs (with particular reference to vaccines and microbicides) and to provide equitable access as they are developed.[29]

4.2.3 *The Canadian Microbicides Action Plan*

The *Canadian Microbicides Action Plan* (CMAP), developed in 2005 and updated in 2008, is a multi-stakeholder call for action that defines Canada's role in developing and distributing microbicides. The plan articulates the vision for Canada's contribution across various stakeholder groups, and all parts of the effort, including: "discovery, trials and testing, production, distribution, community engagement, and leadership".[30] CMAP provides direction for domestic and international efforts to develop, produce and distribute microbicides and to build knowledge across all sectors about microbicides; to develop the sustained public and government commitment required to support a microbicides program; and to guide the allocation of Canadian resources for microbicides, both domestically and internationally.

4.2.4 *The Canadian HIV Vaccines Plan*

The Canadian HIV Vaccines Plan was developed in 2006 as part of a collaborative process involving representatives from Health Canada, the Canadian International Development Agency, the Canadian Institutes of Health Research, the Federal/Provincial/Territorial Advisory Committee on AIDS, the Canadian HIV/AIDS Legal Network, the Canadian AIDS Society, the International AIDS Vaccine Initiative, the Canadian Network for Vaccines and Immunotherapeutics and the British Columbia Centre for Excellence in HIV/AIDS. The Canadian HIV Vaccines Plan articulates the vision for Canada's role in developing and distributing HIV vaccines, enhancing Canada's capacity to do so, developing the public and government commitment required to support HIV vaccines, and helping guide the allocation of resources for HIV vaccines. Among its list of strategies are the discovery, trials and testing, production, distribution, community engagement, political leadership and financial commitment to HIV vaccines. The Canadian HIV

Vaccines Plan led to the development of the Canadian HIV Vaccine Initiative (CHVI).[31]

4.2.5 *The Canadian HIV Vaccine Initiative*

In response to advocacy from Canadian community-based organizations and researchers, in July 2002, at the International AIDS Conference in Barcelona, Spain, Health Canada announced that Canada would develop an HIV vaccines plan. That commitment to HIV vaccines was reinforced in June 2004 when Canada joined the other leaders of the G8 industrialized countries in agreeing to fund a Global HIV Vaccine Enterprise – a consortium of government and private sector groups – to coordinate and accelerate HIV vaccine research.

Established in 2007, the CHVI is a collaborative initiative between the Public Health Agency of Canada, Industry Canada, Health Canada, the Canadian Institutes of Health Research, the Canadian International Development Agency, and the Bill & Melinda Gates Foundation. PHAC coordinates and oversees CHVI governance and management structures; facilitates collaboration with domestic and international stakeholders, serving as the focal point for its implementation; and provides secretariat support. The purpose of CHVI is to accelerate the development of an HIV vaccine and address critical research gaps identified by the Global HIV Vaccine Enterprise.[32]

4.3 Public Health Experience: Lessons Learned and Best Practices

Public health's role in the delivery of other sexual and reproductive health technologies such as the Hepatitis B vaccine, HPV vaccine and condoms makes it well-qualified when considering the delivery of NPTs. Public health's value, beyond its well-developed capacity and infrastructures, rests in its extensive experience in promoting and delivering prevention and treatment technologies, and its knowledge of how other interventions have been received by communities from the perspectives of education, usability and marketing. Public health can leverage its substantial experience in delivering sexual and reproductive health and infectious disease prevention programs. Authorities' experiences will be instrumental in developing key implementation policy decisions and guiding major implementation considerations.

While the benefits of NPTs could include reducing HIV incidence overall and within high-risk populations, there are risks and challenges that need to be carefully considered and planned for in relation to the introduction of any NPT. Listed below are just a few possible examples of some of the public health implementation challenges that could arise around NPTs:

- In most cases, vaccines and other prevention technologies are available first and distributed most successfully in places with the greatest resources, public health infrastructure and political will. However, to ensure the greatest impact, NPTs would need to be made available to those most at risk of HIV infection, and many of those populations pose the greatest challenges in terms of public health reach.

- In deciding who and how many people should receive NPTs, public health authorities will need to take into account the risk of exposure to the infectious disease, the risk of adverse reactions and the efficacy of the NPT.

- HIV vaccines and many NPTs have only been made available to several thousand people within the highly controlled setting of a clinical trial. Implementation in real-world settings requires careful monitoring for safety concerns by public health.

- Trials have demonstrated that efficacy is very closely related to adherence rates. Low adherence to an intervention could seriously compromise its effectiveness. In addition, for many NPTs that are based on antiretroviral drugs, adherence has a direct influence on the risk of drug resistance. Therefore adherence levels and the emergence of possible drug resistance must be planned for carefully by public health.

- Monitoring risk compensation will be necessary to ensure that the introduction of NPTs does not perversely increase HIV incidence. Some NPTs may have moderate levels of efficacy. If users increase their risk-taking behaviours (e.g., reduce condom use, increase the number of sexual partners), then the additional protection offered by the NPT could be lost. Public health will have to carefully plan communication messaging around NPTs.

- Though vaccines for diseases such as influenza, measles and tetanus are widely available through voluntary programs, a significant proportion of people who could benefit have not been immunized. In Canada, the ability to deliver NPTs effectively depends on the capacity to reach marginalized populations, to protect their human rights, to build their trust in the health system and to encourage their willingness to use the intervention.

HPV, Hepatitis B vaccines as well as female condoms are useful case studies in understanding the requirements and preparations that public health must consider to successfully introduce and deliver NPTs in a timely and equitable manner. The lessons learned and best practices from these previous roll-outs have helped identify several key areas of focus when preparing and planning for the introduction and delivery of new biomedical interventions. Below are a few of the more general lessons learned and best practices collected in the delivery of sexual and reproductive health technologies:

- Government must support public health policy that will facilitate the creation of programs supporting the timely and equitable delivery of an NPT.[33]

- Disseminate timely public health guidance; this is essential to ensuring that the characteristics of the NPT are understood and taken into account by both health providers and their patients.[34]

- Public health authorities must use their experience to develop communication messaging that will inform the general public, reinforce previous messaging, encourage comprehensive prevention and prevent risk compensation.[33]

- Education strategies for the general public; preventive programs for community-based programs in schools, community health centres and sexual health clinics; and public awareness campaigns must be developed and delivered.[35]

- Public health must ensure access for vulnerable populations; this will include establishing innovative programs and distribution networks, as well as using traditional health service delivery points, such as pharmacies, to reach them.[34]

- Ensure that there is sufficient capacity in place nationwide to develop needed programs and to deliver the NPT. Provide the necessary resources required in a timely manner to guarantee the successful roll-out of the intervention.[35]

- Strengthen and develop partnerships with other organizations, in particular those already working with populations at risk of HIV, to extend the breadth of the intervention and address delivery barriers in a coordinated and comprehensive manner.[36]

- Ensure monitoring, evaluation and surveillance systems are in place to evaluate the impact of the NPT, allowing public health officials to alter programs and policies to ensure the greatest public health benefit possible.[35]

If the introduction of vaccines and other prevention technologies have taught us anything, it is that every single one is distinct and requires modeling and planning specific to its unique characteristics such that possible road blocks can be anticipated and avoided. In order to ensure the timely and equitable delivery of NPTs once they are approved, public health will need not only to leverage its infrastructure but also to learn from its experiences to guarantee that the mistakes of the past are not repeated.

CHAPTER 5: FINDINGS FOR PUBLIC HEALTH ACTION ON NPTs

The objective of this chapter is to provide an overview and discussion of the role of the public health community in delivering NPTs and examining their knowledge, attitudes and practice regarding HIV prevention and NPTs.

One of the most successful public health interventions in the past century has been the discovery and use of vaccines. "More than 30 common infectious diseases are preventable with vaccines, and one of the most deadly, smallpox, was eliminated from human populations in 1979. The cost of eradicating smallpox was US$300 million, whereas the benefit has been estimated at US$27 billion over 20 years".[37] Vaccines constitute one of the most cost-effective public health interventions that exist. Currently, an HIV vaccine or efficacious new HIV prevention technology are seen by many as the next stage in a comprehensive approach to HIV prevention that could have a major population-level impact. However, as experience with other vaccines and HIV prevention technologies in Canada reveals, the discovery of a biomedical intervention does not automatically guarantee its optimal delivery to the key populations that require them most.[6]

The impact of NPTs in reducing new HIV infections in Canada will depend on several key factors: public health's preparedness and ability to absorb and deliver these new technologies; and how effectively they are used in combination with other available HIV prevention strategies. Public health in Canada needs to prepare itself "to capitalize on the potential success of prevention research currently underway" and "mobilize resources and develop public health guidance, provider training and public health education needed to ensure rapid implementation of new prevention methods".[5] As new HIV prevention technology trials such as CAPRISA 004, the Thai prime-boost vaccine trial, iPrEx, Partners PrEP and TDF2 show promise, the focus has been shifting from clinical research toward delivery preparedness, where the role of public health is particularly salient.

The introduction of an NPT presents significant challenges and there will be complexities that must be anticipated and addressed. In order to prevent a significant delay in the delivery of an NPT, steps to prepare for the introduction of a promising intervention must be taken before the regulatory approval process is completed. Letting a new prevention method sit inactive could result in hundreds or thousands of new infections nationwide. To prepare public health for the introduction of an NPT, it is necessary to look internally to understand the current knowledge, information needs, roles, resources and capacity of public health workers in Canada with respect to existing and new HIV prevention technologies.

5.1 Opportunities and Challenges: Public Health Knowledge, Information and Education around NPTs

The data from the key informant interviews, consultations and the survey show considerable convergence highlighting a number of opportunities and challenges for public health action on new HIV prevention technologies.

5.1.1 Perceptions within the Public Health Workforce

Throughout various consultations, it was widely agreed among public health participants not only that the introduction and delivery of NPTs was the responsibility of public health but that "public health should be engaged with new HIV prevention technologies at this point" (CPHA consultation). In the CPHA survey, 97.8% of public health respondents and 91.1% of all other respondents agreed or strongly agreed that NPTs will play an important role in reducing the spread of HIV in Canada.

Public health informants discussed the role of NPTs in separate terms of vaccine and non-vaccine technologies. This is an important distinction as informants felt that some NPTs fit relatively easily into existing frameworks and systems (HIV vaccines), while others require much more planning and effort to be implemented (non-vaccine NPTs). Key informants consider an effective HIV vaccine to be the best-case scenario for HIV prevention because: it constitutes a "one-off" intervention that does not require the difficult life-long behavioural changes required by other prevention technologies; and Canada already has existing vaccine infrastructure that could be leveraged relatively easily for the purpose of delivering an HIV vaccine.

