More than Just Rolling up Your Sleeve:

AN HIV VACCINE PREPAREDNESS TOOLKIT FOR CANADIAN COMMUNITIES

September 2011

CANADIAN AIDS SOCIETY
SOCIÉTÉ CANADIENNE DU SIDA

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Also available online at: www.vaccines.cdnaids.ca

This document is also available in French, titled: Pas qu'une manche à retrousser :

La préparation à un vaccin contre le VIH parmi les communautés canadiennes.

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Introduction to HIV Vaccine Trials and HIV Vaccines for Canadian Communities

These toolkits are based on research on the Canadian experience with public health programs, and on community and international consultations held in the spring and summer of 2010.

Wherever possible, best practices and lessons learned were adapted from those used by community members, service providers and public health officials working in Canada.

There is no preventive or therapeutic HIV vaccine available anywhere in the world. Recently, progress has been made in the basic science that leads to HIV vaccines, and promising new discoveries in the search for other new prevention technologies (NPTs). This should give us hope that NPTs will soon help reduce HIV transmission in Canadian communities.

In the last two years, researchers proved that a vaginal microbicide, an oral pre-exposure prophylaxis (PrEP) and an HIV vaccine could reduce HIV infections in clinical trials. The discoveries suggest that it's important to be prepared for the availability of NPTs. Their availability in Canada will significantly change the way in which HIV prevention programs are developed. Encouraging combination prevention—the use of NPTs with other prevention methods like condoms— will be essential to using NPTs and vaccines to their fullest to reduce HIV transmission rates.

HIV vaccine preparedness isn't just about making sure a vaccine is available to everyone when one finally exists. It also means educating people on HIV vaccine research and helping them to develop the skills to follow research developments in the media. Vaccine preparedness can also mean encouraging people to get involved in bringing HIV vaccines to the public and by engaging people in discussions of how a vaccine could reduce their own risk for getting HIV. Canada has hosted HIV vaccine trials in the past, and each trial that Canada hosts builds capacity and knowledge among Canadian communities. Because of this, it's likely that future HIV vaccine trials will take place in Canada.

The Canadian AIDS Society has, with generous funding from the Canadian HIV Vaccine Initiative (CHVI), developed HIV vaccine preparedness toolkits for service providers in AIDS service organisations, in community-based organisations, and in community health centres. These primers were designed to be used to raise awareness of and interest in:

- the HIV vaccine trial process;
- HIV vaccine trials in Canada and globally; and
- future deployments of HIV vaccines in Canada.

There are specific resources for Canada's African, Caribbean and Black populations; for people who use injection drugs; for women between the ages of 18 and 29; for gay men and other men who have sex with men; and for people living with HIV/AIDS. Many people will belong to more than one of these populations, so users are encouraged to take resources from all of the toolkits to build a toolkit that is specifically relevant for them and their clients. The toolkits offer information on topics as varied as the basic science of vaccines and the immune system to the action on HIV vaccine development that needs to be taken at the local, national and international levels throughout the clinical trial process.

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The Immune System

The immune system is the body's defense against germs and other invaders that cause infection. Through a series of steps called the immune response, the immune system attacks germs and substances that invade the body and cause disease. This info sheet provides a basic overview of the immune system, how HIV attacks it and how a preventive vaccine would help the immune system fight an HIV infection.

Think of your immune system as an army.

Each component has a specialized role to play to prevent infection.

- Phagocytes, a type of white blood cell, are the infantry.
- Macrophages, another type of white blood cell, are leaders of the infantry who have the special task of alerting the rest of the defence system to an invasion. They start the initial attack on the invaders and display some of their parts so that the specialized army units can identify and eliminate them.
- T- and B-cells are the specialized units. B-cells make antibodies against invaders that the body has already been in contact with before. T-cells recognize invaders that the body has never encountered. The type of T-cell that recognizes invaders is called a CD4 cell. CD4 cells are in charge of sending the signal that an invasion has occurred and mobilising the troops that can battle the virus. Another type of T-cell, known as the killer T-cell, is responsible for killing invaders when CD4 cells give the order.

Think of an infection as a war.

Stage I: Battle Begins

An invader penetrates the body's defences, getting in through the lungs, the skin or through blood or sexual contact. Phagocytes alert the CD4 cells that an invader has entered the body by displaying parts of a captured invader to the other units.

Stage II: Forces Multiply

Once the CD4s know the invader, they get the rest of the defence system to attack and destroy the invaders.

Stage III: Attack and victory

Viruses use our bodies to make copies of their DNA, and they break into our cells to do so. In this stage, killer T-cells have instructions from the CD4 cells to attack and crack open the infected cells, making them spill out their contents. This defeats them.

Stage IV: End of the War!

With the defeat of the invaders, the war is over and the troops are called off. B-cells, also called memory troop cells, will patrol the blood and provide protection against the same invaders in the future. This is what prevents us from getting the same virus twice.

Now think of HIV as the ultimate invader.

Like other viruses, HIV needs a living cell to make copies of itself. Unlike other viruses, HIV attacks CD4 cells, the cells that recognize invaders the body has never encountered before. Because CD4s are so important in alerting the defense system to kill an infection, this increases the power of HIV to beat the immune system.

The body does defend itself against HIV for a time. We know this because people can live with HIV and have no symptoms for years. Ultimately though, HIV changes its armour and shield enough over time that the defences that our body puts up become useless. HIV copies itself inside a cell and it sometimes spells its genetic code wrong while doing this, creating an HIV virus with a different makeup. This makes it difficult and then impossible for the immune system to defend itself against all the different formations of HIV in a body.

There's still no way to cure HIV once you've gotten it. Getting a vaccine against HIV before the body comes into contact with it will help prevent this ultimate invader from attacking the immune system.

How does a vaccine help the immune system defend itself?

A vaccine is basically a trick that you play on your body. A vaccine teaches the body how to fight an invader by faking an invasion. This is done before a real invader has gotten passed the body's defences. A vaccine only knows how to fight a single invader, which is why we get different vaccines against different viruses and bacteria.

How Preventive Vaccines Work

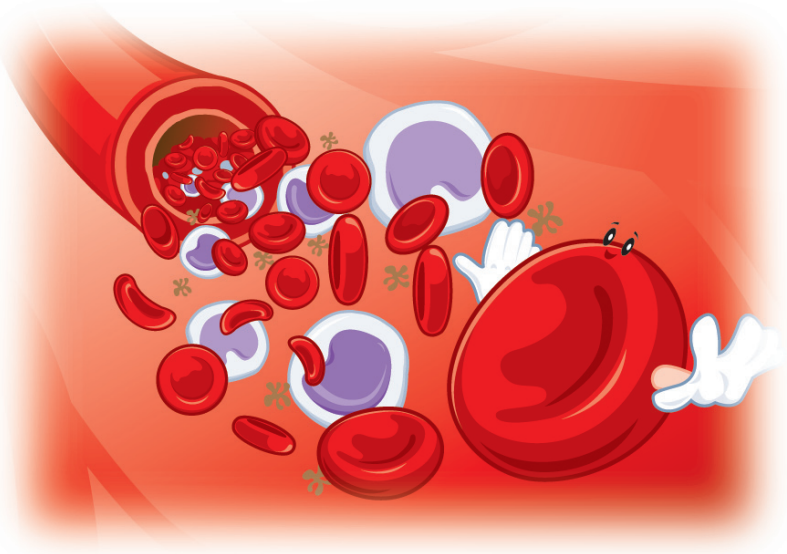
1. A vaccine introduces a safe form of a virus or germ into the body. These are called antigens or immunogens. They resemble the bacteria enough that they trigger a response from the immune system, which is like the war that takes place when a real infection happens.
2. The vaccine, with its pieces of the invader, makes the immune system call up its army, including the B-cells that produce antibodies against the specific virus, and the T-cells, which learn what the invader looks like. If the invader ever returns to the body, the T-cells will recognize and attack it.
3. If the immune system is ever exposed to the actual invader, the immune system will already know how to defend itself and will, in most cases, fight the infection.

For More Information

CDC. (n.d). *Your Immune System*. Available: http://www.bam.gov/sub_diseases/diseases_immuneplatoon_immunesys.html.

IAVI. (2008). *Diagram : Understanding the Immune System and AIDS Vaccine Strategies.* http://www.iavi.org/publications-resources/pages/PublicationDetail.aspx?pubID=a65ac44b-76d6-4e9f-b56a-398b45fa87d8

SAAVI. (2008). *The HIV Vaccines Community Education Programme.* Available: http://www.saavi.org.za/resources.htm.



HIV Vaccine Trial Process—PREVENTIVE Vaccines[1]

This info sheet outlines the vaccine trial process for potential trial participants and for those following the development of HIV vaccines in the media. It provides an overview of the steps in the process, the types of volunteers needed and the actions that service providers and community members can take along the way to make sure that participants are respected.

Every trial vaccine has to go through a rigorous clinical trial process to prove that the vaccine is safe. For preventive vaccines, clinical trials figure out if a vaccine is efficacious at reducing the risk of HIV transmission.

I. Pre-Clinical Studies or Pre-Human Studies

In the case of HIV, vaccines—known as trial vaccines during the clinical trial process—that are effective in labs are then tested in animals.

In order for trial vaccines to be deemed suitable for human trials, scientists must believe there is going to be a significant chance that the trial vaccine will provide useful results in human trial participants.

II. Clinical Trials or Human Trials

Most HIV vaccine trials are randomized, double-blind, and placebo-controlled. This means that neither the participants nor the researchers know who got the vaccine and who got the placebo. The placebo is exactly like the vaccine except without the active ingredient. At all stages, participants receive an HIV prevention package, including condoms, counselling and treatment for any STIs they may develop. They are also reminded at every visit that they can't be sure they received the trial vaccine, that the vaccine might not work, and that they should use proven HIV prevention methods when possible.

Until all three phases of the process have been completed, researchers don't know the effect of the trial vaccine on a person's risk for HIV transmission. The **level of risk of HIV infection may be less, the same or more** than if the person didn't receive the trial vaccine. Because of this, it's important that other HIV prevention methods are used, including condoms and clean injection equipment, so that the risk that volunteers get HIV during the trial is as low as possible.

[1] A modified version of this info sheet is available on therapeutic HIV vaccines.

PHASES OF THE CLINICAL TRIAL PROCESS AND POTENTIAL COMMUNITY ACTION

PHASE Phase I: Safety

NUMBER AND TYPE OF TRIAL PARTICIPANTS

Enrols 20-120 participants who are:

- Healthy adults over 18 years of age.
- HIV negative.
- People at low risk for HIV infection.

DURATION

The trial can take 12-18 months.

3-4 months is also needed to study the data and produce results.

MEASURING SUCCESS AND MOVING FORWARD

At the end of phase I, a vaccine would be considered for phase II if no serious side effects were identified and if the vaccine was well-tolerated by participants.

A vaccine would not be considered for a phase II trial if serious side effects developed in the participants.

Many trial vaccines never progress past this phase.

AIMS To determine:

- the safety of the vaccine in humans. This will establish if there are any serious side effects.
- the tolerance of the vaccine in humans. This will determine how our bodies react to the vaccine.
- the immunogenicity of the vaccine. This will determine if the vaccine causes an immune response.

COMMUNITY ACTION

The community's concerns and contributions must be taken seriously during the trial process. These actions are applicable at every phase of the process, not just in the first phase.

This is usually done through the creation of community advisory boards (CABs) that reflect the community's needs and diversity and defend their rights before, during and after the trial.

CABs, in turn, will be able to work on behalf of the community for:

A true knowledge exchange between communities and researchers, including making sure that the community understands the need for and the goals of the research, and making sure that researchers understand the unique needs and strengths of the community.

The ethical recruitment and informed consent of participants.

Access to a gold standard of harm reduction/risk reduction services, including clean injection equipment, counselling, family planning services, HIV testing, and treatment for STIs.

Research on, and the development of, culturally-appropriate and accessible information about how vaccines can and cannot protect people needs to be done. This information also needs to be made available to both the research participants, and to the communities in which trials take place. This will ultimately serve as a foundation for future HIV vaccine information that will be made available when a vaccine is licensed.

These goals could also be achieved through the engagement of a wider section of civil society, in addition to the establishment of CABs. Civil society groups could include faith and cultural organisations and community-based organisations that don't necessarily do work in HIV. Individuals who are interested in HIV vaccine trials should encourage all groups to which they belong to consider getting involved in the HIV vaccine trial process. This should ensure that the needs and rights of participants are as accurately reflected as possible.

PHASE Phase II: Safety

NUMBER AND TYPE OF TRIAL PARTICIPANTS

Enrols between 100-500 who are:

- Healthy adults over 18 years of age.
- HIV negative.
- Both people at low and high risk for HIV infection.

AIMS To determine:

- the safety of the vaccine in humans. This will establish if there are any serious side effects.
- the immunogenicity of the vaccine. This will determine if the vaccine causes an immune response.
- to find the best dose route, or way to give the vaccine.
- to determine when, how much and how often to give the vaccine (dose and regimen).

DURATION

The trial can take 1-2 years.

4-6 months is also needed to study the data and produce results.

MEASURING SUCCESS AND MOVING FORWARD

At the end of phase II, a vaccine would be considered for phase IIb or phase III if there continues to be no serious side effects and a usable regimen is developed.

A vaccine would not be considered for future phases if serious side effects developed in the participants or if harmful immune responses were detected.

Many trial vaccines never progress past this phase.

PHASE Phase IIb: Proof of Concept

NUMBER AND TYPE OF TRIAL PARTICIPANTS

Enrols 1000-5000 participants who are:

- Healthy adults over 18 years of age.
- HIV negative adults.
- Both people at low and high risk for HIV infection, although usually those at high risk are favoured for enrolment in this phase.

AIMS To determine:

- proof-of-concept. This phase demonstrates if the vaccine protects a person against HIV infection.
- whether the vaccine strategy might work to reduce the risk of HIV transmission.
- whether a Phase III trial should be conducted.

DURATION

2-5 years, including time to study the data and produce results.

MEASURING SUCCESS AND MOVING FORWARD

At the end of phase IIb, a vaccine would be considered for phase III if the vaccine reduced the risk of HIV transmission.

A vaccine would not be considered for future phases if the vaccine didn't demonstrate an ability to reduce the risk of infection or if it increased the risk of infection in some participants.

Merck's V520 vaccine was considered a failure at this stage as it may have increased the susceptibility of some participants to HIV infection.

PHASE Phase III: Safety and Efficacy

AIMS To determine:

- whether the vaccine protects against HIV infection.

NUMBER AND TYPE OF TRIAL PARTICIPANTS

Enrols between 1000-20000 participants, who are:

- Healthy adults over the age of 18.
- HIV negative. Both people at low and high risk for HIV infection although usually those at high risk are favoured for enrolment in this phase.

DURATION

3-4 years to vaccinate all of the participants.

12-18 months to study the data and produce results.

3-4 years of follow up to determine if vaccination slows the progress of the virus in those who received the vaccine and also contracted HIV during the trial.

MEASURING SUCCESS AND MOVING FORWARD

At the end of phase III, a vaccine would be considered for licensure by Health Canada and other international regulatory bodies if it proved to provide a significant protection against HIV infection. A vaccine wouldn't be considered for licensure if it didn't demonstrate an ability to provide significant protection against HIV infection.

It's unknown what efficacy would have to be achieved for Health Canada to issue a license. The US FDA has suggested they would license a vaccine that is 50% efficacious.

Even with a clear result that a vaccine strategy does reduce risk of transmission, there might be more Phase III trials conducted on the same vaccine to confirm this result.

Measuring the Benefits of a Vaccine

Everyone in an HIV vaccine trial, whether they received the vaccine or the placebo, receives the best HIV vaccine prevention package available, including access to STI treatment, condoms and HIV prevention counselling. No one is intentionally exposed to HIV. In order to measure the benefit of a preventive vaccine, researchers compare the rates of new infections in the participants who received the trial vaccine to those that received the placebo.

How do researchers know if a vaccine worked?

If there are significantly fewer infections in those that received the trial vaccine and the prevention package when compared to those who received the placebo and the same prevention package, and **if the difference is greater than can be reasonably attributed to chance** (statistical significance), this suggests that the trial vaccine reduced the risk of HIV transmission.

Vaccine Licensure

Once a vaccine has gone through Phase III testing, and if it reduced HIV transmission, an application for a license to distribute the vaccine can be made by the vaccine developers or other bodies who are authorized by the vaccine developers to do so. This is done through Canada's regulatory bodies. A single Phase III trial doesn't mean that a license will be sought for the vaccine. Usually, a second confirmatory trial will be done to confirm the first trial's results. The licensing process can take years. For more information on the licensing process for vaccines in Canada, please visit the Health Canada website at www.hc-sc.gc.ca.

