Unit 12

Introduction to Research Ethics

|  |
| --- |
| Overview  In this unit, trainees will learn some of the basic ethical issues surrounding HIV vaccine trials, a brief history of research ethics, and become familiar with the basic elements of informed consent. They will be divided into two groups and given a chance to practice discussing and analyzing ethical dilemmas from different viewpoints.  Objectives  By the end of the unit trainees will be able to:   * Identify guidance documents that help ensure that clinical trials are carried out in an ethically sound manner * Incorporate the principles of beneficence, autonomy,and justice when forming arguments for a position during a debate * Describe the ethical issues that surround HIV vaccine research   Materials   * Intro to Research Ethics.ppt – 1 copy per trainee * Ethics Principles.doc – 1 copy per trainee * Ethical considerations in biomedical HIV prevention trials. UNAIDS/WHO guidance document * Flip chart paper and pens   Approximate time  2 hours, 20 minutes |

# Warm-up/Introduction (20 minutes)

## Trainer notes

## There are many ethical issues that come up when discussing HIV vaccine research. In ethics, there is often no right or wrong answer, and the arguments about a certain issue may vary from place to place. However, there are well formulated and poorly formulated arguments and universal ethical principles and that guide ethical debates. This exercise explores those principles

## Procedure

**Step 1**:Explain that the following activity involves a famous ethical dilemma that comes from a wartime scenario. State that this is just an example to get the group thinking about ethical dilemmas

**Step 2:** Read the scenario out loud: “*A woman and her entire family are hiding from the enemy. If they are found, they will surely be executed. The newborn baby begins to cry uncontrollably and the noise will undoubtedly call attention to the family’s hiding place. What should the mother do? Should she suffocate the baby or risk that the whole family be found and killed?”*

**Step 3:** Ask if anyone has an argument for one side or the other.

**Step 4:** If the room seems quiet, try to encourage at least one person to offer their opinion. Try to get at least one person to state an argument for each side. Typically, once one person begins speaking, the rest of the group will become more involved. Do not allow the conversation to last more than ten minutes. You may need to read the scenario aloud a second time.

# Presentation of Information (60 minutes)

## Preparation

* Intro to Research Ethics.ppt
* Ethics Principles.doc

**Procedure**

**Step 1:** Let the group know that this is a basic introduction to health research, the basic principles of research ethics and the essential elements of informed consent.

**Step 2:** Present slides reading through the speaker’s notes. Stop for questions as they come up.

**Step 3:** Distribute the *Ethics of HIV Vaccine Trials* document. Explain that there are a number of ethical issues related to HIV vaccine research that the HVTN works diligently on.

**Step 4:** One by one, have the trainees read the list of ethical issues from the document *Ethics of HIV Vaccine Trials.* They can refer to the three main principles on the handout as needed.

**Step 5:** After each one is read, ask the group to try to identify how the HVTN and/or their HIV vaccine trial site is working (or plans to work) to make sure that the ethical issue is being addressed.

**Step 6:** After reading each bullet point, ask someone to think back to what they have learned so far and explain how the HVTN works to maintain high ethical standards. If trainees are unable to identify an example for each bullet point, use the following *italic* text to guide them.

* **Culturally sensitive informed consent***Unit 9 on Protocols describes community involvement in the development process for protocols and the Informed Consent. Informed Consent documents go to local Community Advisory Boards for additional input, focusing on making the forms culturally and linguistically appropriate for increased understanding by a potential volunteer, before they go to the sites’ local IRBs/Ethics Committees.*
* **Development of vaccines that address the needs of the populations most vulnerable to infection**   
  *The HVTN has worked hard to conduct studies of experimental vaccines that are made from subtypes of HIV found in the hardest hit regions of the world, although we do not yet know if subtype matching for HIV vaccines is important for offering protection against HIV.*
* **Potential for imbalance of power when vaccines are developed in one country and tested in another**   
  *All of the ethical guidance documents recommend that medical research study products be tested first in the country in which they were developed. Therefore, vaccines developed by a research group in the United States would first be tested in the United States. This could include a phase I trial being conducted simultaneously with countries outside the U.S. as long as the first stage of injections occur in the U.S. and pass the initial safety evaluations.*
* **Possibility for social and psychological harm to participants in an HIV related trial**  *The HVTN recognizes and understands the potential for these types of harms. They have provided resources for community engagement and community awareness programs that are aimed at building knowledge and general community support for HIV vaccine trial participants. Sites have made themselves available for confirmatory HIV testing when vaccines may have induced an antibody response that can be detected by common HIV tests, making the person appear to be HIV infected when they may not be. The HVTN also works with the National Institutes of Health who is working to provide assistance to anyone experiencing social or psychological harm from being in a clinical trial.*
* **Availability of a licensed product to trial participants and populations at high risk for infection when one becomes available** *Work is being done by international organizations such as the World Health Organization and UNAIDS to begin to create a plan for distribution of a licensed vaccine once one is found to be effective and becomes available. The HVTN supports these organizations and these plans.*
* **Choice of study populations for all phases of clinical development** *The scientific community is looking for an HIV vaccine as fast as it can. When it comes to Phase III efficacy trials and working with populations with increased risks for HIV infection, we will be able to more quickly identify if the vaccine is effective. In smaller scale safety trials (phase I and phase II), we work with people that have lower risks for HIV infection, because what we are really looking for is data on the basic safety of the vaccine(s). People can change their risk behaviors from one day to the next and over time, so we do the best we can to identify people who met the risk profile for each type of trial using a standard set of guidelines. Sites are also encouraged to work to enroll a balance of men and women, and people from a range of racial and ethnic groups. All trials provide the same level of HIV risk reduction counseling and services to all participants.*
* **Level of care given for adverse reactions to an experimental HIV vaccine during a trial***The HVTN provides the highest level of care available in the host country where the trial is taking place, and will follow and care for a participant that may have experienced an adverse reaction until the issue is resolved.*
* **Influence of benefits from study participation; are the benefits coercive?**  
  *HVTN studies provide no direct benefit to the participants. Participants are reimbursed for their time and transportation. All monies and/or other items provided to participants must go through review by the local IRBs/Ethics Committees and are often reviewed by CABs.*
* **Availability of interventions for risk reduction** *The HVTN does not test HIV vaccines alone in trials. The trials are performed to test vaccines in combination with state of the art risk reduction counseling against a placebo/control and the same risk reduction counseling. Risk reduction counseling is provided to every volunteer throughout a trial. Other risk reduction strategies are offered based on what is commonly available in a particular community, which may not be the same from one country to the next.*
* **Level of care and treatment for HIV/AIDS provided to participants who become infected through their behavior during the trial**   
  *The HVTN was the first HIV prevention research organization to insist on provision of antiretroviral therapy (ART) to its trial participants who become infected with HIV because of their own risk behaviors. Provision of ART is now an integral part of the standard care package in HVTN-run HIV vaccine trials. Before each site can open a study for enrollment it must outline its plan for providing or referring a participant to HIV treatment if she or he becomes infected during study participation.*

