Imagine a world without AIDS
Acknowledgements

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The text of the AIDS Vaccine Literacy Training Manual may be found online at www.iavi.org/vaxlit.

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Website: www.iavi.org

IAVI’s mission is to ensure the development of safe, effective, accessible, preventive HIV vaccines for use throughout the world. Integral to this mission is leaving communities and countries where trials are conducted better off as a result of IAVI’s activities. This goal involves many initiatives, among which is increasing literacy through country- and community-appropriate education and training mechanisms.

All reasonable efforts have been made to ensure the accuracy of information contained in this manual before its publication. However, this information may change from time to time as developments occur in the AIDS vaccine research field.
## Introduction: Instructions for Trainers

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## Sample Training Workshop Agendas

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## Sample Pre-Workshop Test

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Introduction: Instructions for Trainers

What is the VaxLit Training Manual?

The Vaccine Literacy (VaxLit) Training Manual is designed to help members of the AIDS vaccine research field conduct training workshops for relevant audiences about a range of issues related to AIDS vaccine development and clinical trials. The Training Manual is one component of the VaxLit Toolkit, which contains a number of resources that can be used for training, mobilization, and advocacy initiatives around AIDS vaccine development with different audiences.

The Training Manual corresponds directly with the VaxLit Core Content, which is a reference text that provides simple explanations about key aspects of AIDS vaccine development and clinical trials and is the fundamental component of the VaxLit Toolkit. Each training module coincides with each chapter contained in the Core Content. Additionally, Module 12 contains sessions that are not specific to a particular chapter of the Core Content, and can be used as general sessions.

Each module has several training sessions covering the content contained in the corresponding Core Content chapter. Most sessions use a participatory style that will maximize the interaction of trainees. Each module also contains one overview session, which is a comprehensive presentation covering the entire Core Content chapter; these sessions have corresponding PowerPoint presentations which can be found on the CD-ROM included in the User Guide. Please see the VaxLit Toolkit User Guide for a full explanation of the vaccine literacy concept and each Toolkit component.

Who should use the Training Manual?

Anyone who uses the Training Manual to conduct a VaxLit workshop should be well-versed in AIDS vaccine information. Therefore, the Training Manual is meant for use by individuals who work in the AIDS vaccine field. This primarily includes staff from AIDS vaccine trial centres and trial sponsor organisations (e.g., IAVI), but may also include individuals or groups involved in outreach and advocacy activities, such as nongovernmental organisation (NGO) partners of vaccine trial centres.

Much of the content is universal, so prevention research and staff from other research sites (e.g., microbicide trial sites) may find it useful to incorporate relevant topics into their own training programmes.

If an individual or group apart from AIDS vaccine trial sites or sponsor organisations would like to use the Training Manual, generally a “training-of-trainers” (TOT) approach is used. In this case, TOT workshops are conducted for the interested group by staff from an AIDS vaccine trial centre or sponsor organisation. After two or three TOT sessions, select trainees become VaxLit “Master Trainers” and can conduct VaxLit workshops for their respective trainee groups. They may also use the Training Manual to incorporate sessions about AIDS vaccine development into their existing training programmes. These workshops should be planned and conducted in conjunction with the trial centre and sponsor staff whenever possible.

Who should attend a VaxLit workshop?

VaxLit trainee groups may include:

- Clinical trial centre staff, particularly those who are not directly involved in AIDS vaccine work
- Community Advisory Board (CAB) members, and other community members who conduct outreach around clinical trials, (e.g., peer leader network members)
- Civil society groups (NGOs, AIDS service organisations, etc.) in countries and regions where trials are being conducted
• Healthcare providers in communities surrounding clinical trials
• Voluntary Counselling and Testing (VCT) counsellors in communities surrounding trial centre
• Key media representatives in relevant countries who may cover stories on AIDS vaccine development
• Other community leaders such as religious or academic leaders

Planning for the VaxLit Workshop

Trainers may use sample agendas included in the manual (see page 10) to plan a workshop for a given number of days. However, the modular format of the manual also allows trainers to create their own agendas by picking sessions according to a number of factors, described below.

Knowledge level of trainees. Any previous knowledge or experience with AIDS vaccine information should be the primary consideration taken into account when planning the agenda. Please see a full explanation below under Planning for the Trainee Group.

Sector of trainees. The suggested agendas contained in the manual are geared toward community trainees, especially those in areas where trials are conducted or planned. Trainers may choose specific sessions for audiences from sectors that may have a particular interest in one topic. For instance, a trainer may choose sessions that are focused on vaccine science for healthcare providers; sessions on regulatory issues and vaccine access for policymakers; or sessions on ethical issues for civil society representatives.

Total length of the workshop. Suggested agendas list the training sessions to be conducted during the workshop. However, trainers need to allow additional time for activities such as: pre- and post-workshop tests, introductions and establishing group norms, coffee/tea and lunch breaks, energisers, and workshop wrap-up.

Planning for the Trainee Group

When planning for a workshop, it is important to consider the level of understanding the trainees will have about AIDS vaccine development and clinical research prior to the workshop. While all training sessions cover information in the Core Content, some sessions are structured in ways that will be appropriate only for trainees who have previous knowledge or experience with the information. Likewise, some sessions are structured for trainees who have no previous knowledge or experience around AIDS vaccine development, and would not be appropriate for a more experienced trainee group.

Each session suggests a “trainee level”—beginner, intermediate, or advanced—which trainers can use as a guide in selecting sessions (see Guide to Training Sessions on next page). Trainee level may also influence the overall length of the workshop—beginner level trainees may require a longer (two- or three-day) workshop, whereas intermediate or advanced level trainees may benefit most from a short, “refresher” (half- or one-day) workshop.

Some questions that may help trainers determine the background level of the trainee group include:
• Have trainees attended a VaxLit training workshop in the past?
• Are trainees involved in AIDS vaccine clinical trials?
• Have trainees been involved in advocacy or community mobilization efforts for AIDS vaccine development?
• Do trainees have any experience with other clinical research, (e.g., microbicide or malaria research)?
• Do trainees work in the HIV and AIDS field?
• In which sector do trainees work, (e.g., civil society, government, healthcare, education, religious, media)?
Adapting Training Sessions

While each session has been written with specific instructions, trainers should feel free to adapt sessions as necessary. Trainers may alter the timing of sessions depending on the total length of the training workshop, or adapt the content for a trainee group from a given sector.

Trainers should also consider adapting sessions based on the cultural context of trainees. Sessions have been developed with generic content, and where possible, trainers may choose to include culturally-relevant examples, metaphors, or stories as a way to make the subject matter more relevant to trainees.

Guide to Training Sessions

Objectives
States the outcome(s) that trainees should achieve as a result of participating in the session.

Method
Explains the structure of the session (role play, lecture, matching game, etc.).

Trainee level
Gives an indicator of the level of understanding trainees should have in order to effectively participate in the session. Trainee levels include the following:

- Beginner – The session can be used with trainees who have relatively limited knowledge about AIDS vaccine development.
- Intermediate – The session should be used with trainees who have some level of understanding about AIDS vaccine development, perhaps those who have attended previous trainings.
- Advanced – The session is meant for use with trainees who are well-versed in AIDS vaccine development. In general, these sessions are meant to provide in-depth training about a particular topic.

Estimated time
Suggests the amount of time the session will take. This is a general guideline and may vary depending on the background level of the trainee group. Trainers should think about the particular trainee group to determine at what points participants will need more or less time than indicated.

Materials
Lists all materials needed for the session, which may include PowerPoint® slides, flip charts, markers, Work sheets, Info sheets and/or Fact sheets. Materials may be found in the Training Manual, or in other parts of the VaxLit Toolkit, as follows:

- PowerPoint® slides are contained in the CD-ROM found in the User Guide.
- Work sheets are numbered chronologically by session and are grouped together in a separate section in the Training Manual, directly following Module 12.
- Info sheets are numbered chronologically by session and are grouped together in a separate section in the Training Manual directly following the work sheets section.
- Fact sheets are general info sheets for a wide variety of audiences that may supplement certain sessions. Trainers may also distribute these sheets at the end of a workshop as a take-home resource for trainees. They are found in the VaxLit Toolkit. Trainers may request additional copies of fact sheets by contacting pubs@iavi.org or the relevant regional IAVI staff person.

Preparation
Lists everything the trainer should do before the training workshop to prepare for the particular
session. This may include making copies of materials, obtaining background information on the content of the session, etc. Additionally, each session includes a Trainer Notes box at the end where trainers can write additional notes for delivering the session. Trainers should allow adequate preparation time for any workshop they plan to facilitate.

**Delivery**
Gives a step-by-step outline of how to take trainees through the given session. It is important that trainers familiarize themselves with the steps for delivery before conducting the workshop.

**Closing**
Emphasizes important points or steps to take at the end of the session, most often highlighting the key points for trainees to remember.

Additionally, most sessions contain the following components:

**Training tips**
Provides helpful hints for delivering sessions, in particular around content that may be complex or confusing for trainees of any level.

**Discussion prompts**
Lists several questions that trainers can use to prompt a discussion among trainees, if necessary.

**Important!**
Highlights key information or points for the trainer to be aware of when conducting the session. When the point is content-related, it often highlights information which is not included in the Core Content, or which is an expansion of information included in the Core Content. In other cases, these points emphasize an important caveat about conducting the session.

**General Reminders**
includes tracking time and making sure that sessions are neither taking too long, nor kept so short that lessons are not learned. It is also important to follow the established agenda and timeline for the workshop as closely as possible, while remaining flexible in case trainees need more or less time for a given session. Trainers may consider assigning one trainee or co-facilitator to act as the timekeeper for the workshop.

It is also important to establish group norms with the trainee group. Norms may include issues such as returning from breaks on time, not interrupting others, and turning mobile phones off while the workshop is in session. Trainers may take a few minutes after the welcome and introductions to establish a list of norms with the trainees.
Trainers may find the following resources useful:

- **Mainstreaming Gender in AIDS Vaccine Clinical Trials: A Training Manual.** International AIDS Vaccine Initiative. In draft version at the time of this printing. Found at www.iavi.org
- **Glossary of Terms – Appendix 1** found in the VaxLit Core Content or available at www.iavi.org/vaxlit

### Additional Resources

**Trainers' Checklist**

As the trainer, ensure that you have:

- Identified the objectives of your training session
- Finalized the workshop agenda
- Sent invitations and received confirmations
- Reserved the meeting space and made other logistical arrangements
- Determined your trainees' background knowledge about AIDS vaccine development
- Thoroughly reviewed each session you plan to conduct, and prepared adequately
- Corresponded with any co-facilitators to plan relevant sessions
- Made copies of the Pre- and Post-Workshop Test
- Made copies of all work sheets, info sheets, and/or fact sheets needed for the sessions you will conduct
- Gathered other materials needed (flip charts, markers, overhead projector, etc.)
- Contacted any presenters or resource people for the workshop
- Gathered additional resources for trainees, such as newsletters or VaxLit fact sheets
# Sample Training Workshop Agendas

The following agendas may be adapted based on the needs of a specific VaxLit workshop. However, the sessions have been arranged in a specific order for effectiveness, so trainers should keep the order as listed.