Interestingly, the perceptions with regard to the urgency of addressing NPTs were mixed and seemed to depend on the informants' beliefs about how soon the technologies would be ready for "real-world" use. Accordingly, the informants commonly expressed hesitation to take an active role in preparing for NPTs until these technologies are much closer to implementation readiness. Some public health stakeholders do not perceive the urgent need to integrate NPTs into the Canadian HIV response. In particular, HIV vaccines are perceived to be many years away from being available (CPHA Key Informant).

> *"The new prevention technologies are still so unclear that there's kind of a false hope, where in the meantime we know the basic things around condom use and safer sex are still here and will continue to be the main responses."* *Key Informant*
>
> *"When you talk about new [HIV] prevention technology, it's still so far away it's hard to really grasp."* *Key Informant*

Other public health stakeholders perceive the need to initiate preparations for NPT roll-out immediately.

> *"We're starting to see some really promising findings…we have to start thinking seriously about how these can become part of our public health 'arsenal' of HIV prevention."* *Key Informant*

5.1.2 Knowledge Among Public Health Practitioners

These differences in opinion about the urgency in addressing NPT preparedness may be directly related to respondents' level of knowledge of NPTs. Public health respondents self-identified as being knowledgeable about existing technologies or approaches that are currently being delivered in Canada such as male condoms (98.5%), harm reduction strategies (95.6%), health promotion messaging (90.4%), voluntary confidential counseling and testing (VCCT) (87.4%), and partner notification (87.4%). However, public health respondents self-rated their knowledge of newer and emerging technologies/approaches as much lower than all other respondents. Only 35.6% rated themselves as knowledgeable about microbicides, 36.3% about PrEP, and 30.4% about HIV vaccines (CPHA survey, Table 4). Despite reporting that they are knowledgeable about some existing interventions and approaches, most respondents reported that much more education or training is required in their organization for all technologies/approaches (varying between 70% and 80% depending on the technology/approach) with the exception of male condoms (57.1%) (CPHA survey, Table 6).

Based on pre-test and post-test questionnaires for the CPHA and CAHR consultations, participants reported not being as current on the state of NPTs as they had previously thought. The consultations provided an introductory NPT "primer" as well as an update on recent trial results and it became clear that knowledge around NPTs was limited or dated. At each of these consultations, post-evaluation forms revealed that participants did not realize how out of date their knowledge was and how far the research had progressed over the last year around NPTs until they were presented with information on these topics. This identified not only a significant knowledge gap but an information gap around NPT development, characteristics, testing and trial results.

Table 4.

I am knowledgeable about the following types of HIV prevention technologies / approaches

	All respondents (N=473)		Public health unit respondents (N=135)			Other respondents (N=338)		
	%	C.I.	%	C.I.	O.R.	%	C.I.	O.R.
Male condoms	98.9	98-99.9	98.5	96.5-99.9	n.s.	99.1	98.1-99.9	ref.
Harm reduction strategies	95.6	93.7-97.4	95.6	92.1-99.1	n.s.	95.6	93.4-97.8	ref.
Health promotion messaging	92.6	90.2-95	90.4	85.4-95.4	n.s.	93.5	90.9-96.1	ref.
Female/Internal condoms	91.1	88.5-93.7	86.7	80.9-92.4	0.5*	92.9	90.2-95.6	ref.
Voluntary confidential counseling and testing	90.9	88.3-93.5	87.4	81.8-93	n.s.	92.3	89.5-95.2	ref.
Prevention mother-child transmission	85.8	82.7-89	83.0	76.6-89.3	n.s.	87.0	83.4-90.6	ref.
Partner notification	85.2	81.99-88.4	87.4	81.8-93	n.s.	84.3	80.4-88.2	ref.
Post-exposure prophylaxis	81.0	77.4-84.5	79.3	72.4-86.1	n.s.	81.7	77.5-85.8	ref.
Treatment as prevention	74.4	70.5-78.4	65.2	57.1-73.3	0.52**	78.1	73.7-82.5	ref.
Medical male circumcision	67.4	63.2-71.7	60.7	52.5-69.0	0.66*	70.1	65.2-75.0	ref.
Microbicides	56.2	51.7-60.7	35.6	27.4-43.7	0.3***	64.5	59.4-69.6	ref.
Pre-exposure prophylaxis	51.4	46.9-55.9	36.3	28.1-44.5	0.42***	57.4	52.1-62.7	ref.
HIV vaccine	46.1	41.6-50.6	30.4	22.6-38.2	0.4***	52.4	47-57.7	ref.

Significance levels *p≤.05 **p≤.01 ***p≤.001 n.s.: non significant

The percentages represents the respondents answering agree or strongly agree to the question

5.1.3 Information and Public Health Practitioners

Consultation participants indicated that they lacked knowledge around NPTs and would benefit from more training, education and information. Most consultation participants related their low level of knowledge of NPTs to a lack of readily available information on NPT research and trial results. Consultation participants noted that "there is little data and information made available regarding the development, testing and trials of NPTs". Many participants identified the lack of knowledge exchange around NPTs as a significant barrier. The complexity and amount of scientific information around NPT development, testing and trials was identified as "difficult to navigate". Participants noted that public health should be able to access and interpret research and that there should be further opportunities for them to engage with timely and relevant data on NPTs (CPHA consultation).

The timely distribution of information on NPTs was also highlighted as important in order to ensure 'lead time' to prepare for questions from clients who are curious or to prepare for the possible roll-out of the potential intervention. Over 42% of public health respondents disagreed or strongly disagreed that their organization stays current on NPT research (CPHA survey, Table 5). Respondents who reported that their organization stays current on NPT research more often reported agreeing or strongly agreeing that NPTs will play an important role in reducing the spread of HIV compared to those whose organizations do not stay current.

Table 5.

My organization stays current on the new HIV prevention technology research

	All respondents (N=473)		Public health unit respondents (N=135)		Other respondents (N=338)		
	%	C.I.	%	C.I.	%	C.I.	Chi 2
Strongly disagree / disagree	30.7	26.4-34.9	42.4	69.3-79	25.9	21-30.7	12.07**
Agree / strongly agree	69.3	65.1-73.6	57.6	49.1-66.1	74.1	69.3-79	

Significance levels *p≤.05 **p≤.01 ***p≤.001 n.s.: non significant

In identifying how they get their information on HIV prevention, public health survey respondents indicated that they primarily do so through websites (79.3%), presentations/workshops (73.3%), peer to peer (68.9%) and scientific literature (68.9%). However, survey respondents stated that they do not always receive it in their preferred manner. Similarly, consultation participants identified the need for a well-developed knowledge exchange system that would collect, interpret and share promising trial information to all levels of public health across jurisdictions (CPHA consultation). Some participants stated that there should be an ad hoc advisory committee developed to sort through, translate and distribute meaningful trial information to improve knowledge exchange around NPTs (CPHA consultation).

"It's the kind of thing…you can't do overnight. So we'd have to have a heads-up that there was really something good in the pipeline that is going to come onboard, and know about it well-enough in advance that we could start having those conversations so that while we are going through the approval stages…all that other community infrastructure stuff is put in place. So as soon as it's approved you're ready to go." Key Informant

"There should be opportunities for public health to engage with updated, relevant HIV prevention information that includes NPTs." Consultation Participant

5.1.4 Public Health Training and Education

Over 87% of public health respondents indicated that they had received some sort of training or education in HIV prevention during their careers. Ninety-five percent of those respondents agreed or strongly agreed that the knowledge and skills they gained during those training and education sessions were valuable to their practice. Of the 87% of public health respondents who had received training, 46.7% had not had HIV training in the past year and only 51.5% of the HIV prevention training/education sessions contained curriculum that discussed NPTs. This is important as there is a significant difference in the level of understanding about NPTs for respondents who reported receiving training in the past year; 72.7% of them reported discussing NPTs, compared to only 27.3% of those who reported having received training 2 years ago or more (CPHA survey). Over two-thirds of respondents who reported participating in the development of either HIV prevention programs (67.5%) or policies (68.5%) reported receiving training/education in HIV prevention in the last year (CPHA survey). This is significant as the majority of successful NPT proof-of-concept trials have occurred over the last 18 months, i.e., in the latter part of 2010 and throughout 2011 (see Chapter 3).

There was also a strong correlation between staying current on NPTs and the belief in the ability of organizations to deliver NPTs in a timely and equitable manner. Survey respondents indicated that they prefer receiving education or training regarding HIV prevention through presentations/workshops (82.0%) or in-person courses (72.1%), followed by webinars (41.4%) and online courses (40.4%). Key informants identified the need to develop new education tools and materials with a broader reach that can be used by staff at their convenience, rather than one-off sessions or courses with limited participant-reach (e.g., online materials, train-the-trainer approaches, videos, etc.). Overall, consultation participants identified the need for further education around NPTs to allow them to better approach questions from their clients and counseling for them (CPHA consultation). Public health participants also mentioned the need for more staff training around cultural sensitivity, communication skills, and substitution or risk compensation behaviour.

Table 6.

In my organization I believe education / training regarding HIV prevention is needed for:

	All respondents (N=473)		Public health unit respondents (N=135)			Other respondents (N=338)		
	%	C.I.	%	C.I.	O.R.	%	C.I.	O.R.
Male condoms	57.1	52.6-81.6	53.3	44.8-61.8	n.s.	56.6	53.3-63.9	ref.
Harm reduction strategies	79.5	75.8-83.1	82.2	75.7-88.7	n.s.	78.4	74-82.8	ref.
Health promotion messaging	78.2	74.5-82	80.0	73.2-86.8	n.s.	77.5	73-82	ref.
Female/Internal condoms	71.7	67.6-75.7	69.6	61.8-77.4	n.s.	72.5	67.7-77.3	ref.
Voluntary confidential counseling and testing	70.6	66.5-74.7	70.4	62.6-78.1	n.s.	70.7	65.8-75.6	ref.
Prevention mother-child transmission	73.6	69.6-77.6	77.8	70.7-84.8	n.s.	71.9	67.1-76.7	ref.
Partner notification	71.9	67.8-75.9	71.9	64.2-79.5	n.s.	71.9	67.1-76.7	ref.
Post-exposure prophylaxis	81.4	77.9-84.9	82.2	75.7-88.7	n.s.	81.1	76.9-85.3	ref.
Treatment as prevention	86.1	82.9-89.1	91.9	87.2-96.5	2.19*	83.7	78.8-87.7	ref.
Medical male circumcision	74.2	70.3-78.2	79.3	72.4-86.1	n.s.	72.2	67.4-77	ref.
Microbicides	87.5	84.5-90.5	94.8	91.1-98.6	3.32**	84.6	80.7-88.5	ref.
Pre-exposure prophylaxis	87.7	84.8-90.7	94.8	81.1-98.6	3.25**	84.9	81.1-88.7	ref.
HIV vaccine	83.7	80.4-87.1	90.4	85.4-95.4	2.19*	81.1	76.9-85.3	ref.

