

Microbicides: Community Mobilization Kit

3rd Edition, Updated March 2007



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You can make a difference!

- Microbicides could prevent 2.5 million HIV infections over three years.
- Microbicides would provide a user-controlled method of protection that does not necessarily require a partner's consent, which would be particularly important for women.
- Microbicides would provide a desperately needed new HIV prevention option for your community: women, gay men, youth, Aboriginal and ethnocultural communities, prisoners, persons who use drugs, and people living with HIV/AIDS.
- Microbicides can easily be integrated into your existing prevention and advocacy work.

Microbicides need your support to become a reality!

INTRODUCTION

HIV and other sexually transmitted infections (STIs) continue to pose a significant risk to the health of the Canadian population in general. More particularly, HIV infection rates are growing amongst women, gay men, youth, injection drug users, Aboriginals, ethnocultural communities and prisoners.

More than 20 years into the HIV epidemic, abstinence and condom use are still the only available methods to prevent transmission. Unfortunately neither of these options is realistic for those who, for a variety of reasons, are not in a position to negotiate safer sex. This is particularly true for women, who make up 25% of new infections in Canada. As a result, the epidemic continues to spread at alarming rates, both in Canada and worldwide.

Three clinical trials in Kenya, Uganda and South Africa have demonstrated that adult male circumcision significantly reduces a man's risk of acquiring HIV; circumcised men are 40 - 60% less likely to acquire HIV from an infected female partner. However, a woman may actually have a greater risk of acquiring HIV if their newly circumcised partner did not abstain from sex until the surgical wound had fully healed. Both of these findings have enormous ramifications for future prevention messaging and culturally appropriate options for people.

Fortunately, a new 'user controlled' category of prevention products is now under development in an urgent attempt to increase the prevention options available to populations at risk, particularly women. These new products are known as microbicides. Microbicides present a powerful opportunity to prevent new HIV and STI infections, but they require international and national support to be made available as quickly as possible.

In 2000, the Canadian AIDS Society formed the Microbicides Advocacy Group Network (MAG-Net), a coalition of over 70 Canadian AIDS service organizations, sexual and reproductive health organizations, international development organizations and researchers interested in promoting the development of alternative HIV/AIDS and STI prevention options. MAG-Net is the Canadian arm of the Global Campaign for Microbicides, an international coalition of more than 200 organizations that collaborate to build support among policy makers, opinion leaders, and the general public for increased investment into microbicides and other user-controlled HIV prevention methods.

The Canadian AIDS Society has produced this kit with the assistance of MAG-Net and the Global Campaign to help communities mobilize for accelerated development and access to microbicides.

Resources in this kit

The kit contains basic information on microbicides, including information relevant to specific groups, which can be used as fact sheets for distribution in your community. In addition, the kit contains templates of materials to use for advocacy and awareness-raising with governments, media and other community members. The materials could serve as a basis for an article in your organization's newsletter, or as background information on microbicides for your web site. The kit also contains a list of further resources.

We encourage the reproduction of materials found in this kit.

Acknowledgements

We would like to thank the Global Campaign for Microbicides for allowing us to reproduce information in this kit, wholly and/or in part.

For more information about the Global Campaign for Microbicides, please contact:

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An email list service for this group is available as well. You can subscribe by sending an email with "subscribe" (without the quotes) in the subject line to <mag-net@cdnaids.ca>.

BASIC INFORMATION ABOUT MICROBICIDES

What is a microbicide?

A microbicide is any substance that can substantially reduce transmission of HIV and other sexually transmitted infections (STIs) when applied either in the vagina or rectum. Like today's spermicides, microbicides could be produced in many forms, such as gels, creams, suppositories, films, or in the form of a sponge or a vaginal ring that slowly releases the active ingredient over time.

Are microbicides currently available?

No, there are no microbicides currently on the market. However, there are many products in various stages of development. Several of these have proven safe and effective in animals and are now being tested in humans. If one of these products is successful, and with sufficient investment, a microbicide could be on the market by 2010.

How would a microbicide work?

There are four main ways that microbicides work. Scientists are presently exploring substances that:

1. kill or inactivate STI pathogens
2. block infection by creating a barrier between the pathogen and the vagina or rectum
3. prevent the infection from taking hold after it has entered the body (there are two ways: by blocking the virus from attaching to receptor cells; or, by stopping the virus from replicating once it has entered the receptor cell)
4. boost the body's natural defences to protect the vagina or rectum

Would a microbicide eliminate the need for condoms?

No. Used consistently and correctly, condoms provide excellent protection against HIV and other STIs. Microbicides should be promoted along with condoms for extra protection, and as a back up in case of condom breakage. Microbicides can also be promoted on their own as protection for people who are unable or unwilling to use condoms, and for those whose partners refuse to wear condoms.

As is consistent with other harm reduction approaches to HIV prevention, public health messages should promote condoms as the best choice but suggest microbicides as a fallback option when condom use is not possible.



A pathogen is a virus or bacteria that can cause infection.

Barrier methods like male and female condoms will always provide better protection than microbicides, because it's safer to keep a virus out of your body than to try to stop it once it's there.

Impact of Microbicides

Even in far from ideal conditions, microbicides can still have a profound impact on the HIV epidemic. Mathematical models show that if even a small proportion of women in lower income countries used a 60% effective microbicide in half the sexual encounters where condoms are not used, 2.5 million HIV infections could be averted over three years.

How effective will microbicides be?