## Workshop time: One day

**Trainee level: Beginner**

<table>
<thead>
<tr>
<th>Session</th>
<th>Time</th>
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<tbody>
<tr>
<td>Pre-Workshop Test</td>
<td>20 minutes</td>
</tr>
<tr>
<td>Session 1d – A Comprehensive Approach: The Need for Options</td>
<td>60 minutes</td>
</tr>
<tr>
<td>Session 4c – Vaccine Design Analogies</td>
<td>45 minutes</td>
</tr>
<tr>
<td><strong>suggested break</strong></td>
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</tr>
<tr>
<td>Session 5c – AIDS Vaccine Candidates Cannot Cause HIV Infection</td>
<td>75 minutes</td>
</tr>
<tr>
<td>Session 6b – Phases of Clinical Vaccine Trials</td>
<td>45 minutes</td>
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<tr>
<td><strong>suggested lunch break</strong></td>
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<tr>
<td>Session 7b – Can I Participate?</td>
<td>45 minutes</td>
</tr>
<tr>
<td>Session 9d – The Informed Consent Process</td>
<td>60 minutes</td>
</tr>
<tr>
<td><strong>suggested break</strong></td>
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<tr>
<td>Session 5e – Ask the Experts: Common Questions about Vaccines</td>
<td>90 minutes</td>
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<tr>
<td>Post-Workshop Test</td>
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**Total estimated session time:** 7 hours 40 minutes
### Workshop time: One day
#### Trainee level: Intermediate

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<td>Session 1d – A Comprehensive Approach: The Need for Options</td>
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<td>Session 4c – Vaccine Design Analogies</td>
<td>45 minutes</td>
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<tr>
<td><strong>suggested break</strong></td>
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<tr>
<td>Session 6d – Understanding Placebo, Blinding, and Randomisation</td>
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<tr>
<td>Session 5c – AIDS Vaccine Candidates Cannot Cause HIV Infection</td>
<td>75 minutes</td>
</tr>
<tr>
<td>Session 9c – Agree or Disagree: Ethical Issues</td>
<td>45 minutes</td>
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<tr>
<td><strong>suggested break</strong></td>
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<tr>
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<td>90 minutes</td>
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<tr>
<td>Session 12d – Watch Your Language: In Practice</td>
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<td>Post-Workshop Test</td>
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**Total estimated session time:**

- **Day 1:** 8 hours
- **Day 2:** 10 minutes

### Workshop time: Two days
#### Trainee level: Beginner

### Day 1

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<td>Session 1b – The HIV and AIDS Epidemic Globally and Locally</td>
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<td>Session 1d – A Comprehensive Approach: The Need for Options</td>
<td>60 minutes</td>
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<tr>
<td><strong>suggested break</strong></td>
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<tr>
<td>Session 4c – Vaccine Design Analogies</td>
<td>45 minutes</td>
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<tr>
<td>Session 4d – Understanding Vaccine Types</td>
<td>60 minutes</td>
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<td><strong>suggested lunch break</strong></td>
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<tr>
<td>Session 5c – AIDS Vaccine Candidates Cannot Cause HIV Infection</td>
<td>75 minutes</td>
</tr>
<tr>
<td><strong>suggested break</strong></td>
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</tr>
<tr>
<td>Session 5e – Ask the Experts: Common Questions about Vaccines</td>
<td>90 minutes</td>
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**Total estimated session time:**

- **Day 1:** 6 hours
- **Day 2:** 50 minutes
### Workshop time: Two days
### Trainee level: Intermediate

#### Day 1

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<td>Session 4c – Vaccine Design Analogies</td>
<td>45 min</td>
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<td>suggested break</td>
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<tr>
<td>Session 5c – AIDS Vaccine Candidates Cannot Cause HIV Infection</td>
<td>75 min</td>
</tr>
<tr>
<td>Session 2c – The Wrong Foot</td>
<td>60 min</td>
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<td>suggested lunch break</td>
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<tr>
<td>Session 6c – Key Concepts in Vaccine Development and Clinical Trials</td>
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<tr>
<td>Session 9c – Agree or Disagree: Ethical Issues</td>
<td>45 min</td>
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<tr>
<td>suggested break</td>
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<tr>
<td>Session 5e – Ask the Experts: Common Questions about Vaccines</td>
<td>90 min</td>
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**Total estimated session time:**

6 hours 30 minutes

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#### Day 2

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<td>Recap of Day 1</td>
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<tr>
<td>Session 6.b – Phases of Clinical Vaccine Trials</td>
<td>45 min</td>
</tr>
<tr>
<td>Session 7.b – Can I Participate?</td>
<td>45 min</td>
</tr>
<tr>
<td>suggested break</td>
<td></td>
</tr>
<tr>
<td>Session 6.d – Understanding Placebo, Blinding, and Randomisation</td>
<td>90 min</td>
</tr>
<tr>
<td>Session 6.e – Partial Efficacy</td>
<td>45 min</td>
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<tr>
<td>suggested lunch break</td>
<td></td>
</tr>
<tr>
<td>Session 9.d – The Informed Consent Process</td>
<td>60 min</td>
</tr>
<tr>
<td>Session 8.b – Agree or Disagree: Gender Issues</td>
<td>45 min</td>
</tr>
<tr>
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</tr>
<tr>
<td>Wrap-Up – Open Q&amp;A Session</td>
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</tr>
<tr>
<td>Post-Workshop Test</td>
<td>20 min</td>
</tr>
</tbody>
</table>

**Total estimated session time:**

6 hours 30 minutes
### Day 2

| Recap of Day 1 | 10 minutes |
| Session 6d – Understanding Placebo, Blinding, and Randomisation | 90 minutes |
| Session 6e – Partial Efficacy | 45 minutes |

**suggested break**

| Session 7d – Participating in a Trial | 75 minutes |
| Session 8b – Agree or Disagree: Gender Issues | 45 minutes |

**suggested lunch break**

| Session 12d – Watch Your Language: In Practice | 45 minutes |
| Session 12e – Next Steps: Developing a Personal Work Plan | 30 minutes |

**suggested break**

| Post-Workshop Test | 20 minutes |

**Total estimated session time:** 6 hours
I. Preliminary knowledge and experience
Have you ever attended:

| a. An ARV (antiretroviral) workshop? | Yes ☐ | No ☐ |
| b. An HIV workshop? | Yes ☐ | No ☐ |
| c. A VCT (voluntary counselling and testing) course? | Yes ☐ | No ☐ |
| d. Any vaccine workshop? If yes, which one? | Yes ☐ | No ☐ |
| e. Other (specify) | Yes ☐ | No ☐ |
| f. Have you ever heard about AIDS vaccine research? If yes, provide details: | Yes ☐ | No ☐ |

II. Please complete the following questions. Mark one response only for each question.
You have 20 minutes to complete the entire quiz.

1. HIV can be transmitted through all of the following EXCEPT:
   a. Sexual intercourse
   b. Transfusion of infected blood
   c. Injecting dirty needles
   d. From a pregnant or breastfeeding woman to her baby
   e. Sharing food or clothes with an infected person

2. The following interventions can protect against HIV infection EXCEPT:
   a. Abstaining from sexual intercourse
   b. Consistently and properly using condoms
   c. Washing sexual organs immediately after sex
   d. Being faithful to an uninfected partner
   e. Knowing your status by taking an HIV test

3. When used correctly, antiretroviral (ARV) drugs:
   a. Completely destroy HIV
   b. Can cure HIV and AIDS
   c. Enable the body to recover for a time, but cannot eradicate the virus
   d. Eliminate the need to use condoms

4. A vaccine is:
   a. A foreign biological substance that causes disease
   b. An injection
c. A substance to boost the immune system

d. Medicine used to cure a disease

e. A substance that teaches the body to protect itself against a particular disease

5. **Clinical vaccine trials are:**
   a. A process of testing vaccines in humans
   b. A process of testing vaccines in animals
   c. A process of testing vaccines in the laboratory
   d. A process of administering vaccines in clinics

6. **“Informed consent” in clinical trials is:**
   a. A group education process that includes signing an agreement with other potential volunteers in the trial
   b. The continuous process of explaining to volunteers all information about a clinical trial or study to ensure that they understand and independently sign an agreement before joining
   c. The process of informing a participant about a trial
   d. The consent given by volunteers to receive information about a specific issue

7. **AIDS vaccine candidates are made of:**
   a. Blood from infected individuals
   b. Blood from uninfected individuals
   c. Synthetically made genetic material
   d. Live-attenuated HIV
   e. Killed HIV

8. **Which one of the following is NOT a characteristic of an ideal vaccine?**
   a. Safe
   b. Effective
   c. Efficacious
   d. Available
   e. Expensive

9. **Effectiveness of a vaccine refers to:**
   a. The cost of producing the vaccine compared to the profit from the vaccine
   b. The ability of a vaccine to reduce incidence of the disease in the community
   c. The ability of a vaccine to produce an immune response against the disease
   d. The ability of a vaccine to produce an immune response in the shortest time possible

10. **Efficacy of a vaccine refers to:**
    a. The ability of the vaccine to prevent infection or disease in the trial population
    b. The ability of the vaccine to protect against diseases other than the one it was intended for
    c. The ability of the vaccine to protect against the disease 100% of the time
    d. The ability of the vaccine to produce quick results

11. **Randomisation in clinical vaccine trials is:**
    a. A process of choosing at random which participants will get the candidate vaccine or the placebo
    b. A random process of choosing countries where the vaccine trial is going to be conducted
    c. A random process of selecting people from the population to be part of the vaccine trial
    d. When a participant makes a choice to belong to either the placebo group or the candidate vaccine group
12. A placebo is:
   a. A place where the vaccine is being tested in animals
   b. A substance that is given to volunteers to reduce potential side effects
   c. A harmless, inactive substance that resembles the vaccine in appearance
   d. A chemical substance used to determine when someone was infected by HIV

13. The following statement is true with regard to AIDS vaccines:
   a. There will be no need to continue with other prevention behaviours once a vaccine is available and introduced to the population
   b. The candidate AIDS vaccine cannot cause HIV infection
   c. AIDS vaccines are always tested in developing countries before they can be tested in industrialized countries
   d. Only people at risk of HIV infection should participate in AIDS vaccine trials

14. The main objective of a Phase I clinical trial is to find out if the candidate vaccine:
   a. Is safe
   b. Causes an immune response
   c. Protects against infection or disease
   d. Causes disease

15. The main objective of Phase III clinical trial is to find out if the candidate vaccine:
   a. Is safe
   b. Provokes an immune response
   c. Protects against infection or disease
   d. Causes disease

16. Who of the following will NOT be allowed to participate in a vaccine trial (regardless of the trial phase)?
   a. A person who is 18 years old
   b. A sex worker
   c. A person who refuses to be tested for HIV
   d. A man who has sex with other men
   e. A person who cannot read
   f. A person who is unemployed

17. Before a clinical trial starts, all of the following reviews need to be conducted EXCEPT:
   a. Regulatory review
   b. Scientific review
   c. Ethical review
   d. Monetary and good governance review

18. Which of the following is NOT the role of a Community Advisory Board (CAB)?
   a. To provide researchers with information regarding the health, beliefs, and understanding of the study population
   b. To review the informed consent process to ensure it is appropriate for volunteers
   c. To advise on which volunteers should join or withdraw from the study
   d. To advise on effective methods for disseminating information about the trial and its outcomes
   e. To relay community concerns to researchers
   f. To build trust between the community and researchers
19. Which of the following is NOT a role of AIDS service organisations, NGOs, faith-based organisations, traditional healers, and media in the development of an AIDS vaccine?
   a. To help increase awareness and knowledge of AIDS vaccine clinical trials
   b. To ensure the efficient and ethical conduct of AIDS vaccine trials
   c. To streamline AIDS vaccine messages into their existing activities
   d. To tell people that there is already an AIDS vaccine
   e. To advocate for vaccine development activities locally, nationally, and globally

20. Once a vaccine is licensed and ready to be given to the general population, which of the following does NOT represent a challenge to introducing an AIDS vaccine?
   a. Healthcare infrastructure and vaccine delivery systems
   b. Vaccine price
   c. Stigma, myths, and rumours in the community about the vaccine
   d. Determining the priority populations for receiving the vaccine
   e. All of the above represent challenges

If you finish before the time allocated, please stay in your seat and wait. Take this time to check that you have answered all of the questions as accurately as possible.
Please complete the following questions. Mark one response only for each question.
You have 20 minutes to complete the entire quiz.

1. HIV can be transmitted through all of the following EXCEPT:
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Answer key for pre- and post-workshop tests

1. e  2. e  3. c  4. e  5. a  6. b  7. c  8. e  9. b  10. e
The sessions in this module are based on Chapter 1 of the *VaxLit Core Content* which you should read before delivering sessions. Remember that you do not have to use every session for your training workshop; just choose those that are most relevant for your audience and the time available.

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<td>1.a Overview Presentation</td>
<td>• All information in Core Content Chapter 1</td>
<td>30 minutes</td>
</tr>
</tbody>
</table>
| 1.b The HIV and AIDS Epidemic Globally and Locally | • Data on AIDS cases and deaths, worldwide and by region  
• Data on prevalence among men, women, and children  
• Country-specific examples of increasing prevalence | 60 minutes     |
| 1.c Treatment Options    | • Treatment, care, and support strategies  
• ARVs (antiretrovirals)  
• Limitations of treatment | 45 minutes     |
| 1.d A Comprehensive Approach: The Need for Options | • Prevention approaches  
• Currently available options and the need for new methods | 60 minutes     |

**Note:** It is important to assess trainees' level of awareness about AIDS vaccine research when developing your workshop agenda and preparing sessions. This module addresses topics in the HIV prevention field such as microbicides, as well as issues around HIV treatment and care. Please prepare according to the level of understanding your trainee group will have about these topics. You may also choose to involve external experts to speak on these topics during your workshop.
HIV and AIDS represent one of the worst epidemics the world has ever seen. An AIDS vaccine, once developed, will play a major role in halting it.

Although behavioural prevention strategies have slowed the epidemic in some areas of the world, they have not stopped it; a preventive AIDS vaccine is urgently needed.