Significance levels *p≤.05 **p≤.01 ***p≤.001 n.s.: non significant

The percentages represent the respondents answering agree or strongly agree to the question

Increasing not only public health practitioners' awareness of NPTs through education and trainings, but also that of the general public was discussed by informants as a key public health activity that would facilitate successful implementation. In particular, informants mentioned the importance of getting buy-in from both the public (recipients) and healthcare professionals (providers) that the technology is safe and effective (particularly for partially effective technologies). They also mentioned concern about managing the complexities of various groups' understandings and acceptance of these technologies.

5.1.5 Public Health Communication Messaging

Consultation participants identified public health as having extensive experience in developing effective messaging around different HIV prevention strategies to reach key populations at high risk. However, over 49% of public health survey respondents disagree or strongly disagree that HIV prevention messaging is currently appropriate and reaching key populations. A further challenge that key informants highlighted was the unintended consequences of implementing NPTs, including potential risk compensation (e.g., decreased condom use, increased number of partners) that may follow the use of an NPT. Key informants identified the need for a well-developed risk communication strategy as a crucial component of a well-thought-out comprehensive prevention approach.

Messaging was identified by consultation participants as playing a pivotal role in educating people, influencing their perceptions and supporting their uptake of an NPT. Messaging affects how people use NPTs, which relates to issues of safety, access and adherence. Consultation participants, survey respondents, key informants and the literature all point to the importance of targeted and consistent communication from all levels of public health at the federal, provincial and regional levels. Participants stated that messaging around NPTs must be presented as part of a larger combination prevention package (as discussed in Chapter 3), and that communication strategies around NPTs need to increase awareness of and access to already existing prevention services. Informants discussed the future of HIV prevention in Canada in terms of a 'comprehensive prevention' approach where new and existing technologies and approaches would function together in the treatment and prevention of HIV. Consultation participants stated that NPTs, while important,

will not be the "silver bullet", but just one more option among a growing number of prevention options.

> *"I think the message needs to be consistent from all levels of government, so federal, provincial, and then at the local level as well, would have to provide a consistent message. I think that's something that's missing right now, not only with HIV but with all STIs."* *Key Informant*
>
> *"A vaccine would be a 'big win', but if the [new prevention technology] is a less effective one, then likely a combination with other primary prevention, or other interventions, will be important."* *Key Informant*

5.2 Opportunities and Challenges: Public Health Leadership, Policies and Guidance Regarding NPTs

5.2.1 Leveraging Public Health Infrastructure

Canadian public health is seen by many key informants and consultation participants as a credible authority that has extensive experience, understands the demographics, and has an infrastructure in place that can be leveraged to deliver NPTs. Many of the systems that are in place for the introduction of other interventions and vaccines were seen as helpful for public health delivery of NPTs. Specifically, immunization guidelines and National Advisory Committee on Immunization (NACI) were seen as essential to developing guidance around vaccines (CPHA consultation). Participants identified that public health infrastructure and experiences could be leveraged to help introduce NPTs through public health's influence and existing links to important policy decision makers (CPHA consultation).[ix] One informant further noted that public health also has a strong understanding of the social determinants of health and an appreciation of the groups most at risk for HIV infection, and is comfortable working with varied communities (CPHA Key Informant).

The public health sector in Canada has experienced success in preventing the spread of HIV. In particular, public health has played a key role in decreasing HIV prevalence levels through harm reduction programs and the virtual elimination of maternal-child transmission and of the spread of HIV through the blood collection system (CPHA Key Informant). Canadian public health respondents (particularly at the regional level) said they had experience working in awareness raising (91.1%), HIV/STI testing (80.0%), and needle exchange (54.1%) but stated having significantly less experience working with HIV advocacy (34.8%), HIV policy (22.2%) and HIV research (14.8%) (CPHA survey).

In terms of preparing for and implementing NPTs, provincial/territorial public health infrastructure and experience have been identified by informants as being able to:

[ix] Chapter 4 contains further information on lessons learned/best practices of vaccine and other HIV prevention delivery

- Develop communications and awareness (both to high-risk target populations and to the healthcare sector) around NPTs and their effectiveness, risks, etc.;
- Advocate to get these (often expensive) technologies publicly funded;
- Set up programs for the technologies (only if publicly funded);
- Ensure and increase accessibility, once available;
- Conduct post-marketing surveillance for safety and efficacy; and,
- Develop scenario planning (with a larger federal role doing the same).

Key informants see national public health infrastructure and experience as somewhat unique from the provincial/territorial role, identifying the following roles:

- Providing advice and recommendations with a focus on prevention;
- Scenario planning (with a lesser provincial role doing the same);
- Funding community organizations (grants and contributions);
- Surveillance of HIV in each province/territory via their health ministries; and,
- Research.

5.2.2 Public Health Leadership

Consultation participants stated that increased public health leadership is required at the federal level to develop awareness about and prepare for NPTs. "Federal involvement is required if you want every province to do it quickly and at the same time" (CPHA Key Informant). As trials show proof-of-concept through partial efficacy, this leadership role becomes particularly salient.

Consultation participants noted that there is a lack of clarity with regard to who is responsible for NPTs at this time and who will take the lead in addressing many of the issues that arise around them (CPHA consultation). Key informants identified the difficulty in developing programs and prevention campaigns without support from the highest levels of government: in some provinces, HIV is an important public health issue; in others, HIV does not take a prominent place in public health planning or services. Community, primary health care and research stakeholders expressed concern about the lack of engagement from public health authorities in dialogue and planning around NPTs (CPHA consultation). Several participants of the CAHR Ancillary Event commented that public health perspectives were under-represented. As one participant wrote in the evaluation, "I was disappointed that there essentially was not a presentation on the Canadian public health perspective on PrEP." Despite concerted efforts by the organizers to have relevant public health speakers from municipal, provincial or federal public health bodies, there was difficulty in identifying public health representatives who were prepared and/or willing and able to present on the topics of PrEP or other NPTs.

Key informant interviews also stated that public health has a role in keeping HIV on the federal agenda, through good reporting, and communicating trends in HIV vaccine and other NPT research. One key informant thought that the 'buzz' generated around NPTs would be an enabler in terms of its potential for garnering political support.

"The biomedical preventions are really seizing peoples' imaginations as a new avenue for prevention of HIV. So they could potentially garner a lot of support in terms of 'needing to try this'. I think that may create some political will for establishing programs around these new technologies." *Key Informant*

"Work should be spearheaded by the federal government, but have a lot of community stakeholders and other experts involved in the development of the guidelines." *Key Informant*

5.2.3 Public Health Policy

Nearly half of the public health survey respondents (48.2%) identified policies as one of the most important enablers to implementing HIV prevention interventions effectively in their everyday practice. Eighty-five percent of public health respondents and 94.4% of all other respondents agree or strongly agree that HIV is an important public health issue for their region (CPHA survey, Table 7). Half (50.1%) of all survey respondents disagreed or strongly disagreed that HIV is sufficiently prioritized within provincial/territorial documents, and yet 87.5% of all respondents indicated that their work in HIV prevention is guided by standards, policies, practices and guidelines at the provincial/territorial level (CPHA survey, Table 8). Consultation participants further identified the need to adjust and update key policy documents to reflect current NPT research issues.

Table 7.

HIV is an important public health issue for your region

	All respondents (N=473)		Public health unit respondents (N=135)		Other respondents (N=338)		Chi 2
	%	C.I.	%	C.I.	%	C.I.	
Strongly disagree / disagree	8.3	5.8-10.7	14.8	8.8-20.8	5.6	3.2-8.1	10.78**
Agree / strongly agree	91.8	89.3-94.2	85.2	79.2-91.2	94.4	91.9-96.8	

Significance levels *p≤.05 **p≤.01 ***p≤.001

Table 8.

HIV prevention is sufficiently prioritized within your provincial/territorial HIV policy documents

	All respondents (N=473)		Public health unit respondents (N=135)		Other respondents (N=338)		Chi 2
	%	C.I.	%	C.I.	%	C.I.	
Strongly disagree / disagree	50.1	45.6-54.6	48.9	40.4-57.4	50.6	45.2-55.9	n.s.
Agree / strongly agree	49.9	45.4-54.4	51.1	42.6-59.6	49.4	44.1-54.8	

Significance levels *p≤.05 **p≤.01 ***p≤.001 n.s.: non significant

Public health has experience in developing healthy public policy and testing policy impact, however, there appears to be a lack of policy guidance at various jurisdictional levels (CPHA consultation). Key informants noted that most provinces already have a legislative mandate for STI programming, including HIV prevention, but these vary widely from province to province and require more consistency. Consultation participants highlighted the lack of supportive policy around existing HIV interventions such as non-occupational post exposure prophylaxis (nPEP) and how that has negatively affected its availability in Canada. Also identified by key

informants were some future enablers that could facilitate and/or improve HIV prevention and the implementation of NPTs:

- Having uniform, clear and supportive federal policy guidance for new prevention technologies (uniformity avoids confusion across jurisdictions);
- Provincial support, including supportive provincial policies;
- Ensuring public policy/decision-makers are well informed about HIV and new HIV prevention technologies;
- Development of supportive policy and funding decisions;
- Making a case for funding synergistic with current initiatives as new technologies become ready for implementation; and,
- Learning from the examples and precedents around NPTs that are being established elsewhere, while being careful about how they are applied within the specific nuances of the Canadian context (CPHA Key Informant).

5.2.4 Public Health Guidance

All survey respondents stated that public health leadership and policy development are particularly needed in the area of guidance for implementation. Over 54% of public health survey respondents identify public health guidance as an enabler to implementing HIV prevention interventions effectively in their everyday practice. Compared to other respondents, public health respondents more often reported that lack of program development capacity (49.6% vs. 37.8%) and lack of public health guidance (39.1% vs. 25.7%) are barriers. Consultation participants identified the need for national leadership in the development of guidelines and an implementation strategy that will see them delivered provincially and locally. Key informants recognized the need for increased guideline responsiveness to improve HIV prevention and the implementation of NPTs, primarily:

- Acting more quickly on emerging evidence as it becomes available;
- Developing interim guidance on emerging HIV prevention technologies to avoid physicians and providers developing their own unique practices ahead of official guidance; and,
- Ensuring that the interim guidance contains guidelines for testing, use, counseling, target populations, risk assessment details, etc.