Microbicides will only reduce the risk of HIV and other STIs – they will not eliminate that risk altogether. The first microbicides are only likely to be 40-60% protective against HIV; as the products evolve, this protection could increase to between 60-80% in second generation products. Although this makes microbicides less effective than condoms, it still offers far more protection than is currently available if condom use is not possible. In fact, mathematical models show that within many populations, more HIV infections can be prevented with a less effective product that can be used more consistently by more people (such as microbicides), than with a highly effective product that is used inconsistently (such as condoms).

Would a microbicide protect against all sexually transmitted infections?

Since STIs are caused by different pathogens (some viral and some bacterial) a microbicide that works against one STI pathogen would not necessarily protect against another. Eventually, the best products will likely combine several mechanisms of action to protect against a range of STIs, including HIV.

What if a woman wants to get pregnant?

Some of the microbicides being investigated prevent pregnancy and some do not. It is important to have non-contraceptive microbicides in addition to one that prevent pregnancy, so that women and couples can protect their health and still have children. This is not possible with condoms.

Would men benefit from a microbicide as well?

There is every reason to believe that a microbicide would provide protection for both partners (bi-directional protection). Microbicides could help prevent infections from STIs, prevent re-infection with different strains of HIV and provide protection in sero-discordant couples (heterosexual or same sex).

Men accounted for 77% of new HIV infections overall in Canada in 2003 and men who have sex with men (MSM) accounted for 40% of new infections. (Health Canada Epi Update, April 2004), so it is vital that men are included in microbicide advocacy efforts. Currently products are being tested for both vaginal and rectal use.

Would people living with HIV/AIDS benefit from a microbicide as well?

Microbicides could help prevent infections from other STIs, prevent re-infection with different strains of HIV, and provide protection in sero-discordant couples. A non-contraceptive microbicide would also protect sero-discordant couples trying to conceive.

Would such products be safe?

Like any new product, microbicides must go through rigorous safety testing before they can be made available to consumers. Fortunately, many of the substances being investigated have been around a long time, and some are even commonly used in food. Scientists are currently testing the safety of microbicide use in the vagina, the penis and the rectum.

Is there a market for microbicides?

Yes. Research indicates that women in both developing and developed countries are extremely interested in a women-controlled prevention alternative, and are even willing to pay more for it than condoms. However, advocates are working to ensure that microbicides are affordable. Current products in development are likely to be at least as cheap as condoms. Contraceptive microbicides also offer significant market potential in that they combine disease prevention with pregnancy protection.

Sero-discordant is defined as a relationship where one of the partners is HIV-positive and the other negative.

Nonoxynol-9

At one point Nonoxynol-9 (N-9), the contraceptive spermicide, was considered as a potential microbicide. However, research showed that N-9 in fact can increase the risk of HIV infection;

1. when used frequently (more than once a day) or at high doses vaginally
2. when used rectally (even a low dose of N-9 can damage the rectum)

N-9 should never be used rectally. It should also not be used vaginally more than once a day.

Market Research

Parallel to actual product development, research is also being conducted to gauge consumer preferences regarding the characteristics of microbicides, including ease of application, surreptitious use, disposable packaging, lubricating properties, odour, colour, contraceptive properties, etc. It is important to learn as much as possible because the more forms that are available on the market, the greater the appeal to a wider variety of consumers.

What is the current status of microbicide research?

All potential microbicides need to be submitted to rigorous research standards to ensure the product is safe and effective. The entire testing process can take at least ten years. After successfully passing laboratory and animal testing, several of these products have made it to early clinical trials among humans. Several of the microbicide candidates have successfully passed laboratory and animal testing, and have made it to clinical trials among humans. Products in the final stage of testing include BufferGel, Carraguard, Pro 2000, Tenofovir/MPMA gel. This last stage (phase III clinical trials) is the longest and most expensive, because it requires testing among a large number of people over a significant time to ensure there are no long-term side effects.

After successfully passing all the tests, the product must then receive final approval by regulatory authorities before it goes on the market. If all goes well, there could be a microbicide available by the end of this decade.

Recently, there has been a set-back with the halting of the Cellulose Sulfate (CS) trials. This was a promising Canadian microbicide candidate, but early data suggest that CS may be contributing to an increased risk of HIV infection.

POPULATION-SPECIFIC INFORMATION ON MICROBICIDES

Women

HIV cases among women in Canada are rising. Currently, 25% of new infections occur in women, up from 12% just a few years ago. Young women aged 15-29 years account for over 40% of new HIV infections reported among Canadian women. Similar figures exist for Aboriginal women, who now make up 47% of Aboriginal infection rates. According to the Public Health Agency of Canada, heterosexual contact and intravenous drug use are the main causes of HIV transmission in women.

Biologically, women are more vulnerable to HIV infection. In addition, women often have limited control over safer sex decisions, since women can be socially and/or economically dependent on partners, and therefore not in positions of power to insist on condom use. An odourless, tasteless microbicide will be especially useful for women, as its use will not necessarily require consent of the partner. Not only will microbicides prevent HIV or STI re-infection, but also the benefits of microbicides will be bi-directional, protecting both partners. Some microbicides will also have contraceptive properties.

Women who have sex with women may also benefit from future microbicides. Though more research is needed to understand HIV transmission among lesbian women, there is still the potential of STI transmission. As noted above, STIs increase the risk of contracting HIV.

Men

Microbicides will benefit men, including heterosexual men, gay men, and other men who have sex with men. Indeed, men, like women, report low levels of condom use in long-term partnerships. Worldwide, men tend to have more sex partners than women, including partners outside of their primary relationship, and this increases the risk of contracting HIV. Secrecy and stigma may stifle discussion about HIV within couples.