An AIDS vaccine will never be the only answer; the response to HIV and AIDS must be comprehensive, and should include existing behavioural prevention strategies, efforts to develop new technologies including vaccines and microbicides, and treatment and care for those already infected.
Overview Presentation

Objectives
By the end of the session, trainees will be able to provide a general overview of the key concepts and information covered in Chapter 1 of the VaxLit Core Content.

Method
Lecture

Trainee level
Beginner

Estimated time
30 minutes

Materials
PowerPoint® slides on the CD-ROM (or a printed copy of the slides)

Preparation
If you have an LCD projector, your only preparation is to load the PowerPoint® presentation for this session onto a computer. If you do not have a projector, you will need to prepare a lecture based on the slides using a flip chart.

Delivery
Present the overview lecture contained in the slides.

Closing
Reiterate the key messages of this module found on the previous page.
Objectives
By the end of the session, trainees will be able to:
• Describe the scope of the epidemic worldwide, in those areas most affected, and in their country.
• “Make the case” for vaccines and vaccine trials and inform people about the scope of the epidemic.
• Explain how different groups, regions, or communities are affected in the country.
• Explain why different regions have higher or lower prevalence.

Method
Lecture and discussion. Participants learn and react to prevalence data and discuss how the epidemic affects different groups.

Trainee level
Beginner

Estimated time
60 minutes

Materials
Slides and handouts (see Preparation below)

Preparation
Use information in Chapter 1 of the VaxLit Core Content and in the PowerPoint® presentation CD-ROM (Session 1.a). You will also need to obtain some basic data on the HIV epidemic in the country. Please see the UNAIDS website for up-to-date country and region-specific information. If possible, you should try to obtain the following information (and put it on a slide).
• HIV prevalence in the general population
• Percentage increase or decrease in prevalence within a given period (e.g., since the last survey, since the beginning of the epidemic)
• Number of people infected with HIV
• Percentage of those infected who are women/men
• Number of deaths from HIV (during the most recent year, since the beginning of the epidemic, etc.)
If you can easily obtain data on the different groups listed in Step 3 below, prepare an additional slide.

If you are able to find prevalence data by regions or districts of the country, you can prepare the slide to be used in Step 5 below.

**Training tip**

Invite a guest lecturer to deliver this presentation, if there is a local expert or other appropriate individual who would be particularly effective with information on the HIV epidemic.

**Delivery**

**Step 1:** Present the data you have collected on the HIV epidemic in the country. You can either show the slide with the data already filled in, or show a slide with blanks, asking the group to guess the missing statistics, which you then reveal.

**Step 2:** Conduct a discussion of the data with the following suggested questions:

- Which statistics surprise you the most? Why?
- How well informed do you think most people are about the scope of the epidemic in your country?
- Why do you think HIV infection rates and/or AIDS cases have increased/decreased?
- How successful have prevention efforts been in the country?
- How successful have treatment efforts been?
- Why are more women affected than men? (Or vice versa, in some areas?)

**Step 3:** Explain that you would like participants to think about how different groups might be affected by the epidemic for a few minutes. Show participants the following list (on a flip chart or slide):

- Children aged 0 to 15
- Unmarried men aged 15 to 24
- Unmarried women aged 15 to 24
- Married men
- Married women
- Pregnant women
- Injecting drug users
- Men who have sex with men
- Sex workers
- Clients of sex workers

**Important!**

In HIV prevention, the terms “high risk” or “risk” groups are generally avoided in an effort to minimize stigma. Instead, we try to describe vulnerabilities or behaviours that put people at risk. Nevertheless, in order to target interventions and to identify populations for AIDS vaccine efficacy trials, it is necessary to identify certain groups that have a higher incidence of infection, and the term “risk groups” is commonly used.
Divide participants into small groups and assign each group one category from the list above. Ask them to answer the following questions:

- Are people in this group generally at risk of becoming infected with HIV?
- What factors put them at risk?
- What considerations would need to be taken into account if this group was included in HIV prevention research?

**Training tip**
To save time, this step can be conducted with the entire group in the form of a plenary discussion, with one person representing each category.

**Step 4:** Call the groups back together and briefly discuss their answers to each question. If you have prevalence data for each group, present it here.

**Step 5 (optional):** If you have been able to obtain HIV and AIDS data on the various districts/regions of your country, present a slide (or a map) showing the districts and then ask the group which areas they think are the most affected and the least affected. Then reveal the data and conduct a short discussion:

- Why do you think certain areas are more affected than others?
- What significance will a vaccine have for each of these groups and areas?

**Closing**
Highlight once again the groups and regions of the country that are the most vulnerable or most affected.

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**Trainer notes**

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Objectives
By the end of the session, trainees will be able to:
• Describe the various kinds of treatment being used for people with AIDS.
• Discuss the impact of treatments being used in the local setting.
• Describe local HIV prevention options.
• Describe the impact of prevention options used in the local setting.
• Explain why treatment and current prevention options, despite some limitations, must continue to be part of the response even as vaccines and microbicides are being developed and tested.

Method
Small group discussion. Participants discuss local obstacles to the use of antiretrovirals (ARVs) (cost, infrastructure, adherence problems) and to voluntary counselling and testing (VCT).

Trainee level
Intermediate

Estimated time
45 minutes

Materials (click on Work sheet title to jump to its page in the back of the book)
Work sheet 1: Treatment Options
Flip chart as described under Preparation

Preparation
Make copies of Work sheet 1 for all participants.

If possible, obtain data on the use of antiretrovirals (ARVs) and prevention options in your country. This could include: the percentage of those infected with HIV who are qualified to use ARVs and are using them, the percent of people who have access to ARVs, data on ARV adherence/drop out, percentage of people in the community accessing voluntary counselling and testing (VCT), etc.
Training tip
It may be helpful to have a doctor or other clinician who is familiar with antiretroviral (ARV) delivery in the country attend or co-facilitate this session.

Delivery
Step 1: Distribute Work sheet 1, divide participants into groups, and ask the groups to answer the questions on the work sheet. Ask one person in each group to take notes and be prepared to give a summary of the group’s discussion.

Step 2: Call the groups back together and ask each group to explain how they answered one of the questions. Discuss the answers as a large group. You can present any data you have on the use of antiretrovirals (ARVs) here.

Training tip
Question 4 on Work sheet 1 may be tricky, even for intermediate audiences, if they are not familiar with HIV prevention research. Here are some points that may help guide the discussion around this question:

- HIV prevention research will require potential volunteers to be tested for HIV; increased uptake of voluntary counselling and testing (VCT) in the community will create an environment where more people are aware of their status and will also help reduce fear and stigma around HIV testing.

- Everyone who screens as HIV-infected before or during a clinical trial should be provided with comprehensive treatment and care. Access to treatment and care in the community will raise the standards of care that trial sponsors should ensure for volunteers. Also, existing treatment mechanisms in the community will allow easier referrals for volunteers.

Step 3: Discuss the following questions with the group:
- What are some advantages of the treatment options available in your community? What are some of the disadvantages?
- Given the current circumstances around treatment options, is this a realistic answer to the HIV and AIDS situation in your community?
- What lessons should be reinforced with those who are not yet infected?
- How can treatment and prevention messages be combined in your community?

Closing
In concluding this session, emphasize the following messages:
- HIV treatment and prevention options continue to become more available in many places, especially in the developing world.
- Broad provision of treatment can have extremely beneficial effects for the community as a whole, such as increased voluntary counselling and testing (VCT) uptake and higher standards of care.
- Comprehensive HIV treatment options and certain prevention options are not available in all places.
- Even when treatment and prevention options are available, there are a number of factors that may make them difficult to access and use effectively.
- While efforts must be put into providing treatment to those who are already infected, a strong emphasis on prevention must remain for those who are still uninfected.
A Comprehensive Approach: The Need for Options

Objectives
By the end of this session, trainees will be able to:

- Explain why current prevention and treatment efforts have had limited success.
- Describe additional methods that will be available in the future and why they are needed.
- Explain why all prevention strategies must continue, even when future prevention interventions become available.
- Discuss the need for a comprehensive response to HIV and AIDS, including current prevention options, treatment, and future prevention methods.

Method
Brainstorm and group discussion. Participants discuss common prevention strategies in their country and then answer one of four key questions about the relationship between vaccines and prevention.

Trainee level
Beginner

Estimated time
60 minutes

Materials (click on Work sheet title to jump to its page in the back of the book)
Work sheet 2: A Comprehensive Approach: The Need for Options

Preparation
Make copies of Work sheet 2 for everyone.
For Step 1, prepare a flip chart with four columns as follows:

<table>
<thead>
<tr>
<th>Form of prevention</th>
<th>Advantages</th>
<th>Disadvantages</th>
<th>How widely used in your country</th>
</tr>
</thead>
</table>

Delivery
Step 1: In plenary, take 15-20 minutes to brainstorm a list of common forms of HIV prevention
and write them in the left-hand column of the prepared flip chart, leaving plenty of space between each.

**Important!**
As the trainer, your job is to make sure the discussion focuses on the comprehensive response, which includes BOTH current and future prevention methods (e.g., vaccines, microbicides, etc.). Be sure to include these new methods in the list and discussion. This will help transition into Steps 2 and 3 of the exercise. If you think your trainees are not familiar with these concepts, give a brief introductory explanation.

When the list is complete, have the group brainstorm the advantages and disadvantages of each method. Finally, ask participants to describe how widely each prevention technique is used in their community or communities.

**Training tip**
Let participants offer ideas first. However, if this seems challenging, the following chart offers some ideas to get the brainstorm started (note that this is not a complete list).

<table>
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<tbody>
<tr>
<td>Male condom</td>
<td>Available in many places</td>
<td>Undesirable by most men</td>
<td></td>
</tr>
<tr>
<td>Female condom</td>
<td>Female-initiated</td>
<td>Not available in most places</td>
<td></td>
</tr>
<tr>
<td>Microbicides</td>
<td>Female-initiated</td>
<td>Does not exist yet</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>May only be partially effective</td>
<td></td>
</tr>
<tr>
<td>Partner reduction</td>
<td>No resources needed</td>
<td>Not realistic, especially for women</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>No power over partners’ choices</td>
<td></td>
</tr>
<tr>
<td>Vaccines</td>
<td>Provider-initiated</td>
<td>Does not exist yet</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Traditionally, easy to use</td>
<td>May only be partially effective</td>
<td></td>
</tr>
<tr>
<td>Clean needles</td>
<td></td>
<td>Not available in many places where needed</td>
<td></td>
</tr>
<tr>
<td>Male circumcision</td>
<td>Proven to reduce infection risk</td>
<td>Procedure may not be available</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Personal preference may deter some men</td>
<td></td>
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Training tip
Step 1 may involve extensive discussion. Use your best facilitation skills to avoid spending too much time on any one topic. If many participants have comments, try to circulate the discussion so everyone has a chance to give input about at least one of the topics.

Another option is to ask individual trainees to fill in the chart for each given topic, and after the chart is filled in, spend five minutes taking additional input from all participants.

Step 2: For about 5 minutes, discuss the following question with the group: Given the limitations discussed for each prevention option, are the currently available options enough to address HIV and AIDS? Why or why not?

Step 3: Distribute Work sheet 2, divide participants into four groups and assign each group one of the questions from the work sheet. Give them 10 minutes to discuss their question. Each group should designate one person who will present the answer in plenary.

Step 4: Reconvene and ask a representative from each group to briefly present the answer to its question. Then ask the other participants to add any comments.

Closing
In closing, emphasize the key messages of this session:
- Existing prevention efforts are critical, but they have not been sufficient. New methods such as vaccines and microbicides are needed.
- Epidemics of this magnitude have traditionally only been contained or stopped with a vaccine. Before a vaccine is available, however, we must do whatever we can to limit the spread of HIV.
- All existing prevention strategies must continue. The effort to create and test a vaccine must proceed in tandem with—and not replace or come at the expense of—efforts to change behaviours, promote condoms, etc.
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<td>2.a Overview Presentation</td>
<td>• All information in Core Content Chapter 2</td>
<td>30 minutes</td>
</tr>
<tr>
<td>2.b Roles of Advocates and Stakeholders</td>
<td>• Identification of advocates and stakeholders</td>
<td>35 minutes</td>
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<td></td>
<td>• Roles and actions of various stakeholders</td>
<td></td>
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<tr>
<td>2.c The Wrong Foot</td>
<td>• Conducting research in developing countries</td>
<td>60 minutes</td>
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<tr>
<td></td>
<td>• The need to inform and work closely with stakeholders at all levels</td>
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<td></td>
<td>• Benefits of involving partners</td>
<td></td>
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<tr>
<td>2.d Common Concerns of Advocates and Stakeholders</td>
<td>• Descriptions of types of stakeholders</td>
<td>60 minutes</td>
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<tr>
<td></td>
<td>• Common concerns or questions of stakeholders</td>
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<td></td>
<td>• Interaction of trial team with stakeholders</td>
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</table>
Involving community representatives and key stakeholder groups in meaningful dialogue early on can contribute to the success of AIDS vaccine research. These individuals often have important insights that can improve clinical trials.

