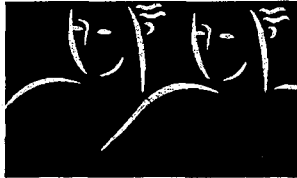


Canadian AIDS
Society



Société canadienne
du sida

FOR YOUR INFORMATION

AIDSVAX Clinical Trial Results: 2 Scenarios

Results of the first large scale (Phase III) efficacy trial for a preventive HIV vaccine (VaxGen's AIDSVAX) are about to be released.

The Canadian AIDS Society (CAS) and the Canadian HIV/AIDS Legal Network have prepared resources that can be used to prepare a response to media inquiries, and to integrate into awareness and education efforts surrounding HIV vaccines.

A copy of 2 fact sheets providing key messages adapted to potential results from the trial are included in this package. In addition, the media advisory issued jointly by CAS and the Legal Network is included. Canada News Wire ranked it as one of the Top Ten accessed files on its web site, receiving 374 hits on the first day alone. This gives us an indication of the media interest this story is likely to generate.

Electronic copies of these resources are available on the CAS web site, at www.cdnaids.ca, as well as on the Canadian HIV/AIDS Legal Network's web site, at www.aidslaw.ca. Additional resources and information on AIDSVAX and on HIV vaccines in general can be found on both sites.

Other relevant internet links :

VaxGen : www.vaxgen.com

AIDS Vaccine Advocacy Coalition : www.avac.org

International AIDS Vaccine Initiative: www.iavi.org

For more information, please feel free to contact Marc-André LeBlanc, Programs Consultant, at 1-800-884-1058, ext. 120 or at marcl@cdnaids.ca

AIDSVAX Clinical Trial Results: Scenario No. 1

Preventive Effectiveness less than 30% (or indeterminate)

Key Messages

1. **Prevention efforts must continue**
 2. **Research must continue**
 3. **Much has been learned to advance further research**
 4. **Canada must prepare an HIV vaccine plan.**
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1. **Prevention efforts must continue**

No vaccine is 100 percent effective. Even if AIDSVAX proves to be partially effective, prevention measures currently used against HIV are still necessary. People must continue to protect themselves using condoms and clean syringes (safer sex and harm reduction).

2. **Research must continue**

HIV/AIDS vaccine research is not a short-term project. It will likely be many years before a highly effective HIV/AIDS vaccine becomes available. Continuing efforts to achieve the best possible outcomes and to minimize the possibility of harm will be necessary during this time.

More than 22 other experimental vaccines are already in clinical trials with human subjects. A list of these vaccines and their progress are available at the web site of the International AIDS Vaccine Initiative (IAVI) at: <http://www.iavi.org/iavireport/0103/trialswatch.htm> .

As well, many other experimental vaccines are under laboratory development, and some are in clinical trials with animals. One or more of these prospective vaccines may prove effective within the next few years.

3. **Much has been learned to advance further research**

The results are not disappointing: a great deal of knowledge and experience was gained through this vaccine trial. Although it did not produce a new prevention tool, we must not lose hope. We already have prevention tools that can effectively lower the risk of HIV transmission: use of condoms and sterile syringes.

The following is an example of what the study taught us:

- We learned how to organize, conduct and evaluate Phase III clinical trials designed to establish the effectiveness of a preventive experimental vaccine.
- The trial was conducted on a very large scale and showed the various preventive counselling methods needed to ensure that participants realize they cannot rely on an experimental vaccine to protect them against HIV infection. For example, during the first 30 months of this trial in Canada, risk behaviour diminished among participants. (The data for the past six months are not yet available.)
- In some cases, collaboration developed among the communities targeted for recruitment and researchers. Together, they were able to improve public understanding of the study and generate stronger support for an ongoing program of vaccine research.
- The results of this clinical trial made it possible to eliminate the need for further research on the gp 120 B/B protein. From now on, researchers will focus their efforts on other experimental vaccines.

Congratulations to VaxGen and thanks to all of the volunteers and community groups who participated in the clinical trial! They managed to complete the first Phase III clinical trial for a preventive vaccine against HIV/AIDS.