In Canada, gay men and MSM continue to account for the largest number of new infections. In 2005 they represented 51% of all people living with HIV/AIDS (PLWHIV/AIDS) and 45% of newly reported HIV infections. This population also had the largest increase in infections, up 10% since 1999.

*** Statistics provided in this fact sheet are the most recent available as of January 2006 from the Public Health Agency of Canada (Epi Updates from April 2005). For more recent information as it becomes available, please consult Epi Updates at <http://www.phac-aspc.gc.ca/aids-sida/hiv_aids/index.html>. Consult your provincial government for more recent statistics in your region. ***



A microbicide
will be
especially
useful for
women.

Microbicides
will benefit
men.

Engaging Aboriginal and ethnocultural communities in microbicide advocacy efforts will help ensure their needs are met.

Although most gay men practice safer sex, the complexities of sexual decision making for some gay men has highlighted the need for more targeted education and other resources such as microbicides to practice safer sex. People protect themselves most effectively when they have a range of options from which to choose. Microbicides could thus offer an alternative to the current “condom versus no condom” decision. In addition, microbicides will allow skin-to-skin intimacy and thus enhance pleasure. Microbicides will also provide bi-directional protection, protecting both partners during sex.

For these reasons, microbicides, including products that have been tested for rectal use, will be an important prevention option for all men to be used in combination with condoms. It should be noted that scientists have begun to investigate a microbicide suitable for rectal use, but developing such a microbicide is more difficult due to the different biology of the colon and the vagina. It is likely that a rectal microbicide will be available a few years after a vaginal microbicide.

Aboriginal communities

In 2005, Aboriginal people constituted nearly 23% of all newly reported HIV cases, although they only represent 3.3% of Canada’s total population.* Aboriginal women make up half the total Aboriginal people living with HIV/AIDS, which is a proportion considerably higher than in the general population. Research on receptivity to the female condom indicates that Aboriginal women would welcome female-controlled STI prevention tools, as long as they are accompanied by culturally appropriate support and education on use.

Broadening HIV/STI prevention options by introducing safe, inexpensive and easily accessible microbicides will benefit Aboriginal people both on and off reserve. Even in isolated Aboriginal communities where HIV is not viewed as a serious local problem, microbicides could offer protection against high rates of STIs and teenage pregnancy. Engaging Aboriginal communities in microbicide advocacy efforts will help ensure their needs are met in terms of product development, marketing and delivery.

Ethnocultural communities

In Canada, members of ethnocultural communities and immigrants from countries where HIV has become endemic can be at a particularly high risk of HIV infection. At the end of 2005, 12% of all HIV infections in Canada were attributed to people in the HIV-endemic exposure subcategory, although only 1.5% of Canadian populations was born in an HIV-endemic country. In addition, almost 80% of people in the subcategory were less than 40 years of age when they had a positive HIV test result.* Also, HIV prevalence in the Black communities of Ontario has increased by 85% since 1996 with an average annual increase of 13% representing the highest increase of HIV prevalence of any exposure categories.

* It is important to note that It is important to note that on 29% of reported HIV tests contained information on ethnicity. Neither Ontario nor Québec include ethnicity information when reporting HIV positive test results, while these two provinces have the highest numbers of new infections every year. Therefore, proportions of members of Aboriginal and Black communities among newly reported HIV infections might be different if ethnicity was reported in these two provinces.

In their countries of origin, HIV-positive individuals, particularly women are at risk for abandonment by their family and friends, discrimination at work, the loss of their land and children, violence and abuse, and many other negative consequences. Within Canada, ethnocultural communities, as well as immigrants and refugees from endemic countries, also face barriers in access to appropriate services associated with levels of literacy, language, cultural taboos against talking about sex, fear of the impact of a positive test on immigration status, and the lack of targeted prevention messages. Microbicides would be a valuable additional tool to protect the health of ethnocultural communities. In addition, engaging ethnocultural communities in microbicide advocacy efforts will help ensure their needs are met in terms of product development, marketing and delivery.

People living with HIV/AIDS

There are currently approximately 58,000 people living with HIV/AIDS in Canada, including about one third who do not know that they are HIV-positive. For people living with HIV/AIDS, microbicides could help prevent infections from other STIs, prevent re-infection with other strains of HIV and provide protection in sero-discordant couples (one partner is HIV positive and one partner is HIV negative). A non-contraceptive microbicide would allow protection for couples trying to conceive.

People who use drugs

The rate of HIV among injection drug users (IDUs) in Canada remains high, especially among Aboriginal populations. In 2002, IDUs represented 14% of new HIV infections and 17% of people living with HIV/AIDS.

Sharing used needles creates a high risk of HIV transmission, but the link between substance use and HIV goes beyond needles. People who use alcohol, speed, crack cocaine, crystal meth or other non-injected drugs are at higher risk of contracting HIV than non-substance users. People with a history of drug use are also more likely to engage in high-risk sexual activities, and research has also acknowledged the more prominent role that sexual transmission may play in women IDUs.

Raising awareness about microbicides among persons who use drugs could help ensure they will be aware of and have easy access to an additional tool for prevention of the sexual transmission of HIV/STIs once they become available.

Prisoners

It is estimated that HIV rates within the Canadian prison system are 10 times higher than those in the general population. In addition, rates of infection are much higher in female inmates (4.7%) than in males (1.7%).