Public health has the ability to reach the general population with guidance around the use of new biomedical interventions, but guidance has not always been developed in a timely manner around important interventions, for example around nPEP. The lack of nPEP guidelines and the lack of awareness, access and policy around nPEP were mentioned by consultation participants. One consultation participant simply stated that "guidance is required from the top level (federal) in order to ensure appropriate delivery". Key informants also specifically identified joint roles for federal/national and provincial/territorial public health to work collaboratively in terms of providing guidance around the implementation of NPTs, including: working with the relevant authorities and organizations to develop guidelines, depending on the technology [vaccine (i.e., NACI[38]) vs. non-vaccine (i.e., AIDS Bureau, PHAC[39])] and, adapting national policies, guidelines and recommendations to develop provincial/territorial guidelines.

> *"There certainly is a place for national recommendations around the appropriate use of new technologies. Then, the decision needs to be made under provincial level in terms of how they're applied, using those guidelines as a starting point. And in the absence of that we have to look at developing those kinds of guidelines ourselves."* *Key Informant*

5.3 Opportunities and Challenges: Public Health Resource Capacity and Planning around NPTs

5.3.1 Public Health Program Delivery

Data from CPHA's survey identified that 39.8% of public health respondents and 27.9% of other respondents reported that they disagree or strongly disagree that their organization is providing HIV prevention interventions in a timely and equitable manner (CPHA survey, Table 9). Similarly, 52.7% of public health respondents and 32.3% of other respondents reported that they disagree or strongly disagree that their organization is responsive enough to deliver NPTs in a timely and equitable manner once the latter are approved (CPHA survey, Table 10). There is a positive correlation between the organizations' reported ability to provide current HIV prevention interventions in a timely and equitable manner and the organizations' reported responsiveness to deliver NPTs in a timely and equitable manner once these are approved. Among organizations identified as providing existing HIV prevention interventions in a timely and equitable manner, 76.3% were also identified as being responsive enough to deliver NPTs in a timely and equitable manner once these are approved (CPHA survey).

Table 9.

My organization is providing HIV prevention interventions in a timely and equitable manner

	All respondents (N=473)		Public health unit respondents (N=135)		Other respondents (N=338)		Chi 2
	%	C.I.	%	C.I.	%	C.I.	
Strongly disagree / disagree	31.5	27.1-35.9	39.8	31.3-48.4	27.9	22.8-33	5.93*
Agree / strongly agree	68.5	64.1-72.9	60.2	51.6-68.7	72.1	67-77.2	

Significance levels *p≤.05 **p≤.01 ***p≤.001 n.s.: non significant

Table 10.

My organization is responsive enough to deliver new HIV prevention technologies in a timely and equitable manner once they are approved

	All respondents (N=473)		Public health unit respondents (N=135)		Other respondents (N=338)		Chi 2
	%	C.I.	%	C.I.	%	C.I.	
Strongly disagree / disagree	38.6	33.9-43.2	52.7	44.1-61.3	32.3	27-37.7	15.89***
Agree / strongly agree	61.5	56.8-66.1	47.3	38.7-55.9	67.7	62.3-73	

Significance levels *p≤.05 **p≤.01 ***p≤.001 n.s.: non significant

Consultation participants noted that before NPTs are made widely available, "existing testing and prevention programs must be optimized". Some consultation participants pointed out the need for more appropriate and innovative access points for NPTs than exist now, while other participants identified the need to address stigma, discrimination and issues of criminalization that may impede access to NPTs. For the implementation of NPTs in Canada, consideration needs to be given to issues of access, in particular for marginalized

or disadvantaged groups. This includes exploring the provision of subsidies to mitigate inequities or disparities in HIV prevention (CAHR ancillary event). Key informants also encouraged public health actors to identify and take advantage of opportunities for synergies in programming and service delivery (e.g., consolidated testing when the homeless or people who use injecting drugs are testing for tuberculosis or other STIs) as a way to improve program delivery. Interestingly, NPT delivery and programs were identified not only as a vehicle to extend prevention options, but also as an opportunity to strengthen and enhance existing HIV prevention services and approaches (CPHA consultation).

5.3.2 Public Health and Key Populations at High Risk

Most survey respondents report that their organizations' HIV interventions are reaching people who use injection drugs, women and at-risk youth (70.7%, 68.5% and 62.1%, respectively). However, Aboriginal people, prison inmates and people from countries where HIV is endemic are being reached significantly less (46.0%, 43.7% and 43.4% respectively). Specifically, public health respondents said they were much less able to reach those groups (32.5%, 39.0% and 28.1%, respectively) than all other respondents (CPHA survey). Respondents stated their organization has specific programs or projects that target key populations at higher risk of HIV, and primarily focus on people who inject drugs (50.5%) and at-risk youth (47.4%) (CPHA survey, Table 11). Again, public health respondents self-identified as having significantly less programs or projects targeting women, Aboriginal people, people from countries where HIV is endemic, and gay, bisexual and other men who have sex with men than other respondents.

While it was stated that public health has good awareness of the social determinants of health and an appreciation of the groups most at risk for HIV infection, and comfort working with varied communities, public health respondents report having less success reaching marginalized populations. Current public health prevention efforts have been identified as requiring further development in order to better reach key populations at high risk (CPHA consultation). Public health survey respondents self-identify that they have been less effective in reducing HIV incidence among men who have sex with men (MSM), Aboriginal people, and people coming from endemic countries than other respondents. In addition, concern was expressed that there are a significant number of people who test positive who do not follow through on treatment or are 'lost to treatment' (CPHA Key informant). Public health officials largely recognized the challenges they face in reaching certain populations and identified the important funding and support that they provide to local organizations that strive to reach these populations more efficiently (CPHA Key Informant).
Table 11.

Do you have any specific programs or projects that target key populations at higher risk of HIV exposure?

	All respondents (N=473)		Public health unit respondents (N=135)			Other respondents (N=338)		
	%	C.I.	%	C.I.	O.R.	%	C.I.	O.R.
People who inject drugs	50.5	46-55.1	51.9	43.4-60.3	n.s.	50.0	44.6-55.4	ref.
At risk youth	47.4	42.8-51.9	44.4	39-52.9	n.s.	48.5	43.2-53.9	ref.
Gay, bisexual and other men who have sex with men	46.9	42.4-51.4	36.3	28.1-44.5	0.54**	51.2	45.8-56.5	ref.
Women	39.8	35.3-44.2	22.2	15.2-29.3	0.33***	46.8	41.4-52.1	ref.
Aboriginal people	38.5	34.1-42.9	28.2	20.5-35.8	0.53**	42.6	37.3-47.9	ref.
Sex workers and their clients	34.3	30-38.5	32.6	24.6-40.5	n.s.	34.9	29.8-40	ref.
Prison inmates	28.5	24.5-32.6	28.1	20.5-35.8	n.s.	28.7	23.9-33.5	ref.
People from countries where HIV is endemic	27.5	23.4-31.5	20.0	13.2-26.8	0.57*	30.5	25.5-35.4	ref.
No programs or projects that target key populations at higher risk of HIV exposure	22.6	18.8-26.4	30.4	22.6-38.2	1.8*	19.5	15.3-23.8	ref.

Significance levels *p≤.05 **p≤.01 ***p≤.001 n.s.: non significant

The percentages represent the prevalence of each element individually

5.3.3 Public Health Resource Capacity

Most survey respondents identified well-informed staff with appropriate training, and understanding the importance of HIV prevention as the most important enablers (60.9% and 57.3%, respectively) to their everyday practice. Respondents reported that the most significant constraints and barriers to implementing HIV prevention effectively in their everyday practice are lack of funding (69.1%) and lack of human resource capacity (67.2%) (CPHA survey, Table 12). Public health's capacity to fund and follow up on delivery of NPTs was cited as a major implementation issue. While many consultation participants and key informants identified that public health has extensive experience and an infrastructure that can be leveraged to deliver NPTs, they also stated that public health does not have sufficient expertise, human resource capacity or infrastructure to deliver NPTs in a timely and equitable manner. They identified existing financial, distribution and human resource limitations as issues that could affect the roll-out of NPTs, and the need for public health to more effectively optimize their resources.

Table 12.

What are constraints and barriers to implementing HIV prevention effectively in your everyday practice?

	All respondents (N=473)		Public health unit respondents (N=135)			Other respondents (N=338)		
	%	C.I.	%	C.I.	O.R.	%	C.I.	O.R.
Lack of funding	69.1	65-73.3	65.9	57.9-74	n.s.	70.4	65.5-75.3	ref.
Lack of human resource capacity	67.2	63-71.5	66.7	58.7-74.7	n.s.	67.5	62.4-72.5	ref.
Stigma and discrimination	50.7	46.2-55.3	34.8	26.7-42.9	0 4***	57.1	51.8-62.4	ref.
Community and cultural norms	43.1	38.6-47.6	39.3	31-47.5	n.s.	44.7	39.4-50	ref.
Lack of program development capacity	42.1	37.6-46.5	**49.6**	**41.1-58.1**	**1.54***	**39.1**	**33.8-44.3**	**ref.**
Lack of information / training among staff	37.0	32.6-41.4	43.7	35.3-52.1	n.s.	34.3	29.2-39.4	ref.
Geographic location of target populations	33.0	28.7-37.2	30.4	22.6-38.2	n.s.	34.0	29-39.1	ref.
Lack of understanding of importance	31.3	27.1-35.5	36.3	28.1-44.5	n.s.	29.3	24.4-34.2	ref.
Poor information, education and communication campaings	30.9	26.7-35	35.6	27.4-43.7	n.s.	29.0	24.1-33.9	ref.
Lack of / restrictive policies	29.2	25.1-33.3	34.8	26.7-42.9	n.s.	26.9	22.2-31.7	ref.
Lack of public health guidance	29.2	25.1-33.3	**37.8**	**29.5-46**	**1.76****	**25.7**	**21.1-30.4**	**ref.**
Lack of leadership	29.2	25.1-33.3	35.6	27.4-43.7	n.s.	26.6	21.9-31.4	ref.
Criminalization	27.1	23.-31.1	12.6	7-18.2	0.29***	32.8	27.8-37.9	ref.
Lack of partnership	20.5	16.9-24.2	22.2	15.2-29.3	n.s.	19.8	15.6-24.1	ref.
No anonymous testing	12.3	9.3-15.2	5.2	1.4-8.9	0.31**	15.1	11.3-18.9	ref.
No constraints / barriers	3.8	2.1-5.5	0.7	0.01-2.2	n.s.	5.0	2.7-7.4	ref.