4. Canada must prepare an HIV vaccine plan

The Canadian HIV/AIDS Legal Network and the Canadian AIDS Society have called on Health Canada to coordinate and provide funding for a Canadian HIV Vaccine Plan, and to implement this plan as quickly as possible in consultation with the community. Health Canada has indicated its intention to carry out this recommendation, but the Plan is still awaited. The need for a Canadian HIV Vaccine Plan is one of the issues examined in a background paper and series of info sheets on *HIV Vaccines in Canada: Legal and Ethical Issues*, available at www.aidslaw.ca/Maincontent/issues/vaccines.htm.

Relevant internet links :

VaxGen : www.vaxgen.com

AIDS Vaccine Advocacy Coalition : www.avac.org

International AIDS Vaccine Initiative: www.iavi.org



AIDSVAX Clinical Trial Results: Scenario No. 2

Preventive Effectiveness higher than 30%.

Key Messages

1. **Prevention efforts must continue**
 2. **Research must continue**
 3. **Much as been learned to advance further research**
 4. **Canada must prepare an HIV vaccination plan.**
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1. Prevention efforts must continue

No vaccine is 100 percent effective. Even if AIDSVAX proves to be partially effective, prevention measures currently used against HIV are still necessary. People must continue to protect themselves using condoms and clean syringes (safer sex and harm reduction) because:

- **The vaccine is not yet available and it is preventive, not curative.** To obtain an eventual preventive vaccine, one must remain HIV negative.
- **The vaccine will not be available in Canada for a long time yet** (for example, not for two years), and even then, only limited quantities will be administered. First, the vaccine will be submitted for US FDA approval, which will require at least six months. Then, it will have to be approved in Canada. The vaccine will then have to be produced in sufficient quantity for sale. Many questions remain concerning the sale and distribution of the vaccine in Canada (see item 4 on the Canadian HIV vaccine plan below).
- **The vaccine will not provide 100% protection.** The vaccine has been proven only partially effective. Therefore, many questions will require further research before they are answered. For example:
 - a. We do not know whether the X% effectiveness of AIDSVAX B/B means that:
 - i. X% of people will obtain 100% protection from exposure to HIV;
 - ii. Everyone vaccinated will be X% safe once they come in contact with HIV; or
 - iii. Something else, between (i) and (ii).
 - b. Furthermore, we do not yet know how the vaccine should be administered. In the AIDSVAX B/B vaccine trial, subjects received 7 doses (one at the start and then once every six months for three

years). The program is difficult, perhaps unreasonable, to operate on a large scale. Therefore, a realistic, effective and suitable vaccination schedule remains to be determined.

- c. We still do not know how long the vaccine's protection will last. Although one clinical trial showed some effectiveness, VaxGen will ask immunized participants to continue taking blood tests for two years to detect signs of early weakening of immunity.
- d. By all indications, it will not be possible to determine whether a vaccinated person is protected by the vaccine. Almost all vaccinated individuals will have antibodies. However, it has yet to be established whether all of these antibodies are effective against HIV transmission. In other words, the biological protection markers have not yet been identified and a test has therefore not been developed to determine who is or is not protected, or to what extent a person might be protected.

2. Research must continue

HIV/AIDS vaccine research is not a short-term project. It will likely be many years before a highly effective HIV/AIDS vaccine becomes available. Continuing efforts to achieve the best possible outcomes and to minimize the possibility of harm will be necessary during this time.

Furthermore, the vaccine only affects strains of the virus primarily existing in North America and Europe. We do not know whether this kind of vaccine will also provide protection against all of the other strains of HIV in existence in the various parts of the world.

3. Much has been learned to advance further research

Whatever the results soon to be announced, this clinical trial will have taught us important lessons about how to conduct such experiments with humans, in communities. Congratulations to VaxGen and thanks to all of the volunteers and community groups who participated in the clinical trial! They managed to complete the first Phase III clinical trial for a preventive vaccine against HIV/AIDS.

4. Canada must prepare an HIV vaccine plan

The Canadian HIV/AIDS Legal Network and the Canadian AIDS Society have called on Health Canada to coordinate and provide funding for a Canadian HIV Vaccine Plan, and to implement this plan as quickly as possible in consultation with the community. Health Canada has indicated its intention to carry out this recommendation, but the Plan is still awaited. The need for a Canadian HIV Vaccine Plan is one of the issues examined in a background paper and series of info sheets on *HIV Vaccines in Canada: Legal and Ethical Issues*, available at www.aidslaw.ca/Maincontent/issues/vaccines.htm.

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