Trust must be built with communities and in-country stakeholders. They have the right to know about the research and to be involved. Failing to involve them could result in misunderstandings, negative perceptions of trials, and delays in progress.

Communities where trials are conducted should experience benefits beyond their contribution to the trial, and should be left better off after the trial is completed. Such benefits might include improved services for HIV prevention and care.

There are very important reasons to conduct AIDS vaccine research in the developing world, even though some may question the motivations for doing so. We must know if the vaccines work where they are needed most, and conducting trials in these countries could help make them available more quickly there.
Objectives
By the end of this session, trainees will be able to provide a general overview of the key concepts and information covered in Chapter 2 of the VaxLit Core Content.

Method
Lecture

Trainee level
Beginner

Estimated Time
30 minutes

Materials
PowerPoint® slides on the CD-ROM (or a printed copy of the slides)

Preparation
If you have an LCD projector, your only preparation is to load the PowerPoint® presentation for this session onto a computer. If you do not have a projector, you will need to prepare a lecture based on the slides, using a flip chart.

Delivery
Present the overview lecture contained in the slides.

Closing
Reiterate the key messages of this module found on the previous page.
Roles of Advocates and Stakeholders

**Objectives**

By the end of this session, trainees will be able to:

- Identify possible advocates and stakeholders for vaccine trials.
- Explain why it is important to involve advocates and stakeholders at multiple levels.
- Describe the actions advocates and stakeholders may take to create a supportive environment for a vaccine trial.

**Method**

Brainstorm and group discussion. Participants identify and discuss the advantages of involving advocates and stakeholders in four “circles” of closeness to a trial participant: family, community, national, global.

**Trainee level**

Beginner

**Estimated time**

35 minutes

**Materials**

Flip chart

**Trainer notes**

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Preparation
On a flip chart, draw a large version of the diagram below, leaving plenty of space in each circle to fill in responses from the group.
Delivery

Step 1: Explain the purposes of the exercise, which are: to identify advocates and stakeholders at various levels; to discuss why they should be involved; and to understand the actions they can take to promote AIDS vaccine research.

Training tip

Your trainee group may include some of the stakeholders being discussed. If so, be sure to rely on their unique expertise and request their input throughout the session.

Step 2: In plenary, present the diagram on the flip chart. You may use the language below to help explain it.

“This diagram shows the different levels of stakeholders that surround a vaccine trial. Starting from the innermost circle (a participant’s family and close friends) to the outermost circle (the international level), the diagram shows that there is a vast range of external influences on one individual trial participant.”

For each circle, ask participants to list examples of stakeholders in AIDS vaccine research. It may be best to start with the innermost circle and move out. Write the groups in the appropriate circle on the diagram. For each named group, participants should state why they should be involved. Allow 10 to 15 minutes for this step.

Step 3: After groups have been identified, go back to each level, and ask participants to list two or three key actions that the individuals or groups could take to promote AIDS vaccine research. Write these on a separate piece of flip chart paper.

Discussion prompts

If it seems like the group is having a hard time thinking of actions, try to facilitate the discussion by asking...

Could this group or individual:

- Encourage voluntary counselling and testing (VCT)?
- Promote education about clinical research?
- Help change or develop policies around AIDS vaccine development and/or research?
- Facilitate the conduct of an AIDS vaccine trial in the community?
- Help manage expectations or misconceptions about AIDS vaccine research?

Step 4: Ask the group, “Why is it important to involve stakeholders at various levels?” Try to bring the discussion back to the varying roles and responsibilities that have been identified for groups at each level. Also ask someone to explain how the various levels may interact or influence each other.

Closing

Emphasize the key messages of the session:

- Setting up and conducting a vaccine trial requires the support and participation of a wide variety of advocates and stakeholders at all levels.
- Each stakeholder group has key roles and specific actions it may take to support vaccine research.
- The various levels may overlap and influence each other.
Objectives
By the end of the session, trainees will be able to:
• Explain the reasons why it is important to lay the foundation for a vaccine trial.
• Envision a vaccine trial from the point of view of various community members.

Method
Modified role play and group discussion. Participants play one of eight community roles in responding to news of an AIDS vaccine trial.

Trainee level
Intermediate

Estimated time
60 minutes

Materials (click on Work sheet title to jump to its page in the back of the book)
Work sheet 3: The Wrong Foot

Preparation
Make copies of Work sheet 3 for all participants. Adapt the details of the setup to reflect the local setting by adding appropriate details in the blanks provided. You may also want to change other details of the introduction on the work sheet, or the list of community types, based on the type of participant in the training.

Delivery
Step 1: Distribute Work sheet 3 and ask one volunteer to read the introductory paragraph, filling in the blank spaces with locally relevant information.
Important!
Be sure to explain that the example used here is atypical. In most cases trial sponsors will do some kind of preparation in the community, whether partial or comprehensive.

Divide participants into eight groups, and assign one role from the list on Worksheet 3 to each group, asking group members to role play answers to the questions on the handout according to their assigned role. Circulate among the groups, answering any questions. Allow 15 minutes for group work.

Training tip
If there are not enough participants for eight groups, make four groups and assign each group two roles from the work sheet.

Step 2: Bring the groups together in plenary. Ask for several volunteers to demonstrate their role play. Allow 15 to 20 minutes for this step.

Step 3: Lead a 15 to 20 minute discussion using the following question.

What are the greatest risks of starting a clinical trial without informing and educating people in the community ahead of time?

Discussion prompts
Some of the possible answers here would include:
- Rumours may start about who you are and what you are really doing in the community.
- You may raise expectations about a cure for AIDS.
- People may think they are being used as “guinea pigs”.
- People may be worried that the vaccine spreads AIDS.

Closing
Close the session by making the following points:
- Before conducting a trial, it is important to prepare communities by raising awareness about HIV, AIDS, and vaccines and to seek input from various stakeholders.
- Generally, if important stakeholder groups are not informed about the trial, it will be harder to conduct research in the community.

Trainer notes
Common Concerns of Advocates and Stakeholders

Objectives
By the end of the session, trainees will be able to:
- Describe which groups need to be involved in preparing for and carrying out a vaccine trial.
- Identify the common concerns or questions of these groups.
- Practice responding to common stakeholder concerns.

Method
Role play. Trainees will pretend to be either a stakeholder or a trial site staff member and role play questions and answers between the two.

Trainee level
Intermediate

Estimated time
60 minutes

Materials
Flip chart, if needed
Blank paper or writing pads for all trainees

Preparation
If you decide it is needed, write the list of questions included under Discussion prompts on a flip chart for the group to look at while they complete the activity.

Training tip
This session may be most effective if conducted at the end of a training workshop, since trainees will be more familiar with “vaccine literacy” concepts at that point. It may also function well as a wrap-up Q&A session for a training workshop.
**Delivery**

**Step 1:** Explain the purpose of the exercise, which is to think about the issues, concerns, and requests of advocates and stakeholders around trials, and how someone from the trial site would respond.

**Step 2:** Divide participants into two groups.

1. Trial site staff members
2. Stakeholder groups, including:
   - NGOs, community- and faith-based organisations
   - Parliamentarians, policymakers, ministries of health
   - Media outlets and journalists
   - Medical professionals
   - Academic leaders
   - Religious leaders
   - Community Advisory Boards (CABs)

Have trial staff sit on one side of the room and stakeholders sit on the other side.

**Step 3:** Give everyone 5 to 10 minutes to individually brainstorm various questions that may be asked by the stakeholder groups. They can write these questions down on a blank sheet of paper or writing pad. The trial staff group should also think about the answers they would give to common questions.

**Discussion prompts**

Examples of stakeholder questions include:

- What can we do? What role can we play?
- How is this trial going to help my community or region?
- What are the risks to those who participate?
- What happens if we decide not to support or participate in this trial?
- What do you want me to do to support your trial?

These may also be written on a flip chart for the group to look at while they work in their groups.

**Step 4:** When it seems like everyone has come up with several questions and answers, ask for two volunteers: one person to role play a stakeholder and ask a question, and the other to role play a trial site staff member and respond to the question. Trainees can either come to the front of the room, or role play at their seats.

Have the stakeholder introduce him/herself by saying something like: “I am [name] from [name of stakeholder group] and I have a question about the vaccine trial starting in my community. My question is…”

Have the trial staff member introduce him/herself, stating his/her role at the trial centre, and then answer the question. If it seems like he/she is having trouble answering a question, you may need to help, or use your facilitation skills to solicit help from other trainees.

Try to conduct enough role plays to address questions from a number of different stakeholder groups. Use your judgment in terms of timing to allow as many pairs to role play a question and answer scenario as possible, and to cover as many topics as possible.
Step 5: When the role playing is complete, conduct a short debrief asking the following questions.

- Was anyone surprised by any of the questions asked?
- Were most answers given by the trial centre staff members satisfactory?
- Were any concerns common to all stakeholders?
- Would stakeholders feel comfortable about vaccines and trials after the Q&A session?

Closing
In closing, reemphasize the main points.

- Many different stakeholders have important roles to play in a vaccine trial and should be involved at an early stage.
- Stakeholders and advocates need to fully understand the benefits of conducting a trial in their country or community and of participating in a trial.
The sessions in this module are based on Chapter 3 of the *VaxLit Core Content* which you should read before delivering sessions. Remember that you do not have to use every session for your training programme; just choose those that are most appropriate for your audience and the time available.

<table>
<thead>
<tr>
<th>Session</th>
<th>Topics addressed</th>
<th>Estimated time</th>
</tr>
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<tbody>
<tr>
<td><strong>3.a</strong> Overview Presentation</td>
<td>• All information in <em>Core Content</em> Chapter 3</td>
<td><strong>30 minutes</strong></td>
</tr>
<tr>
<td><strong>3.b</strong> The Vocabulary of the Immune System</td>
<td>• Key terms: pathogens, antigens, B-cells, CD4⁺ cells, CD8⁺ cells, antibodies, memory cells, T-cells, opportunistic infections</td>
<td><strong>20 minutes</strong></td>
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</tbody>
</table>
| **3.c** The Immune System Responds | • How the immune system works  
• How the immune system responds to pathogens | **30 minutes** |
| **3.d** Understanding the Immune System | • How antibodies work | **60 minutes** |
The immune system is a powerful tool for fighting infections and keeping us well. It even helps control HIV in the early stages of infection.

HIV is particularly harmful because it directly attacks the parts of the immune system that would normally fight off other infections, and it makes the immune system incapable of fighting HIV itself.

An effective AIDS vaccine will teach the immune system to fight HIV. This may prevent initial infection and/or lessen the occurrence of disease after infection.
Objectives
By the end of this session, trainees will be able to provide a general overview of the key concepts and information covered in Chapter 3 of the VaxLit Core Content.

Method
Lecture

Trainee level
Beginner

Estimated time
30 minutes

Materials
PowerPoint® slides on the CD-ROM (or a printed copy of the slides)

Preparation
If you have an LCD projector, your only preparation is to load the PowerPoint® presentation for this session onto a computer. If you do not have a projector, you will need to prepare a lecture based on the slides, using a flip chart.

Delivery
Present the overview lecture contained in the slides.

Closing
Reiterate the key messages of this module found on the previous page.
Objectives
By the end of the session, trainees will be able to:

- Correctly use technical terms referring to the immune system.
- Describe how the immune system works.

Method
Matching exercise. Participants match the terms with the definitions for key technical vocabulary of the immune system.

Trainee level
Beginner

Estimated time
20 minutes

Materials (click on Work sheet or Info sheet title to jump to its page in the back of the book)
Work sheet 4: The Vocabulary of the Immune System
Info sheet 1: The Immune Response

Preparation
If possible, distribute Info sheet 1 well in advance of the session so participants can review it. Make copies of Work sheet 4 for all participants.

Delivery

Step 1: Distribute Work sheet 4 and Info sheet 1 (if not previously distributed), and divide participants into pairs. Ask them to complete the matching exercise with their partners. If they need to, they can use Info sheet 1 to complete the exercise.

Step 2: Go through Work sheet 4 in plenary and ask for volunteers to give responses (See Answer Key on the next page).

Step 3: Lead participants in a discussion of key issues.
Discussion prompts
Some questions that may prompt discussion include:
• Why do you think it’s important to know how the immune system works?
• When do you think you might use this information?