References

AVAC. (n.d). *Clinical Trials.* Available: http://www.avac.org/ht/d/sp/i/298/pid/298.

IAVI. (2009). *VAXLit:AIDS Vaccine Literacy Toolkit.* Available: http://www.iavi.org/working-with-communities/Pages/vaccine-literacy.aspx.

International Centre for Research on Women and IAVI. (2008). *Clinical Science Meets Social Science: Gender and AIDS Vaccine Research.* Available: http://www.icrw.org/publications/clinical-science-meets-social-science.

National Institutes of Health. (2007). *Understanding Clinical Trials.* Available: http://www.clinicaltrials.gov/ct2/info/understand#Q06.

SAAVI. (2008). *HIV Vaccines Learner's Handbook.* Available: http://www.saavi.org.za/resources.htm.

POST CLINICAL TRIAL PROCESS AND POTENTIAL COMMUNITY ACTION

PHASE
Licensing/Regulatory Process

AIMS
To determine:

- if the clinical trial process was sound.
- whether the vaccine is safe and that there is significant benefit to licensing the vaccine and allowing it to be sold to the Canadian public.

NUMBER AND TYPE OF TRIAL PARTICIPANTS

At this stage there are no participants, and given the bureaucratic nature of licensing processes, it is difficult to determine how long it could take.

COMMUNITY ACTION

Ensuring that the vaccine licensing process is efficient and thorough.

Ensuring that the National Advisory Committee on Immunisation issues its recommendations in a timely fashion if the vaccine is licensed.

Ensuring that the Public Health Agency of Canada prepares a public health response that is effective and culturally-appropriate.

PHASE
Development of an Effective Public Health Response

AIMS

- To raise awareness of the availability of a vaccine, and the benefits and risks of vaccination.
- To ensure that Canadians are encouraged to evaluate their risk for HIV infection honestly and to determine for themselves if an HIV vaccine is an appropriate HIV prevention strategy for them.

NUMBER AND TYPE OF TRIAL PARTICIPANTS

Developing an effective public health response requires extensive consultation and could take months or even years. Ideally these conversations would take place throughout the clinical trial process.

COMMUNITY ACTION

At this stage, there are several issues that need to be addressed:

Communities and organisations must engage public health officials and politicians to making sure that culturally-appropriate and accessible information about how vaccines can and cannot protect people is developed and distributed.

Consent guidelines for youth and for those who temporarily or permanently lack the capacity to provide informed consent, including those under the influence of drugs and alcohol and those with developmental disabilities must be written, debated and standardized.

Broad and affordable access to an HIV vaccine must be secured so that every individual who might benefit receives the vaccine.

This access should include broad and fair access in developing countries where vaccines could have the most impact on reducing HIV transmission.

PHASE

Phase IV: Postlicensure/Field Studies

NUMBER AND TYPE OF TRIAL PARTICIPANTS

Participants are recruited from the general public and are usually in the thousands.

DURATION

It takes several years to see what effect a vaccine has on the general public.

AIMS

The aims are to:

- test the effectiveness of the vaccine in the general public in real life conditions and to determine how the vaccine reduces the number of new HIV infections.
- check for rare adverse drug reactions and to test how well the vaccine does when stored, transported and distributed on a large scale.

COMMUNITY ACTION

In this phase of the process, efforts shift to ensuring that trials:

Explore the maximum benefits of the vaccine, while exposing the short/long term effects.

Ensure that youth/pregnant women are followed to determine efficacy in their populations.

HIV Vaccine Trial Process—THERAPEUTIC Vaccines[2]

This info sheet outlines the vaccine trial process for potential trial participants and for those following the development of HIV vaccines in the media. It provides an overview of the steps in the process, the types of volunteers needed and the actions that service providers and community members can take along the way to make sure that participants are respected.

Every trial vaccine has to go through a rigorous clinical trial process to prove that the vaccine is safe. For therapeutic vaccines, clinical trials figure out if a vaccine is efficacious at slowing the progression of HIV to AIDS.

As a therapeutic HIV vaccine has never reached a later phase of the trial process, it's difficult to know how a therapeutic vaccine would be tested and it may differ significantly from what is presented here which is based on the process for preventive HIV vaccines.

I. Pre-Clinical Studies or Pre-human Studies

In the case of HIV, vaccines—known as trial vaccines during the clinical trial process—that are effective in labs are then tested in animals.

In order for vaccine strategies to be deemed suitable for human trials, scientists must believe there is going to be a significant chance that the strategies will provide useful results in human trial participants.

II. Clinical Trials or Human Trials

Most HIV vaccine trials are randomized, double-blind, and placebo-controlled. This means that neither the participants nor the researchers know who got the vaccine and who got the placebo. The placebo is exactly like the vaccine except without the active ingredient. At all stages, participants receive an HIV prevention package, including condoms, counselling and treatment for any STIs they may develop. They are also reminded at every visit that they can't be sure they received the trial vaccine, that the vaccine might not work, and that they should use proven HIV prevention methods when possible.

Until all three phases of the process have been completed, researchers don't know the effect of the trial vaccine on a person's risk for HIV transmission. The **level of risk of HIV infection may be less, the same or more** than if the person didn't receive the trial vaccine. As a result, it is essential that proven HIV prevention methods are maintained, including the use of condoms and clean injection equipment, so that the risk that volunteers contract HIV during the trial is reduced as much as possible.

[2] A modified version of this info sheet is available on preventive HIV vaccines.

PHASES OF THE CLINICAL TRIAL PROCESS AND POTENTIAL COMMUNITY ACTION

PHASE Phase I:Safety

NUMBER AND TYPE OF TRIAL PARTICIPANTS

- Enrols 20-120 participants who are:
- HIV positive adults with strong immune systems.

DURATION

The trial can take 12-18 months.

3-4 months is also needed to study the data and produce results.

MEASURING SUCCESS AND MOVING FORWARD

At the end of phase I, a vaccine would be considered for phase II if no serious side effects were identified and if the vaccine was well tolerated by participants.

A vaccine would not be considered for a phase II trial if serious side effects developed in the participants.

Many trial vaccines never progress past this phase.

AIMS To determine:

- the safety of the vaccine in humans. This will establish if there are any serious side effects.
- the tolerance of the vaccine in humans. This will determine how our bodies react to the vaccine.
- the immunogenicity of the vaccine. This will determine if the vaccine causes an immune response.

COMMUNITY ACTION

The community's concerns and contributions must be taken seriously during the trial process. These actions are applicable at every phase of the process, not just in the first phase.

This is usually done through the creation of community advisory boards (CABs) that reflect the community's needs and diversity and defend their rights before, during and after the trial.

CABs, in turn, will be able to work on behalf of the community for:

A true knowledge exchange between communities and researchers, including making sure that the community understands the need for and the goals of the research, and making sure that researchers understand the unique needs and strengths of the community.

The ethical recruitment and informed consent of participants.

Access to a gold standard of harm reduction/risk reduction services, including clean injection equipment, counselling, family planning services, HIV testing, and treatment for STIs.

Research on, and the development of, culturally-appropriate and accessible information about how vaccines can and cannot protect people needs to be done. This information also needs to be made available to both the research participants, and to the communities in which trials take place. This will ultimately serve as a foundation for future HIV vaccine information that will be made available when a vaccine is licensed.

These goals could also be achieved through the engagement of a wider section of civil society, in addition to the establishment of CABs. Civil society groups could include faith and cultural organisations and community-based organisations that don't necessarily do work in HIV.

Individuals who are interested in HIV vaccine trials should encourage all groups to which they belong to consider getting involved in the HIV vaccine trial process. This should ensure that the needs and rights of participants are as accurately reflected as possible.

PHASE Phase II: Safety

NUMBER AND TYPE OF TRIAL PARTICIPANTS

Enrols between 100-500 who are:

- HIV positive adults with strong immune systems.
- Sero-discordant couples.

DURATION

The trial can take 1-2 years.

4-6 months is also needed to study the data and produce results.

AIMS To determine:

- the safety of the vaccine in humans. This will establish if there are any serious side effects.
- the immunogenicity of the vaccine. This will determine if the vaccine causes an immune response.
- to find the best dose route, or way to give the vaccine.
- when, how much and how often to give the vaccine (dose and regimen).

MEASURING SUCCESS AND MOVING FORWARD

At the end of phase II, a vaccine would be considered for phase IIb or phase III if there continues to be no serious side effects and a usable regimen is developed.

A vaccine would not be considered for future phases if serious side effects developed in the participants or if the vaccine didn't reduce viral load or increase CD4 count.

Many trial vaccine never progress past this phase.

PHASE Phase IIb: Proof of Concept

NUMBER AND TYPE OF TRIAL PARTICIPANTS

Enrols 1000-5000 participants who are: HIV positive adults with strong immune systems. Sero-discordant couples

DURATION

The trial can take 2-5 years, including time to study the data and produce results.

AIMS To determine:

- proof-of-concept. This phase demonstrates if the vaccine delayed HIV progression.
- whether a Phase III trial should be conducted.

MEASURING SUCCESS AND MOVING FORWARD

At the end of phase IIb, a vaccine would be considered for phase III if the vaccine reduced viral load or increased CD4 count significantly. A vaccine would not be considered for future phases if the vaccine didn't reduce viral load or increase CD4 count.

No therapeutic vaccine has ever been tested at this stage.

PHASE

Phase III: Safety and Efficaciousness

AIMS

To determine:

- whether the vaccine delays the progression of HIV disease.
- whether the vaccine reduces viral load and increases CD4 count.

NUMBER AND TYPE OF TRIAL PARTICIPANTS

Enrols between 1000-20000 participants, who are:

HIV positive adults with immune systems that are still quite strong.

DURATION

The trial can take 3-4 years to vaccinate all of the participants.

12-18 months to study the data and produce results.

3-4 years of follow up to determine if vaccination slows progress of the virus in those who received the vaccine and also contracted HIV during the trial.

MEASURING SUCCESS AND MOVING FORWARD

At the end of phase III, a vaccine would be considered for licensure by Health Canada and other international regulatory bodies if it proved to significantly reduce viral load and increase CD4 count. A vaccine would not be considered for licensure if it didn't demonstrate an ability to provide a significant delay in the progression of HIV.

No therapeutic vaccine has ever been tested at this stage.

Even with a clear result that a vaccine strategy does reduce viral load or the risk of transmission, there might be more Phase III trials conducted on the same strategy to confirm this result.

Measuring the Benefits of a Vaccine

Everyone in an HIV vaccine trial, whether they received the vaccine or the placebo, receives the best HIV vaccine prevention package available, including access to STI treatment, condoms and HIV prevention counselling. In order to measure the benefit of a therapeutic vaccine, researchers compare the viral loads and CD4 counts of those who received the vaccine to those of those who received the placebo.

How do researchers know if a vaccine worked?

If viral loads are significantly lower, and **if the difference is greater than can be reasonably attributed to chance** (statistical significance), this suggests that the trial vaccine was beneficial at improving the immune response and slowing the progression of HIV to AIDS. Some studies may also compare numbers of new HIV infections in the HIV- partners of participants who received the vaccine and participants that received the placebo to see if the vaccine reduces the risk of infecting others.

Vaccine Licensure

Once a vaccine has gone through Phase III testing, and if it proved to delay the development of HIV, an application for a license to distribute the vaccine can be made by the product developers or other bodies who are authorized by the product developers to do so. This is done through Canada's regulatory bodies. A single Phase III trial doesn't mean, however, that a license will be sought for the vaccine. Usually, a second confirmatory trial will be done to confirm the first trial's results. The licensing process can take years. For more information on the licensing process for vaccines in Canada, please visit the Health Canada website at www.hc-sc.gc.ca.

References

AVAC. (n.d). *Clinical Trials.* Available: http://www.avac.org/ht/d/sp/i/298/pid/298.

IAVI. (2009). *VAXLit:AIDS Vaccine Literacy Toolkit.* Available: http://www.iavi.org/working-with-communities/Pages/vaccine-literacy.aspx.

International Centre for Research on Women and IAVI. (2008). *Clinical Science Meets Social Science: Gender and AIDS Vaccine Research.* Available: http://www.icrw.org/publications/clinical-science-meets-social-science.

National Institutes of Health. (2007). *Understanding Clinical Trials.* Available: http://www.clinicaltrials.gov/ct2/info/understand#Q06.

SAAVI. (2008). *HIV Vaccines Learner's Handbook.* Available: http://www.saavi.org.za/resources.htm.

POST CLINICAL TRIAL PROCESS AND POTENTIAL COMMUNITY ACTION

PHASE
Licensing/Regulatory Process

NUMBER OF PARTICIPANTS NEEDED AND DURATION

At this stage there are no participants, and given the bureaucratic nature of licensing processes, it is difficult to determine how long it could take.

AIMS

To determine:

- if the clinical trial process was sound.
- whether the vaccine is safe and if there is significant benefit to licensing the vaccine and allowing it to be sold to the Canadian public.

COMMUNITY ACTION

Ensuring that the vaccine licensing process is efficient and thorough.

Ensuring that the National Advisory Committee on Immunisation issues its recommendations in a timely fashion if the vaccine is licensed.

Ensuring that the Public Health Agency of Canada prepares a public health response that is effective and culturally-appropriate.

PHASE
Development of an Effective Public Health Response

NUMBER OF PARTICIPANTS NEEDED AND DURATION

Developing an effective public health response requires extensive consultation and could take months or even years.

AIMS

- To raise awareness of the availability of a vaccine, and the benefits and risks of vaccination.
- To ensure that all Canadians living with HIV/AIDS evaluate the benefit of a vaccine and to determine for themselves if an HIV vaccine would improve their health and the health of their sexual and drug injection networks.

COMMUNITY ACTION

At this stage, there are several advocacy issues that need to be addressed:

Culturally-appropriate and accessible information about how vaccines can and cannot protect people needs to be developed and disseminated.

Consent guidelines for youth and for those who temporarily or permanently lack the capacity to provide informed consent, including those under the influence of drugs and alcohol and those with developmental disabilities must be drawn up, debated and standardized.

Broad and affordable access to an HIV vaccine must be secured so that every individual who might benefit receives the vaccine.

This access should include broad and equitable access in the Global South where vaccines could have the most impact on reducing HIV transmission.

PHASE

Phase IV: Postlicensure/Field Studies

NUMBER OF PARTICIPANTS NEEDED AND DURATION

Participants are recruited from the general public of those living with HIV and are usually in the thousands.

It takes several years to see what effect a vaccine has on the general public.

AIMS

The aims are to:

- test the effectiveness of the vaccine in the general public in real life conditions and to determine how the vaccine reduces the number of new HIV infections.
- to check for rare adverse drug reactions and to test how well the vaccine does when stored, transported and distributed on a large scale.

COMMUNITY ACTION

In this phase of the process, advocacy efforts shift to ensuring that trials:

Explore the maximum benefits of the vaccine, while exposing the short/long term effects.

Ensure that youth/pregnant women are followed to determine efficacy in their populations.

What's the Role of Community Organisations during HIV Vaccine Trials?

This info sheet provides a brief outline of the role that community organisations play when an HIV vaccine trial site is established.

When HIV vaccine trials are planned by organisations like the HIV Vaccine Trials Network or the International AIDS Vaccine Initiative—major sponsors of HIV vaccine trials worldwide--they partner with local organisations in communities where trials will be hosted. Trusted community-based and AIDS service organisations are often approached for their input into the trial design and then, later when the trial has started, take on the role of knowledge brokers in their communities.

Their contribution to community advisory boards, usually called CABs, is the primary role of community-based organisations during an HIV vaccine trial. The HIV Vaccine Trials Network has developed a model in order to facilitate and maximize the work of these CABs. In this model, CABs perform the following three roles:

- assist in the planning, development and implementation of research
- assess community impact and ensure community concerns are considered
- serve as a voice for the community and study participants.

Throughout the process, one of the roles that community organisations play is that of go-between. They foster partnerships between the research team and the larger community. These partnerships allow community members to feel they have a stake in how vaccine trials are conducted. This investment in the trial enables community participants to more fully participate in decision-making throughout the process.

"The CAB is the umbilical cord that connects the researchers to the community."

Prior to an HIV Vaccine Trial

Community organisations offer insight into the community, its challenges, strengths and needs and how this will impact the trial design and development. In addition to increasing the knowledge of the research team, community organisations are also responsible for raising awareness in the community about HIV vaccine research in general, the clinical trial process and the HIV vaccine trial that is being hosted in the community. These educational initiatives include accurate and honest information about previous HIV vaccine trials and should

dispel myths about HIV vaccines and HIV vaccine trials. This is especially important when explaining why previous HIV vaccine trials have failed.