Significance levels *p≤.05 **p≤.01 ***p≤.001 n.s.: non significant

The percentages represent the prevalence of each constraint or barrier individually

Key informants identified numerous existing public health resources that could be leveraged to facilitate and support the implementation of NPTs, including:

- Vaccine distribution systems, infrastructure and guidelines;
- HIV treatment clinics, typically led by infectious disease specialists;
- Public coverage of certain STI medications through certain providers;
- Working groups and committees both federally and provincially that are often represented by stakeholders from public health, research and the community; and,
- Provision of new HIV prevention technologies by select providers (e.g., in sexual assault treatment centres post-exposure prophylaxis programs exist and guidelines for them and medications are publicly funded in some cases).

A concern that was consistently mentioned throughout the key informant interviews was how to implement NPTs without losing focus or significantly shifting capacity and funding away from proven interventions (i.e., routine testing and treatment for people living with HIV, promotion of condom use, etc.). Key informants identified funding limitations vis-à-vis other public health priorities; specifically, it would be a challenge to fulfill the expectation of incorporating NPTs into existing public health budgets. They noted that the scope of public health work has increased greatly in recent years, that everyone is under pressure to allocate scarce resources, and that it is already a challenge to find the capacity to implement and evaluate new programs. While infrastructures exist that could be leveraged to deliver NPTs, they are likely to become overloaded by the complex nature of delivering these technologies (CPHA consultation).

"I think that we're all under pretty substantial pressures in terms of allocating scarce resources, even actually just finding the capacity to implement and evaluate existing programs. So I think that will be an ongoing challenge that will affect all public health programs, including new HIV prevention programs, without a significant injection in cash to go along with these programs." *Key Informant*

"I think the main barrier just comes down to fiscal. So, for example, if you are trying to fund a PrEP program and you have a fixed amount of money for the HIV medication budget, where does that money come from? I think it's probably just going to come down to the operational realities that will be a barrier for implementation." *Key Informant*

5.3.4 Public Health Collaboration and Partnerships

Public health has successfully established collaborative working relationships with community groups that work with key populations at risk of HIV. Public health key informants observed that these relationships have become more organized over time, and both sides have become more open to working with each other. Public health units have engaged in effective and long-term partnerships with community-based organizations. Key informants also noted that strong collaboration with local organizations is essential for effective community support and education, and acknowledged that peers in vulnerable and marginalized populations often are best positioned to deliver HIV prevention interventions. All key informants spoke of the importance of working collaboratively with community organizations and AIDS service organizations, as well as primary care providers and HIV care providers.

Consultation participants identified the need for sustained and even increased cooperation among public health, community-based organizations and AIDS service organizations. Public health can partner more with organizations that deliver services to specific populations and extend its reach, but participants warned that depending on partnerships too heavily could result in delivery problems (CPHA consultation). Developing new innovative partnerships and collaboration will not only improve the delivery of NPTs but will allow these organizations to address delivery barriers in a coordinated and comprehensive manner. Key informants also highlighted the need to be "acting on the evidence as it becomes available" and how that could be better achieved by federal, provincial/territorial and local public health working closer together to ensure uniform, consistent and timely introduction and delivery of new HIV prevention technologies.

"No one organization or community can do this alone. You have to have good surveillance, you have to have community working with government, you have to have government funding/supporting community, and there has to be an understanding of the need to let the at risk populations decide how best to do this; and giving them support to do it." *Key Informant*

"Often local organizations can reach some of the people that we need to reach more efficiently than public health can, in terms of HIV prevention." *Consultation Participant*

5.3.5 Public Health Monitoring, Evaluation, Research and Modeling

Consultation participants questioned if our existing Canadian HIV surveillance, and monitoring and evaluation systems are able not only to appropriately measure efficacy but also to monitor issues such as risk compensation, resistance, uptake, side effects, etc. Informants specifically highlighted the lack of social science research around NPTs and the need for further research around behavioural issues that could inform the creation of an appropriate monitoring and evaluation system.

Key informants noted specific challenges with respect to the roll-out of NPTs, suggesting there may be adherence difficulties and various safety concerns, including long-term side effects, around NPTs that are unknown until they are delivered, and that may only become apparent years down the road. One consultation participant was concerned that "NPTs are new and their characteristics are largely unknown". Further issues identified were that populations to which an NPT is targeted may not be interested, resulting in low uptake; there may be risk compensation that takes place; and anti-vaccine sentiments may pose problems to HIV vaccine delivery (CPHA consultation). All of these potential challenges require not only surveillance but additional monitoring systems to ensure that corrective actions can be taken to mitigate any undesirable public health impact.

Consultation participants highlighted the need to begin modeling and planning around the public health impact of certain NPTs that have begun to show efficacy. This modeling can be used not only to develop cost-benefit analyses around emerging NPTs to gauge their possible impact but also to focus on the delivery of NPTs to different communities. Consultation participants noted that modeling can be used to support surveillance work and help anticipate areas where monitoring and evaluation will need to be conducted and how it will be conducted.

> *"In depth research on evidence and what implications it will have is required."*
> *Consultation Participant*

CHAPTER 6: ANALYSIS AND AREAS FOR PUBLIC HEALTH ACTION ON NPTs

The objective of this chapter is to provide a road-map for comprehensive public health action on the delivery of NPTs, based on an analysis of the data from the project.

As the data presented demonstrates, respondents are of the opinion that public health should be assuming a clearer role in a number of areas of action to prepare for NPTs. For NPTs to have an impact on HIV incidence, public health must take action to ensure that future HIV prevention breakthroughs will be accessible to those who need them, and that they will be used optimally in combination with existing prevention methods. Building awareness, creating an enabling environment and preparing for the delivery of NPTs are all vital steps in achieving the timely and equitable implementation of NPTs. To ensure an effective public health response, it is paramount to develop public health leadership, supportive policies, guidance, knowledge exchange, education and training, resource capacity, partnerships, and monitoring and evaluation.[1] The following recommended areas for public health action on NPTs are based on an analysis of the data presented in Chapter 5 and are grounded in the specific core competencies for public health in Canada.

6.1 Building Awareness: Public Health Knowledge, Information and Education around NPTs

6.1.1 Develop Appropriate Education and Training Opportunities

The willingness and ability of an individual or organization to act and implement new strategies requires an ongoing process of informing and sensitizing. The public health community has identified frontline provider education and training as essential to the successful introduction of NPTs. As identified in the findings, public health workers with recent training on NPTs were more likely to believe that their organizations could deliver NPTs in a more timely and equitable manner. Before NPTs can be promoted and delivered to populations at risk of HIV, the public health workforce must have adequate NPT literacy themselves. The public health community must not only be aware of NPTs but also be able to explain their use, importance and possible implications. Providers' understanding of NPTs will invariably have an effect on access, uptake, adherence, etc.[40] Education and training on NPTs must be designed to complement and even reinforce existing prevention options, promoting a comprehensive approach. This will be particularly important to ensure that the introduction of new HIV prevention technologies does not lead to risk compensation. Education and training will also be required on how to monitor and evaluate the benefits and limitations of the technology.

Areas for Action:

i. **Develop and deliver an ongoing education and training strategy for public health workers to raise their awareness of the state of NPT science and its implications for Canadian HIV prevention efforts in order to reinforce existing prevention approaches, and to promote combination prevention. This strategy includes:**

   - **Developing and delivering training opportunities for the public health workforce, offered as professional development through workshops, in-person or online e-learning courses, webinars and making use of existing conferences and training opportunities.**

   - **Provide public health with ongoing opportunities in their everyday practice to interact with new HIV prevention education materials through information and resource access such as listservs, mailing lists and newsletters.**

6.1.2 Ensure the Application of Information and Evidence

To prepare for the roll-out of NPTs, public health needs a clear understanding of existing information and policies, their effectiveness, and ongoing research around NPTs. The public health community has identified the need for a knowledge transfer and exchange system among federal, provincial and regional levels of public health that will synthesize, translate and distribute information about ongoing HIV prevention clinical trials. According to the data presented in Chapter 5, there is little consistency in the public health community in terms of level of NPT knowledge. This varied level of knowledge was directly associated with public health workers difficulty in obtaining, sorting through and understanding extensive trial information. Perceptions of the potential impact of NPTs as well as the perceived importance and sense of urgency to incorporate these were also identified as important literacy factors. Making relevant research information available and accessible to stakeholders for use in practice, planning and policy-making is necessary to spur public health action on NPTs. A knowledge transfer exchange system will support consistent, uniform and easily accessible information for public health workers, clinicians and community-based service providers. A well-informed workforce with a developed knowledge base is a precursor to any public health action on NPTs.

Areas for Action:

ii. **Public health should actively support the development of a knowledge exchange working group for federal, provincial and regional levels of public health. Possible distribution mechanisms include the Canadian Microbicides Action Plan (CMAP) Implementation Committee, or the MAG-Net listserv. This working group would include public health representation and would:**

- **Regularly review, translate and distribute relevant trial information, and stimulate dialogue, to improve knowledge exchange around NPTs.**

- **Develop knowledge synthesis tools for partners and clients that identify best practices and lessons learned in the roll-out of sexual and reproductive health technologies, identifying sub-topics such as delivery preparedness, messaging, communicating efficacy, and counseling to avoid risk compensation.**

6.2 Creating an Enabling Environment: Public Health Leadership, Policies and Guidance Regarding NPTs

6.2.1 Provide Leadership for a Harmonized Approach

Leadership is essential to spur action when discussing a sensitive public health issue like HIV. The public health community has indicated that there is a need to re-energize HIV prevention in Canada, specifically highlighting the importance of leadership around the implementation of NPTs. In order to address the many policy and programmatic challenges identified by public health in working across jurisdictions on HIV, increased federal leadership was identified as necessary to address the complexities of policy, guidance, resources, capacity, etc. Increased public health leadership will strengthen government collaboration at the federal, provincial/territorial and regional levels and will ensure a clearer vision and a harmonized approach and possibly achieve consensus. Consultation participants and key informants consistently highlighted the need for federal leadership to provide direction for provincial/territorial and regional public health with regard to NPT implementation. This is particularly important when discussing the integration of NPTs within a comprehensive public health approach to HIV prevention and examining issues related to the timely and equitable delivery of NPTs across Canada.