**Step 7:** Transition to the next activity by asking “Is it ethical to provide antiretroviral therapy to trial participants who become infected through their own risk behavior?” Move on to the group work. Tell them to start thinking about this question as it will be the topic of discussion in the next section.

**Group work (45 minutes)**

**Preparation**

* *Flip chart paper and pens*

Write the 2 debate questions on flip chart paper and keep them covered until you introduce the debate topic.

**Procedure**

**Step 1:** State that the HVTN is committed to providing access to anti-retroviral therapy to participants who become infected while participating in HVTN vaccine studies in countries outside that do not have widespread access to ART via a government or national plan. This policy may raise concerns of undue inducement to join trials since in many countries where the HVTN works, local health care does not typically provide anti-retroviral drugs to HIV-infected people. If a trial participant comes from a country where the rate of infection is incredibly high and they believe there is a high chance of becoming infected in their lifetime, it is possible that he/she may view trial participation as the only way to get access to these life-saving drugs.



Debate 1:

1. Will volunteers join the trial because they want to have access to the drugs if they become infected?
2. Is this coercive?

**Step 2:** Write on a flipchart sheet the questions that this ethical dilemma poses: ***Will volunteers join the trial because they want to have access to the drugs if they become infected? Is this coercive?***

**Step 3:** Divide the trainees into two groups and begin discussing access to anti-retroviral therapy (ART). Prepare for a debate: Have the groups elect a spokesperson that will present the arguments from each group.

**Step 4: Debate #1.**

* Tell Group 1 to argue that yes, giving anti-retroviral treatment is coercive within this scenario.
* Tell Group 2 to argue that giving anti-retroviral treatment is *not* coercive and that it should be provided to all volunteers who may become infected with HIV through their own risk behavior.

Each group will have 10 minutes to talk amongst themselves and prepare an argument. Even if they are not in agreement with the position, their team must argue their assigned point of view. They need to produce a coherent argument as to why their side of the argument is correct.

Be sure that the groups understand the ethical dilemma. Pass between the two groups to clarify any misunderstandings as they are writing their arguments. Be sure that both groups have an elected spokesperson. Try to encourage participation by those who are less vocal.

After ten minutes of preparation, have the groups debate the issue for 10 minutes.

**Step 5: Debate #2.**



Debate 2:

Should participants who become infected during HVTN trials receive the world’s best-proven treatment or should they get the best locally available treatment?

Repeat the exercise using the following ethical dilemma: ***Should participants who become infected during HVTN trials receive the world’s best-proven treatment or should they get the best locally available treatment?***

**Wrap-up Activities (15 minutes)**

**Preparation**

* *Ethical considerations in biomedical HIV prevention trials.*

**Procedure**

**Step 1:** Explain that what they just debated are two of many ethical issues surrounding HIV vaccine trials. Make reference to the information presented earlier in the presentation section. Let the trainees know that there are many resources available for them to learn more about the ethics of research and HIV vaccine trials. Refer them to the HVTN website <http://www.hvtn.org/en/science/hiv-vaccine-basics/ethics-hiv-vaccine-trials.html>.

**Step 2:** Finally, tell the participants that if they are interested in learning more about research ethics, there are many online internet courses that are available to anybody. A listing of these different courses can be found on the members’ side of the HVTN website Training section.

Write the following Internet address on a flipchart sheet: https://members.hvtn.org/training/regoversight/SitePages/Research%20Ethics.aspx

The HIV Vaccine Trials Network is supported through a cooperative agreement with the National Institute of Allergy and Infectious Diseases