Once a foundation of knowledge is created in the community, community organisations assist in the design and distribution of recruitment materials and provide the knowledge necessary for potential participants to make an informed decision about whether they want to participate in the trial.

During the Trial

Community organisations ensure that the community's concerns are respected and addressed, and act as the first point of contact for participants and the larger community when they have questions about any aspect of the trial. The primary way they do this is through the community advisory board. CABs advise the research team, build understanding between the research team and the community and bring community concerns to the research team.

Throughout the trial, community organisations are responsible for explaining the sometimes difficult scientific and procedural concepts that are part of any HIV vaccine trial. This helps trial participants remain engaged and informed.

Once the Trial is Closed

Because these organisations have a long-standing relationship with the wider community, the responsibility for keeping participants up to date about trial results and developments after a trial has been completed falls to them. Community organisations provide the support and counselling that participants and community members need in the longer term.

The Bottom Line

The success of HIV vaccine trials—whether participants are recruited, well-informed and respected—falls mostly to these organisations and the people that work in them. Without community involvement and representation through these organisations, it would be impossible to run HIV vaccine trials smoothly and effectively.

For More Information

For more detailed information on the role that community organisations can play during an HIV vaccine trial, please visit the HIV Vaccine Trials Network's website at www.hvtn.org.

You can also consult ICASO's *Community Involvement in HIV Vaccine Research: Making it work,* which is available at : http://www.icaso.org/vaccines_toolkit/subpages/files/English/Vaccine_E_WEB_2009Update.pdf.

Things Volunteers Need to Know about Participating in an HIV Vaccine Trial

Key Messages

Vaccine trials are expensive and take a long time but they are essential to developing a safe and effective vaccine.

Participants cannot get HIV from the vaccine used in any HIV vaccine trial. No live or weakened HIV is used in HIV vaccines tested in humans.

Safer sex and harm reduction practices must be used throughout an HIV vaccine trial. Participants aren't told if they've received the vaccine or the placebo.

Before a trial is complete, there is no evidence that the trial vaccine will reduce the risk of HIV transmission even if a participant received it.

Canada has hosted HIV vaccine trials in the past and will surely host future HIV vaccine trials.

This info sheet answers some basic questions potential trial volunteers might have regarding volunteering in an HIV vaccine trial. It includes links to short videos on the experiences of HIV vaccine trial volunteers.

Q: Do trial HIV vaccines cause HIV infection?

No. Trial HIV vaccines don't cause HIV infection. In fact, that is scientifically impossible since no live or weakened virus is ever used in HIV vaccines that are tested in humans. Instead, proteins or genes from proteins found in HIV are sometimes used to develop HIV vaccines. These cannot, under any circumstances, cause an HIV infection.

Participants are never intentionally exposed to the virus to see if the vaccine works.

In every trial, some trial participants become infected with HIV. These infections aren't caused by the vaccine but by the participants being exposed to the virus through blood or sexual contact in their personal lives. To reduce the risk of infection, participants are counselled throughout the trial to maintain proven HIV prevention methods. They are also given regular HIV tests, and care and treatment for any STIs they may develop.

Q: Is it possible to test positive for HIV during a clinical trial and not actually have contracted the virus?

Yes. A study released in 2010 suggested that 41.7% of HIV vaccine trial participants between 2000 and 2010 who were enrolled in vaccine studies sponsored by the HIV Vaccine Trials Network (a major sponsor of HIV vaccine trials around the world) had presented with a false positive test result. This is because HIV vaccines are designed to trick your body into creating antibodies to fight HIV, and the most common HIV test, the ELISA test, is designed to search for those antibodies in your blood. If your body reacted to the vaccine, then it's possible that you could test positive for HIV and not actually have the virus.

When false positives occur among participants, specialized tests are sometimes used to detect antibodies to HIV proteins that weren't used to develop the vaccine. In this way, if the body has produced antibodies to a protein that wasn't used to create the vaccine, technicians know the test is an actual HIV infection, and not a false positive. Clinicians can also use more definitive tests that detect the virus itself instead of the antibodies your body produces to fight the virus.

Trial site staff are trained to do specific tests to determine if participants have actually contracted HIV or if they've had a false positive test, so it's always important for vaccine trial participants to get their HIV tests at their vaccine trial site and to avoid getting tested at other testing venues while they are in the trial. Staff and counsellors at the trial site are trained to provide HIV testing and advice, guidance and support for those who falsely test positive for HIV infection during a vaccine trial. In this way, volunteers can be assured that the results of their HIV tests are accurate.

Q: Do participants need to continue to practice proven HIV prevention methods during the trial?

Yes. The trial vaccine, regardless of the phase, has not yet been proven to prevent or control HIV. Therefore, it's unreliable for participants to use only it as an HIV prevention method. Some participants may wrongly believe that being in an HIV vaccine trial will give them some added protection against HIV infection and will have more unprotected sexual encounters. This is a misconception and participants are always counselled to maintain proven HIV prevention practices.

We need an HIV vaccine because no viral epidemic has ever been stopped without one and current prevention efforts are not successfully slowing the transmission of the virus.

Q: Have HIV vaccine trials taken place in Canada before?

Yes. Canada has hosted three preventive HIV vaccine trials in the past. The last vaccine trial to take place in Canada had trials sites in Montreal, Toronto and Vancouver, and ended in 2007. Currently, there are no HIV vaccine trials taking place in Canada.

Q: Why should I take the risk when I could wait and get the vaccine when it has been approved by Health Canada?

An HIV vaccine will never be licensed if people don't volunteer to be trial participants. Individuals can't expect that others will always shoulder the responsibility. And HIV vaccine trials need a diversity of volunteers, including people who use injection drugs, members of ethnic or cultural communities, Aboriginal peoples, men, women and transpeople, and people of all sexual orientations. Everyone should at least consider participating because as long as you maintain proven prevention methods, your risk of HIV infection is no higher than it would be if you were not involved in the trial.

Q: What are the benefits and risks of participating in an HIV vaccine trial?

Benefits include:

- Contributing to medical research that may benefit you and your community, and contributing to raising awareness of the need for an effective HIV vaccine.
- Receiving the most accurate HIV prevention information and best prevention tools, including condoms, HIV testing, risk reduction counselling, and STI screening and treatment, and receiving medical care, treatment and support.
- Receiving the opportunity to be first to benefit from an effective vaccine if the trial vaccine is ever licensed.

Risks include:

- The occurrence of unpleasant reactions, side effects (headaches and soreness) and serious reactions.
- False positive tests for HIV infection can occur, which may impact ability to travel, acquire insurance or make blood, tissue and organ donations.
- Stigma and discrimination that may be associated with participation, including the assumption that you've done something to put yourself at risk for HIV is a possibility.

Volunteering for an HIV vaccine trial isn't necessarily something that everyone should do. People considering volunteering should talk to their doctors, their families, their friends, and their local AIDS service organisations in order to make the right decision for them.

Participants need to continue to practice the best possible harm reduction and safer sex strategies because the vaccine, in any stage of the process, hasn't been proven to reduce the risk of HIV transmission.

Q: Where can I learn more about HIV vaccine trials in Canada?

Your local AIDS service organisation (ASO) is the best place to start asking questions regarding HIV vaccine trials in your community. Each trial site has a community advisory board, known as a CAB, in which members of the community provide guidance on how to best conduct the trial in the community. Your local ASO should be included in these discussions, so if a trial is in the works, they'll know about it.

A complete listing of clinical trials taking place in Canada, including HIV vaccine trials, can be found here: http://www.hivnet.ubc.ca/home/.

A spreadsheet outlining what trials are currently taking place around the world, including start and projected end dates, phases and trial vaccines, can be found here: http://www.avac.org/ht/a/GetDocumentAction/i/3436

A searchable database of current HIV vaccine trials around the world supported by the American Department of Health and Human Services can be found here: http://www.aidsinfo.nih.gov/vaccines/

Participants are never intentionally exposed to the virus to see if the vaccine works.

HIV vaccine trials must have a cross-section of people participating in order to be able to successfully determine that the vaccine works for everyone.

For More Information

These short videos were designed to raise awareness about the HVTN 505 vaccine trial, which recruited volunteers in early 2011 in 15 cities in the USA. While some of the videos provide information for this specific trial, the general information captures the HIV vaccine trial process and provides answers to many of the questions volunteers might have.

The Rochester Victory Alliance. (2010). What is it like?
Available: http://www.youtube.com/watch?v=Hdpn3GtFdIA&NR=1.

Emory University. (2010). Hope for an AIDS Vaccine.
Available: http://www.youtube.com/watch?v=lAGalwExVdg.

References

Canadian HIV/AIDS Legal Network. (2005). *HIV Vaccines and Human Rights: Community Action Kit*. Available: http://www.aidslaw.ca/publications/publicationsdocEN.php?ref=350.

IAVI. 2009. *AIDS Vaccine Literacy Toolkit.* Available: http://www.iavi.org/working-with-communities/Pages/vaccine-literacy.aspx.

IAVI. (2005). *Understanding HIV Testing.* Available: http://www.iavireport.org/vax-primers/clinical-trials/Pages/VAX-prime-HIV-testing.aspx.

National Institutes of Health. (2007). *Understanding Clinical Trials.* Available: http://clinicaltrials.gov/ct2/info/understand#Q06.

WHO. 2009. *Pandemic Preparedness.* Available: http://www.who.int/csr/disease/influenza/pandemic/en/.

What's New in New HIV Prevention Technology Research?

Key Messages

Canada occasionally hosts HIV vaccine trials. Currently, there are no HIV vaccine trials being hosted in Canada. For up to date information, on trials near you, consult: http://www.hivnet.ubc.ca/home/.

Despite the results of the STEP Study, volunteering in an HIV vaccine trial is safe when proven prevention methods are used.

The Thai Trial proved that an HIV vaccine was possible and researchers now have a model on which to develop better vaccines.

Vaccine research is slow and discoveries such as natural antibodies and proteins that may seem small are often more important than anyone realizes.

Other new prevention technologies (NPTs), including pre-exposure prophylaxis (PrEP) and microbicides, are also showing great advances and will impact how future HIV vaccine trials are run and how future HIV vaccines are rolled out.

For up-to-date information regarding vaccine trials, please visit:

http://www.avac.org/ht/a/GetDocumentAction/i/3436.

This info sheet provides information on the latest[1] developments in research on HIV vaccines and other new prevention technologies (NPTs).

Canada's role in NPT clinical trials

Canada isn't currently hosting any vaccine trials. Montreal, Toronto and Vancouver have all been vaccine trial sites in the past. The most recent trial to be held in Canada ended in 2007. Canada has never hosted a trial site for a microbicide or for pre-exposure prophylaxis (PrEP). As of June 2011, there was a plan for a phase I study of intermittent (occasional use) PrEP use in Montreal as part of a larger study being conducted in France.

Vaccines

The STEP Study: A Step Back?

The STEP Study was a Phase IIb clinical trial for a Merck vaccine that ended prematurely in 2007. The study had locations in North America, including three sites in Canada. The study ended early when it was discovered that some participants who received the vaccine were more susceptible to getting HIV when compared to those who received the placebo. This was not caused by the vaccine itself but by the vector that was used to deliver the vaccine. The vector was a common cold virus known as adenovirus 5 (Ad5). While the vaccine was a failure, the research process was not. Scientists were able to determine that using what appears to be a harmless vector could have serious consequences for vaccine efficacy. Recruitment for HVTN 505 (started in late 2010), a clinical trial with sites in the USA, has been informed by the learnings from the STEP Study. In the STEP Study, uncircumcised men who had antibodies to Ad5 were most susceptible to HIV infection. In HVTN 505, only circumcised men who don't have antibodies to Ad5 are being enrolled. The trial vaccine being tested in HVTN 505 will never be licensed, since the study's purpose is to discover other vaccine strategies. Because of the

[1] As of June 2011

risk of using Ad5 and similar vectors in vaccines, these will never be used in any HIV vaccines destined for use in the general public.

The Thai Trial: The First Proof of Concept

The Thai Trial, the results of which were revealed in October 2009, was the first trial vaccine to reduce the risk of HIV transmission in a trial. The vaccine was shown to reduce transmission by 31%. Ongoing analysis of the results will hopefully determine exactly how the vaccine reduced this risk. The trial used a prime-boost strategy and delivered two vaccines, which researchers believe provides a better immune response than a single vaccine could produce on its own. Indeed, both of these vaccines had failed on their own to induce an immune response in previous clinical trials.

Broadly Neutralizing Antibodies Found to Block 90% of HIV infections

In 2010, American government researchers announced that they had isolated two antibodies in HIV-infected blood that prevent the virus from infecting the body's T-cells, which are key in fighting HIV infection. Because HIV is constantly changing its surface proteins, it's hard for the immune system to fight the infection. Scientists have discovered, however, that these antibodies target a part of the virus that remains unchanged. These antibodies block 90% of HIV strains in lab testing. This might allow scientists to develop improved vaccines against HIV that will target more than a single sub-type of the virus and help the body's immune system fight an infection.

HLA-B Proteins Considered Essential in Long-Term Controllers of HIV infection

About 1 in 300 people infected with HIV control the virus without treatment. The results of a study of 2000 of these people, known as elite controllers or long-term non-progressors, found that these people all had proteins, known as HLA-B, that were different from other people with HIV. The proteins are involved in triggering an immune response, although researchers still don't know how they are involved in controlling the virus. Because a future HIV vaccine will be designed to provoke an immune response, knowing that HLA-B proteins have the ability to help control HIV is key to developing an effective vaccine.

Future Releases of HIV Vaccine Trial Results

As of June 2011, 24 HIV vaccine trials were taking place around the world. For a complete listing, please go to: http://www.iavireport.org/trials-db/Pages/default.aspx. For information on other new prevention technologies, please visit: http://www.avac.org/ht/d/sp/i/189/pid/189.

Microbicides and Pre-Exposure Prophylaxis (PrEP)

Microbicides

In July 2010, a trial of a vaginal microbicide, known as the CAPRISA 004 Study, released results that showed that applying a gel that contained 1% tenofovir, an anti-retroviral drug, to the vagina at least 12 hours before sex and no more than 12 hours after sex could reduce the transmission of HIV by 39%. Proof of concept in vaginal microbicides has boosted confidence in the ability to find an efficacious rectal microbicide. MTN007, a Phase I trial of a rectal microbicide with the same 1% tenofovir gel, was recruiting volunteers in the US as of June 2011.

Pre-Exposure Prophylaxis (PrEP)

In November 2010, a trial of oral PrEP used by men who have sex with men and transgender women, known as the iPrEx Study, released results that showed that taking Truvada, an anti-retroviral, daily could reduce transmission of HIV by 44%. Efficacy results varied significantly depending on a person's adherence to the daily regimen. Because Truvada is already available for treatment, there is significant interest in PrEP among

some populations. Some Canadians may already be using Truvada for PrEP, with or without the guidance of their doctors.

In April 2011, FEM-PrEP, a study among heterosexual women in sub-Saharan Africa, used the same regimen as the iPrEx Study. The study was closed early when a scheduled, interim review of the data concluded that continuing the trial would not answer the question of whether PrEP would reduce HIV transmission among heterosexual women. Without a complete analysis of the data, which is currently being conducted, the causes of this result remain unknown.

In July 2011, Partners PrEP, a study of PrEP use in 4758 HIV sero-discordant couples in Uganda and Kenya released its results. All participants were provided risk reduction counselling, STI treatment, HIV testing and male and female condoms. The study, which was a double-blind, randomized, placebo-controlled trial, found that 62% fewer infections were recorded in those who were given tenofovir, an anti-retroviral, once daily when compared to those who were given a placebo. This study also compared a group taking Truvada (TDF/FTC), another anti-retroviral, and when that group was compared to the placebo group, it was found that 73% fewer infections occurred in those taking Truvada. This is the first instance where PrEP was determined to be effective in heterosexual couples and for reducing the risk of infection in both men and women. Early analysis suggests that adherence, which was at 97%, was the single most important factor in the results of this study. It has been suggested that adherence was so high in this study because those taking PrEP knew that their primary sexual partner was HIV positive.