Closing
Emphasize that it is important to have a basic understanding of key terms in the immune system, especially as they relate to the immune response a vaccine is meant to produce.

Answer key
Corresponds with Work sheet 4

1 D 2 E 3 B 4 G
5 A 6 F 7 C

Trainer notes
Objectives
By the end of the session, trainees will be able to describe step-by-step how the immune system responds to a pathogen.

Method
Sequencing exercise. Participants play different steps in the immune system response and line up in the right sequence.

Trainee level
Intermediate

Important!
This exercise can be used with a training group that does not have extensive knowledge of scientific concepts. However, you should have someone present, either yourself, someone from the trial centre, or one of the workshop participants, who is familiar with immune system concepts to co-facilitate the exercise.

Estimated time
30 minutes

Materials (click on Info sheet title to jump to its page in the back of the book)
Info sheet 1: The Immune Response

Preparation
Make copies of Info sheet 1.
Prepare seven large cards with a string attached so that participants can wear the cards around their necks. On each, write one of the seven following steps:
- CD8+ cells kill cells infected with the pathogen.
- Memory cells are activated as a known pathogen reappears.
- Antigens are “presented” by certain immune cells to the rest of the immune system.
- B-cells direct the production of antibodies.
• Lymphocytes recognise the antigens.
• A pathogen (such as HIV) enters the body.
• Antibodies bind to pathogens, making them inactive.

Delivery
Step 1: Ask for seven volunteers, one to wear each one of the prepared cards. Bring the volunteers to the front of the room.

Step 2: Distribute Info sheet 1 and give the remaining participants a few minutes to read it.

Training tip
It may be valuable here to use a metaphor that would help your training group understand the immune system. Once participants have read over Info sheet 1, present the metaphor, and if appropriate, lead a short discussion to solicit thoughts and questions from participants.

Step 3: Ask participants to line up the seven card-wearers in the order that the events occur in the immune response.

Step 4: Lead a closing discussion. Ask one participant to recap the steps of the immune response, and allow participants to ask any final questions.

Emphasize the following key points:
• A person’s immune system follows a distinct process to respond to invading organisms, and it will remember this response if it encounters the same organism in the future.
• The immune response involves T-cells and B-cells, which fight foreign pathogens, and help prevent future infection.
• HIV specifically attacks T-cells, which is why infection will lead to a breakdown of the immune system.

Alternate delivery
Divide participants into groups of seven and give each member one of the seven steps of the process. Ask members to consult with each other and then line up in the proper sequence. Follow Step 4 as outlined above.

Solution
The correct sequence of these seven steps is:
• A pathogen (such as HIV) enters the body.
• Antigens are “presented” by certain immune cells to the rest of the immune system.
• Lymphocytes recognise the antigens.
• B-cells direct the production of antibodies.
• Antibodies bind to pathogens, making them inactive.
• CD8+ cells kill cells infected with the pathogen.
• Memory cells are activated as a known pathogen reappears.

Closing
Make the point that while this is highly technical information, it is important for all those involved in vaccine work—especially those without a scientific background—to have a basic understanding of how the immune system works.
Objectives
By the end of the session, trainees will be able to:
• Describe generally how the immune system works.
• Describe how HIV affects the immune system.
• Explain to another person the immune system and how HIV affects it.

Method
Participant presentation. Participants read about the immune system, then design and deliver a short presentation to the plenary on their topic.

Trainee level
Advanced

Estimated time
60 minutes

Materials (click on Work sheet or Info sheet title to jump to its page in the back of the book)
Work sheet 5: Understanding the Immune System
Info sheet 1: The Immune Response
Flip chart paper and markers for presentations

Preparation
Make copies of Work sheet 5 and Info sheet 1 for all participants.

Delivery
Step 1: Distribute Work sheet 5 and Info sheet 1, divide participants into small groups, and assign each group one of the five concepts listed on the work sheet.

Explain the assignment, which is to design a five-minute presentation for the group that defines the concept and explains its relationship and relevance to HIV. Presentations should be designed in a way that a general lay audience can understand. Provide flip chart paper and markers if groups need them for preparing presentations.
Training tip
You may want to prepare a sample visual aid ahead of time that illustrates one of the five concepts. You can then show this to participants to give them an idea of how to incorporate a visual aid into their presentation.

Step 2: Reconvene the groups and ask each group to deliver its presentation. At the end of each presentation, invite audience members to ask questions.

Step 3: Lead a discussion of key issues.

Discussion prompts
Consider asking trainees:
• What has this exercise taught you about the problems and pitfalls of explaining technical, scientific topics to lay audiences?
• What can you do to make it easier for non-technical people to understand you?
• Can you recall an occasion when a speaker did a good job explaining something very technical? What did he/she do that was so effective?

Closing
Review the three main messages of this module:
• The immune system fights infections, even HIV in its early stages.
• HIV attacks and weakens the immune system, making it harder to fight that infection (HIV), as well as other infections.
• The purpose of an AIDS vaccine is to teach the immune system how to fight HIV and prevent HIV infection.

Trainer notes

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The sessions in this module are based on Chapter 4 of the *VaxLit Core Content* which you should read before delivering sessions. Remember that you do not have to use every session for your training programme; just choose those that are most appropriate for your audience and the time available.

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<tr>
<td>4.a</td>
<td>All information in Core Content Chapter 4</td>
<td>30 minutes</td>
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<tr>
<td>4.b</td>
<td>How a vaccine generates a response from the immune system</td>
<td>75 minutes</td>
</tr>
<tr>
<td>4.c</td>
<td>Whole-killed/whole-inactivated vaccines, Live-attenuated vaccines, Subunit vaccines, DNA and recombinant vector vaccines</td>
<td>45 minutes</td>
</tr>
<tr>
<td>4.d</td>
<td>Whole-killed/whole-inactivated vaccines, Live-attenuated vaccines, Subunit vaccines, DNA and recombinant vector vaccines</td>
<td>60 minutes</td>
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<tr>
<td>4.e</td>
<td>Definition of a vaccine, Therapeutic vs. preventive vaccines and how they work, Common vaccine types, Herd immunity, Concepts of safety, availability, affordability, stability</td>
<td>30 minutes</td>
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Traditionally, vaccines are made to prevent healthy people from getting infection or disease. This is also the goal in developing a preventive AIDS vaccine.

No existing vaccine works on all people 100% of the time. It is likely that an AIDS vaccine, once available, will be less effective than some vaccines used for other diseases, and will decrease, rather than eliminate, the risk of HIV infection. Even after people receive the vaccine, they will still need to continue other prevention practices (e.g., condom use).

The traditional approaches for developing vaccines have either not worked well, or would be unsafe when applied to AIDS vaccine development, so scientists are using new techniques to develop AIDS vaccines. Using new techniques, there is no chance of an AIDS vaccine candidate causing HIV infection.
Overview Presentation

Objectives
By the end of the session, trainees will be able to provide a general overview of the key concepts and information covered in Chapter 4 of the VaxLit Core Content.

Method
Lecture

Trainee level
Beginner

Estimated time
30 minutes

Materials
PowerPoint® slides on the CD-ROM (or a printed copy of the slides)

Preparation
If you have an LCD projector, your only preparation is to load the PowerPoint® presentation for this session onto a computer. If you do not have a projector, you will need to prepare a lecture based on the slides, using a flip chart.

Delivery
Present the overview lecture contained in the slides.

Closing
Reiterate the key messages of this module found on the previous page.
Objectives
By the end of the session, trainees will be able to:
• Describe how a vaccine works.
• Explain to someone else how a vaccine works and answer simple questions about the process.

Method
Participant presentation. Participants read information on how the vaccines work, then prepare and deliver a presentation at a mock community meeting and take questions from the audience.

Trainee level
Intermediate

Estimated time
75 minutes

Materials (click on Work sheet or Info sheet title to jump to its page in the back of the book)
Work sheet 6: How a Vaccine Works
Info sheet 2: How a Vaccine Works
Info sheet 4: Additional Vaccine Facts
Flip chart paper and markers

Preparation
Make copies of work sheets and info sheets for everyone.

Delivery
Step 1: Distribute Work sheet 6 and Info sheets 2 and 4, divide participants into small groups, and explain the assignment: to develop a short presentation for a community meeting explaining how a vaccine works. The presentation should use non-technical language for an audience who may not have previous knowledge about vaccines.

Step 2: Call the groups together and have each group give its presentation. At the end of each presentation, invite the audience to ask questions. Facilitate as needed if trainees have problems presenting their topics.
**Training tips**

- It may be helpful to have a physician or other clinician from the trial centre attend this session to help explain technical concepts and answer questions.
- You may wish to appoint one or two participants to be “language monitors”. Ask them to listen carefully to each presentation and to write down any words or phrases the presenter uses that would not be understood by many people in a community audience. After presentations are finished, ask the monitors to share their lists.

**Step 3:** Lead a discussion of some of the key issues.

**Discussion prompts**

Consider asking trainees:

- What are the one or two most important points to make about how a vaccine works?
- What are the most likely problems and difficulties you will have trying to explain how a vaccine works to the average person?
- What can you do about these difficulties?
- If the person or audience just doesn’t understand, what should you do?

**Closing**

Re-emphasize the following points:

- Preventive vaccines are intended primarily for people who are not infected with HIV.
- A vaccine does not cure someone with HIV or AIDS.
- Candidate AIDS vaccines (those in clinical trials) will not cause HIV infection.

**Trainer notes**

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Objectives
By the end of the session, trainees will be able to:
• Describe the various types of vaccines.
• Explain why only certain types of vaccines are being tested in AIDS vaccine clinical trials.
• Answer basic questions about vaccine design.

Method
Role play. Participants read a handout describing a scenario, participate in a role play, and relate the scenario back to concepts around types of vaccines.

Trainee level
Beginner

Training tip
This is an excellent exercise to use with beginner audiences, especially those with very minimal background knowledge of science or technical concepts. If time allows, use this session in conjunction with Session 4.d to provide a strong understanding of vaccine types for trainees.

Estimated time
45 minutes

Materials (click on Work sheet or Info sheet title to jump to its page in the back of the book)
Work sheet 7: Vaccine Design Analogies
Info sheet 3: Common Vaccine Types
Flip chart paper and markers

Preparation
Make copies of the work sheet and, if you feel it is needed for your group, the info sheet. Make large signs for each of the vaccine types as follows:
• Whole-killed
• Live-attenuated
• Subunit
• DNA
• Recombinant vector

Tape the signs to the wall in separate areas of your training space.

Delivery

Step 1: Distribute Work sheet 7 to all participants and explain the exercise: Trainees will read through the scenario described, choose which “vaccine type” group they want to join according to the instructions, and present a rationale to the rest of the group.

Step 2: Allow trainees at least 15 to 20 minutes to read through the handout. When it seems like people have finished reading, encourage them to join a group by standing underneath the corresponding sign.

Step 3: Once all participants have chosen a group, give them 10 to 15 minutes to discuss amongst themselves why they chose that particular group. They should prepare to explain this to the rest of the participants when everyone reconvenes.

Step 4: Bring the full group back together in plenary and ask for a volunteer from each group to share the group’s reasoning behind choosing the particular strategy.

Step 5: Ask the participants the following questions.
  • What did the exercise teach them about the way vaccines are made?
  • Why is it important to understand different approaches for making vaccines?
  • Which approaches do they think are being used to make AIDS vaccines? Why?

Training tip

If needed, you may reference information on vaccine types in Chapter 4 of the VaxLit Core Content. You may also provide this text, or a copy of Info sheet 3 to the trainees at the start or end of the session.

Let this be an open discussion, but be sure to emphasize the following points:
• Throughout the history of vaccine development, different strategies have been used to develop vaccines against different diseases.
• We must be sure there is no chance of HIV infection from an AIDS vaccine candidate; this is why DNA and recombinant vector strategies are currently being used.

Closing

Close by making the following points:
• The approaches currently being used to make AIDS vaccines do not pose any risk of HIV infection from the vaccine.
• Researchers are using these strategies in the hopes that they will create a strong immune response against HIV.
Understanding Vaccine Types

Objectives
By the end of the session, trainees will be able to:
- Describe the various types of vaccines.
- Explain why only certain types of vaccines are being used for HIV and AIDS research.
- Explain the various types of vaccines to others and answer basic questions.

Method
Participant presentation. Participants read about vaccine types and either prepare/deliver a presentation to the plenary or ask questions while listening to a presentation.

Trainee level
Intermediate

Estimated time
60 minutes

Materials (click on Work sheet or Info sheet title to jump to its page in the back of the book)
Work sheet 8: Understanding Vaccine Types
Info sheet 3: Common Vaccine Types
Flip chart paper and markers

Preparation
Make copies of Work sheet 8 and Info sheet 3.