The high rates of infection in Canadian prisons are largely due to unsafe injection drug use, unsafe tattooing and unprotected sex. In Canada, condoms, lubricants, dental dams and clean needles are not universally available in our prisons. There must be an expansion of harm reduction initiatives, including the provision of new needles and safe tattoo parlors in the prison system in Canada, as well as microbicides, when they become available.

People protect themselves most effectively when they have a range of options from which to choose.

An HIV/STI prevention method that would be easy to use and that young people could control themselves would significantly reduce their vulnerability to HIV/STIs.

Youth

Presently, half of all new infections in the world occur among young people between the ages of 15-24. Although currently the prevalence of HIV is low among Canadian youth (10-24 years old according to Health Canada) young people are at a high risk of HIV infection due to misperceptions of their vulnerability, risky sexual behavior substance use and lack of access to appropriate resources.

In 2001, 35% of Canadians who tested positive between the ages of 15-29 were women, a slight decrease from 43% in 2004. The limited data available about this group indicate that young women are involved in behaviours that put them at risk of contracting HIV infection, including having sex with partners who are older and therefore more likely to have been exposed to STIs. Rates of STIs among Canadian youth continue to be very high, especially among young women. Because of changes to the cervix over the course of a woman's life, young girls and post-menopausal women are also more vulnerable to HIV infection and other STIs.

An HIV/STI prevention method that would be easy to use and that young people could control themselves would significantly reduce their vulnerability to HIV/STIs. Once the microbicide becomes available, getting young people habituated to using microbicides and other safer sex options early on is key to socializing them into a safe sex practice for the rest of their lives.

MOBILIZING FOR MICROBICIDES

The need for public investment in microbicide research

Before they can have a payoff in terms of prevention, microbicides must go through a long and expensive research and development process. Unfortunately, as with other important prevention technologies such as vaccines, most large pharmaceutical companies are not interested in microbicide research and development. They cite concerns about liability and an uncertain regulatory environment, as well as the perceived lack of a sufficient market to make their investment profitable.

Microbicides aren't the only products to be ignored by pharmaceuticals. There are several products, such as malaria vaccines and new contraceptives, which would also yield huge returns to society in terms of productivity and health benefits, but hold little profit potential for private investors. Such products are known as 'public health goods' and they are developed only if government and foundations invest the necessary funds.

Several small biotechnology companies and university researchers are actively engaged in microbicide research but they rely entirely on government grants and contributions from foundations. Unfortunately, at the current levels, these funds are not sufficient. There is a backlog in the research and development pipeline, so that innovative and promising product concepts are languishing, while HIV infection rates are growing.

Given the expense of clinical trials and the scarcity of resources available, money has become the limiting factor in how rapidly microbicide research can proceed. That is why advocacy efforts must focus on securing stable and adequate resources to ensure a microbicide is available by the end of this decade. The public sector must take the lead in microbicide research and development.

Canada can take a leadership role

Canada was the first of seven countries to invest in microbicide development in 2000. On December 1, 2004, World AIDS Day, the Government of Canada announced significant investments towards microbicides and other initiatives to prevent infections among women and youth.

Canada has shown further leadership by becoming the first country in the world to develop a microbicide plan. The Canadian Microbicides Plan outlines Canada's contributions to microbicide development, delivery and equitable access both domestically and internationally. It is linked to the Canadian HIV Vaccines Plan which was completed in 2005.



Canada has shown leadership by becoming the first country in the world to develop a Microbicide Plan.

Global Campaign for Microbicides

The GCM's web site contains a wealth of resources for advocates that can be downloaded for free or ordered, including fact sheets, standardized presentations, a petition, how-to guides, FAQs, a video, pins, pens, T-shirts, and many other useful resources to help you raise awareness in your community and to advocate for microbicides.

<www.global-campaign.org>

What can we do to accelerate microbicide development?

Given that public sector support is required to fund microbicide research, it is important for our governments to hear that all Canadians will benefit significantly from the availability of microbicides.

Therefore we can:

- ✂ Raise awareness about microbicides in our communities.
- ✂ Make our politicians and government policy makers aware that we need access to microbicides as soon as possible and at a reasonable cost to protect our health.
- ✂ Make the media aware of microbicides and their importance to our communities.

Specifically, get your group or organization involved in raising awareness by:

- ✂ Distributing microbicides information to your membership through newsletters, action alerts, journal articles, or e-mail list serves.
- ✂ Including information about microbicides in your organization's education and advocacy activities.
- ✂ Planning a workshop or session on microbicides for your next meeting or conference
- ✂ Posting information on your website.
- ✂ Sending an op-ed piece (letter to the editor expressing your opinion) or a press release regarding microbicides to your local media. Please send copies to CAS.
- ✂ Organize a showing of the Global Campaign for Microbicides' video *In Women's Hands*.

Advocate by:

- ✂ Writing or meeting with your provincial and/or federal legislators and asking them to strongly support microbicide related legislation and funding. Feel free to contact CAS for the latest updates on microbicides before meeting with your legislator. Please send a copy of your letter to CAS and let us know how your meeting with your legislator went.
- ✂ Distributing petitions from the Global Campaign for Microbicides web site.
- ✂ Joining the Microbicides Advocacy Group Network (MAG-Net) by contacting CAS.

Stay informed:

- ✂ Join the email list service for this group by sending an email with "subscribe" (without the quotes) in the subject line to <mag-net@cdnaids.ca>.

MAG-Net

MAG-Net is a coalition of Canadian AIDS service organizations, international development NGOs and researchers interested in promoting the development of new HIV and STI prevention options. MAG-Net is coordinated by CAS and serves as the Canadian affiliate of the Global Campaign for Microbicides. MAG-Net meets quarterly by teleconference.