On the same day as the release of the Partners PrEP trial results, TDF2, a much smaller study of 1219 HIV uninfected men and women, which was conducted in Botswana, released its results. All participants were provided with risk reduction counselling, HIV testing, treatment of STIs and both male and female condoms. This study, which was also a double-blind, randomized, placebo-controlled trial, had two arms: one that received Truvada and the other that received a placebo. The study concluded that when comparing those who received Truvada to those who received a placebo, those who received Truvada were 62.6% less likely to have contracted HIV. Though smaller than the Partners PrEP study, TDF2's results are important because they suggest that daily PrEP use in heterosexuals reduces significantly the risk of HIV infection even when the HIV status of one's sexual partners is unknown. It also challenges the results of FEM-PrEP, a study that was ended early in 2011, that suggested PrEP wasn't effective in reducing risk of HIV transmission in heterosexual women.

References

AVAC. 2008. "An Advocates' Guide to Recent Publications on the STEP AIDS Vaccine Trial Data." Available: http://www.avac.org/ht/d/sp/i/3429/pid/3429.

AVAC. 2010. CAPRISA 004." Available: http://www.avac.org/ht/d/sp/i/28226/pid/28226.

CDC. 2011. CDC Trial and Another Major Study Find PrEP Can Reduce Risk of HIV Infection among Heterosexuals. Available: http://www.cdc.gov/nchhstp/newsroom/PrEPHeterosexuals.html.

iPrEx. 2010. "Study Result." Available: http://www.iprexnews.com/english.html.

University of Washington. 2011. Pivotal Study Finds that HIV Medications Are Highly Effective as Prophylaxis against HIV Infection in Men and Women in Africa. Available: http://depts.washington.edu/uwicrc/research/studies/files/PrEP_PressRelease-UW_13Jul2011.pdf.

US Department of Health and Human Services. 2010. "NIH-Led Scientists Find Antibodies that Prevent Most HIV Strains from Infecting H uman Cells Discovery to Advance HIV Vaccine Design, Antibody Therapy for Other Diseases." *NIH News* National Institutes of Health. Available: http://www.nih.gov/news/health/jul2010/niaid-08.htm.

The More You Know: HIV Vaccine FAQs for African, Caribbean and Black Communities in Canada

HIV Vaccine Preparedness in Canada's African, Caribbean and Black Communities

Resources in this Module

The More You know: FAQs for African, Caribbean and Black Communities in Canada

Talking Points: Some Easy Answers to Tough Questions about HIV Vaccines

There's No Vaccine for That? An Introduction to HIV Vaccines for Black Youth

Canada is welcoming an increasing number of immigrants from sub-Saharan Africa and the Caribbean. In some of these countries, HIV is endemic in the adult population and as a result, Canada is witnessing an increase in the number of HIV infections in these populations. In 2009,[1] 5.5% of all new infections in Canada were attributed to the heterosexual/endemic country category of exposure, and this despite the fact that immigrants from these countries only represent 2.2% of the Canadian population.[2] Overall, where ethnic data were collected, 11.6% of all positive test reports in 2009 were among those who identified as Black.

How could a vaccine reduce the risk of infection in Canada's African, Caribbean and Black (ACB) communities?

A vaccine represents yet another prevention option available to those who are not comfortable with the current prevention methods available in the toolbox. While it should be used with other HIV prevention tools, including condoms, a vaccine doesn't need to be negotiated at every sex act and provides an added barrier against infection when another prevention method is in use.

What puts ACB communities in Canada at risk?

Canada welcomes many immigrants from countries where HIV is endemic in the adult population, making the chance that these populations will be infected with HIV significantly higher than other immigrant populations. While this shouldn't impact their contribution to Canadian society, it does mean that efforts to reduce the risk of infection among these populations should be undertaken.

Once in Canada, their vulnerability to HIV infection is increased by racism, homophobia, stigma, immigration status, lack of socio-economic opportunities, lack of education, language barriers, a poor understanding of the Canadian health care system, and, in some communities, a reticence to speak openly about sex and safer sex options.

[1] 2009 is the most recent year for which a surveillance report has been released by the Public Health Agency of Canada.

[2] According to the 2006 census.

Are members of the ACB community aware of their risk?

Many in the community are aware that HIV transmission is a risk in their home countries. For some, though, when they reach Canada, they adopt the general perception held by Canadians that HIV isn't a problem in Canada for anyone other than gay men and people who use injection drugs. This makes it important to ensure that culturally-appropriate outreach is done in these communities to raise awareness about the risk of HIV infection.

A vaccine won't be available for a decade or more. What can be done now?

HIV vaccine research needs supporters to ensure that it is relevant to the communities that are most likely to seek HIV vaccination in the future. Protocols and processes for testing trial vaccines need to be informed by the communities in which they are being run. Supporters are needed to ensure that every aspect of the trial process is culturally-appropriate and that researchers are aware of the specific needs and concerns of the communities in which they are working.

Get informed about HIV vaccines and consider volunteering for an HIV vaccine trial when one becomes available in your community. Despite a legacy of mistrust of the clinical research trial process that lives in the collective memories of ACB communities, members of these communities need to be a part of HIV vaccine trials to ensure that the vaccines work in their bodies and in their lives. For a complete list of preventive HIV vaccine trials currently taking place, please go to http://aidsinfo.nih.gov/vaccines/. On the left under "Preventive AIDS Vaccine Trials," click "New and Recruiting Trials."

Inform your peers of the need for a wide range of effective prevention strategies for African, Caribbean and Black communities, including vaccines. Increasing the capacity of individuals and the local organisations that represent them to speak knowledgeably about HIV vaccine research will ensure that regional, provincial and federal policy-makers don't forget their commitment to reducing new HIV infections.

Visit your local AIDS service organisation (ASO) and ask how you can get involved in starting a new prevention technology (NPT) committee to ensure that awareness continues to be raised in communities about NPTs. Outreach and capacity-building can be done in communities that won't be hosting HIV vaccine trials as a way to increase local knowledge of HIV vaccines in the face of increasing reports of breakthroughs in the biomedical prevention of HIV.

Support the need for culturally-appropriate HIV prevention tools and messages, and for acceptance and respect in your communities. HIV stigma and homophobia in some of these communities continue to ease the spread of HIV.

Contact your Member of Parliament to support funding for research into HIV vaccines in Canada, and to restore funding to the International AIDS Vaccine Initiative and the International Partnership for Microbicides, which play an important role in the wider international effort to develop new prevention technologies like vaccines. These organisations are committed to developing and delivering affordable and effective new prevention technologies globally.

Create a network of advocates between your local ASO and those in countries in which you have strong ties. Vaccine trials are already taking place in many of these places, and creating relationships between organisations and communities could improve capacity in your community here in Canada. These contacts will provide a better global picture of what vaccine research is currently taking place around the world.

References

BlackCAP. (2007). *Visibility Hidden: Rethinking BMSM & HIV Prevention.*
Available: http://www.getthelowdown.ca/visibly_hidden_report%5B1%5D.pdf.

IAVI. 2009. Estimating the Impact of an AIDS Vaccine in Developing Countries.
Available: http://www.iavi.org/publications-resources/Pages/PublicationDetail.aspx?pubID=5ebd3b8f-532f-44fa-8bbc-d2d3e14fb2e6.

PHAC. (2010). *HIV and AIDS in Canada: Surveillance Report to December 31, 2009.*
Available: http://www.phac-aspc.gc.ca/aids-sida/publication/survreport/2009/dec/index-eng.php.

Statistics Canada.(2009). Immigration in Canada: A Portrait of the Foreign-born Population, 2006 Census: Immigrants came from many countries.
Available: http://www12.statcan.ca/census-recensement/2006/as-sa/97-557/p5-eng.cfm.

UNAIDS. (2009). *AIDS Epidemic Update*. Available: http://www.unaids.org/en/dataanalysis/epidemiology/2009aidsepidemicupdate/.

Winston Husbands et al., (n.d), *MaBwana; Health, Community and Vulnerability to HIV among African, Caribbean and Black Gay and Bisexual Men in Toronto.* Toronto: The African and Caribbean Council on HIV/AIDS in Ontario and the AIDS Committee of Toronto.
Available: http://www.accho.ca/?page=home.MaBwana.

Talking Points: Some Easy Answers to Tough Questions about HIV Vaccines

Key Messages

Currently, there is no preventive or therapeutic vaccine for HIV.

A preventive vaccine would help to prevent the transmission of HIV between individuals, as it does for other viruses.

As of June 2011, there were 24 preventive vaccine trials taking place around the world.

The majority of those trials are for preventive HIV vaccines.

Only one HIV vaccine has reduced the number of HIV infections in clinical trials.

Current investment in vaccines internationally totals 859 million USD (HIV Vaccine and Microbicide Resource Tracking Working Group, 2010).

Preventive HIV vaccine trials need volunteers from a range of individuals, including women, Aboriginal peoples, ethnic and cultural minorities and people who have a varied risk of exposure to HIV, including those at low risk.

This info sheet focuses on addressing questions and concerns that individuals may have regarding the relevance, cost and need for preventive HIV vaccine trials.

We already have effective HIV prevention tools. Why do we need an HIV vaccine?

No viral epidemic has ever been stopped without a vaccine. Behavioural change and education aren't working fast enough to prevent the transmission of HIV. Condoms, the most common HIV prevention tool, aren't always used correctly or consistently. The number of new infections remains stable in Canada. A vaccine has the potential to reduce this number considerably.

Why do we need vaccine trials?

A vaccine will never be licensed without proving it was effective at controlling or preventing HIV in a clinical trial. Even when vaccines fail during a trial, they provide information that advances the development of other HIV vaccines, and they provide information that couldn't be gathered any other way. Hosting vaccine trials in Canada also raises awareness in the general public that a vaccine is in development. This generates interest, and even support, for HIV vaccines in a wider segment of the population.

Vaccine trials cost a lot. Why are they so expensive?

HIV vaccine trials are expensive for a number of reasons. First, they require the participation of highly trained researchers, clinicians and counsellors. Later stage trials, especially Phase IIb and Phase III trials, enroll thousands of volunteers to ensure that a result that is statistically significant can be obtained. Providing services and support to these volunteers is costly.Finally, the analysis and storage of the thousands of blood and tissue samples that are collected over the duration of the trial is costly.

Do vaccine trials recruit volunteers from the general public?

They do. The earliest phases of HIV vaccine trials take place with volunteers from the general public. Phase I and many Phase II trials are open to all healthy people between 18 and 45 who aren't at high risk for HIV infection. It's only in later trials of the vaccine, Phase IIb and Phase III, that the vaccine is tested in populations at higher risk for HIV infection. Later trials recruit individuals who engage in higher-risk behaviour because researchers have to know that those in the trial have the potential to come into contact with the virus. That's the only way they know if the vaccine is effective at controlling or preventing HIV. This is why later trials test the trial vaccine predominantly in men who have sex with men (MSM), women who have sexual relations with MSM and women with multiple sex partners as the rates of infection in these populations suggest that they have the potential to come into contact with the virus more frequently than the general public.

Although Phase IIb and Phase III trials don't take place in the general public in Canada, they do take place in the general population in sub-Saharan Africa where a generalized heterosexual epidemic is a reality.

For More Information

AIDS Vaccine Advocacy Coalition: http://www.avac.org

HIV Vaccine Trials Network : http : www.hvtn.org

International AIDS Vaccine Initiative: http://www.iavi.org

National Institute of Allergies and Infectious Diseases: http://www.niaid.nih.gov/topics/hivaids/research/vaccines/Pages/default.aspx

There's No Vaccine for That? An Introduction to HIV Vaccines for Black Youth

In Canada, every 500th person is HIV positive.

That's about how many friends some of you have on Facebook.

You should know: There isn't a vaccine available for HIV. There are trials testing vaccines right now around the world, and so there's hope. This info sheet outlines some of the questions you might have about vaccines and gives you some idea about what you can do now to prepare yourself and your friends for an HIV vaccine.

Isn't there a vaccine for HIV already?

No, there isn't already a vaccine for that. And no, there isn't already a cure for that either. Recent progress has been made in the search for a vaccine, but we are still years away from a vaccine becoming a reality.

An HIV infection never goes away. There are treatments that manage the disease, but many of these have unpleasant side effects. They can make you nauseous, and make your body store fat in places you never thought it could, and some of the drugs can give you uncontrollable diarrhea.

Can I get HIV?

You can. Unless you abstain from sex forever and never inject drugs into your body.

Youth between the ages of 15-29 accounted for 24% of all new HIV infections in 2009.[3] Among African, Caribbean and Black populations in Canada, 15% of all positive test results were reported in youth between the ages of 15 and 29. It's great that youth are getting tested, but positive test results mean that youth aren't protecting themselves against infection when they have sex or when they use injection drugs.

Your risk for HIV infection might be low, depending on your risk behaviour, but it's still a risk. Preventing HIV infection is still the only way to stay free of HIV.

How could a vaccine help me?

A vaccine isn't an HIV prevention method that has to be negotiated, so no one will know you've gotten the vaccine unless you tell them. If you get vaccinated before you start having sex, it'll be there when you come into contact with the virus, whether you know your partner is HIV positive or not.

[3] 2009 is the most recent year for which a surveillance report has been released by the Public Health Agency of Canada.

A vaccine should always be used with condoms and other prevention methods, because it won't be 100% effective at stopping an infection. When you can't use a condom, a vaccine is designed to provide you with some protection against infection. If you do have unprotected sex with a partner whose sero-status you aren't sure of, even if you're vaccinated, you should get an HIV test anyway.

What can I do now until a vaccine or a clinical trial is available?

Start talking to your friends about HIV vaccines. HIV vaccines might be a thing of the future but it's important to raise awareness today that they are being developed. This will get people thinking about whether or not they would get vaccinated themselves.

Contact your local AIDS service organisation (ASO) and stay informed. Raise awareness among your friends about HIV prevention, including how vaccines can one day work to complement current HIV prevention strategies such as condom use.

Looking for something to complain about? Here are some things you can act on now that are relevant to youth:

1. Currently youth younger than 18 can't participate in HIV vaccine trials in Canada even if they are at risk for HIV. Only when a vaccine has been determined to be safe and effective in adults is it then tested in people under the age of 18. There are valid concerns about exposing teens to the potential harms of a vaccine before it has been tested in adults. Youth who want to participate in the process need to be given the tools to advocate for their participation in the research process.

15% of new infections among Black people in Canada in 2009 occurred in young people between the ages of 15 and 29.

2. There are currently no guidelines for allowing minors to consent to vaccination without their parents' knowledge. That means if you hadn't turned 18 yet, and a vaccine were available and you wanted to get it without your parents' knowledge, you couldn't. Only British Columbia recognizes that mature minors can consent to controversial vaccines for themselves. Youth need to contact their provincial politicians in order to push for better consent guidelines now before a vaccine is rolled out.

For more information

Consult AVAC: A global AIDS vaccine advocacy group http://www.avac.org

Read IRMA: A blog devoted to developments in new prevention technologies http://irma-rectalmicrobicides.blogspot.com/

Join Mag-Net: A listserv for those interested in new prevention technologies including vaccines. Send an email to: mag-net@cdnaids.ca.

References

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The More You Know: FAQs for People who Use Injection Drugs about HIV Vaccines

People who use injection drugs have been disproportionately affected by HIV since the virus appeared in Canada in the early 1980s. A poor understanding of transmission, their injection drug using patterns and the lack of harm reduction services fueled the early years of the epidemic. Today, people who use injection drugs continue to shoulder a significant proportion of the burden of HIV infection in Canada. According to the Public Health Agency of Canada (PHAC), in 2009[1], 21.6% of all new infections were among people who self-reported using injection drugs.

How could a vaccine reduce this risk?

In settings and communities where safe, clean injection drug use is sometimes impossible—for example in communities where overnight harm reduction services are lacking or where an ability to access the service is limited—a vaccine will provide a measure of protection against HIV transmission from dirty works. For rural and remote injection drug users, for those in prisons and for those who, for whatever reason, believe that sharing needles is worth the risk, a vaccine would provide protection against HIV when clean needles and condoms aren't accessible.

A vaccine also provides an HIV prevention tool that is individually controlled and that doesn't have to be negotiated at every sex act or injection drug use. Since studies demonstrate that most users begin using between the ages of 15 and 24, young injection drug users would benefit from a vaccine that would provide some protection against HIV while they are still learning how to protect themselves in other ways.

What puts people who use injection drugs at risk for HIV infection?

Injecting with drugs, needles and equipment used by other injectors puts these populations at risk for HIV infection. Risks are eliminated with effective and accessible harm reduction and the consistent use of clean injection equipment. When those resources and materials are unavailable, injection drug use is the single riskiest behaviour for HIV transmission. People who use injection drugs are also put at risk by the belief (of some) that they aren't at risk for the sexual transmission of HIV.