Areas for Action:

i. **In response to calls from stakeholders for a strengthened national response, and consistent with its mandate, public health at the national level should provide timely leadership around NPT delivery. This includes:**
   - **Establishing priorities**
   - **Developing policy and guidance**
   - **Provincial/Territorial coordination**
   - **Allocating resources**
   - **Scenario planning**
   - **Engaging stakeholders**

ii. **The F/P/T-AIDS Committee should engage in discussions to understand jurisdictional roles and responsibilities with respect to NPTs, and to support uniform guidance and coordination between jurisdictions**.

6.2.2 Support Necessary Policy Development

Dealing with the increasing complexities posed by HIV infection in Canada requires a supportive and responsive policy environment. Public health stakeholders have called on federal government to demonstrate leadership and commitment to comprehensive HIV prevention by developing new policies and strengthening existing policies relating to NPTs. Specifically, public health key informants called on the federal government to take leadership and collaborate with other levels of government and other stakeholders in developing policy frameworks that will support a renewed approach to the delivery of existing and new HIV prevention approaches. Public health stakeholders require governments at federal, provincial/territorial and regional levels to provide clear and uniform guidance, including interim guidance, and quicker policy/practice responsiveness around NPTs. These policies would ensure enabling conditions for NPTs by providing direction for public health capacity, partnerships, knowledge and resources needed to reach key populations at higher risk. Anticipating challenges through policy analysis will also play an important part in ensuring the timely and equitable delivery of NPTs to those populations that require them most.[41]

Areas for Action:

iii. **The federal government should adjust, update and develop key documents and commitments to more explicitly refer to and integrate NPTs as part of a comprehensive HIV prevention approach (e.g., the Federal Initiative, Leading Together).**

iv. **Public health stakeholders and other partners should ensure public policy/decision-makers are well informed about HIV and NPTs to facilitate timely development of supportive policy and funding decisions.**

6.2.3 Provide Timely Evidence-Based Guidance

Timely guidance is needed around NPTs to maximize their benefits as they are proven to be effective and become available, and to minimize the harm that may be caused by improper or off-label use. Guidelines should be based on a "full review of trial data and other research, and will incorporate input from providers, HIV prevention partners, and affected communities"[42] and should provide both healthcare providers and patients with accurate information. Canada is lacking guidance on prevention approaches already in use, with nPEP as a case in point.[43] Several provinces have developed their own public health guidance around the use of nPEP to fill the protocol void. The public health sector, in particular, has a leadership role in developing recommendations based on evidence-based criteria for determining who will receive NPTs; on how NPTs will be distributed and promoted, based on different scenarios (e.g., NPT supply, NPT efficacy); on the settings in which NPTs will be delivered; on how adverse events (e.g., reactions, side effects) will be monitored; on how liability will be managed; and on how the implementation program will be evaluated.

Areas for Action:

v. **Develop and disseminate evidence-based and timely public health guidance for NPT implementation, including interim guidelines in advance of regulatory approval. This guidance should be initiated at federal levels, and subsequently adapted to provincial and regional levels.**

vi. **Full guidelines should be immediately developed for non-occupational post-exposure prophylaxis and the use of treatment-as-prevention and interim guidelines should be developed for pre-exposure prophylaxis to build inter-jurisdictional consistency in NPT awareness and access.**

6.3 Preparing for Delivery: Public Health Resource Capacity and Planning around NPTs

6.3.1 Build Organizational and Resource Capacity

Addressing the procedures, policies, structures and practices of organizations is required to optimize and expand their response to HIV. Public health stakeholders identified the need for increased capacity to deliver both existing and new HIV prevention interventions in a timely and equitable manner. Integrating NPTs into existing HIV prevention, sexual health and clinical care programs will be challenging due to competing priorities and will be ineffective if existing delivery challenges are not addressed first. There are already constraints in reaching vulnerable populations with existing prevention interventions as regional public health HIV prevention efforts are already under-resourced, and HIV-specific funding is threatened. Sexual health and general health services are also under strain; they have little time and few resources specifically dedicated to HIV. While existing public health systems (e.g., vaccine distribution systems, infrastructure and guidelines; HIV and STI testing and treatment clinics; sexual and reproductive health centres; sexual assault treatment centres) could be leveraged to deliver NPTs, additional public health resources (infrastructure, financial, human resources, etc.) must be dedicated to ensure the system does not become overloaded. Ensuring the long-term capacity required to deliver existing HIV prevention methods as well as newer technologies will require a significant boost in resources and careful resource distribution.

Areas for Action:

i. **In anticipation of NPT availability, the public health sector should make a case for dedicated funding, additional infrastructure and human resources to avoid overstretching the existing public health system as NPTs are integrated into comprehensive HIV prevention programs.**

ii. **Public health should optimize existing public health programs to ensure appropriate resource distribution, and:**

- **Extend service delivery points (e.g., pharmacies, harm reduction programs, HIV/STI testing clinics, etc.) to key populations at high risk to ensure NPT access.**
- **Further address stigma, discrimination and issues of criminalization that may impede NPT access.**

6.3.2 Expand and Develop Strategic Collaboration and Partnerships

Public health stakeholders understand the importance of working collaboratively with community partners which are often better situated to reach key populations, and of identifying and taking advantage of opportunities for synergy in order to efficiently make use of limited resources and capacity. These partnerships are especially helpful in extending public health's reach to marginalized populations such as gay, bisexual and other men who have sex with men, people who use injection drugs, Aboriginal peoples, people from countries where HIV is endemic, and HIV-positive individuals not accessing care. Strong collaboration with partners and stakeholders was identified as essential to strengthen ongoing prevention efforts and effectively integrate NPTs into existing HIV prevention strategies. It is also important for public health stakeholders to collaborate across departments and across jurisdictions so that there is consistency and cooperation in NPT delivery. Strong partnerships between the federal, provincial and territorial governments will further enable the development of health policy; the allocation of funds for the health system; and the promotion of disease prevention, health promotion and healthy living, all of which will in turn ensure a consistent and comprehensive approach to NPT delivery.

Areas for Action:

iii. **Public health stakeholders should strengthen existing programs through the development of partnerships with other organizations (community-based organizations, AIDS service organizations, primary care providers, HIV specialists) and with vulnerable communities to extend the breadth and cultural appropriateness of existing HIV prevention interventions and address delivery barriers in a coordinated and comprehensive manner.**

iv. **Commit to, and build on, formal mechanisms for collaboration and consensus between levels of government to implement NPTs consistently across jurisdictions.**

6.3.3 Support Modeling, Planning and Implementation Research

Understanding the specifics of each NPT is critical for planning how to approach their implementation. Preliminary decisions on the availability of NPTs should largely be based on research, modeling and planning around the public health impact of specific NPTs, to identify scenarios, plans and recommendations for their use as well as monitoring and evaluation of their impacts. Research, modeling and planning can also inform how best to integrate NPTs into existing prevention programs and campaigns. Particularly important is the use of operations research, with meaningful involvement of vulnerable populations, to identify the optimal

strategies for delivering NPTs. Demonstration projects such as those currently under development in the United States on PrEP[44] and the one currently running in BC on treatment-as-prevention are needed to inform implementation in Canada. Cost-benefit analyses would consider costs of delivery and messaging, manufacturing costs and capacity, supply, associated healthcare costs, infections averted, adherence issues, risk compensation, populations targeted, and medical side effects. Planning will allow for short-, medium- and long-term strategies to be developed to achieve an "overarching public health goal."[45] Identifying delivery challenges due to "existing public health capacity to deliver vaccines and healthcare to specific populations"[41] is particularly important. When considering partially effective NPTs, modeling will play a vital role in determining expected outcomes and exposing potential challenges around uptake, reach, coverage, access, adherence and acceptability.

Areas for Action:

v. **Public health at the national level should support social science research and the development of a multi-sectoral steering committee that will monitor promising HIV technologies and develop modeling, scenarios, plans and recommendations regarding the introduction and delivery of NPTs.**

   - **Develop modeling around a monitoring and evaluation system for prevention programming to measure the impact of existing interventions and to prepare for measuring and comparing the impacts of NPTs.**

   - **Examine how to integrate NPTs into a comprehensive prevention approach and develop HIV prevention messaging to optimize uptake, access and adherence but minimize safety concerns and risk compensation of both existing interventions as well as NPTs.**

vi. **Engage multiple public health jurisdictions with other partners (researchers, community-based service providers, clinicians) in scenario planning and demonstration projects to develop knowledge about the delivery of NPTs for specific populations, to provide cost-benefit analyses, to gauge their possible impact, and to optimize delivery methods to specific communities.**

CHAPTER 7: CONCLUSIONS

This document was designed to provide guidance for the public health community working in HIV prevention to develop policies, resources and programs that address issues of equity and accessibility of new HIV prevention technologies. It outlines the Canadian public health community's understanding, knowledge, information needs, challenges, and potential role with regard to the introduction and delivery of NPTs. The report further assesses the capacity of public health to introduce and deliver NPTs in a timely and equitable manner and identifies areas of action for Canada's public health community.

In describing the challenges public health currently is encountering with delivering existing HIV prevention interventions, we begin to appreciate some of the issues that will be encountered in providing NPTs in a timely and equitable manner as they are proven to work, approved and become available. While Canada's response to HIV has reduced the spread of HIV, public health's unpreparedness to capitalize on the success of recent research is concerning. More must be done to develop public health guidance around existing and emerging prevention technologies, meet information needs, supply needed training and education to the public health community, and optimize existing HIV prevention programs and continue social research for NPTs. There is a growing body of information around NPTs and priorities are quickly shifting from scientific trials to issues of implementation that must be addressed.

Public health has been identified as one of the central mechanisms required for the effective and efficient delivery of NPTs. The public health workforce needs not only to build its own preparedness, knowledge, and capacity, but also to engage more meaningfully in NPT research, policy and planning. This report has outlined a series of areas for action calling on public health leaders at each system level and across jurisdictions for a renewed prevention response to HIV in Canada. The action areas address issues of leadership, policy, guidance, research, partnership, knowledge exchange, resource capacity, information, education, monitoring and evaluation in a manner that identifies the way forward and recommended next steps. The success and failure of NPTs will ultimately be measured by the preparedness of public health to implement these needed interventions and will be judged on how these interventions are introduced, communicated and adopted by the communities that require them most.