TEMPLATE LETTER TO MEMBERS OF PARLIAMENT

Insert date

Insert MP name and address

Dear insert MP name:

We write on behalf of *(name and describe your organization. If you are a member of MAG-Net, or support its work, indicate that and include the following paragraph).*

The Microbicides Advocacy Group Network (MAG-Net) is a coalition of over 70 Canadian AIDS service organizations, sexual and reproductive health organizations, international development NGOs and researchers interested in promoting the development of alternative HIV/AIDS and STI prevention options. MAG-Net is the Canadian arm of the Global Campaign for Microbicides, an international coalition of more than 200 NGOs worldwide that collaborate to build support among policymakers, opinion leaders, and the general public for increased investment into microbicides and other user-controlled HIV prevention methods.

Canada has been a leader in the global fight against AIDS, supporting vaccine development and ensuring access to treatment for HIV/AIDS and opportunistic infections. Indeed, Canada has shown its commitment to an AIDS vaccine through the Canadian HIV Vaccines Initiative (CHVI), a multi-million dollar initiative to fund vaccines research and development. Canada is also the first industrialized country to develop a comprehensive HIV vaccines plan.

With respect to treatment, Canada has the Access to Medicine Regime, which was passed in 2004. This law allows for the export of generic versions of medicines still under patent in Canada. This country has also committed substantial funding to the World Health Organization to ensure access to antiretroviral therapies for people in developing countries. Canada has also continued to contribute to the Global Fund to Fight AIDS, Tuberculosis and Malaria.

Despite these successes, we can still do more. HIV/AIDS continues to spread at the alarming rate of 14,000 new infections each day globally, and 4,200 new infections each year in Canada. Over 58,000 Canadians were estimated to be living with HIV/AIDS at the end of 2005. In addition to support for HIV vaccines and treatments, the world must also make a substantial investment in the development of, and eventual access to, HIV microbicides. Protecting and fulfilling our basic human right to attain the highest standard of health requires pro-active measures to equip people with accessible, affordable HIV prevention tools that are fully under their control. While all people will benefit from the eventual availability of microbicides, the need is particularly urgent when it comes to protecting women's health. Women's subordination around the world, and the denial of women's human rights, exacer-



Remember to send a copy of your letter to CAS.

No postage is required when you send a letter to your Member of Parliament's Ottawa office.

TIP: Prepare an information kit on microbicides and your organization in preparation for your in person meeting.

bates their vulnerability to HIV infection, particularly in the absence of female-controlled prevention methods.

(Among (your population)... insert incidence/prevalence statistics and arguments in favour of microbicides from the population-specific fact sheet.)

We applaud the Government of Canada's investments towards microbicides and other initiatives to prevent infections among women and youth over the past few years. This is an important first step to ensuring a comprehensive Canadian response to the HIV/AIDS pandemic, and to meeting our domestic and international commitments in this regard, including the Federal Initiative on HIV/AIDS in Canada, the CIDA HIV/AIDS Action Plan, and the UN Declaration of Commitment on HIV/AIDS endorsed by Canada.

In addition, Canada has shown leadership on the global stage by developing the Canadian Microbicides Action Plan. Such a Plan, much like the Canadian HIV Vaccines Plan, outlines Canada's contributions to microbicides development, delivery and equitable access both domestically and internationally. It is linked to the Vaccines Plan, and includes Canadian contributions from multiple sectors (government, researchers, community organizations, private sector), thus ensuring a comprehensive, coordinated Canadian response. It is important that the action steps outlines both of these plans are followed-up and implemented.

We are enclosing additional background information on the importance of microbicides. I encourage you to show leadership and serve as a champion for this important public health issue within your caucus (or cabinet). I will contact your office shortly to arrange a meeting to further discuss how you can help support the fight against HIV/AIDS, in your constituency, and on the national and global fronts.

Sincerely,

Your name, title and organization



TEMPLATE LETTER TO THE EDITOR

WHEN CONDOMS CAN'T BE USED

More than twenty-five years into the AIDS crisis and at a time when the incidence of STIs is reaching epidemic proportions, the only public health messages about the prevention of HIV and other STIs are “be monogamous” or “use condoms”. But for many, these messages are inadequate or unrealistic at best. At worst they are life-threatening. Millions of people at risk for HIV lack both the power within relationships to insist on condom use and the social and economic resources to abandon partnerships that put their health at risk.

Sexually transmitted infections (STIs), including HIV/AIDS, represent a public health emergency, particularly for women. Not only are women at greater risk of acquiring STIs than men but, in most cases, the consequences of contracting STIs – including infertility, ectopic pregnancy, and cervical cancer – are more serious and permanent for women. Today, women are the fastest-growing population with HIV/AIDS. And most are becoming infected through heterosexual contact.

(Among (your population)... insert incidence/prevalence statistics and arguments in favour of microbicides from the population-specific fact sheet.)

Women and other vulnerable populations need products designed to protect them against HIV/AIDS and other STIs. Research is now underway to develop such products, known as “microbicides”, which could substantially reduce the transmission of HIV and STIs when used in the vagina or rectum. Microbicides could come in many forms, including gels, creams, suppositories, films, or in the form of a sponge or vaginal ring. They would provide an alternative method of disease protection for people who, for a variety of reasons, cannot use condoms to prevent HIV/STI transmission.