Beyond biological explanations for their vulnerability, the susceptibility of injection drug users to HIV is also affected by stigma, discrimination, poor sexual health awareness, homophobia, gender-based violence, a lack of stable housing, a reticence

[1] 2009 is the most recent year for which a surveillance report has been released by the Public Health Agency of Canada.

to engage with health and other authorities, and a mistrust of society which make accessing harm reduction services difficult for these populations.

Are people who use injection drugs aware of their risk?

Yes. These populations, having been the focus of outreach and education programs since the 1980s, are very aware of the risk of HIV transmission through injection drug use. Some who use injection drugs are, however, less well-informed of their risk of contracting HIV from sex. This is no surprise considering other predominantly heterosexual populations also consistently underestimate their risk of contracting HIV through sex.

A vaccine won't be available for a decade or more. What can be done now?

HIV vaccine research needs supporters to ensure that it is relevant to the communities that are most likely to seek HIV vaccination in the future. Protocols and processes for testing trial vaccines need to be informed by the communities in which they are being run. Supporters are needed to ensure that every aspect of the trial process is culturally-appropriate and that researchers are aware of the specific needs and concerns of the communities in which they are working.

People who use injection drugs are largely ignored in Canadian HIV vaccine trials. People who use injection drugs and the groups and service providers that represent them must **take action** to support the inclusion of these populations in future HIV vaccine trials, both with agencies that sponsor HIV vaccine trials, including the HIV Vaccine Trials Network and the local hosts of vaccine trials. For a complete list of current HIV vaccine trials, please go to http://aidsinfo.nih.gov/vaccines/. On the left under "Preventive AIDS Vaccine Trials," click "New and Recruiting Trials."

Inform yourself about new prevention technology (NPT) trials in countries where people who use injection drugs have been included. A trial is currently being conducted in Thailand among people who use injection drugs. The trial is testing the efficacy of pre-exposure prophylaxis (PrEP) and results are expected in 2012. Following international trials will help you and your organisation prepare for future trials in Canada that will include people who use injection drugs.

Visit your local AIDS service organisation (ASO) or drug users' network and ask them what they are doing to prepare for HIV vaccine trials and deployments in your communities. **Get involved** in starting a NPT committee in your organisation to ensure that preparedness continues. Increasing the capacity of individuals and the local organisations that represent them to speak knowledgeably about HIV vaccine research will ensure that regional, provincial and federal policy-makers don't forget their commitment to reducing new HIV infections.

Contact your Member of Parliament to support funding for research into HIV vaccines in Canada, and to restore funding to the International AIDS Vaccine Initiative and the International Partnership for Microbicides, which play an important role in the wider international effort to develop new prevention technologies like vaccines.

References

Gagnon, H. & Godin, G. (2009). "Psychosocial factors explaining drug users' intention to use a new syringe at each injection." *Addiction Research and Theory* 17(5): 481-492.

PHAC. (2010). *HIV and AIDS in Canada: Surveillance Report to December 31, 2009.* Available: http://www.phac-aspc.gc.ca/aids-sida/publication/survreport/2009/dec/index-eng.php.

Strathdee, Steffanie A., et al. (2000). "Factors Associated with Willingness to Participate in HIV Vaccine Trials among HIV-Negative Injection Drug Users and Young Gay and Bisexual Men. *AIDS and Behavior* 4 (3): 271-278.

Talking Points: Some Easy Answers to Tough Questions about HIV Vaccines

Key Messages

Currently, there is no preventive or therapeutic vaccine for HIV.

A preventive vaccine would help to prevent the transmission of HIV between individuals, as it does for other viruses.

As of June 2011, there were 24 preventive vaccine trials taking place around the world.

The majority of those trials are for preventive HIV vaccines.

Only one HIV vaccine has reduced the number of HIV infections in clinical trials.

Current investment in vaccines internationally totals $ 859 million USD (HIV Vaccine and Microbicide Resource Tracking Working Group, 2010).

Preventive HIV vaccine trials need volunteers from a range of individuals, including women, Aboriginal peoples, ethnic and cultural minorities and people who have a varied risk of exposure to HIV, including those at low risk.

This info sheet focuses on addressing questions and concerns that individuals may have regarding the relevance, cost and need for HIV vaccine trials.

We already have effective HIV prevention tools. Why do we need an HIV vaccine?

No viral epidemic has ever been stopped without a vaccine. Behavioural change and education aren't working fast enough to prevent the transmission of HIV. Condoms and clean needles, the most common HIV prevention tools, aren't always used correctly or consistently. The number of new infections remains stable in Canada. A vaccine has the potential to reduce this number considerably.

Why do we need vaccine trials?

A vaccine will never be licensed without proving it was effective at controlling or preventing HIV in a clinical trial. Even when vaccines fail during a trial, they provide information that advances the development of other HIV vaccines, and they provide information that couldn't be gathered any other way. Hosting vaccine trials in Canada also raises awareness in the general public that a vaccine is in development. This generates interest, and even support, for HIV vaccines in a wider segment of the population.

Vaccine trials cost a lot. Why are they expensive?

HIV vaccine trials are expensive for a number of reasons. First, they require the participation of highly trained researchers, clinicians and counsellors. Later stage trials, especially Phase IIb and Phase III trials, enroll thousands of volunteers to ensure that a result that is statistically significant can be obtained. Providing services and support to these volunteers is costly. Finally, the analysis and storage of the thousands of blood and tissue samples that are collected over the duration of the trial is costly.

Why don't vaccine trials recruit people who use injection drugs?

Clinical trial sponsors have not recruited injection drug users in Canada for several reasons. They believe that the lives of injection drug users are too unstable to support the commitment that participation in a clinical trial requires. Volunteers are required to keep appointments, interact with health professionals and advise frontline staff of side effects or unusual occurrences in their bodies. While harm reduction supplies are widely available in Canada, harm reduction is not necessarily supported by the major funders of HIV vaccine trials. Ethically, Canada may not be able to host trials among injection drug users without providing them harm reduction, including clean needles. Finally, some drug users' groups and researchers may question whether people who use injection drugs can give informed consent to participate, especially if incentives for participation are available, including cash pay outs for visits.

Do vaccine trials recruit volunteers from the general public?

Yes. The earliest phases of HIV vaccine trials do take place with volunteers from the general public. Phase I and many Phase II trials are open to all healthy people between 18 and 45 who aren't at high risk for HIV infection. It's only in later trials of the vaccine, Phase IIb and Phase III, that the vaccine is tested in populations at higher risk for HIV infection. Later trials recruit individuals who engage in higher-risk behaviour because researchers have to know that those in the trial have the potential to come into contact with the virus. That's the only way they know if the vaccine is effective at controlling or preventing HIV. This is why later trials test the trial vaccine predominantly in men who have sex with men (MSM), women who have sexual relations with MSM and women with multiple sex partners as the rates of infection in these populations suggest that they have the potential to come into contact with the virus more frequently than the general public.

Although Phase IIb and Phase III trials don't take place in the general public in Canada, they do take place in the general population in sub-Saharan Africa where a generalized heterosexual epidemic is a reality.

For More Information

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National Institute of Allergies and Infectious Diseases: http://www.niaid.nih.gov/topics/hivaids/research/vaccines/Pages/default.aspx

There's No Vaccine for That? An Introduction to HIV Vaccines for Youth who Use Drugs

In Canada, every 500th person is HIV positive.

That's about how many friends some of you have on Facebook.

You should know: There isn't a vaccine available for HIV. There are trials testing vaccines right now around the world, and so there's hope. This info sheet outlines some of the questions you might have about vaccines and gives you some idea about what you can do now to prepare yourself and your friends for an HIV vaccine.

Isn't there a vaccine for HIV already?

No, there isn't already a vaccine for that. And no, there isn't already a cure for that either. Recent progress has been made in the search for a vaccine, but we are still years away from a vaccine becoming a reality.

An HIV infection never goes away. There are treatments that manage the disease, but many of these have unpleasant side effects. They can make you nauseous, and make your body store fat in places you never thought it could, and some of the drugs can give you uncontrollable diarrhea.

Can I get HIV?

You can. Unless you abstain from sex forever and never inject drugs into your body.

Youth between the ages of 15 and 29 accounted for 24% of all new HIV infections in 2009[2] and youth represented a third of all positive HIV test results among people who use injection drugs. It's great that youth are getting tested, but positive test results mean that youth aren't protecting themselves against infection either when they have sex or when they use injection drugs.

Your risk for HIV infection might be low if you're using clean needles and injection equipment and protecting yourself with a condom when you have sex, but HIV infection is still a risk. Preventing HIV infection is still the only way to stay free of HIV.

How can a vaccine help me?

A vaccine is designed to give you some protection at every sex act and every drug injection. If you're on a bend or you didn't think you'd be having sex and so you don't have clean needles and equipment or you don't have condoms, a vaccine will give you some protection. Vaccines work best, though, when you do use condoms and when you have clean injection equipment.

[2] 2009 is the most recent year for which a surveillance report has been released by the Public Health Agency of Canada.

What can I do now until a vaccine or a clinical trial is available?

Start talking to your friends about HIV vaccines. HIV vaccines might be a thing of the future but it's important to raise awareness today that they are being developed. This will get people thinking about whether or not they would get vaccinated themselves.

Contact your local AIDS service organisation (ASO) and stay informed. Raise awareness among your friends about HIV prevention, including how vaccines can one day work to complement current HIV prevention strategies such as condom use.

Looking for something to complain about? Here are some things you can act on now that are relevant to youth:

1. Currently youth younger than 18 can't participate in HIV vaccine trials in Canada even if they are at risk for HIV. Only when a vaccine has been determined to be safe and effective in adults is it then tested in people under the age of 18. There are valid concerns about exposing teens to the potential harms of a vaccine before it has been tested in adults. Youth who want to participate in the process need to be given the tools to argue for their desire to participate in the research process.
2. There are currently no guidelines for allowing minors to consent to vaccination without their parents' knowledge. That means if you hadn't turned 18 yet, and a vaccine were available and you wanted to get it without your parents' knowledge, you couldn't. Only British Columbia recognizes that mature minors can consent to controversial vaccines for themselves. Youth need to contact their provincial politicians in order to push for better consent guidelines now before a vaccine is rolled out.

1 out of 3 positive test results for HIV in people who use injection drugs were in young users in 2009.

3. Canadian injection drug users have the most to benefit from future HIV vaccines, and yet they have never been included in vaccine trials that take place in Canada. It's important that people who use injection drugs be included in vaccine development to ensure that vaccines are effective in their bodies and their lives. Contact your local ASO to encourage them to support the inclusion of people who use injection drugs in HIV vaccine trials in Canada.

For more information

Consult AVAC: A global AIDS vaccine advocacy group http://www.avac.org

Read IRMA: A blog devoted to developments in new prevention technologies http://irma-rectalmicrobicides.blogspot.com/

Join Mag-Net: A listserv for those interested in new prevention technologies including vaccines. Send an email to: mag-net@cdnaids.ca.

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The More You Know: FAQs for Gay Men and Other Men Who have Sex with Men (MSM) about HIV Vaccines

Since the 1980s, gay men and other men who have sex with men (MSM) have borne a disproportionate burden of HIV/AIDS infections and deaths in Canada. The good news is that the proportion has declined from a height of 60% between 1985 and 2002 to 41.8% in 2009.[1]

The bad news is that this is still two out of every five infections in Canada. In some of Canada's cities, infection rates are as high in MSM as they are in some adult populations in sub-Saharan Africa. In Vancouver, 15% of all MSM are believed to be HIV positive; in Toronto, 20% of all MSM are estimated to be living with HIV.

Some of these men don't know they are infected.

How could a vaccine reduce these rates?

A vaccine would put yet another prevention method at the disposal of those who have difficulty finding an HIV prevention method that is suitable for their lives. A vaccine could provide some protection against HIV infection when other proven protection methods are impossible to access, impossible to negotiate or are not being used. When used in combination with condoms, lube and harm reduction, a vaccine would be optimally effective at blocking transmission of the virus. For youth, and for MSM who frequently have unplanned sex, or have unprotected sex, a vaccine provides a measure of protection at every sex act, regardless of the availability of condoms and lube.

What puts these communities at risk?

Unprotected anal sex is the riskiest kind of sex for HIV transmission. Like most people, MSM don't use condoms and lube consistently at every sex act and they don't always practice harm reduction when using alcohol or drugs. Doing so for MSM is riskier than for straights simply because vastly higher infection rates within MSM communities increase the likelihood of encountering an HIV+ sexual partner and because a significant minority of MSM continue to have unprotected sex.

Are gay guys and other MSM aware of the risk?

Most AIDS service organisations (ASOs) have specific MSM outreach, information and education programs that raise awareness of the risk that HIV poses to MSM. In larger cities, there are clinics that cater to the specific needs of gay men. This alone ensures

[1] 2009 is the most recent year for which a surveillance report has been released by the Public Health Agency of Canada.

that those MSM who frequent gay-friendly or gay-focused public spaces and events are exposed to some information and thus are at least moderately aware of their risk of infection.

Men who don't identify as gay may not consider that their same sex behaviour might put them at risk for HIV infection. In smaller and rural communities, MSM may not have access to gay-friendly spaces where sexual health information relevant to them is readily available. Youth, who don't have first-hand knowledge of a time before effective HIV treatment and thus may not perceive HIV as a risk for them and their peers, also continue to engage in high risk behaviours, including unprotected sex combined with drugs and alcohol.

A vaccine won't be available for a decade or more. What can be done now?

HIV vaccine research needs supporters to ensure that it is relevant to the communities that are most likely to seek HIV vaccination in the future. Protocols and processes for testing trial vaccines need to be informed by the communities in which they are being run. Supporters are needed to ensure that every aspect of the trial process is culturally-appropriate and that researchers are aware of the specific needs and concerns of the communities in which they are working.

Get informed about HIV vaccine research and consider volunteering for an HIV vaccine trial. In Canada, gay men and other men who have sex with men are often the most likely candidates for trial participation, and this is something for which the communities they represent should be proud. For a complete list of preventive HIV vaccine trials currently taking place, please go to http://aidsinfo.nih.gov/vaccines/. On the left under "Preventive AIDS Vaccine Trials," click "New and Recruiting Trials."

Inform your peers of the need for a wide range of effective prevention strategies for MSM, including new prevention technologies and vaccines. Outreach and capacity-building can be done in communities that won't be hosting HIV vaccine trials as a way to increase local knowledge of HIV vaccines in the face of increasing reports of breakthroughs in the biomedical prevention of HIV.

HIV stigma, both inside and outside communities of MSM as well as HIV apathy within these same communities, contributes to the spread of HIV. **Start a dialogue** with your peers regarding both. Working to reduce HIV stigma and HIV apathy before a vaccine is available will reduce the barriers to access that both of these create.

Contact your Member of Parliament to support funding for research into HIV vaccines in Canada, and to restore funding to the International AIDS Vaccine Initiative and the International Partnership for Microbicides, which play an important role in the wider international effort to develop new prevention technologies like vaccines. These organisations are committed to developing and delivering affordable and effective new prevention technologies globally.

Engage local groups working on gay men's health in a discussion of how they can support the effort to find and disseminate a vaccine. Increasing the capacity of individuals and the local organisations that represent them to speak knowledgeably about HIV vaccine research will ensure that regional, provincial and federal policy-makers don't forget their commitment to reducing new HIV infections.

References

PHAC. (2010). *HIV and AIDS in Canada: Surveillance Report to December 31, 2009.*
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Talking Points: Some Easy Answers to Tough Questions about HIV Vaccines

Key Messages

Currently, there is no preventive or therapeutic vaccine for HIV.

A preventive vaccine would help to prevent the transmission of HIV between individuals, as it does for other viruses.

As of June 2011, there were 24 preventive vaccine trials taking place around the world.

The majority of those trials are for preventive HIV vaccines.

Only one HIV vaccine has reduced the number of HIV infections in clinical trials.

Current investment in vaccines internationally totals $859 million USD (HIV Vaccine and Microbicide Resource Tracking Working Group, 2010).

Preventive HIV vaccine trials need volunteers from a range of individuals, including women, Aboriginal peoples, ethnic and cultural minorities and people who have a varied risk of exposure to HIV, including those at low risk.

This info sheet focuses on addressing questions and concerns that individuals may have regarding the relevance, cost and need for preventive HIV vaccine trials.

We already have effective HIV prevention tools. Why do we need an HIV vaccine?