Training tip
If time allows, this session would be most effective when used in a workshop in conjunction with Session 4.c.
**Delivery**

**Step 1:** Divide participants into five groups, distribute the work sheet and info sheet, and assign four of the groups one of the following types of vaccines:

- Whole-killed/whole-inactivated
- Live-attenuated
- Subunit
- DNA and recombinant vector

Assign the fifth group to come up with questions to ask the presenters from the other four groups. Give the groups 30 minutes to design and practice a presentation or think of questions on the vaccine type it has been assigned.

**Training tip**

You may want to prepare a sample visual aid in advance that illustrates one of the four types. You can then show this to participants as an example of how to use a visual aid in this exercise. You could also suggest that each group split into two subgroups: one subgroup works on the presentation content and the other works on a visual aid.

**Step 2:** Reconvene the groups and have each group deliver its presentation. After each presentation, members of the fifth group will ask questions.

**Step 3:** Lead a discussion of the key issues.

**Discussion prompts**

Consider asking trainees:

- Why is it important to understand the different types of vaccines?
- Which types of candidate vaccines are being used in AIDS vaccine development?
- What are the most common misconceptions people are likely to have about a vaccine?

**Closing**

Close by making the following points:

- Some traditional methods for making vaccines cannot be used with AIDS vaccine candidates because they would not eliminate the chance of HIV infection from the vaccine.
- The approaches that are being used to make an AIDS vaccine do not pose any risk of HIV infection from the vaccine.

**Trainer notes**
Objectives
By the end of the session, trainees will be able to explain key concepts pertaining to vaccines.

Method
Matching exercise. Participants read a Fact sheet about vaccine types, qualities, and characteristics, and then match key phrases to their definition.

Trainee level
Beginner

Estimated time
30 minutes

Materials (click on Work sheet or Info sheet title to jump to its page in the back of the book)
Work sheet 9: Vaccine Facts
Info sheet 3: Common Vaccine Types
Info sheet 4: Additional Vaccine Facts

Preparation
Make copies of Work sheet 9 and Info sheets 3 and 4.

Training tip
This session may be effective as a way to summarize vaccine concepts covered earlier during the training workshop, especially for beginner audiences.

Delivery
Step 1: Distribute the work sheet and info sheets, divide participants into groups, and have them complete the exercise on the work sheet as a group.
Step 2: Reconvene the groups and review the handout, soliciting their answers.

Closing
Make sure that everyone understands the key concepts presented, and answer any outstanding questions. Emphasize that it is important to understand general information about vaccines and how these concepts relate (or not) to future AIDS vaccines.

Answer Key
Corresponds with Work sheet 9

1 B 2 C 3 D 4 A 5 G 6 E
7 N 8 I 9 F 10 K 11 M 12 L 13 J

Trainer notes

________________________________________________________________________
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________________________________________________________________________
The sessions in this module are based on Chapter 5 of the *VaxLit Core Content* which you should read before delivering sessions. Remember that you do not have to use every session for your training programme; just choose those that are most appropriate for your audience and the time available.

<table>
<thead>
<tr>
<th>Session</th>
<th>Topics addressed</th>
<th>Estimated time</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.a Overview Presentation</td>
<td>• All information in Core Content Chapter 5</td>
<td>30 minutes</td>
</tr>
<tr>
<td>5.b Facts About the Development</td>
<td>• History of vaccine development&lt;br&gt;• Status of vaccine research&lt;br&gt;• Challenges in developing a vaccine</td>
<td>20 minutes</td>
</tr>
<tr>
<td>of AIDS Vaccines</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.c AIDS Vaccine Candidates</td>
<td>• How trial AIDS vaccines are being developed&lt;br&gt;• Why they cannot cause HIV infection</td>
<td>75 minutes</td>
</tr>
<tr>
<td>Cannot Cause HIV Infection</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.d Overcoming Challenges in</td>
<td>• How to make the vaccine&lt;br&gt;• Lack of a known predictive animal model&lt;br&gt;• Insufficient knowledge about correlates of protection&lt;br&gt;• Complexities related to mutation and subtype</td>
<td>75 minutes</td>
</tr>
<tr>
<td>AIDS Vaccine Development</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.e Ask the Experts: Common</td>
<td>• General information on AIDS vaccine development</td>
<td>90 minutes</td>
</tr>
<tr>
<td>Questions About Vaccines</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
No AIDS vaccine that has been proven to be effective currently exists, but there are a number of candidate vaccines being developed and tested.

There is NO chance that any candidate AIDS vaccine could cause HIV infection.

Developing an AIDS vaccine is very difficult for many scientific reasons. First, the virus is extremely effective at evading the immune system because it can mutate within an individual, meaning that HIV can learn how to avoid the effects of a vaccine. Second, mutation leads to different subtypes of the virus throughout the world, which may react differently to different vaccines.
Objectives

By the end of the session, trainees will be able to provide a general overview of the key concepts and information covered in Chapter 5 of the VaxLit Core Content.

Method

Lecture

Trainee level

Beginner

Estimated time

30 minutes

Materials

PowerPoint® slides on the CD-ROM (or a printed copy of the slides)

Preparation

If you have an LCD projector, your only preparation is to load the PowerPoint® presentation for this session onto a computer. If you do not have a projector, you will need to prepare a lecture based on the slides, using a flip chart.

Delivery

Present the overview lecture contained in the slides.

Closing

Reiterate the key messages of this module found on the previous page.
Facts about the Development of AIDS Vaccines

Objectives
By the end of the session, trainees will be able to explain a few key facts about AIDS vaccine development.

Method
Quiz. Trainees take a quiz about vaccine development.

Trainee level
Beginner

Estimated time
20 minutes

Materials (click on Work sheet title to jump to its page in the back of the book)
Work sheet 10: Facts About the Development of AIDS Vaccines

Preparation
Make copies of Work sheet 10.
Depending on your group of trainees, you may chose to copy relevant information from Chapter 5 of the VaxLit Core Content and ask them to read the material as homework prior to conducting this activity. If you decide not to do this, spend some extra time going through the correct answers at the end of the activity.

Delivery
Step 1: Distribute the Work sheet, divide participants into small groups (3 or 4 people per group), and have them complete the quiz as a group. Alternatively, participants can complete the quiz individually. Allow 10 to 15 minutes for this step.

Step 2: Bring the groups together and solicit their answers. Make sure to spend enough time explaining correct answers, focusing on any questions that seemed to be problematic.
Closing
In closing, make the point that the process of developing an AIDS vaccine is more difficult than other diseases and may take longer.

Answer Key
Corresponds with Work sheet 10

1  True  2  B  3  True  4  C  5  C
6  B  7  False  8  C  9  C  10 True

Trainer notes
AIDS Vaccines Cannot Cause HIV Infection

Objectives
By the end of the session, trainees will be able to explain to others why candidate AIDS vaccines cannot cause HIV infection.

Method
Writing a letter. Participants read an Info sheet and then write a newspaper column responding to a letter asking about vaccines.

Trainee level
Intermediate

Estimated time
75 minutes

Materials (click on Work sheet or Info sheet title to jump to its page in the back of the book)
Work sheet 11: Candidate AIDS Vaccines Cannot Cause HIV Infection
Info sheet 5: Candidate AIDS Vaccines Cannot Cause HIV Infection
Flip chart paper, markers

Preparation
Make copies of Work sheet 11 and Info sheet 5 for all participants.
Write the question from Work sheet 11 on a flip chart for display during the exercise.

Delivery
Step 1: Explain the exercise. Trainees pretend to be writers for a weekly health column at a national newspaper. In their next column they aim to answer a reader’s question about whether it is safe to participate in a vaccine trial and receive an experimental AIDS vaccine. Trainees will write the column individually, and then share it with fellow participants.

Step 2: Distribute Work sheet 11 and have one volunteer read the scenario for the group. Distribute Info sheet 5. Each person should then complete the activity individually. Participants can discuss ideas with their neighbours, but each person should write his or her own column. They should also reference Info sheet 5 to complete the column.
Step 3: When participants have completed writing, or after about 15 minutes, ask for several volunteers to read their columns to the whole group. For each, ask the group to discuss the following ideas:

- Is all the information accurate?
- Is there anything missing that should be included?
- Are there any words that some people might not understand?
- Did trainees understand the difference between testing for safety and the vaccine being safe from causing HIV infection?

Training tip
As some trainees’ columns may be missing different important facts, you may want to compile a master list of all the key points that should be covered when explaining that candidate AIDS vaccines cannot cause HIV infection.

Closing
Repeat that there is no chance of any candidate AIDS vaccine causing HIV infection.

Trainer notes

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________________________________________________________________________
Overcoming Challenges in AIDS Vaccine Development

Objectives
By the end of the session, trainees will be able to:
- Describe the unique difficulties of developing an AIDS vaccine.
- Demonstrate the ability to explain these difficulties to others.

Method
Participant presentation. Participants read an info sheet about the challenges in developing a vaccine and then prepare and deliver a presentation to the plenary on one particular challenge.

Trainee level
Intermediate

Estimated time
75 minutes

Materials (click on Work sheet or Info sheet title to jump to its page in the back of the book)
Work sheet 12: Overcoming Challenges in AIDS Vaccine Development
Info sheet 6: Overcoming Challenges in AIDS Vaccine Development
Flip chart paper, markers

Preparation
Make copies of Work sheet 12 and Info sheet 6 for everyone.

Delivery
Step 1: Distribute Work sheet 12 and Info sheet 6. Briefly review the four challenges and then explain the assignment: Trainees will prepare a short presentation on one of the challenges in developing an AIDS vaccine.

Step 2: Divide the participants into four small groups, assign one challenge to each group, and ask them to design a presentation about that challenge as described on Work sheet 12.

Step 3: Bring the groups together and ask each group to give the presentation it has designed. After each presentation, allow other trainees to ask questions.
Step 4: Following Q&A, lead a brief discussion of the key issues.

Discussion prompts
Consider asking trainees:
- Was this presentation easy to follow?
- Could it be understood by a lay person with no medical background?
- What questions will people probably have about this topic?

Closing
Make the following two points in closing:
- Developing an AIDS vaccine has posed several scientific challenges that have not been encountered to the same degree in the development of vaccines for other diseases.
- These challenges help explain why AIDS vaccine development is a slow process.

Trainer notes

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__________________________________________________________________________
Ask the Experts: Common Questions About Vaccines

Objectives
By the end of the session, trainees will be able to:
• Anticipate questions they may be asked about vaccines.
• Demonstrate the ability to answer common questions about vaccines.

Method
Simulating a radio call-in show. Participants develop and play various roles in a simulated radio call-in show.

Trainee level
Beginner/Intermediate (refer to the Delivery section on recommended trainee levels for different roles).

Estimated time
90 minutes

Materials (click on Work sheet or Info sheet title to jump to its page in the back of the book)
Work sheet 13: Ask the Experts: Common Questions About Vaccines
Info sheet 7: Cheat Sheet for Asking the Experts

Preparation
Make copies of Work sheet 13 and Info sheet 7 for all participants.
You may want to distribute Info sheet 7 in advance of the session to give participants time to review it.

Give some thought to any questions or issues that might be particular to the community in which you are conducting this training. Make sure you are prepared to facilitate the discussion around any of these issues.
**Training tip**

If you would like to expand this session to include any other chapter of the VaxLit Core Content, you can easily do so by adjusting the instructions and work sheet to add topics from that chapter to the topic list on the second page of the work sheet.

**Delivery**

**Step 1:** Explain the activity. The group is simulating a radio call-in show and participants will be assigned to play one of three roles: a caller from the listening audience, an expert panelist in the studio, or the talk show host.

**Step 2:** Divide participants into groups as follows:

1. One or two trainees to play the role of host of the radio talk show. Ideally, these should be outgoing people with good sense of humour, and who like being “on stage”.
2. A group of five people to play the roles of experts (see work sheet for definitions of roles).
   - Vaccine trial principal investigator or other site staff
   - Ethicist
   - Voluntary counselling and testing (VCT) counsellor
   - Community Advisory Board (CAB) member
   - Epidemiologist

**Important!**

This group should include trainees considered “Intermediate” level, since they will be answering questions from the rest of the participants.

3. All remaining trainees to play the role of community members who will call into the radio show with questions. If this group is too large, split it into smaller groups during the preparation time. Assign one of these people to be the facilitator to keep track of the group’s questions.

Distribute Work sheet 13 (and Info sheet 7 if not previously distributed) and ask the groups to complete the task that has been assigned to their role.