Although microbicides would probably never be as effective as condoms in preventing infection, people who are seldom or never able to use condoms could lower their overall risk of STI or HIV infection by using a microbicide. Moreover, there is a demand for microbicides: a recent survey by the Alan Guttmacher Institute estimated that 21 million US women are interested in a microbicide product. In other acceptability studies conducted in Zimbabwe, Uganda, and South Africa, both women and men expressed willingness to use microbicides.

With sufficient human and scientific resources, a microbicide product could be available by the end of this decade. However, most large pharmaceutical companies are simply not interested in investing in microbicide development. They are skeptical about whether microbicides would be profitable after the costs of research and marketing are met because such products would have to be inexpensive to be made available globally. They have also raised concerns over issues of liability, since microbicides would promise to offer some protection against life-threatening illness.



Send your letter to coincide with key dates and events. For example: World AIDS Day, International Development Week, AIDS Walk for Life, International Women's Day etc.

Use this letter as the basis for an editorial in your agency's newsletter.

Don't forget to send a copy of the published letter to CAS.

In the absence of leadership by major pharmaceutical companies, a number of university and small, independent biopharmaceutical firms have taken the lead on microbicide research. However, researchers estimate that it costs up to \$50 million to complete research on an existing compound (and twice that to start from scratch with a new compound) – far more than many of these small companies and nonprofit entities have the capacity to invest.

Public funds are necessary to fill the gaps in the research and development process and to create incentives for greater investment by private industry. Without federal leadership and funding, a microbicide is not likely to be available anytime soon.

There are a number of promising microbicides in development, and we have everything we need to bring a microbicide to market within five years except money. We need to raise awareness about microbicides, and ensure that the action steps outlined in the Canadian Microbicides Action Plan are followed so that people in Canada have more ways to protect themselves against the ravages of HIV/AIDS and other STIs.

Sincerely,

Your name, title and organization



RESOURCES

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<www.cdnaids.ca>

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The Legal Network web site includes background materials on joint advocacy on HIV/AIDS, Microbicides, Treatment and Vaccines (MTV).

APPENDICES

Fact Sheets



BASIC INFORMATION ABOUT MICROBICIDES

What is a microbicide?

A microbicide is any substance that can substantially reduce transmission of HIV and other sexually transmitted infections (STIs) when applied either in the vagina or rectum. Like today's spermicides, microbicides could be produced in many forms, such as gels, creams, suppositories, films, or in the form of a sponge or a vaginal ring that slowly releases the active ingredient over time.

Are microbicides currently available?

No, there are no microbicides currently on the market. However, there are many products in various stages of development. Several of these have proven safe and effective in animals and are now being tested in humans. If one of these products is successful, and with sufficient investment, a microbicide could be on the market by 2010.

How would a microbicide work?

There are four main ways that microbicides work. Scientists are presently exploring substances that:

1. kill or inactivate STI pathogens
2. block infection by creating a barrier between the pathogen and the vagina or rectum
3. prevent the infection from taking hold after it has entered the body (there are two ways: by blocking the virus from attaching to receptor cells; or, by stopping the virus from replicating once it has entered the receptor cell)
4. boost the body's natural defences to protect the vagina or rectum

Would a microbicide eliminate the need for condoms?

No. Used consistently and correctly, condoms provide excellent protection against HIV and other STIs. Microbicides should be promoted along with condoms for extra protection, and as a back up in case of condom breakage. Microbicides can also be promoted on their own as protection for people who are unable or unwilling to use condoms, and for those whose partners refuse to wear condoms.

As is consistent with other harm reduction approaches to HIV prevention, public health messages should promote condoms as the best choice but suggest microbicides as a fallback option when condom use is not possible.



A pathogen is a virus or bacteria that can cause infection.

Barrier methods like male and female condoms will always provide better protection than microbicides, because it's safer to keep a virus out of your body than to try to stop it once it's there.

Impact of Microbicides

Even in far from ideal conditions, microbicides can still have a profound impact on the HIV epidemic. Mathematical models show that if even a small proportion of women in lower income countries used a 60% effective microbicide in half the sexual encounters where condoms are not used, 2.5 million HIV infections could be averted over three years.

How effective will microbicides be?

Microbicides will only reduce the risk of HIV and other STIs – they will not eliminate that risk altogether. The first microbicides are only likely to be 40-60% protective against HIV; as the products evolve, this protection could increase to between 60-80% in second generation products. Although this makes microbicides less effective than condoms, it still offers far more protection than is currently available if condom use is not possible. In fact, mathematical models show that within many populations, more HIV infections can be prevented with a less effective product that can be used more consistently by more people (such as microbicides), than with a highly effective product that is used inconsistently (such as condoms).

Would a microbicide protect against all sexually transmitted infections?

Since STIs are caused by different pathogens (some viral and some bacterial) a microbicide that works against one STI pathogen would not necessarily protect against another. Eventually, the best products will likely combine several mechanisms of action to protect against a range of STIs, including HIV.

What if a woman wants to get pregnant?

Some of the microbicides being investigated prevent pregnancy and some do not. It is important to have non-contraceptive microbicides in addition to one that prevent pregnancy, so that women and couples can protect their health and still have children. This is not possible with condoms.

Would men benefit from a microbicide as well?

There is every reason to believe that a microbicide would provide protection for both partners (bi-directional protection). Microbicides could help prevent infections from STIs, prevent re-infection with different strains of HIV and provide protection in sero-discordant couples (heterosexual or same sex).

Men accounted for 77% of new HIV infections overall in Canada in 2003 and men who have sex with men (MSM) accounted for 40% of new infections. (Health Canada Epi Update, April 2004), so it is vital that men are included in microbicide advocacy efforts. Currently products are being tested for both vaginal and rectal use.