APPENDICES

APPENDIX 1: NPT SURVEY QUESTIONS

Description

A growing number of potential HIV prevention technologies are in various stages of clinical research and may "have the potential to significantly reduce the burden of HIV/AIDS around the world". The impact of new HIV prevention technologies in reducing new HIV infections in Canada will depend on how effectively we use them in combination with other available HIV prevention strategies. New HIV prevention technologies include medical male circumcision, HIV vaccines, microbicides, pre-exposure prophylaxis and treatment as prevention. The Canadian Public Health Association (CPHA) is conducting a survey to understand the knowledge, information needs, challenges and potential role of public health workers and civil society in Canada with respect to the introduction and delivery of new HIV prevention technologies throughout Canada. The people kindly requested to respond to this survey are those working in HIV prevention in the following settings: AIDS Service Organization, Community-Based Organization, Community Health Centre, Infectious Disease Clinic, Provincial/Territorial Ministry of Health, Other Non-governmental Organization or Public Health Unit. The results of this survey will inform a CPHA discussion paper to be submitted to the Public Health Agency of Canada in September 2011 on policies, programs and practices related to public health and civil society preparedness for new HIV prevention technologies in Canada. This survey should take 7-10 minutes to complete and is anonymous and confidential. CPHA thanks you in advance for your participation.

1. Where is your organization located? (Province)

- ○ Alberta
- ○ British Columbia
- ○ Manitoba
- ○ New Brunswick
- ○ Newfoundland and Labrador
- ○ Northwest Territories
- ○ Nova Scotia
- ○ Nunavut
- ○ Ontario
- ○ Prince Edward Island
- ○ Quebec
- ○ Saskatchewan
- ○ Yukon

2. What type of organization do you work for?

- ○ AIDS Service Organization (ASO)
- ○ Community Based Organization (CBO)
- ○ Community Health Center
- ○ Infectious Disease Clinic
- ○ Ministry of Health (Provincial)
- ○ Other Non Governmental Organization (NGO)
- ○ Public Health Unit (Health Authority)
- ○ Professional Associations
- ○ Other, please specify: _____

3. Which geographic populations does your organization serve? (Choose all that apply)

- ☐ Urban
- ☐ Rural
- ☐ Remote

4. Please check the types of organizations with which you partner (Choose all that apply)

- ☐ AIDS Service Organizations (ASO)
- ☐ Community Based Organizations (CBO)
- ☐ Community Health Centers
- ☐ Infectious Disease Clinics
- ☐ Ministry of Health (Provincial)
- ☐ Other Non Governmental Organizations (NGO)
- ☐ Public Health Units
- ☐ Professional Associations
- ☐ Other, please specify: _____

5. Approximately how many full-time equivalent employees does your organization have working on HIV-related activities?

6. My organization works in the following areas (Choose all that apply)

- ☐ Awareness-raising, including general information on HIV and AIDS
- ☐ HIV testing/STI testing

- ☐ HIV community outreach
- ☐ HIV care (medical treatment)
- ☐ HIV support and counseling
- ☐ HIV and AIDS treatment information
- ☐ Needle exchange
- ☐ Other harm reduction programs
- ☐ HIV research
- ☐ HIV policy
- ☐ HIV advocacy
- ☐ Other, please specify: _____

7. Do you have any specific programs or projects that target key populations at higher risk of HIV exposure? (Choose all that apply)

- ☐ Aboriginal peoples
- ☐ At risk youth
- ☐ Gay, bisexual and other men who have sex with men
- ☐ People from countries where HIV is endemic
- ☐ People who inject drugs
- ☐ Prison inmates
- ☐ Sex workers and their clients
- ☐ Women
- ☐ No programs or projects that target key populations at higher risk of HIV exposure

8. How many HIV-related client contacts does your organization deal with on a monthly basis?

- ○ 0-250
- ○ 251-500
- ○ 501-1000
- ○ 1000+
- ○ Not applicable

9. I am knowledgeable about the following types of HIV prevention technologies/approaches (please select for each)

	strongly agree	agree	disagree	strongly disagree

Female/Internal condoms	○	○	○	○
Harm reduction strategies	○	○	○	○
Medical male circumcision	○	○	○	○
Treatment as prevention	○	○	○	○
Post-exposure prophylaxis	○	○	○	○
HIV vaccine	○	○	○	○
Male condoms	○	○	○	○
Microbicides	○	○	○	○
Pre-exposure prophylaxis	○	○	○	○
Prevention of mother-to-child transmission	○	○	○	○
Voluntary confidential counseling and testing	○	○	○	○
Partner notification	○	○	○	○
Health promotion messaging	○	○	○	○

10. Which statement is true regarding microbicides?

○ It is a substance usually in pill form the purpose of which is to reduce the risk of HIV infection during vaginal or rectal intercourse.

○ It is a substance usually in gel, cream or suppository form the purpose of which is to reduce the risk of HIV infection during vaginal or rectal intercourse.

○ It is a substance usually in gel, cream or suppository form that eliminates the risk of HIV infection during vaginal or rectal intercourse.

11. Which statement is true regarding HIV oral pre-exposure prophylaxis?

○ It is a one-time pill taken prior to a single exposure to HIV; its purpose is to prevent, rather than treat or cure HIV.

○ It is a pill regimen started before exposure to HIV; its purpose is to prevent, rather than treat or cure HIV.

○ It is a pill regimen started immediately after exposure to HIV; its purpose is to prevent infection and development of disease.

12. When was the last time you received training/education in HIV prevention?

○ In the last year

○ Two to five years ago

○ Over five years ago

○ Never

13. The knowledge/skills that I gained during the HIV prevention training/education session(s) I attended was valuable to my practice

strongly agree	agree	disagree	strongly disagree	not applicable
○	○	○	○	○

14. The HIV prevention training/education curriculum discussed new HIV prevention technologies

○ Yes

○ No

15. In my organization I believe education/training regarding HIV prevention is needed for the following (please select for each)

	strongly agree	agree	disagree	strongly disagree
Female/Internal condoms	○	○	○	○
Harm reduction strategies	○	○	○	○
Medical male circumcision	○	○	○	○
Treatment as prevention	○	○	○	○
Post-exposure prophylaxis	○	○	○	○
HIV vaccine	○	○	○	○
Male condoms	○	○	○	○
Microbicides	○	○	○	○
Pre-exposure prophylaxis	○	○	○	○
Prevention of mother-to-child transmission	○	○	○	○
Voluntary confidential counseling and testing	○	○	○	○
Partner notification	○	○	○	○
Health promotion messaging	○	○	○	○

16. What is your preferred way of receiving education/training regarding HIV prevention? (Choose all that apply)

☐ Webinars

☐ Online courses

☐ In-person courses

☐ Presentations/workshops

☐ Multimedia

☐ Other, please specify: _____

17. How do you get your information on HIV prevention? (Choose all that apply)

☐ Websites

☐ Scientific literature

☐ Grey literature

☐ Databases

☐ Peer to peer

☐ Interact with researchers

☐ Media

☐ Listserv or blog

☐ Presentations/workshops

☐ Published reports

☐ Other, please specify: _____

18. What is your preferred way of receiving information regarding HIV prevention? (Choose all that apply)

☐ Websites

☐ Scientific literature

☐ Grey literature

☐ Databases

☐ Peer to peer

☐ Interact with researchers

☐ Media

☐ Listserv or blog

☐ Presentations/workshops

☐ Published reports

☐ Other, please specify: _____

19. My organization is providing HIV prevention interventions in a timely and equitable manner

strongly agree	agree	disagree	strongly disagree	not applicable
○	○	○	○	○

20. HIV prevention technologies/approaches are being promoted effectively by my organization (please select for each)

	strongly agree	agree	disagree	strongly disagree	not applicable
Male condoms	○	○	○	○	○
Post-exposure prophylaxis	○	○	○	○	○
Female Condoms	○	○	○	○	○
Medical male circumcision	○	○	○	○	○
Harm reduction	○	○	○	○	○
Partner Notification	○	○	○	○	○
Preventing mother-to-child transmission	○	○	○	○	○
Voluntary confidential counseling and testing	○	○	○	○	○
Health promotion messaging	○	○	○	○	○

21. In my organization HIV prevention interventions are reaching key populations at high risk of exposure to HIV (please select for each)

	strongly agree	agree	disagree	strongly disagree	not applicable
Aboriginal peoples	○	○	○	○	○
At risk youth	○	○	○	○	○
Gay, bisexual and other men who have sex with men	○	○	○	○	○
People from countries where HIV is endemic	○	○	○	○	○
People who inject drugs	○	○	○	○	○
Prison inmates	○	○	○	○	○
Sex workers and their clients	○	○	○	○	○
Women	○	○	○	○	○

22. I feel that HIV prevention messaging is appropriate and reaching key populations at high risk of exposure to HIV with which I work

strongly agree	agree	disagree	strongly disagree	not applicable
○	○	○	○	○

23. What are the constraints and barriers to implementing HIV prevention effectively in your everyday practice? (Choose all that apply)

- ☐ Lack of/restrictive policies
- ☐ Lack of funding
- ☐ Lack of public health guidance
- ☐ Lack of human resource capacity
- ☐ Lack of understanding of importance
- ☐ Stigma and discrimination
- ☐ Community and cultural norms
- ☐ Lack of leadership
- ☐ Lack of partnership
- ☐ No anonymous testing
- ☐ Criminalization
- ☐ Poor information, education and communication campaigns
- ☐ Geographic location of target populations
- ☐ Lack of information/training among staff
- ☐ Lack of program development capacity
- ☐ No constraints/barriers
- ☐ Other, please specify: _____

24. What enables the implementation of effective HIV prevention in your everyday practice? (Choose all that apply)

- ☐ Policies
- ☐ Funding
- ☐ Public health guidance
- ☐ Human resources capacity
- ☐ Understanding of importance
- ☐ Tolerance and acceptance
- ☐ Community and cultural norms
- ☐ Leadership
- ☐ Partnership
- ☐ Anonymous testing
- ☐ Good information, education and communication campaigns
- ☐ Well informed staff with appropriate training

- ☐ Program development capacity
- ☐ No enablers
- ☐ Other, please specify: _____

25. Within my organization I believe I can influence the following regarding HIV prevention (please select for each)

	strongly agree	agree	disagree	strongly disagree
Accessibility	○	○	○	○
Acceptability	○	○	○	○
Awareness	○	○	○	○
Adherence	○	○	○	○
Quality	○	○	○	○
Equity	○	○	○	○
Messaging	○	○	○	○
Delivery	○	○	○	○

26. My organization stays current on new HIV prevention technology research

strongly agree	agree	disagree	strongly disagree	not applicable
○	○	○	○	○

27. My organization is responsive enough to deliver new HIV prevention technologies in a timely and equitable manner once they are approved

strongly agree	agree	disagree	strongly disagree	not applicable
○	○	○	○	○

28. I believe new HIV prevention technologies will play an important role in reducing the spread of HIV

strongly agree	agree	disagree	strongly disagree
○	○	○	○

29. HIV is an important public health issue for your region

strongly agree	agree	disagree	strongly disagree
○	○	○	○

30. HIV prevention is sufficiently prioritized within your provincial/territorial HIV policy documents

strongly agree	agree	disagree	strongly disagree
○	○	○	○

31. My work in HIV prevention is guided by standards, policies, practices and guidelines at the- (please select for each)

	strongly agree	agree	disagree	strongly disagree	not applicable
International level	○	○	○	○	○
National level	○	○	○	○	○
Provincial/Territorial level	○	○	○	○	○
Organizational level	○	○	○	○	○
Professional association level	○	○	○	○	○
Cultural appropriateness	○	○	○	○	○

32. I have participated in developing HIV prevention

	Yes	No
Policies	○	○
Programs	○	○

Sex

○ Male

○ Female

○ Other

Age-

[ ]

Highest level of education achieved

○ Secondary

○ Undergraduate

○ Graduate

○ PhD

○ BScN

- ○ MD
- ○ Other

Occupation

Years experience working with HIV

Comments

APPENDIX 2: WEBINAR SERIES TOPICS

Webinar Series
New HIV prevention technologies and their implications for HIV prevention in Canada

Canadian Public Health Association (CPHA), CATIE, the Interagency Coalition on AIDS and Development (ICAD) and the Canadian AIDS Society (CAS) developed a webinar series exploring new HIV prevention technologies (NPTs) and their implications for HIV prevention in the Canadian context.