**Step 3:** During the preparation session, circulate between the groups, make sure each understands its task, and answer any questions. Encourage the community member group(s) to think of questions on various issues, but make sure that they focus on AIDS vaccines (as opposed to general HIV issues, treatment, etc.). See Info sheet 7 for examples of questions.

**Step 4:** After about 15 minutes of preparation, bring everyone back together. Seat the panellists in five chairs at the front of the room, with the host off to one side. Make sure the members of the small groups sit together with the rest of their group, if they were split into more than one group.

Have the host begin the radio show by introducing the panel members and then asking community members to call in with their questions. Allow the talk show to last for 30 to 40 minutes and facilitate if needed.
Training tips

• Make sure the host keeps this “show” moving.
• Allow two minutes maximum for each question and answer.
• Try to ensure that most community members get to ask their questions.
• Stay near the host and prompt him/her whenever the panellists/audience members need to be interrupted to keep things moving along.

Closing

Conclude the radio show by recapping any important comments or questions that may not have been answered fully. Close by asking participants what they think are the two or three most important things for people to know about AIDS vaccines and trials.
The sessions in this module are based on Chapter 6 of the VaxLit Core Content which you should read before delivering sessions. Remember that you do not have to use every session for your training programme; just choose those that are most appropriate for your audience and the time available.

<table>
<thead>
<tr>
<th>Session</th>
<th>Topics addressed</th>
<th>Estimated time</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.a</td>
<td>Overview Presentation</td>
<td>30 minutes</td>
</tr>
<tr>
<td>6.b</td>
<td>Phases of Clinical Vaccine Trials</td>
<td>45 minutes</td>
</tr>
<tr>
<td>6.c</td>
<td>Key Concepts in Vaccine Development and Clinical Trials</td>
<td>45 minutes</td>
</tr>
<tr>
<td>6.d</td>
<td>Understanding Placebo, Blinding, and Randomisation</td>
<td>90 minutes</td>
</tr>
<tr>
<td>6.e</td>
<td>Partial Efficacy</td>
<td>45 minutes</td>
</tr>
</tbody>
</table>

- All information in Core Content Chapter 6
- Description of trial phases
- Benefits and risks of trial participation
- Definition of key terms: clinical trial, safety, adverse and serious adverse event/reaction, dose, regimen, route, immunogenicity, effectiveness, efficacy, experimental vs. licensed vaccines
- Placebo
- Blinding
- Randomisation
- Partial efficacy
- Difference between efficacy and effectiveness
Before a clinical trial is completed and the data are analyzed, no one knows whether any experimental AIDS vaccine is protective, so volunteers in an AIDS vaccine trial cannot assume that they are protected against HIV.

Like all clinical trials, AIDS vaccine trials have benefits and risks for volunteers. However there is no risk that the candidate vaccine itself will cause HIV infection and no volunteer is ever intentionally exposed to HIV.

All clinical trials are held to the same high ethical and scientific standards, no matter where in the world they are conducted.
Overview Presentation

Objectives
By the end of the session, trainees will be able to provide a general overview of the key concepts and information covered in Chapter 6 of the VaxLit Core Content.

Method
Lecture

Trainee level
Beginner

Estimated time
30 minutes

Materials
PowerPoint® slides on the CD-ROM (or a printed copy of the slides)

Preparation
If you have an LCD projector, your only preparation is to load the PowerPoint® presentation for this session onto a computer. If you do not have a projector, you will need to prepare a lecture based on the slides, using a flip chart.

Delivery
Present the overview lecture contained in the slides.

Closing
Reiterate the key messages of this module found on the previous page.
Objectives
By the end of the session, trainees will be able to:
• Describe and distinguish the phases of vaccine trials.
• Discuss clinical AIDS vaccine trials that are underway in their area.

Method
Quiz. Participants read a series of statements about trial phases and decide which phase each statement applies to.

Trainee level
Beginner

Estimated time
45 minutes

Materials (click on Work sheet title to jump to its page in the back of the book)
Work sheet 14: Phases of Clinical Vaccine Trials

Preparation
Make copies of Work sheet 14.

For Alternate delivery (see next page), make four banners and cut the handout as described.

If you think it will help the group, copy relevant information on vaccine trial phases from Chapter 6 of the VaxLit Core Content and ask them to read these ahead of time for background information.

In preparation for Step 4, contact the relevant IAVI (or other trial sponsor) or trial site staff member to review the current status of clinical trials in your community, country, or region, depending on what is most relevant for your trainee group. If possible, invite this individual to attend and help facilitate this session of the workshop.
Important!
Be sure to review the specific details and objectives of ongoing trials in your area. Remember that the definitions of trial phases in Chapter 6 of the VaxLit Core Content are generic and describe the standard process of clinical trial testing. Specific details such as the number of volunteers and type of population will change depending on the objectives of each trial. Write these notes in the Trainer Notes box below. This may be especially important if any Phase IIb trials are being conducted in your area.

Delivery
Step 1: Distribute Work sheet 14 and explain the activity. Then divide participants into groups and have them complete the exercise on the handout as a group.

Step 2: After 15 to 20 minutes, bring everyone back together and go over their answers.

Alternate delivery
Step 1: Take the list of characteristics on Work sheet 14, cut it into 11 slips of paper, and give each participant (or pair of participants) one slip. Make four banners with the words PHASE I, PHASE II, PHASE IIb, and PHASE III and tape them to the wall.

Step 2: Ask each participant to decide which phase the characteristic on his/her slip of paper describes and then tape that piece of paper under the correct banner. Explain that one of the characteristics does not belong under any banner and the participant with that item should tape his/her slip of paper off to one side. Also explain that some characteristics apply to more than one phase; participants should make additional slips of paper with their characteristic and tape them under all relevant banners.

Step 3: Lead a short discussion of the key points.

Discussion prompts
To highlight key points, ask:
- Why do you think it is important to know about the different phases of clinical trials and be able to explain their differences?
- What misconceptions or “wrong ideas” do you think people are most likely to have about each phase?

Step 4: Give a short update (or have the visiting site staff member give an update) of the current status of AIDS vaccine trials in the relevant community, country, or region, based on your preparatory discussions. Facilitate a short discussion to answer any questions trainees may have. Remember that if you are unclear about trial-specific information, refer trainees to trial site or sponsor staff if they are not present for this session.
Closing
Close by making these points:
- Vaccines are carefully tested according to international standards.
- The time it takes to complete all three phases of clinical trials can vary greatly, but will generally take at least 8 to 10 years.
- This exercise has discussed general information about phases of clinical trials. Specific details of an AIDS vaccine trial are tailored according to the objectives of the particular trial, and may differ from the information presented in this session.

Answer Key

<table>
<thead>
<tr>
<th>Phase I</th>
<th>Phase II</th>
<th>Phase IIb</th>
<th>Phase III</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>This phase could involve 2,000 or more people.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>This phase assesses safety of the vaccine.</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>3</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The primary purpose of this phase is to measure safety and immunogenicity in a small number of healthy volunteers.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The purpose of this phase is to measure effectiveness.</td>
<td>None</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>As of 2008, only three candidate AIDS vaccines had reached this phase.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>This phase can enrol less than 100 volunteers.</td>
<td></td>
<td></td>
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<tr>
<td>7</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The primary purpose of this phase is to find the best dose and regimen of the experimental vaccine.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>This phase usually involves volunteers who are likely to be at risk for the disease the vaccine is meant to protect against.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>This phase usually involves 50-500 volunteers.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>A goal of this phase is to learn about the efficacy of the vaccine.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Key Concepts in Vaccine Development and Clinical Trials

Objectives
By the end of the session, trainees will be able to:
• Describe key concepts in vaccine development and clinical trials.
• Demonstrate the ability to explain these concepts to others.

Method
Pairing-up exercise and presentations. Participants match terms and definitions, and then prepare a short presentation on a particular concept.

Trainee level
Beginner

Estimated time
45 minutes

Materials
Photocopies of pages with terms and definitions OR index cards for writing terms and definitions (see Preparation)

Preparation
Photocopy pages 91 and 92 with terms and definitions. Cut up the terms and definitions into slips of paper for distribution. You may also hand write the terms and definitions on individual index cards or slips of paper.

Training tip
The ideal number of participants for this activity is 28. If you have less than 28, some participants can be assigned two terms or definitions. If you have more than 28, assign the appropriate number of people to one term. Make sure that if a term is assigned twice, its definition is also assigned twice.
Delivery

Step 1: Briefly explain the purpose of the session and how it will be conducted. Distribute the slips of paper or index cards with terms and definitions.

Step 2: Ask participants to walk around the room and find their partners by matching terms and definitions. As each one does, the pair should raise their hands and you should check to make sure the match is correct. If it is, the partners should briefly discuss how they are going to explain their concept to the large group. This step should take **10 to 15 minutes**.

Step 3: After all matches have been made, have each pair briefly explain its concept to the group. After each presentation, give any needed explanation and ask for questions.

Important!

Make sure concepts are presented in the order they appear on the handout (starting with “safety” and ending with “licensed vaccine”).

Training tip

If it will be useful or important for participants to have their own copy of these terms with their definitions (to take with them), make a handout before the session and have copies available for everyone after the activity is complete.

Closing

Address any of the trainees’ outstanding questions about the terms discussed. Emphasize that it is important to have a strong understanding of these terms when discussing AIDS vaccine trials with interested individuals.
<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>safety</td>
<td>a Establishing that the vaccine does not cause severe or serious side effects in trial volunteers.</td>
</tr>
<tr>
<td>adverse event/reaction</td>
<td>b Any unfavourable event or physical condition that an individual experiences during participation in a clinical trial.</td>
</tr>
<tr>
<td>bias</td>
<td>c Any unfair judgment; in clinical research, this is avoided by conducting blinded or double-blinded studies.</td>
</tr>
<tr>
<td>effectiveness</td>
<td>d How well the vaccine reduces disease when it is used in the general population.</td>
</tr>
<tr>
<td>efficacy</td>
<td>e The ability of a candidate vaccine to protect against infection or disease.</td>
</tr>
<tr>
<td>placebo</td>
<td>f A harmless, inactive substance given to some trial volunteers instead of the vaccine.</td>
</tr>
<tr>
<td>dose</td>
<td>g How much of the vaccine to give at one time.</td>
</tr>
<tr>
<td>randomisation</td>
<td>h The process of assigning volunteers by chance to receive either a placebo or the vaccine.</td>
</tr>
<tr>
<td>regimen</td>
<td>i How often to give the vaccine and how far apart the doses should be.</td>
</tr>
<tr>
<td>blinding</td>
<td>j Refers to the fact that participants do not know whether they have received the experimental vaccine or the placebo.</td>
</tr>
<tr>
<td>route</td>
<td>k The “path” by which to give the vaccine: by mouth, through scratches in the skin, or by injection.</td>
</tr>
<tr>
<td>experimental/candidate vaccine</td>
<td>l A vaccine that has not completed all the phases of clinical trials and has not been approved by a regulatory authority.</td>
</tr>
<tr>
<td>immunogenicity</td>
<td>m The ability, strength, and type of immune response in humans.</td>
</tr>
<tr>
<td>licensed vaccine</td>
<td>n A vaccine that has completed clinical trials, is known to be safe and effective, and has been approved by regulatory authorities for use in the general population.</td>
</tr>
</tbody>
</table>
Establishing that the vaccine does not cause severe or serious side effects in trial volunteers.

Any unfavourable event or physical condition that an individual experiences during participation in a clinical trial.

Any unfair judgment; in clinical research, this is avoided by conducting blinded or double-blinded studies.

How well the vaccine reduces disease when it is used in the overall population.

The ability of a candidate vaccine to protect against infection or disease.

A harmless, inactive substance given to some trial volunteers instead of the vaccine.

How much of the vaccine to give at one time.

The process of assigning volunteers by chance to receive either a placebo or the vaccine.

How often to give the vaccine and how far apart the doses should be.

Refers to the fact that participants do not know whether they have received the experimental vaccine or the placebo.

The “path” by which to give the vaccine: by mouth, through scratches in the skin, or by injection.

A vaccine that has not completed all the phases of clinical trials and has not been approved by a regulatory authority.

The ability, strength, and type of immune response in humans.

A vaccine that has completed clinical trials, is known to be safe and effective, and has been approved by regulatory authorities for use in the general population.
Understanding Placebo, Blinding, and Randomisation

Objectives
By the end of the session, trainees will be able to:

- Explain the three concepts.
- Demonstrate the ability to answer questions about these concepts from typical trial volunteers.

Method
Simulation and discussion. Trainees role play the process of participating in a vaccine trial.