Would people living with HIV/AIDS benefit from a microbicide as well?

Microbicides could help prevent infections from other STIs, prevent re-infection with different strains of HIV, and provide protection in sero-discordant couples. A non-contraceptive microbicide would also protect sero-discordant couples trying to conceive.

Would such products be safe?

Like any new product, microbicides must go through rigorous safety testing before they can be made available to consumers. Fortunately, many of the substances being investigated have been around a long time, and some are even commonly used in food. Scientists are currently testing the safety of microbicide use in the vagina, the penis and the rectum.

Is there a market for microbicides?

Yes. Research indicates that women in both developing and developed countries are extremely interested in a women-controlled prevention alternative, and are even willing to pay more for it than condoms. However, advocates are working to ensure that microbicides are affordable. Current products in development are likely to be at least as cheap as condoms. Contraceptive microbicides also offer significant market potential in that they combine disease prevention with pregnancy protection.

Nonoxynol-9

At one point Nonoxynol-9 (N-9), the contraceptive spermicide, was considered as a potential microbicide. However, research showed that N-9 in fact can increase the risk of HIV infection;

1. when used frequently (more than once a day) or at high doses vaginally
2. when used rectally (even a low dose of N-9 can damage the rectum)

N-9 should never be used rectally. It should also not be used vaginally more than once a day.

Sero-discordant is defined as a relationship where one of the partners is HIV-positive and the other negative.

Market Research

Parallel to actual product development, research is also being conducted to gauge consumer preferences regarding the characteristics of microbicides, including ease of application, surreptitious use, disposable packaging, lubricating properties, odour, colour, contraceptive properties, etc. It is important to learn as much as possible because the more forms that are available on the market, the greater the appeal to a wider variety of consumers.

What is the current status of microbicide research?

All potential microbicides need to be submitted to rigorous research standards to ensure the product is safe and effective. The entire testing process can take at least ten years. After successfully passing laboratory and animal testing, several of these products have made it to early clinical trials among humans. Several of the microbicide candidates have successfully passed laboratory and animal testing, and have made it to clinical trials among humans. Products in the final stage of testing include BufferGel, Carraguard, Pro 2000, Tenofovir/PMPA gel. This last stage (phase III clinical trials) is the longest and most expensive, because it requires testing among a large number of people over a significant time to ensure there are no long-term side effects.

After successfully passing all the tests, the product must then receive final approval by regulatory authorities before it goes on the market. If all goes well, there could be a microbicide available by the end of this decade.

Recently, there has been a set-back with the halting of the Cellulose Sulfate (CS) trials. This was a promising Canadian microbicide candidate, but early data suggest that CS may be contributing to an increased risk of HIV infection.



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POPULATION-SPECIFIC INFORMATION ON MICROBICIDES

Women

HIV cases among women in Canada are rising. Currently, 25% of new infections occur in women, up from 12% just a few years ago. Young women aged 15-29 years account for over 40% of new HIV infections reported among Canadian women. Similar figures exist for Aboriginal women, who now make up 47% of Aboriginal infection rates. According to the Public Health Agency of Canada, heterosexual contact and intravenous drug use are the main causes of HIV transmission in women.

Biologically, women are more vulnerable to HIV infection. In addition, women often have limited control over safer sex decisions, since women can be socially and/or economically dependent on partners, and therefore not in positions of power to insist on condom use. An odourless, tasteless microbicide will be especially useful for women, as its use will not necessarily require consent of the partner. Not only will microbicides prevent HIV or STI re-infection, but also the benefits of microbicides will be bi-directional, protecting both partners. Some microbicides will also have contraceptive properties.


Women who have sex with women may also benefit from future microbicides. Though more research is needed to understand HIV transmission among lesbian women, there is still the potential of STI transmission. As noted above, STIs increase the risk of contracting HIV.

Men

Microbicides will benefit men, including heterosexual men, gay men, and other men who have sex with men. Indeed, men, like women, report low levels of condom use in long-term partnerships. Worldwide, men tend to have more sex partners than women, including partners outside of their primary relationship, and this increases the risk of contracting HIV. Secrecy and stigma may stifle discussion about HIV within couples.

In Canada, gay men and MSM continue to account for the largest number of new infections. In 2005 they represented 51% of all people living with HIV/AIDS (PLWHIV/AIDS) and 45% of newly reported HIV infections. This population also had the largest increase in infections, up 10% since 1999.

*** Statistics provided in this fact sheet are the most recent available as of January 2006 from the Public Health Agency of Canada (Epi Updates from April 2005). For more recent information as it becomes available, please consult Epi Updates at <http://www.phac-aspc.gc.ca/aids-sida/hiv_aids/index.html>. Consult your provincial government for more recent statistics in your region. ***



A microbicide
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Microbicides
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Engaging Aboriginal and ethnocultural communities in microbicide advocacy efforts will help ensure their needs are met.

Although most gay men practice safer sex, the complexities of sexual decision making for some gay men has highlighted the need for more targeted education and other resources such as microbicides to practice safer sex. People protect themselves most effectively when they have a range of options from which to choose. Microbicides could thus offer an alternative to the current “condom versus no condom” decision. In addition, microbicides will allow skin-to-skin intimacy and thus enhance pleasure. Microbicides will also provide bi-directional protection, protecting both partners during sex.

For these reasons, microbicides, including products that have been tested for rectal use, will be an important prevention option for all men to be used in combination with condoms. It should be noted that scientists have begun to investigate a microbicide suitable for rectal use, but developing such a microbicide is more difficult due to the different biology of the colon and the vagina. It is likely that a rectal microbicide will be available a few years after a vaginal microbicide.