Webinar 1

New HIV prevention technologies (NPTs) - The basics and the state of the research

English: Tuesday, July 12th, 2011 (2pm-3pm EST)
French: Wednesday, July 13th, 2011 (2pm-3pm EST)

If you're wondering what all the buzz is about around new HIV prevention technologies, you're not alone. Recent research advances have reinvigorated the field, with new findings around medical male circumcision, female condoms, vaccines, microbicides and ARV-based prevention strategies.

Join this webinar to learn about the basics of new HIV prevention technologies – what they are, what the research tells us and what it means in the Canadian context.

Webinar 2

Preparing for NPTs: Learning from the past and preparing for the future

English: Wednesday, July 27th, 2011 (2pm-3pm EST)
French: Thursday, July 28th, 2011 (2pm-3pm EST)

New prevention technologies like PrEP, microbicides and vaccines are starting to show promise in research studies. Advances in research raise questions about the challenges that exist for roll out in communities, how to ensure equitable access and how to successfully incorporate NPTs into the wider HIV prevention landscape.

Join this webinar to learn about what's already known about the potential challenges to NPT roll out and how to prepare for an HIV prevention landscape that includes NPTs.

Webinar 3

Can we prevent infection with HIV after an exposure? The world of post-exposure prophylaxis (PEP)

English: Wednesday, August 3rd, 2011 (2pm-3pm EST)
French: Thursday, August 4th, 2011 (2pm-3pm EST)

Much of the work we do in HIV prevention is aimed at trying to stop people from engaging in behaviors that could expose them to HIV and potentially lead to infection. But what happens if someone thinks they may have recently been exposed to HIV? Is there a way we can stop them from getting infected? Post-exposure prophylaxis, or PEP, could be an option.

Join this webinar to learn about how PEP works, when it can be used, and why it isn't more available for certain types of exposures.

Webinar 4

Preparing for pre-exposure prophylaxis (PrEP) to prevent HIV infection

English: Wednesday, August 10th, 2011 (2pm-3pm EST)
French: Thursday, August 11th, 2011 (2pm-3pm EST)

What if a person at risk of HIV infection could start taking preventative medications on a regular basis *before* being exposed to HIV in order to reduce their risk of infection? This strategy, known as pre-exposure prophylaxis (or PrEP), is beginning to show promise in research studies and could potentially provide another much needed prevention option for those at risk of infection. Despite its promise, this strategy raises a number of concerns and—if we aren't prepared—its introduction could end up doing more harm than good.

Join this webinar to learn about the PrEP research, the concerns that PrEP raises, and how we can make sure these concerns are avoided.

Webinar 5

Are people living with HIV less likely to pass HIV to others if they are on treatment? Exploring the use of treatment as prevention

English: Wednesday, August 24th (2pm-3pm EST)
French: Thursday, August 25th (2pm-3pm EST)

You may have heard that people living with HIV are less likely to pass HIV to others if they are on treatment - a strategy often referred to as "treatment as prevention"- but many misconceptions and unanswered questions still remain. How effective is treatment at reducing the risk of transmission? Does an undetectable blood viral load mean that someone can't transmit HIV through unprotected sex? What exactly is a "test and treat" strategy?

Join this webinar to learn the answers to these questions and get updated on the latest research.

APPENDIX 3: CAHR ANCILLARY EVENT OVERVIEW

Emerging New HIV Prevention Technologies: Community and Public Health Preparedness in Canada

Overview

The Canadian AIDS Society (CAS), the Interagency Coalition on AIDS and Development (ICAD), the Canadian AIDS Treatment Information Exchange (CATIE) and the Canadian Public Health Association (CPHA) worked in close partnership to highlight the importance of HIV prevention technologies development in the Canadian response to HIV. This ancillary meeting brought together researchers, community and public health workers, healthcare providers/physicians, community members and government stakeholders to explore whether and how new HIV prevention technologies may be advanced for use in Canada.

Session Purpose

The purpose of the event was to bring communities and researchers together with other key stakeholders to foster a dialogue in light of the recent encouraging HIV NPT trial results.

Session Objectives

The objectives for the meeting were: to promote continuing dialogue and partnership between researchers, communities and other stakeholders; to identify specific research, policy needs and capacities in the area of new prevention technologies; and to foster further NPTs development in Canada and partnership between communities and researchers.

Part 1: Presentations

Part 2: Discussion Questions

Question 1: When looking at partnerships and stakeholder engagement from the iPrEx experience, what are some of the key lessons learned and best practices?

Question 2: How can researchers, public health and communities work together to advance the new HIV prevention technology agenda/process?

APPENDIX 4: CPHA PRE-CONFERENCE SESSION OVERVIEW

Preparing the Canadian Public Health Community for New HIV Prevention Technologies

Overview

CPHA, as part of the Preparing the Public Health Community for HIV NPTs project, conducted a session to draw on the experience of the public health community on the topic of new HIV prevention technologies. Participants engaged in a dialogue on how public health can capitalize on the potential success of new HIV prevention technologies and research as part of Canada's response to HIV.

Session Objective

To improve understanding of the potential role and capacity of public health with respect to the introduction and delivery of an HIV vaccine and other new prevention technologies in Canada.

Part 1: Presentation & Participatory Discussion Questions

98% of survey respondents feel new HIV prevention technologies will play an important role in reducing the spread of HIV, however, much remains to be done to engage public health in discussions around new HIV prevention technologies.

Question 1: Should public health be engaged with new HIV prevention technologies at this point? If so, how?

Part 2: Scenario Questions

Scenario 1: Vaccine

A vaccine has been shown to reduce the risk of acquiring HIV by 60%. Among those who still become HIV-positive despite being vaccinated, it leads to slower disease progression (stronger immune response; less virus circulating in their system). The vaccine subsequently has received approval by Health Canada and the National Advisory Committee on Immunization (NACI) recommends its use in certain key populations at higher risk (e.g., gay, bisexual and men who have sex with men, people who inject drugs). The vaccine is safe except for a few minor side effects, and is effective against the HIV strains circulating in Canada, though a full vaccination course will require three injections during the first year.

Overall it is heralded as a major step in the response to HIV. However, there is concern about uptake due to the stigma surrounding HIV and opposition to vaccines.

What is the role of public health in the introduction and delivery of this HIV vaccine in Canada? And what is the place of an HIV vaccine in current prevention efforts?

Scenario 2: Microbicides

A trial that assessed the effectiveness and safety of a vaginal gel formulation for the prevention of HIV acquisition in women has successfully completed trials showing an efficacy of 75%. The drug showed very few side effects and is cheap, but efficacy rates varied according to adherence to the product and the proper application method of the product. This product is safe for rectal use but efficacy has not yet been confirmed by ongoing trials. The new biomedical intervention has not yet received approval from the regulatory authority but is certain to be licensed even though the process takes several months. Since its main active ingredient is an antiretroviral drug, a prescription will be required to access the gel.

This vaginal gel could potentially offer protection to women unable to successfully negotiate mutual monogamy, power relations or condom use.

What is the role of public health in the introduction and delivery of microbicides in Canada? And what is the place of microbicides in current prevention efforts?

Scenario 3: PrEP

The results of a pre-exposure prophylaxis (PrEP) trial with HIV-negative gay and bisexual men and transgender women has shown that study participants who took the daily oral antiretrovirals experienced an average of 43.8% fewer HIV infections than those who received a placebo pill. However, trial participants who reported taking the drug on 90% or more days had 72.8% fewer HIV infections. The trial concluded that the once-daily pill was safe and effective but that it is a powerful pharmaceutical. The pill used in the trial is already licensed and being used to treat people living with HIV.

Since the release of the trial results, some members of key populations at higher risk, organizations working with HIV and others are demanding access to PrEP as reports of off-label use become more common.

What is the role of public health in the introduction and delivery of PrEP in Canada? And what is the place of PrEP in current prevention efforts?

APPENDIX 5: KEY INFORMANT INTERVIEW GUIDE

Research Question

What should public health be doing regarding the introduction of an HIV vaccine and other new prevention technologies, and what needs to be done to enable them to do so?

Purpose

To understand the role and capacity of public health in HIV prevention; particularly the implementation of an HIV vaccine and other new prevention technologies.

Informants

Our informants will be key individuals with experience working in HIV prevention in Public Health Units and Regions, Provincial/Territorial Health Ministries, Governmental and Non-governmental organizations.

Informant Interview Questions

1) In your opinion, what is the role for public health vis à vis HIV prevention in Canada today?

2) In your opinion, is public health doing a good job of preventing the spread of HIV in Canada?

3) What should public health currently be doing regarding the introduction of HIV vaccines and new HIV prevention technologies?

4) What role do you think HIV vaccines and other new prevention technologies will play in reducing the spread of HIV in Canada?

5) Enablers and Barriers…
    i) What do you see as enablers to public health implementation of existing and new HIV prevention technologies?
    ii) What do you see as barriers to public health implementation of existing and new HIV prevention technologies?

6) Assuming an HIV vaccine or other new prevention technology is shown to be safe and effective for widespread use,
    i) What guidance is needed for public health in Canada to successfully implement it?
    ii) What might the guidance look like?
    iii) Where should it come from, ideally? For example, should it come from a government organization or ministry, multi-sectoral, etc.?

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