No viral epidemic has ever been stopped without a vaccine. Behavioural change and education aren't working fast enough to prevent the transmission of HIV. Condoms, the most common HIV prevention tool, aren't always used correctly or consistently. The number of new infections remains stable in Canada. A vaccine has the potential to reduce this number considerably.

Why do we need vaccine trials?

A vaccine will never be licensed without proving it was effective at controlling or preventing HIV in a clinical trial. Even when vaccines fail during a trial, they provide information that advances the development of other HIV vaccines, and they provide information that couldn't be gathered any other way. Hosting vaccine trials in Canada also raises awareness in the general public that a vaccine is in development. This generates interest, and even support, for HIV vaccines in a wider segment of the population.

Vaccine trials cost a lot. Why are vaccine trials so expensive?

HIV vaccine trials are expensive for a number of reasons. First, they require the participation of highly trained researchers, clinicians and counsellors. Later stage trials, especially Phase IIb and Phase III trials, enroll thousands of volunteers to ensure that a result that is statistically significant can be obtained. Providing services and support to these volunteers is costly. Finally, the analysis and storage of the thousands of blood and tissue samples that are collected over the duration of the trial is costly.

Why don't vaccine trials recruit volunteers from the general public instead of focusing on MSM?

They do. The earliest phases of HIV vaccine trials take place with volunteers from the general public. Phase I and many Phase II trials are open to all healthy individuals between 18 and 45 who aren't at high risk for HIV infection. It's only in later trials of the vaccine, Phase IIb and Phase III, that the vaccine is tested in populations at higher risk for HIV infection, like many MSM. Later trials recruit individuals who engage in higher-risk behaviour because researchers have to know that those in the trial have the potential to come into contact with the virus. That's the only way they know if the vaccine is effective at controlling or preventing HIV. This is why later trials test the trial vaccine predominantly in MSM, women who have sexual relations with MSM, trans women and women with multiple sex partners as the rates of infection in these populations suggest that they have the potential to come into contact with the virus more frequently than the general public.

Although Phase IIb and Phase III trials don't take place in the general public in Canada, they do take place in the general population in sub-Saharan Africa where a generalized heterosexual epidemic is a reality.

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San Francisco AIDS Foundation. (2010). Jamie—HIV Vaccine Trial Participant. Available: http://www.youtube.com/watch?v=cKUbS9flCQU.

San Francisco AIDS Foundation. (2010). Sean—HIV Vaccine Trial Participant. Available: http://www.youtube.com/watch?v=ixJ6gOmMIbE.

San Francisco AIDS Foundation. (2010). Steven—HIV Vaccine Trial Participant. Available: http://www.youtube.com/watch?v=_toxeoi_kuU.

There's No Vaccine for That? An Introduction to HIV Vaccines for Gay Youth

In Canada, every 500th person is HIV positive.

That's about how many friends some of you have on Facebook.

You should know: There isn't a vaccine available for HIV. There are trials testing vaccines right now around the world, and so there's hope. This info sheet outlines some of the questions you might have about vaccines and gives you some idea about what you can do now to prepare yourself and your friends for an HIV vaccine.

Isn't there a vaccine for HIV already?

No, there isn't already a vaccine for that. And no, there isn't already a cure for that either. Recent progress has been made in the search for a vaccine, but we are still years away from a vaccine becoming a reality.

An HIV infection never goes away. There are treatments that manage the disease, but many of these have unpleasant side effects. They can make you nauseous, and make your body store fat in places you never thought it could, and some of the drugs can give you uncontrollable diarrhea.

Can I get HIV?

You can. Unless you abstain from sex forever and never inject drugs into your body.

Young people between the ages of 15-29 made up 24% of all new HIV infections in Canada in 2009.[2] And one out of every three HIV positive test results among gay and bisexual men were in men between the ages of 15 and 29. It's great that youth are getting tested, but positive test results mean that many young people aren't protecting themselves against infection either when they have sex or when they use injection drugs.

Your risk for HIV infection might be low, depending on your risk behaviour, but it's still a risk. Preventing HIV infection is still the only way to stay free of HIV.

How can a vaccine help me?

Gay and bi guys sometimes have sex on drugs and when they drink. And sometimes they have sex unexpectedly when the opportunity comes up or don't think to use a condom until it's too late. In order to protect yourself against HIV, it's key to plan ahead for those times. That can mean remembering to keep condoms and lube beside your bed or to keep them on you when you go out. It can also mean getting

[2] 2009 is the most recent year for which a surveillance report has been released by the Public Health Agency of Canada.

vaccinated when a vaccine is eventually available. Vaccines are designed to protect you when you aren't using condoms. No vaccine is a 100% effective, so a vaccine won't be able to protect you every time you are exposed to HIV. But used with condoms it will be the best possible prevention.

What can I do now until a vaccine or a clinical trial is available?

Start talking to your friends about HIV vaccines. HIV vaccines might be a thing of the future but it's important to raise awareness today that they are being developed. This will get people thinking about whether or not they would get vaccinated themselves.

Contact your local AIDS service organisation (ASO) and stay informed. Raise awareness among your friends about HIV prevention, including how vaccines can one day work to complement current HIV prevention strategies such as condom use.

Looking for something to complain about? Here are some things you can act on now that are relevant to youth:

1. Currently youth can't participate in HIV vaccine trials in Canada even if they are at risk for HIV. Only when a vaccine has been determined to be safe and effective in adults is it then tested in people under the age of 18. There are valid concerns about exposing teens to the potential harms of a vaccine before it has been tested in adults. Youth who want to participate in the process need to be given the tools to argue for their desire to participate in the research process.
2. There are currently no guidelines for allowing minors to consent to vaccination without their parents' knowledge. That means if you hadn't turned 18 yet, and a vaccine were available and you wanted to get it without your parents' knowledge, you couldn't.

In 2009, 1 out of every 3 HIV positive test results among gay and bi guys were in guys between the ages of 15 and 29.

Only British Columbia recognizes that mature minors can consent to controversial vaccines for themselves. Youth need to contact their provincial politicians in order to push for better consent guidelines now before a vaccine is rolled out.

For more information

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Join Mag-Net: A listserv for those interested in new prevention technologies. Send an email to: mag-net@cdnaids.ca.

References

Public Health Agency of Canada. (2010). *HIV and AIDS in Canada: Surveillance Report to December 31, 2009.* Available: http://www.phac-aspc.gc.ca/aids-sida/publication/survreport/2009/dec/index-eng.php.

The More You Know: FAQs for People Living with HIV/AIDS about HIV Vaccines

Canada is not at the frontline of the global HIV/AIDS epidemic. Indeed, the city of Los Angeles counts as many HIV+ individuals as our whole country counted in 2009.[1] Although we don't have a generalized epidemic in this country, we do have epidemics in certain populations, including in gay men and other men who have sex with men (MSM) and in people who use injection drugs. While in the 1980s HIV was considered only an issue for these populations, the surveillance data from the Public Health Agency of Canada's (PHAC) 2009 report revealed that this is no longer true. Today's epidemic is far more complex, and those who live with HIV and AIDS in Canada are as diverse as Canada's communities themselves.

While the burden of infection continues to be carried disproportionately by MSM (41.8% of all infections), in 2009 data revealed that the demographics of the epidemic are no longer as certain as they once were. According to PHAC, 33% of women reporting new infections attributed their infection to heterosexual contact, only 2% fewer than those who attributed their infection to injection drug use. In 2009, 11.6% of new infections for which ethnicity was recorded were in those who self-identified as Black.

But I'm already HIV positive, why should I care about an HIV vaccine?

In addition to preventive vaccines—vaccines that protect those who are negative from becoming positive—there are currently vaccines being tested for those who are HIV positive. These are called therapeutic vaccines and could have several different effects:

1. A therapeutic vaccine would control the development of HIV to AIDS and delay the time at which treatment needs to be started. In a best case scenario, it would remove the need for treatment altogether.
2. A therapeutic vaccine would reduce the likelihood of transmission from an HIV positive individual to his HIV negative sex and drug injection networks through a reduction in viral load.

[1] 2009 is the most recent year for which a surveillance report has been released by the Public Health Agency of Canada.

Why haven't I heard about a therapeutic HIV vaccine?

Fewer therapeutic vaccine trials take place compared to preventive vaccine trials, which is why fewer people are aware that therapeutic vaccines are being developed. Since Canada has never hosted a trial for a therapeutic vaccine, Canadians are even less aware that a therapeutic vaccine might one day be a possibility.

That said, there is reason for poz people to follow developments in both preventive and therapeutic vaccine research. Each late phase preventive vaccine trial usually follows those individuals who got the vaccine and still sero-converted. This is done to determine if receiving the vaccine has any effect on the progression of an HIV infection. This includes determining whether the vaccine improves immune response and thus delays the progression of the disease from HIV to AIDS. In effect, this means that each preventive vaccine is analysed to determine if it might also be developed into a therapeutic vaccine for those who live with HIV.

How does a therapeutic vaccine reduce the risk of transmission between a person with HIV and her sexual and drug injection networks?

Therapeutic vaccines are designed to control HIV infection by boosting the body's natural immune response. They are not designed to cure an infection. Boosting the immune response will increase the number of CD4 cells in the blood of a person infected with HIV. An increased number of CD4 cells in the blood allows the immune system to better fight an HIV infection and reduces the viral load, or the amount of the virus that is found in the blood of a person infected with HIV. Less HIV in the blood of an infected person means a reduced likelihood that HIV will be passed on in sexual relationships and networks of people who use injection drugs.

Will a therapeutic vaccine reduce the risk of transmission so much that someone living with HIV will no longer have to worry about his sexual and drug using networks contracting the virus?

We don't know yet. While a therapeutic vaccine is designed to control HIV and reduce the risk of transmission between someone who is HIV positive and their sexual and injection drug using networks, we won't know until the clinical trial process is complete. Findings from studies of other prevention methods involving people living with HIV suggest that reducing viral load and increasing CD4 counts reduces the likelihood of HIV transmission significantly.

You should remember that a vaccine will be a valuable addition to HIV prevention rather than a magic bullet. Other forms of proven prevention, including condoms and clean injection equipment, will continue to have to be used whenever possible.

How can I participate in the process?

Levels of awareness about and involvement in the development of therapeutic HIV vaccines among poz people are low. The emphasis in the media and in communities on the benefits of introducing a preventive vaccine to reduce rates of transmission has overshadowed the potential for these same vaccines to provide some benefit to those living with HIV. Therapeutic vaccines, although they receive less funding than preventive vaccines, remain an important part of vaccine research.

Inform yourself about therapeutic HIV vaccines and **consider** volunteering for an HIV vaccine trial when one becomes available in your community. For a complete list of therapeutic HIV vaccine trials currently taking place, please go to http://aidsinfo.nih.gov/vaccines/. On the left under "Therapeutic AIDS Vaccine Trials," click "New and Recruiting Trials."

Visit your local AIDS service organisation (ASO) and ask how you can get involved in starting a new prevention technology (NPT) committee to ensure that awareness continues to be raised in communities about NPTs. Outreach and capacity-building can be done in communities that won't be hosting HIV vaccine trials as a way to increase local knowledge of HIV vaccines in the face of increasing reports of breakthroughs in the biomedical prevention of HIV.

Support the right of people with HIV to make their own decisions regarding uptake of any future HIV vaccine. Poz people may be pressured to be vaccinated, as some have been to begin anti-retroviral treatment. Those who may benefit from a therapeutic HIV vaccine must be given the most accurate, relevant prevention information so that they may make an informed decision on whether they wish to be vaccinated or not.

Contact your Member of Parliament to support funding for research into HIV vaccines in Canada, and to restore funding to the International AIDS Vaccine Initiative and the International Partnership for Microbicides, which play an important role in the wider international effort to develop new prevention technologies like vaccines. These organisations are committed to developing and delivering affordable and effective new prevention technologies globally.

Use networks such as the Global Network of People Living with HIV/AIDS (GNP+) to keep HIV vaccines on the agenda at international gatherings and in international bodies and to ensure that the voices of poz people are heard.

References

PHAC. (2010). *HIV and AIDS in Canada: Surveillance Report to December 31, 2009.*
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Talking Points: Some Easy Answers to Tough Questions about HIV Vaccines

Key Messages

Currently, there is no therapeutic or preventive vaccine for HIV.

As of June 2011, there were 24 preventive vaccine trials taking place around the world.

Currently, there are 3 early phase studies for therapeutic vaccines.

No therapeutic vaccine has ever been tested in a Phase III trial.

Current investment in vaccines internationally totals $859 million USD (HIV Vaccine and Microbicide Resource Tracking Working Group, 2010).

A therapeutic vaccine could do one of two things: it could slow the progression of HIV to AIDS. It could also reduce the transmissibility of HIV between sero-discordant people.

Therapeutic vaccine trials need PLWHIV/AIDS and their HIV-partners to volunteer to determine if the vaccine is efficacious.

This info sheet focuses on addressing questions and concerns that people living with HIV may have regarding the risk, relevance, cost and need for therapeutic HIV vaccine trials.

We're already HIV positive. Why do we need an HIV vaccine?

People living with HIV could benefit significantly from the development of a therapeutic HIV vaccine. Trial vaccines have been designed first to decrease viral loads and thus boost the immune system, and second to delay the need for treatment in those who haven't started HAART and to increase the time off treatment for those who have been on HIV treatment previously.

The reduction of the risk of HIV transmission between sexual partners and injection drug using networks is a realistic secondary benefit to future therapeutic vaccines. This would reduce the risk of infecting the negative partner in a sero-discordant couple and might even reduce the risk of vertical transmission of HIV from mother to child during childbirth and breastfeeding.

An effective therapeutic vaccine would prolong an HIV positive person's opportunity for a full and healthy life without lifelong treatment.

Why do we need vaccine trials?

A therapeutic vaccine will never be licensed without proving it was effective at controlling HIV in a clinical trial. Even when vaccines fail during a trial, they provide information that advances the development of a vaccine, and they provide information that couldn't be gathered any other way.

Therapeutic vaccines can only be tested on those who are already HIV positive. Therapeutic HIV vaccine trials usually enroll sero-discordant couples to determine if rates of transmission are reduced when the HIV+ partner is vaccinated.

Has a therapeutic vaccine ever worsened the health of those participating in the trial?

In 2008, a phase II trial of a therapeutic vaccine known as ALVAC 1452 determined that the trial vaccine didn't meet its goals. These goals were to decrease viral loads and/or increase the time that participants could control the virus without treatment. Instead, the vaccine increased viral load and reduced the number of weeks that participants who received the vaccine could remain off their treatment. Participants in this trial were given the option to stop their ARV-based treatment after vaccination or to continue on with their regular treatment.

This study demonstrated that participants, their physicians and researchers must have an open discussion about the risks to participants' health that participating in a vaccine trial can entail. In the case of ALVAC 1452, when a participants' CD4 count dropped to below 250 cells/mm3 treatment was restarted.

Why should I risk my health to participate in a trial?

Therapeutic vaccine research is only conducted with people living with HIV who have healthy immune systems. For the majority of trials, most volunteers must have a CD4 count of 350 cells/mm3 or greater. This reduces the potential for harmful effects of the vaccine on the health of people living with HIV. Trial designs vary and some recruit those who are treatment naïve—that is they have never taken ARVs. Other trials require that participants remain on treatment while in the study.

Participating in a trial that could interfere with the stability of your health is an important decision that should be discussed with your healthcare provider and with peer workers and clinicians who are conducting the trial.

There is almost a billion dollars a year being invested in HIV vaccine research (as of 2010). Why is only 9.8 million dollars being invested in therapeutic vaccines?

The investment in preventive vaccines is actually an investment in therapeutic vaccines too. When participants in preventive vaccine trials become HIV positive, as some do during trials, those people are followed by researchers to determine if there are any therapeutic effects of the vaccine on the progression of their HIV. In this case, HIV vaccines, during trials, are monitored for both their preventive and therapeutic effects.

Why are vaccine trials so expensive?

HIV vaccine trials are costly for a number of reasons. First, they require the participation of highly trained researchers, clinicians and counsellors. Later stage trials, especially Phase IIb and Phase III trials, enroll thousands of volunteers to ensure that a result that is statistically significant can be obtained. Recruiting, retaining, treating and counselling these participants is expensive. Finally, the analysis and storage of the thousands of blood and tissue samples that are collected over the duration of the trial is costly.