Aboriginal communities

In 2005, Aboriginal people constituted nearly 23% of all newly reported HIV cases, although they only represent 3.3% of Canada’s total population.* Aboriginal women make up half the total Aboriginal people living with HIV/AIDS, which is a proportion considerably higher than in the general population. Research on receptivity to the female condom indicates that Aboriginal women would welcome female-controlled STI prevention tools, as long as they are accompanied by culturally appropriate support and education on use.

Broadening HIV/STI prevention options by introducing safe, inexpensive and easily accessible microbicides will benefit Aboriginal people both on and off reserve. Even in isolated Aboriginal communities where HIV is not viewed as a serious local problem, microbicides could offer protection against high rates of STIs and teenage pregnancy. Engaging Aboriginal communities in microbicide advocacy efforts will help ensure their needs are met in terms of product development, marketing and delivery.

Ethnocultural communities

In Canada, members of ethnocultural communities and immigrants from countries where HIV has become endemic can be at a particularly high risk of HIV infection. At the end of 2005, 12% of all HIV infections in Canada were attributed to people in the HIV-endemic exposure subcategory, although only 1.5% of Canadian populations was born in an HIV-endemic country. In addition, almost 80% of people in the subcategory were less than 40 years of age when they had a positive HIV test result.* Also, HIV prevalence in the Black communities of Ontario has increased by 85% since 1996 with an average annual increase of 13% representing the highest increase of HIV prevalence of any exposure categories.

* It is important to note that It is important to note that on 29% of reported HIV tests contained information on ethnicity. Neither Ontario nor Québec include ethnicity information when reporting HIV positive test results, while these two provinces have the highest numbers of new infections every year. Therefore, proportions of members of Aboriginal and Black communities among newly reported HIV infections might be different if ethnicity was reported in these two provinces.

In their countries of origin, HIV-positive individuals, particularly women are at risk for abandonment by their family and friends, discrimination at work, the loss of their land and children, violence and abuse, and many other negative consequences. Within Canada, ethnocultural communities, as well as immigrants and refugees from endemic countries, also face barriers in access to appropriate services associated with levels of literacy, language, cultural taboos against talking about sex, fear of the impact of a positive test on immigration status, and the lack of targeted prevention messages. Microbicides would be a valuable additional tool to protect the health of ethnocultural communities. In addition, engaging ethnocultural communities in microbicide advocacy efforts will help ensure their needs are met in terms of product development, marketing and delivery.

People living with HIV/AIDS

There are currently approximately 58,000 people living with HIV/AIDS in Canada, including about one third who do not know that they are HIV-positive. For people living with HIV/AIDS, microbicides could help prevent infections from other STIs, prevent re-infection with other strains of HIV and provide protection in sero-discordant couples (one partner is HIV positive and one partner is HIV negative). A non-contraceptive microbicide would allow protection for couples trying to conceive.

People who use drugs

The rate of HIV among injection drug users (IDUs) in Canada remains high, especially among Aboriginal populations. In 2002, IDUs represented 14% of new HIV infections and 17% of people living with HIV/AIDS.

Sharing used needles creates a high risk of HIV transmission, but the link between substance use and HIV goes beyond needles. People who use alcohol, speed, crack cocaine, crystal meth or other non-injected drugs are at higher risk of contracting HIV than non-substance users. People with a history of drug use are also more likely to engage in high-risk sexual activities, and research has also acknowledged the more prominent role that sexual transmission may play in women IDUs.

Raising awareness about microbicides among persons who use drugs could help ensure they will be aware of and have easy access to an additional tool for prevention of the sexual transmission of HIV/STIs once they become available.

Prisoners

It is estimated that HIV rates within the Canadian prison system are 10 times higher than those in the general population. In addition, rates of infection are much higher in female inmates (4.7%) than in males (1.7%).

The high rates of infection in Canadian prisons are largely due to unsafe injection drug use, unsafe tattooing and unprotected sex. In Canada, condoms, lubricants, dental dams and clean needles are not universally available in our prisons. There must be an expansion of harm reduction initiatives, including the provision of new needles and safe tattoo parlors in the prison system in Canada, as well as microbicides, when they become available.

People protect themselves most effectively when they have a range of options from which to choose.

An HIV/STI prevention method that would be easy to use and that young people could control themselves would significantly reduce their vulnerability to HIV/STIs.

Youth

Presently, half of all new infections in the world occur among young people between the ages of 15-24. Although currently the prevalence of HIV is low among Canadian youth (10-24 years old according to Health Canada) young people are at a high risk of HIV infection due to misperceptions of their vulnerability, risky sexual behavior substance use and lack of access to appropriate resources.

In 2001, 35% of Canadians who tested positive between the ages of 15-29 were women, a slight decrease from 43% in 2004. The limited data available about this group indicate that young women are involved in behaviours that put them at risk of contracting HIV infection, including having sex with partners who are older and therefore more likely to have been exposed to STIs. Rates of STIs among Canadian youth continue to be very high, especially among young women. Because of changes to the cervix over the course of a woman's life, young girls and post-menopausal women are also more vulnerable to HIV infection and other STIs.

An HIV/STI prevention method that would be easy to use and that young people could control themselves would significantly reduce their vulnerability to HIV/STIs. Once the microbicide becomes available, getting young people habituated to using microbicides and other safer sex options early on is key to socializing them into a safe sex practice for the rest of their lives.



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