

Parliamentary Briefing

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Vaccines and microbicides: the future of HIV prevention?

New methods of HIV prevention, in the form of vaccines and microbicides, are currently being researched and developed. Even early versions with limited efficacy could have an enormous impact on controlling the spread of HIV.

THIS BRIEFING EXPLAINS WHAT VACCINES AND MICROBICIDES ARE, WHY THEY ARE NEEDED AND HOW THEY FIT WITH OTHER HIV PREVENTION STRATEGIES.

What are vaccines and microbicides?

Vaccines are arguably the most effective public health response to infectious disease. They are substances that stimulate the body's immune system to recognise and protect itself against a disease caused by a virus. Scientists believe that a vaccine against HIV is possible — experimental vaccines have been proven to work in laboratory tests, and promising strategies for effective HIV vaccines are currently being tested in humans in clinical trials.

For further details about current vaccine trials, see <http://www.iavireport.org/trialsdb>

Microbicides are substances designed to be applied internally (vaginally or rectally) to reduce the risk of HIV and other sexually transmitted infections (STIs). They could exist in a number of forms (such as gel, cream, film or a timed-release vaginal ring) that could be active in the body for several hours or even weeks. Microbicides should not be confused with spermicides, which prevent conception, although some microbicides could potentially have contraceptive properties.

For further details about current microbicide trials, see: <https://secure.microbicide.org/DesktopDefault.aspx>

What would the ideal vaccine do?

HIV presents particular challenges to vaccine research and development: many other vaccines work by stimulating the body's own immune response, but HIV attacks the immune system itself. HIV mutates and there are numerous subtypes found in different areas of the world — whilst the ideal vaccine would be effective against all of them, early versions are more likely to be effective against only certain subtypes. Furthermore, early vaccines are likely to be only partially effective.

However, it is worth noting that the first polio vaccine was only 60% effective, but still prevented an epidemic in the USA in the 1960s.

Research by the World Bank suggests that a partially effective vaccine given to 65% of adults over a ten-year period could reduce HIV incidence by up to 60%.

The ideal vaccine would be inexpensive, easy to store and, with one dose, would give long-lasting protection to men, women and children against HIV from sexual contact or infected blood. In the absence of universal HIV testing, it would also have to be safe for HIV positive people.

HIV and AIDS today — the facts

- Almost forty million people are living with HIV worldwide
- Twenty million people have already died of AIDS
- There were over 3 million deaths and nearly 5 million new HIV infections in 2004 alone
- Developing countries are hardest hit, although infection rates are increasing across the world
- On current trends, 45 million more people are predicted to contract HIV by 2010
- There is still no cure

And a microbicide?

Scientists are exploring a number of ways in which microbicides could prevent the spread of HIV by:

- disabling the virus before it infects the body
- preventing the attachment of HIV to body cells
- strengthening the body's own natural defences against the virus
- limiting the ability of HIV to replicate inside the body

Microbicides could eventually contain a combination of these properties for maximum effectiveness. They would need to be applied before intercourse, or used in a timed-release method like a sponge or vaginal ring.

Research has suggested that even a partially effective microbicide could avert 2.5 million HIV infections over three years.

Who would use these products?

Like vaccines, the ideal microbicide could potentially be used by anyone, regardless of their gender, sexuality, age or HIV status.

They could also be of particular benefit to women, who are increasingly and disproportionately affected by HIV.

Whilst we have to address all the issues that keep women vulnerable, **microbicides would empower women** because they:

- are self-applied
- do not require medical intervention
- potentially do not require a partner's knowledge or consent
- for the first time, could enable women to conceive and be protected from HIV

When will vaccines and microbicides be available?

The development of an HIV vaccine has been described as a marathon, not a sprint and in the case of both polio and measles it took over 40 years to develop a vaccine. Scientific development is unpredictable but, with sufficient resources, **it is hoped a vaccine against HIV will be available in the next 10 to 15 years.**

If one of the five potential vaginal microbicides currently in advanced stages of trials proves successful and investment is sufficient, a partially effective **microbicide could be available by the end of the decade.** A 'second generation' of products (likely to be even more effective) is in earlier stages of development — if one of these is found to be successful, it is hoped it would become available early in the next decade.

Development of rectal microbicides poses even greater challenges to those of vaginal microbicides but **rectal microbicides, for use by women and men, are in early stages of research and development.**

Cost and benefit

The International AIDS Vaccine Initiative (IAVI) has estimated that **less than 1% of spending on health and pharmaceutical-related research and development is on AIDS vaccine research.** However, AIDS kills more people worldwide than any other infectious disease.

Women at risk of HIV

In some countries, being a young monogamous woman is the highest risk factor for contracting HIV. Enabling women to protect themselves is a key aspect of tackling HIV worldwide.

- *Women are physiologically more susceptible than men to HIV after one exposure*
- *Existing prevention strategies depend on women having control over their reproductive and sexual health and for millions of women this is not the case. In many countries women's status in society leaves them economically dependent on their partners and unable to leave relationships which may put them at risk of HIV*
- *Condom use may be undesirable or impossible in a long-term relationship or a marriage — it can raise questions of fidelity, and is obviously not an option for couples wishing to have children*

Whilst development of new products is a costly process, the discovery of safe and effective vaccines and microbicides could prevent millions of new HIV infections. Compared to the cost of treatment for HIV and the long-term devastating effect of HIV on global economies, investment in research now will reap long-term social and economic rewards.