For More Information

AIDS Vaccine Advocacy Coalition: http://www.avac.org

HIV Vaccine Trials Network : http : www.hvtn.org

International AIDS Vaccine Initiative: http://www.iavi.org

National Institute of Allergies and Infectious Diseases: http://www.niaid.nih.gov/topics/hivaids/research/vaccines/Pages/default.aspx

There's No Vaccine for That? A Positive Youth's Introduction to HIV Vaccines

You should know: There isn't a vaccine available for HIV. There are trials testing vaccines right now around the world, and so there's hope. This info sheet outlines some of the questions you might have about vaccines and gives you some idea about what you can do now to prepare yourself and your friends for an HIV vaccine.

I already have HIV. Isn't a vaccine too late for me?

Actually, there are clinical trials for a vaccine for people already living with HIV. These types of vaccines are designed to slow the progress of HIV to AIDS by boosting your immune response to the infection. This means treatment will be delayed, and ideally, never needed. They are designed to make people with HIV less infectious to others too.

How can a vaccine help me?

A vaccine would be designed to boost your immune response, lower your viral load and would delay the progression of HIV to AIDS. This would keep you healthier for longer.

Lower viral loads have been associated with reduced risk of transmission to those who are HIV negative. You'd still have to use condoms and clean injection equipment whenever possible but a vaccine could drastically improve your quality of life.

What can I do now until a vaccine or a clinical trial is available?

Become an advocate for HIV vaccines among your peers. HIV vaccines might be a thing of the future but it's important to raise awareness today that they are being developed. This will get people thinking about whether or not they would consider volunteering for an HIV vaccine trial.

Contact your local AIDS service organisation (ASO) and stay informed. Raise awareness among your peers about HIV prevention and treatment, including how vaccines can one day work to complement current prevention and treatment strategies.

In Canada, every 500th person is HIV positive.

That's about how many friends some of you have on Facebook.

Looking for something to complain about? Here are some things you can act on now that are relevant to youth:

1. Currently youth can't participate in HIV vaccine trials in Canada even if they are at risk for HIV. Only when a vaccine has been determined to be safe and effective in adults is it then tested in people under the age of 18. There are valid concerns about exposing teens to the potential harms of a vaccine

before it has been tested in adults. Youth who want to participate in the process need to be given the tools to argue for their desire to participate in the research process. A positive youth is better placed than anyone to explain why HIV vaccines need to be available to teens.

2. There are currently no guidelines for allowing minors to consent to vaccination without their parents' knowledge. That means if you hadn't turned 18 and a vaccine were available and you wanted to get it without your parents' knowledge, you couldn't. Only British Columbia recognizes that mature minors can consent to controversial vaccines for themselves. Youth need to contact their provincial politicians in order to push for better consent guidelines now before a vaccine is rolled out.

Twenty-four percent of all new HIV infections in Canada in 2009 were in youth between the ages of 15 and 29.

That's every fourth infection.

For More Information

Consult AVAC: A global AIDS vaccine advocacy group http://www.avac.org

Read IRMA: A blog devoted to developments in new prevention technologies http://irma-rectalmicrobicides.blogspot.com/

Join Mag-Net: A listserv for those interested in new prevention technologies including vaccines. Send an email to: mag-net@cdnaids.ca.

References

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The More You Know: FAQs for Young Women about HIV Vaccines

Despite their vulnerability, the effect of the HIV epidemic on women in Canada is hidden. Both the media, in its coverage of HIV, and the medical community, who consistently underestimate the exposure risks of their female patients, allow women to believe that they are not at risk for HIV infection. The Public Health Agency of Canada's (PHAC) surveillance data for 2009[1] suggest this isn't true. In 2009, 26% of all new positive HIV test reports were among women.

Young women between the ages of 15 and 19 appear to be especially vulnerable to infection. Young women account for 57% of all new infections among youth in this age category, a statistic that points to the failure of our families, communities, schools and health clinics to prepare young women for safer sex and injection drug use.

How can a vaccine reduce this risk?

A vaccine is a prevention technology that women can control, that doesn't need to be negotiated at every sex act or injection and that once given provides some long-lasting protection against HIV. A vaccine has the potential to provide some protection against infection when there is no other way for women to protect themselves. When used in combination with condoms, lube and harm reduction, a vaccine would be optimally effective at blocking transmission of the virus.

What puts young women at risk for HIV infection?

Biologically, women are more vulnerable to HIV infection than men because of the large surface area of the vagina and cervix and the potential for small tears in the vaginal wall during sex. Young women are even more susceptible because their bodies have not yet fully developed. They are also at higher risk for HIV infection because of underdeveloped self-esteem, lack of appropriate sexual education, and an inability to confidently negotiate safer sex and injection drug use. In Aboriginal and Black communities, this is compounded by racism and differing cultural norms that can affect a young woman's ability to make and defend healthful decisions. Some research demonstrates that women who use injection drugs are more likely to share needles than other users.

Are women, in general, aware of their risk?

Outreach efforts have been successful at sensitising sex workers and women who use injection drugs to their risk for HIV infection.

[1] 2009 is the most recent year for which a surveillance report has been released by the Public Health Agency of Canada.

In general, though, women are not aware of their risk for HIV infection. Adequate and informed sex education isn't given in schools. There is also a common belief among many health professionals that young women who don't use injection drugs don't have an elevated risk for HIV infection. This gives many young women a false sense of security. The fact is that 33% of those women infected with HIV in 2009 were infected through heterosexual contact, a statistic that suggests that it is time to move away from the idea that HIV only affects women who use injection drugs.

A vaccine won't be available for a decade or more. What can be done now?

HIV vaccine research needs supporters to ensure that it's relevant to the communities that are most likely to seek HIV vaccination in the future. Protocols and processes for testing trial vaccines need to be informed by the communities in which they are being run. Supporters are needed to ensure that every aspect of the trial process is culturally-appropriate and that researchers are aware of the specific needs and concerns of the communities in which they are working.

Get informed and inform your peers about HIV vaccines and **consider** volunteering for an HIV vaccine trial. Women and transwomen are consistently under-represented in clinical trials. It's essential that they participate to ensure that vaccines work in women's bodies and lives. For a complete list of preventive HIV vaccine trials currently taking place, please go to http://aidsinfo.nih.gov/vaccines/. On the left under "Preventive AIDS Vaccine Trials," click "New and Recruiting Trials."

Encourage your local AIDS service organisation (ASO) to support a frank discussion among researchers about allowing adolescent girls and pregnant women to participate in trials so that if trials come to your community, your ASO will be a vocal supporter of inclusion. It's important that vaccines be tested in these populations in order to ensure that the vaccines work in their bodies and their lives.

Engage groups working on women's health at the local, national and international level in a discussion of how they can support the effort to find and disseminate a vaccine. Increasing the capacity of individuals and the organisations that represent them to speak knowledgeably about HIV vaccine research will ensure that regional, provincial, federal and global policy-makers don't forget their commitment to reducing new HIV infections.

Contact your Member of Parliament to support funding for research into HIV vaccines in Canada, and to restore funding to the International AIDS Vaccine Initiative and the International Partnership for Microbicides. These organisations play an important role in the wider international effort to develop new prevention technologies and are committed to prevention methods that are useful for women.

Link your local efforts to the global dialogue! **Encourage** your ASO or community-based organisation to join the ATHENA Network, which advocates for gender equity in the response to HIV/AIDS globally. Encourage them to support efforts to increase funding and awareness of the need for a viable HIV vaccine, especially in countries where HIV is endemic.

And in the meantime, **promote** other female-controlled HIV prevention methods that are already available, especially female condoms. Women need as many HIV prevention options that they control as possible.

References

Gagnon, H. & Godin, G. (2009). "Psychosocial factors explaining drug users' intention to use a new syringe at each injection." *Addiction Research and Theory* 17(5): 481-492.

PHAC. (2010). *HIV and AIDS in Canada: Surveillance Report to December 31, 2009*. Available: http://www.phac-aspc.gc.ca/aids-sida/publication/survreport/2009/dec/index-eng.php.

Talking Points: Some Easy Answers to Tough Questions about HIV Vaccines

Key Messages

Currently, there is no preventive or therapeutic vaccine for HIV.

A preventive vaccine would help to prevent the transmission of HIV between individuals, as it does for other viruses.

As of June 2011, there were 24 preventive vaccine trials taking place around the world.

The majority of those trials are for preventive HIV vaccines.

Only one HIV vaccine has reduced the number of HIV infections in clinical trials.

Current investment in vaccines internationally totals $859 million USD (HIV Vaccine and Microbicide Resource Tracking Working Group, 2010).

Preventive HIV vaccine trials need volunteers from a range of individuals, including women, Aboriginal peoples, ethnic and cultural minorities and people who have a varied risk of exposure to HIV, including those at low risk.

This info sheet focuses on addressing questions and concerns that individuals may have regarding the relevance, cost and need for preventive HIV vaccine trials.

We already have effective HIV prevention tools. Why do we need an HIV vaccine?

No viral epidemic has ever been stopped without a vaccine. Behavioural change and education aren't working fast enough to prevent the transmission of HIV. Condoms, the most common HIV prevention tool, aren't always used correctly or consistently. The number of new infections remains stable in Canada. A vaccine has the potential to reduce this number considerably.

Why do we need vaccine trials?

A vaccine will never be licensed without proving it was effective at controlling or preventing HIV in a clinical trial. Even when vaccines fail during a trial, they provide information that advances the development of other HIV vaccines, and they provide information that couldn't be gathered any other way. Hosting vaccine trials in Canada also raises awareness in the general public that a vaccine is in development. This generates interest, and even support, for HIV vaccines in a wider segment of the population.

Vaccine trials cost a lot. Why are they so expensive?

HIV vaccine trials are expensive for a number of reasons. First, they require the participation of highly trained researchers, clinicians and counsellors. Later stage trials, especially Phase IIb and Phase III trials, enroll thousands of volunteers to ensure that a result that is statistically significant can be obtained. Providing services and support to these volunteers is costly. Finally, the analysis and storage of the thousands of blood and tissue samples that are collected over the duration of the trial is costly.

Do vaccine trials recruit volunteers from the general public?

Yes. The earliest phases of HIV vaccine trials take place with volunteers from the general public. Phase I and many Phase II trials are open to all healthy people between 18 and 45 who aren't at high risk for HIV infection. It's only in later trials of the vaccine, Phase IIb and Phase III, that the vaccine is tested in populations at higher risk for HIV infection. Later trials recruit individuals who engage in higher-risk behaviour because researchers have to know that those in the trial have the potential to come into contact with the virus. That's the only way they know if the vaccine is effective at controlling or preventing HIV. This is why later trials test the trial vaccine predominantly in MSM, women who have sexual relations with MSM and women with multiple sex partners as the rates of infection in these populations suggest that they have the potential to come into contact with the virus more frequently than the general public.

Although Phase IIb and Phase III trials don't take place in the general public in Canada, they do take place in the general population in sub-Saharan Africa where a generalized heterosexual epidemic is a reality.

For More Information

AIDS Vaccine Advocacy Coalition: http://www.avac.org

HIV Vaccine Trials Network : http : www.hvtn.org

International AIDS Vaccine Initiative: http://www.iavi.org

National Institute of Allergies and Infectious Diseases: http://www.niaid.nih.gov/topics/hivaids/research/vaccines/Pages/default.aspx

San Francisco AIDS Project. (2010). Deirdre---HIV Vaccine Trial Participant. Available: http://www.youtube.com/watch?v=WnkYqXEggnE.

San Francisco AIDS Project. (2010). Iris—HIV Vaccine Trial Participant. Available: http://www.youtube.com/watch?v=-XzucSi1nWQ.

There's No Vaccine for That? An Introduction to HIV Vaccines for Young Women

In Canada, every 500th person is HIV positive.

That's about how many friends some of you have on Facebook.

You should know: There isn't a vaccine available for HIV. There are trials testing vaccines right now around the world, and so there's hope. This info sheet outlines some of the questions you might have about vaccines and gives you some idea about what you can do now to prepare yourself and your friends for an HIV vaccine.

Isn't there a vaccine for HIV already?

No, there isn't already a vaccine for that. And no, there isn't already a cure for that either. Recent progress has been made in the search for a vaccine, but we are still years away from a vaccine becoming a reality.

An HIV infection never goes away. There are treatments that manage the disease, but many of these have unpleasant side effects. They can make you nauseous, and make your body store fat in places you never thought it could, and some of the drugs can give you uncontrollable diarrhea.

Can I get HIV?

You can. Unless you abstain from sex forever and never inject drugs into your body.

Youth between the ages of 15-29 accounted for 24% of all new HIV infections in 2009[2], and among young people between 15 and 19, young women account for 57% of all new infections. It's great that youth are getting tested, but positive test results mean that youth aren't protecting themselves against infection when they have sex or when they use injection drugs.

Your risk for HIV infection might be low, depending on your risk behaviour, but it's still a risk. Preventing HIV infection is still the only way to stay free of HIV.

How could a vaccine help me?

A vaccine isn't an HIV prevention method that has to be negotiated, so no one will know you've gotten the vaccine unless you tell them. If you get vaccinated before you start having sex, it'll be there when you come into contact with the virus, whether you know your partner is HIV positive or not.

A vaccine should always be used with condoms and clean injection drug equipment, because it won't be 100% effective at stopping an infection. When you

[2] 2009 is the most recent year for which a surveillance report has been released by the Public Health Agency of Canada.

can't use a condom, a vaccine is designed to provide you with some protection against infection. If you do have unprotected sex with a partner whose status you aren't sure of, even if you're vaccinated, you should get an HIV test anyway.

What can I do now until a vaccine or a clinical trial is available?

Start talking to your friends about HIV vaccines. HIV vaccines might be a thing of the future but it's important to raise awareness today that they are being developed. This will get people thinking about whether or not they would get vaccinated themselves.

Contact your local AIDS service organisation (ASO) and stay informed. Raise awareness among your friends about HIV prevention, including how vaccines can one day work to complement current HIV prevention strategies such as condom use.

Looking for something to complain about? Here are some things you can act on now that are relevant to youth:

1. Currently youth younger than 18 and pregnant women can't participate in HIV vaccine trials in Canada even if they are at significant risk for HIV. Only when a vaccine has been determined to be safe and effective in adults is it then tested in people under the age of 18. There are valid concerns about exposing teens and pregnant women to the potential harms of a vaccine before it has been tested in healthy adults. Youth who want to participate in the process need to be given the tools to advocate for their participation in the research process.

Young women made up 57% of all new infections in teens between the ages of 15 and 19 in 2009.

2. There are currently no guidelines for allowing minors to consent to vaccination without their parents' knowledge. That means if you hadn't turned 18 yet, and a vaccine were available and you wanted to get it without your parents' knowledge, you couldn't. Only British Columbia recognizes that mature minors can consent to controversial vaccines for themselves. Youth need to contact their provincial politicians in order to push for better consent guidelines now before a vaccine is rolled out.

For More Information

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Glossary

This glossary contains terms that relate to HIV vaccines and HIV vaccines trials. These terms don't relate exclusively to the HIV vaccine trial process and are also used during the clinical trial process for testing other products and interventions.

Adverse drug reactions: harmful events caused by the trial product (e.g. the vaccine). They are most often as mild as soreness around the injection site and a headache. They can, in rare circumstances, be severe.

Arm: the randomized grouping of participants in a clinical trial. In a vaccine trial, there is a control arm—the group of participants who received the placebo—and there is at least one arm that receives the vaccine.

Antigen: commonly known as a germ. An antigen is any substance that makes the body produce antibodies, a process that is also known as an immune response. Antigens are usually foreign substances such as bacteria or viruses.

Attenuated: weakened. Attenuated versions of viruses are used in some vaccines because they still produce an immune response without causing the actual illness. Attenuated viruses are not used to develop HIV vaccines.

Antibodies: proteins produced by the body to fight foreign toxins, bacteria and viruses that enter the body.

Clinical trial: any precisely controlled test of an experimental vaccine, drug or other intervention performed on human volunteers.

Community Advisory Board: commonly referred to as a CAB. It's a group of people that provides community input into vaccine trial design and local procedures at each trial site. CAB members include community members and professionals associated with HIV/AIDS prevention and service delivery. Many have a considerable understanding of scientific research or relevant professional training, while others have no medical or scientific background but have a strong interest in HIV prevention. Trial participants can be members of the CAB at their trial site.

Control: a subset of the entire group of volunteers in a clinical trial that is given the standard care or, in the case of a vaccine, a placebo vaccine. They are compared to another subset of volunteers from the entire group who are given the vaccine candidate.

Double-blind study: a study where neither the researchers nor the participants know who received the trial product (e.g. the vaccine) and who received the placebo.

Dose: how much of the vaccine to deliver; **regimen**: how far apart the doses should be given; and route: how the vaccine dose should be given (injection, orally etc.).

Efficacy: the ability of the intervention (e.g. the vaccine) to protect against HIV infection under the controlled conditions of a clinical trial.

Effectiveness: the ability of the intervention (e.g. the vaccine) to protect against HIV infection in the general public in real-life conditions.

ELISA (enzyme-linked immunoabsorbent assay): a blood test that detects antibodies based on a reaction that leads to a noticeable colour change in the test tube. This test is the first test used to detect HIV because it's easy and cheap. Since ELISA tests are sensitive and detect all people with HIV antibodies, including some false positives, a positive test is always confirmed by a more specific test, usually the Western Blot.

Elite Controllers: also known as long term non-progressors. About 1 in 300 people infected with HIV keep their viral load at an undetectable level without treatment.

Immune system: the body's defense against organisms that cause infection and other invaders.

Immunity: natural or vaccine-induced resistance to a specific disease. Immunity can be partial or complete, specific or non-specific, long-lasting or temporary.

Immunogenicity: the ability of a vaccine to create an immune response to a certain infection. This is measured through test samples of blood or other bodily fluids.

Informed consent: the final product of the process of explaining trial benefits and risks to participants. Informed consent is the agreement that participants make with researchers to participate in the trial, and the agreement between researchers and participants that participants have understood clearly and correctly the objectives, risks and benefits of participating in the trial.

Macrophages: a type of white blood cell that eats invading disease-causing germs. It also alerts the rest of the defence system when an invader is present.

Microbicide: also known as **topical pre-exposure prophylaxis**. A microbicide is a product that can be applied to the vagina or the rectum before sex. This would reduce the risk of HIV transmission. Microbicides are not yet available but could come in creams, gels, films, suppositories, or be delivered through a sponge or ring that would release the microbicide over a period of time. In 2010, a clinical trial of a gel microbicide administered to the vagina before and after sex found that it reduced infection in women by 31%.

New prevention technology: also known as **biomedical intervention**. This refers to a group of HIV prevention tools that employ medical interventions to reduce the risk of HIV infection. This category of HIV prevention includes male circumcision, microbicides, PEP, PrEP, preventive and therapeutic vaccines, and treatment as prevention.

Oral pre-exposure prophylaxis (PrEP): also known simply as **pre-exposure prophylaxis**. PrEP is the practice of allowing people who are HIV- and who are at high risk for HIV infection to take one or more anti-retrovirals regularly to prevent infection. In 2010, clinical trial results from a study known as iPrEx were released that demonstrated that PrEP taken orally on a daily basis reduced the risk of infection by 44%.

Phagocytes: a type of white blood cell that eats invading bacteria and organisms.

Placebo: also known as a blank or a dummy. A placebo is a harmless, inactive substance that looks like the trial intervention (e.g. the vaccine).

Placebo-controlled: Studies where at least one of the arms of the trial has a placebo group.

Post-exposure prophylaxis (PEP): the practice of giving anti-retrovirals to those who may have been exposed to HIV to attempt to prevent HIV infection. PEP would usually be administered within 72 hours of the exposure to HIV and last for 30 days.

Preventive vaccine: a vaccine that reduces the risk for people who are HIV- to acquire HIV by inducing an immune response, and the development of antibodies against HIV.

Prime-boost: in HIV vaccine research, prime-boost is the administration of one type of vaccine, followed by a second type of vaccine. The intent of this combination is to trigger different types of immune responses and enhance the overall immune response to HIV, a response that may not occur if only one type of vaccine were given by itself.

Proof of concept: the first trial that proves that an intervention's (e.g. vaccine) drug formulation, dose and regimen reduce the transmission of the virus.

Randomized: A type of trial that divides participants into vaccine and placebo groups. This is done so that every participant has an equal chance of receiving the vaccine or the placebo. Randomized trials limit, as much as possible, the bias (or influence) of researchers on the trial results.

Safety: in the context of an HIV vaccine trial, safety means that the vaccine doesn't cause side effects. Safety trials, usually phases I and II, don't test whether the vaccine makes people safe from HIV infection.

Statistical significance: when the difference measured between the effect of the intervention (e.g. the vaccine) and placebo arms of a trial is most likely due to the intervention and not to chance.

Therapeutic vaccine: a vaccine that delays the progression of HIV to AIDS in PLWHIV/AIDS and that reduces the risk of transmitting HIV to those who are uninfected.

Treatment naïve: a term that refers to people who have been diagnosed with HIV and have not been treated with any medications that control their infection.

Vaccine: a product that stimulates an immune response that can prevent an infection or create resistance to an infection.

Vector: a harmless bacterium or virus that doesn't cause disease in humans and that is used in genetically engineered vaccines to deliver an HIV vaccine into the body to induce an immune response.

Vertical transmission: also known as mother-to-child or parent-to-child transmission. It's the transmission of HIV from a parent to her child during childbirth or through breastfeeding.

Viral epidemic: a widespread occurrence of a disease caused by a virus in an area or a community. These epidemics are characterized by higher rates of infection than should normally occur in a population.

Viral load: the amount of HIV circulating in the body.

Western Blot: blood test that detects specific antibodies to HIV infection. This test is used to confirm the results of initial positive blood tests and is the most accurate HIV test available.

For More Information

For more information and to keep up-to-date on the latest developments in the fields of HIV vaccines and other new prevention technologies (NPTs), consult the following list of resources. Wherever possible, the latest versions and the most recent publications have been included in this list. Websites, blogs and listservs are especially useful for locating the latest information in the area of NPTs. Where indicated, the resources are also available in French.

Vaccines

Blogs and Listservs

For the latest information on new prevention technologies, consider subscribing to the IRMA blog (http://irma-rectalmicrobicides.blogspot.com/) and AVAC's Weekly NewsDigest (http://www.avac.org/ht/d/sp/i/4558/pid/4558). Consider joining the IRMA listserv (https://lists.critpath.org/mailman/listinfo/rectalmicro) or the Mag-Net listserv (MAG-Net@cdnaids.ca)

Fact Sheets

AVAC. (n.d). *Introduction to AIDS Vaccines*.
Available: http://nmac.org/vt/en/AVAC_pt5.html.

This is a six part presentation on HIV vaccines and includes slides and audio.

AVAC. (2010). *AIDS Vaccines*.
Available: http://www.avac.org/ht/a/GetDocumentAction/i/5847.

Provides an overview of AIDS vaccines, including an explanation of what a vaccine is, why scientists believe it will be useful to prevent HIV infection and where the clinical trial process currently is in the search for an effective vaccine.

Guidelines and Backgrounders

ICASO and AVAC. (2005). *Finding Your Way: A guide to understanding ethical issues related to participation in clinical trials for preventive HIV vaccines*.
Available: http://www.icaso.org/guidelines.html. Available in French.

Guidelines that offer practical guidance to support community sector involvement in HIV preventive vaccine research. This document provides information on standards, structures, processes and methods for community action on HIV vaccines.

ICASO. (2006). *Community Involvement in HIV Vaccine Research: Making it work*.
Available: http://www.icaso.org/vaccines_toolkit/subpages/files/English/Vaccine_E_WEB_2009Update.pdf

This document examines the lessons learned about community involvement from previous HIV vaccine trials globally. It's especially useful when outlining the recommendations about the ways in which communities can be better integrated into HIV vaccine research and how this will improve the overall experience of HIV vaccine trials for both participants and researchers.

IAVI. (n.d.). *Vax Primer.*
Available: http://www.iavireport.org/vax-primers/Pages/default.aspx.

Vax Primer is the general name for a series of short backgrounders on topics related to the clinical trial process and the science of HIV vaccines. The documents provide information on a variety of subjects, and are aimed at isolating one part of the HIV vaccine clinical trial process and explaining it in some depth.

Timelines

AVAC. (2011). *Ongoing Trials of Preventive HIV/AIDS Vaccines Worldwide (September 2010)*.
Available: http://www.avac.org/ht/a/GetDocumentAction/i/3436

AVAC. (2011). *HIV Prevention Research: Timeline of Expected Efficacy Trial Results*.
Available: http://www.avac.org/ht/a/GetImageAction/i/35333

Toolkits

Canadian HIV/AIDS Legal Network. (2005). *HIV Vaccines and Human Rights: Community Action Kit*.
Available: http://www.aidslaw.ca/publications/publicationsdocEN.php?ref=350

This toolkit is a series of 12 info sheets on HIV vaccines and human rights, including human rights issues during HIV vaccine research for women, children and vulnerable populations. Available in French.

Canadian HIV/AIDS Legal Network. (2002). *HIV Vaccines in Canada*. Available: http://www.aidslex.org/site_documents/V002E.pdf

This short toolkit provides Canadian-specific information on the HIV vaccine clinical trial process. Available in French.

ICASO. (2009). *The Science of HIV Vaccines: An Introduction for Community Groups, Second Edition*.
Available: http://www.icaso.org/vaccines_toolkit/subpages/files/English/ICASO_SciencePrimer_EN_FINAL_121009.pdf

This toolkit provides an overview of the science of HIV vaccines in plain-language, beginning with the immune system and ending with the challenge of developing an HIV vaccine. A comprehensive glossary is included.

IAVI. (2008). VaxLit: AIDS Vaccine Literacy Toolkit. Available: http://www.iavi.org/working-with-communities/Pages/vaccine-literacy.aspx.

This toolkit is a comprehensive set of educational materials on HIV vaccines and HIV vaccine trials with a generalized focus. The language is more advanced than other toolkits but doesn't presume a pre-existing knowledge of HIV vaccines. It includes a comprehensive glossary and a trainer's manual. Available in French.

National Institutes of Health. (2009). *Be the Generation*. Available: http://bethegeneration.nih.gov/go/initiative-toolkit.

This toolkit is geared toward MSM, Blacks, women and Latinos in the American context. It provides specific information for each population about how a preventive HIV vaccine could benefit them and their communities. The information in this toolkit would be easily adaptable to the Canadian context.

NIAID. (2008). *Understanding Vaccines: What They Are, How They Work*. Available: http://www.niaid.nih.gov/topics/vaccines/documents/undvacc.pdf.

This toolkit provides plain-language general information on vaccines, including HIV vaccines. The information is geared toward the general public and includes sections that explain what a vaccine is, the types of vaccines that are currently in use and vaccine technologies of the future.

SAAVI. (2008). *The HIV Vaccines Community Education Programme*. Available: http://www.saavi.org.za/resources.htm.

This is a comprehensive HIV vaccine toolkit, including trainer's and learner's manuals. The toolkit is divided into 7 modules and has two distinct themes. The first 4 modules explain the science of HIV vaccines and HIV vaccines research, while the last three modules focus on ethics and the challenges and strengths of community participation. Developed for the African context, this toolkit may be especially useful in African, Caribbean and Black communities in Canada.

Websites

AVAC is an advocacy coalition committed to the development, licensure and accessibility of new prevention technologies. Resources are available on PrEP, microbicides, circumcision and vaccines. Some resources are available in French. http://www.avac.org.

IAVI is an organisation committed to the discovery and licensure of an HIV vaccine. This site contains information on HIV vaccines and IAVI's efforts to push HIV vaccine development forward. Some resources are available in French. http://www.iavi.org.

The Canadian HIV Trials Network has a complete listing of the clinical trials taking place in Canada on HIV. These include HIV vaccine trials. Available in French. http://www.hivnet.ubc.ca/home/.

The HIV Vaccine and Microbicides Resource Tracking Working Group was established to track and disseminate information on global investment in HIV vaccines and other HIV new prevention technologies research, development, policy and advocacy activities. The site contains detailed information about financial investment globally for HIV vaccine development. http://www.hivresourcetracking.org/

Other New Prevention Technologies

Fact Sheets

AVAC. (2010). *Pre-Exposure Prophylaxis* (PrEP). Available: http://www.gmhc.org/files/editor/file/a_pa_PrEP_091310.pdf, http://www.avac.org/ht/a/GetDocumentAction/i/31350

These resources provide an overview of PrEP, and iPrEx including an explanation of what PrEP is, why scientists believe it will be useful to prevent HIV infection and where the clinical trial process currently is in the search for an effective PrEP.

FHI. (2011). FHI Statement on the FEM-PrEP HIV Prevention Study. Available: http://www.fhi.org/en/AboutFHI/Media/Releases/FEM-PrEP_statement041811.htm.

This is the initial statement from the sponsors of the FEM-PREP trial, announcing the trial's closure. The page also includes fact sheets on key findings, adherence, community engagement, drug resistance, pregnancy and contraceptive effectiveness in the FEM-PrEP trial, safety and the socio-behavioral aspects of FEM-PrEP.

IRMA. (2010). *Rectal Microbicides 101*. Available: http://www.rectalmicrobicides.org/docs/RM%20101%20Fact%20Sheet%20IRMA%202010%20FINAL.pdf.

Provides an overview of microbicides, including an explanation of what a microbicide is, why scientists believe it will be useful to prevent HIV infection and where the clinical trial process currently is in the search for an effective microbicide.

Microbicides Trials Network. (2011). *Fact Sheet: Rectal Microbicides*. Available: http://www.mtnstopshiv.org/node/2864

This factsheet provides a brief overview of microbicides, an explanation of why a rectal microbicide is needed and why it has taken so long to develop one. It includes a listing of closed and current rectal microbicide trials.

University of Washington. (2011). Pivotal Study Finds that HIV Medications Are Highly Effective as Prophylaxis against HIV Infection in Men and Women in Africa. Available: http://depts.washington.edu/uwicrc/research/studies/files/PrEP_PressRelease-UW_13Jul2011.pdf.

This is the initial statement from the sponsors of the Partners PrEP trial. The resource outlines the trial design, the trial's findings, and what those results tell us about PrEP.

Timelines

AVAC. (2010). *PrEP Trials Timeline*. Available: http://www.globaliprex.com/pdfs/AVAC-PrEP_timeline_graphic.November-2010.jpg.

AVAC. (2010). *Ongoing and Planned Clinical Trials of Topical Microbicide Candidates (June 2010)*. Available: http://www.avac.org/ht/a/GetDocumentAction/i/3109.

Toolkits

Canadian AIDS Society. 2007. *Community Mobilization Kit - Microbicides: A Female-Controlled Method of Preventing HIV and other Sexually Transmitted Diseases*. Available: http://www.cdnaids.ca/communitykitmicrobicides.

This kit is designed to be used at the local level by those organisations interested in increasing awareness about microbicides: a female-controlled method of reducing the risk of HIV and other STIs. Included in this kit are suggested ways of raising awareness around this issue. This kit can help organisations get the message out to the media, government officials, as well as to other like-minded organisations. We encourage the reproduction of materials found in this kit.

Canadian AIDS Society. (2010). PrEP Community Mobilization Kit.
Available: http://www.cdnaids.ca/files.nsf/pages/microsoftword-cas_prep-kit_final/$file/Microsoft%20Word%20-%20CAS_PrEP-Kit_Final.pdf

This toolkit provides information on pre-exposure prophylaxis (PrEP), including an extensive chart outlining the advantages and concerns about the introduction of PrEP. This toolkit also includes a resource listing. Available in French.

GNP+. (2010). *New Prevention Technologies Toolkit*. Available: http://www.gnpplus.net/images/stories/PHDP/NPT_Toolkit_ENG_web.pdf.

This toolkit provides an overview of all new prevention technologies through the lens of their impact on the lives and health of those already living with HIV. Short, easy-to-understand discussions of all NPTs, including treatment as prevention, are examined with the implications these new developments have on PLWHIV/AIDS globally.

Websites

CATIE has developed resources on microbicides, PrEP, PEP and treatment as prevention. They provide plain-language explanations of new developments in each of these areas. From this link, resources from other organisations are also available and include fact-sheets and primers on all of the new prevention technologies currently under development. Most resources are available in French. http://www.catie.ca/eng/PreventingHIV/prevention-approaches.shtml#biomedical

Global iPrEx is the name of the first study of PrEP to prove efficacy at reducing the transmission of HIV. Its official website includes all research and information relating to the study and its results, with downloadable backgrounders and factsheets. Available in English only. http://www.globaliprex.com/web/index.do

International Partnership for Microbicides is guided by a singular global health mission: to provide women with safe, effective and affordable products they can use to protect themselves against HIV infection and to make these products available as quickly as possible in developing countries where the need is most urgent. Available in English only. http://www.ipmglobal.org.

IRMA is a rectal microbicide advocacy organisation with the goal of creating safe, effective, acceptable and accessible rectal microbicides for the women, men, and transgender individuals around the world who engage in anal intercourse. Some resources are available in French. http://www.rectalmicrobicides.org/

CANADIAN AIDS SOCIETY

SOCIÉTÉ CANADIENNE DU SIDA