Recent increases in both political commitment and investment in vaccines, from governments and private foundations, are of course welcome and necessary — yet it is just a small proportion of the amount needed to eventually bring a vaccine into public use, estimated at US\$1.1 billion a year.

Microbicide research is also under-funded. US\$140m was committed to research, development and advocacy last year, mostly from governments and private foundations, but it is estimated that US\$280m annually is required for research and development. It is vital that sufficient public sector resources are secured to enable critical microbicide research to progress.

Shouldn't resources be focused on providing treatment instead of developing new products?

Whilst progress on drug therapy means that for many people, particularly in the developed world, HIV has become a manageable (although long-term and incurable) condition, these drugs remain out of reach for the vast majority who desperately need them. **Without question, it is vital that access to treatment is scaled up urgently.**

Yet without progress in prevention, and a reduction in the number of new infections, the number of people living with HIV will ultimately outstrip the resources available for treatment.

Treatment, care and prevention of HIV should not be set against each other in competition for resources.

A comprehensive approach is the best way of tackling HIV worldwide — involving a range of prevention strategies, as well as treatment, care and support, and challenging stigma and discrimination.

But why are we developing vaccines AND microbicides?

Vaccines are a powerful and cost-effective method of preventing disease. But microbicides could be available sooner, making a difference to HIV infection rates — particularly for women (in some areas there are as many as six young women living with HIV to every one man). Microbicides would continue to be a valuable weapon against HIV, even when vaccines are first introduced.

Existing prevention strategies cannot be used by everyone. The development of new technologies will enable more people to protect themselves against HIV. Until HIV is brought under control by a fully effective vaccine, expanding the range of prevention options will enable people to better protect themselves. Experience in the contraceptive field shows that when a new product is added to the range of existing options, there is an increase in the overall use of contraceptives. There is every reason to believe that the same applies to HIV and that HIV transmission rates would be reduced by the introduction of additional prevention options.

What needs to happen for vaccines and microbicides to become a reality?

In addition to securing resources for research and development:

- Private pharmaceutical companies must be encouraged to play a greater role in the search for a vaccine against HIV. Governments will be able to assist with this through tax incentives, making advance purchase commitments, and clarifying regulatory and licensing requirements for new products.
- Social research — addressing issues such as gender relations and stigma — must be conducted in tandem with clinical research to ensure a new product is effectively taken up when it actually becomes available.
- Engagement and support from affected communities is crucial if clinical trials of new technologies are to be effective, as is building capacity for this research and development to take place in developing countries.

Unlike a vaccine, with which most people are familiar, a microbicide is a completely new concept. **Raising awareness** is an important step in their being accepted. NAT is committed to increasing awareness of both these new technologies, and to **ensuring that sufficient funding is made available** for their development.

The UK Government has given financial support to HIV vaccines and microbicides, and made commitments to the development of both of these new technologies at the G8 summit in Gleneagles. **NAT wants the Government to continue to support and promote HIV microbicides and vaccines.**

The National AIDS Trust

The National AIDS Trust (NAT) is the UK's leading independent policy and campaigning voice on HIV and AIDS. A registered charity, we develop policies and campaign to halt the spread of HIV, ensure people living with HIV have access to treatment and care, and eradicate HIV-related stigma and discrimination, both in the UK and internationally.

NAT is campaigning for the UK to support the development of HIV vaccines and microbicides. They should not only be a priority for use in developing countries but should also be put on the UK's sexual health agenda.

As a Member of Parliament, you can help make microbicides and vaccines a reality by:

- **Raising the issue of microbicides and vaccines in your parliamentary work**
 - NAT can supply information on these issues for use in relevant debates
- **Informing your constituents of these important HIV prevention methods**
 - NAT can provide resources for use at meetings, or distribution at surgeries
- **Supporting the microbicides and vaccines work of the All Party Parliamentary Group on AIDS and the National AIDS Trust**
 - contact NAT, details below
- **Urging Government Ministers to prioritise the search for HIV vaccines and microbicides**

For example, by:

- increasing funding for microbicide and vaccine research and development
- encouraging greater private sector involvement through business incentives such as advance purchase commitments and tax exemptions
- addressing industry concerns about liability, patents and regulation
- supporting the capacity of developing countries to participate in clinical trials
- providing funds for international advocacy efforts in order to increase leverage of other public and private funding sources
- providing political leadership in promoting vaccines and microbicides on the international stage, to encourage other world leaders to increase their support for these new prevention technologies.

For further information please see:

- NAT policy bulletin Impact 10: HIV Prevention — Condoms and Beyond
<http://www.nat.org.uk/documents/Impact10.pdf> [July 2005]
- NAT report 'Completing the Preventive Barrier — Vaccines and Microbicides: an agenda for the UK'
<http://www.nat.org.uk/documents/ACFIdWDMw.doc> [October 2004]
- AIDS Vaccine Advocacy Coalition — www.avac.org
- Alliance for Microbicide Development — www.microbicide.org
- Global Campaign for Microbicides — www.global-campaign.org
- HIV Vaccine Trials Network — www.hvtn.org
- International AIDS Vaccine Initiative — www.iavi.org
- International Partnership for Microbicides — www.ipm-microbicides.org

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