Trainee level
Intermediate/advanced (see notes in Delivery section on recommended trainee levels for different roles)

Estimated time
90 minutes

Materials (click on Work sheet or Infos heet title to jump to its page in the back of the book)
Work sheet 15: Volunteer Questions
Info sheet 8: Understanding Placebo, Blinding, and Randomisation
Work sheet 16: Doctor and Assigner Roles
Work sheet 17: Volunteer Roster
A desk, a flip chart, a curtain or screen, a hat or box, labels, something to represent vaccine syringes (either actual syringes or paper cut-outs in the shape of syringes), a volunteer roster for recording information

Preparation
For Parts 1 and 2, complete the following steps:
- Make copies of Work sheet 15 and Info sheet 8 for all trainees.
- Make two copies of Work sheet 16.
- Make one copy of Work sheet 17.
- Make four mock syringes and attach a “Vaccine” label to two and a “Placebo” label to the other two. You can use post-it notes for labels. Put these in a hat, box, or other container.
• Arrange a screen or curtain for the “Assigner of Vaccine or Placebo” to stand behind and a desk for the doctor to sit at. You can use a flip chart stand as a barrier if nothing else is available, or just ask trainees to picture an imaginary curtain or barrier between the assigner and the rest of the group.
• Prepare a flip chart with the volunteer roster. Include enough rows to number through volunteer #32, as shown.

<table>
<thead>
<tr>
<th>Volunteer #</th>
<th>Vaccine</th>
<th>Placebo</th>
<th>HIV-uninfected</th>
<th>HIV-infected</th>
</tr>
</thead>
<tbody>
<tr>
<td>01</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>02</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>etc. through 32</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

• Prepare a second flip chart with the following table:

<table>
<thead>
<tr>
<th>Trial data table</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV-infected</td>
</tr>
<tr>
<td>Vaccine</td>
</tr>
<tr>
<td>Placebo</td>
</tr>
</tbody>
</table>

Delivery
This exercise is divided into three parts.

Part 1: Role Play

Step 1:
• Give an overview of the exercise.
• Give a 5 to 10 minute introduction of the three concepts: placebo, blinding, and randomisation. To prepare, consult relevant information in Chapter 6 of the VaxLit Core Content. If a trial site or IAVI staff member is present, you could invite that person to give the introduction.

Step 2:
• Select an assigner and a doctor; you may want to choose trainees with a higher level of understanding for these roles.
• Assign four trainees to be volunteers.
• Distribute Work sheet 15 and Info sheet 8 to all trainees. Ask everyone but the doctor and assigner to divide into pairs and complete Work sheet 15 as described.
• Take the doctor and assigner aside, give both of them Work sheet 16, also give the Assigner Work sheet 17, and review their roles as outlined.

**Step 3:**
• Bring the doctor and assigner to their places at the front of the room. Place the assigner behind the flip chart with the prepared volunteer roster.
• Have the doctor lead the role play as per instructions in Work sheet 16.
• Remember to provide assistance if the doctor has any problem answering volunteers’ questions or moving the role play along. Try to keep the role play between 15 and 20 minutes.
• All trainees who are not part of the role play should continue to add questions to Work sheet 15 while they watch.

**Step 4:** When all four volunteers have received their injections, announce the end of the role play and proceed to the next part.

**Part 2: Questions and Discussion**

Remind the assigner to follow the instructions on Work sheet 17 during this discussion.

Ask trainees to share the questions they wrote on Work sheet 15. Try to get a variety of questions. Specifically ask the doctor for input. Conduct a discussion around whether questions were different from the volunteers’ and doctor’s point of view.

**Discussion prompts**

Trial participants questions may include:
• What is in my syringe?
• Why can’t I know what is in my syringe?
• Why does it matter if I know what I’m getting?
• How do we know if anyone is getting the vaccine?
• When will I find out what was in my syringe?
• How does taking the placebo help me?
• Will I get sick from this vaccine?
• Will the vaccine give me HIV infection? How can you be sure?
• My family will be upset if they find out I got the placebo. So how will I explain this to them?
• I don’t want the placebo, I want the vaccine. How can I get it?
• Someone said you are trying to see if this vaccine is safe. If it’s not safe, I don’t want to take it. What does “testing for safety” mean?

**Part 3: Follow-Up Role Play**

**Important!**

In this part, some trainees playing the volunteer role will be assigned to the “HIV-infected” group. If you feel that trainees may be uncomfortable with this, you should consider completing this part through discussion, rather than role play. Replace the role play in Step 2 with a discussion in which you present hypothetical results from the trial as outlined in the role play, then follow with the remaining steps.
Step 1: Introduce the follow-up role play. Remember to involve the trainees in this discussion (e.g., ask for a trainee to explain what an efficacy trial is). Below is some language you may use or draw from.

“Now we are going to ‘fast-forward’ several years to the end of the trial. We are pretending that this was a large efficacy trial involving thousands of volunteers. The volunteers, including the four we have here, have received all injections and have been followed for a few years. They have been counselled along the way on prevention behaviour, but as we all know, even with the best counselling, some people still become infected.

Now the volunteers are coming back for their final visit to the trial clinic where they will find out whether they received the candidate vaccine or placebo.”

Step 2: Ask the Doctor to start the second part of the role play as per the instructions in Worksheet 16. When all four volunteers have had their “final appointments”, announce the end of the role play.

Step 3: Present the trial results on the Volunteer Roster as prepared by the Assigner.

Important! Explain that, for the sake of the exercise, the roster shows only 32 volunteers, and trainees need to remember that normally thousands of volunteers are involved in an efficacy trial.

Tape the Trial Data Table next to the Volunteer Roster.

Step 4: Ask trainees to complete the Trial Data Table by counting up how many volunteers:

- received the experimental vaccine and remained HIV-uninfected
- received the experimental vaccine and became HIV-infected
- received a placebo and remained HIV-uninfected
- received a placebo and became HIV-infected

Fill in the boxes accordingly. The table should be completed as follows:

<table>
<thead>
<tr>
<th>Trial data table</th>
<th>HIV-infected</th>
<th>HIV-uninfected</th>
<th>TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vaccine</td>
<td>1</td>
<td>15</td>
<td>16</td>
</tr>
<tr>
<td>Placebo</td>
<td>5</td>
<td>11</td>
<td>16</td>
</tr>
</tbody>
</table>
Step 5: Calculate infection rates for each group. You can write the following information on the flip chart below the Trial Data Table.

Infection rate for vaccine group = 1 HIV-infected / 16 Total = 0.0625 = 6.25%

Infection rate for placebo group = 5 HIV-infected / 16 Total = 0.3125 = 31.25%

Step 6: Lead a discussion about what this calculation shows. Ask participants the following questions:
- Which group had the higher infection rate?
- Do you think this means that the vaccine might be efficacious?

Important!
Explain again that these are NOT real-life numbers and that they are made up to illustrate how scientists calculate infection rates in the trial groups. Explain that real-life efficacy calculations are much more in-depth, involving complex computer programmes and much larger numbers of volunteers.

Step 7: Lead a closing discussion about the concepts presented in the exercise. To prompt discussion, ask trainees the following questions:
- Why is using a placebo necessary?
- Why is blinding important?
- Why is randomisation important?
- Which volunteer question was the most difficult to answer?
- How did volunteers feel at the end of the trial when they found out if they received the candidate vaccine or placebo?

Closing
Emphasize the following important points:
- Using a placebo is necessary to create a control group for comparison with the test vaccine group.
- Randomisation helps keep the trial fair and the vaccine and placebo groups evenly divided.
- Blinding ensures that no volunteer knows whether or not he/she received the test vaccine, which helps guarantee that participants and researchers will not behave in special ways that might unfairly influence the trial results.
Objectives
By the end of the session, trainees will be able to:
- Explain the concept of partial efficacy.
- Identify the relevance of partial efficacy to introduction of an AIDS vaccine, once available.
- Explain the difference between efficacy and effectiveness.

Method
Question and answer. Participants discuss questions about partial efficacy in groups and then discuss in plenary.

Trainee level
Intermediate

Estimated time
45 minutes

Materials (click on Work sheet title to jump to its page in the back of the book)
Work sheet 18: Partial Efficacy

Preparation
Make copies of Work sheet 18 for all participants.

Step 1: Ask if anyone knows the difference between the terms “efficacy” and “effectiveness”. If so, have that person explain it to the group.

If not, explain the difference to the group yourself, as follows:
- “Efficacy” refers to how well the vaccine works under the conditions of a large (usually Phase III) clinical trial.
- “Effectiveness” refers to how well the vaccine works once it is widely used in the community or country.

Explain that although these terms have different meanings, they are often used interchangeably.
Step 2: After the explanation has been given, begin a discussion by asking, “Why is the difference between efficacy and effectiveness important?” Add any of the following information if it is not offered by participants:

Efficacy refers to how well the vaccine works under conditions of a clinical trial, which may be more optimal than conditions of the community or country where the vaccine will be widely used once licensed. Efficacy is, therefore, only a prediction of how well a vaccine will work in the population at large. Once the vaccine is licensed and widely distributed, it is important to continue studies around how safe and effective the vaccine is, in order to truly determine its effectiveness.

You may reference chapters 4 and 6 in the VaxLit Core Content for more information.

Step 3: Distribute Worksheet 18 to all participants. Explain that now that everyone understands the difference between efficacy and effectiveness, the group will discuss the concept of ‘partial efficacy’. Ask for three volunteers to read the questions (one each) on Worksheet 18 aloud. Divide participants into groups of four people. Have them discuss the questions and write answers. You may want to circulate to various groups and help any that may be having trouble answering the questions.

Important!
The most important concept to discuss is that vaccine recipients will need to continue using other HIV prevention methods, given that an AIDS vaccine is likely to have partial efficacy.

Although trainees may not discuss the concept at this level of detail, remember that the concept of a partially effective vaccine has had different meanings. It can refer to either: (a) a vaccine that protects some people in a population who receive the vaccine but not others, or (b) a vaccine which does not completely prevent infection but does help reduce the severity of disease caused by the pathogen.

There is no such thing as a vaccine that provides 100% protection, 100% of the time. In this sense, all vaccines are partially effective, and the same will be true for eventual AIDS vaccines. There is also a chance that, if an AIDS vaccine does not prevent a person from becoming infected with HIV, it may instead prevent progression to AIDS in people who still get infected through blood or sexual exposure after receiving the vaccine. This is because the vaccine might keep the amount of virus circulating in the blood at a low level, also referred to as lowering the viral load.

AIDS vaccines that are partially effective but prevent progression to disease could have a significant impact on the epidemic by reducing HIV transmission, and delaying the need for antiretroviral (ARV) treatment and illness or death for infected individuals.

Step 4: Bring everyone together and ask for several volunteers to share answers from their group discussion. In particular look for someone who may have an answer to the second question. If no one has real-life examples of partially effective vaccines, turn to other examples. Ask the following questions:
- Is everyone who uses a bed net fully protected from malaria?
- Do safety belts work 100% of the time?
Step 5: Ask participants to discuss what it will mean if an AIDS vaccine is only partially effective once it is available in the community.

- Do they think people who receive the vaccine will return to behaviour that may put them at risk of HIV infection?
- How can this be avoided?

Discussion prompts

- When people receive an AIDS vaccine, they will need to continue using condoms, other new prevention tools if available, and reducing their number of partners.
- An AIDS vaccine will NOT be a “magic bullet”. It will not guarantee protection against HIV infection.
- An AIDS vaccine will NOT protect against other STIs or pregnancy; this is another reason people will still need to continue safe sex practices as much as possible.

Closing

In closing, emphasize that it is important for people to understand the difference between efficacy and effectiveness, as well as partial efficacy, so as not to set up false expectations in using these terms.
The sessions in this module are based on Chapter 7 of the *VaxLit Core Content* which you should read before delivering sessions. Remember that you do not have to use every session for your training programme; just choose those that are most appropriate for your audience and the time available.

<table>
<thead>
<tr>
<th>Session</th>
<th>Topics addressed</th>
<th>Estimated time</th>
</tr>
</thead>
<tbody>
<tr>
<td>7.a Overview Presentation</td>
<td>• All information in Core Content Chapter 7</td>
<td>30 minutes</td>
</tr>
<tr>
<td>7.b Can I Participate?</td>
<td>• Criteria for trial participation</td>
<td>45 minutes</td>
</tr>
</tbody>
</table>
| 7.c Recruiting and Retaining Volunteers | • The screening visit  
• The screening process  
• Steps involved in a trial | 60 minutes     |
| 7.d Participating in a Trial      | • Informed consent  
• HIV counselling during a trial  
• Voluntary counselling and testing (VCT)  
• False-positive tests  
• Pregnancy  
• Sexual activity during a trial  
• Volunteer protection and confidentiality  
• Treatment and care for volunteers | 75 minutes     |
Most experimental AIDS vaccines have been designed to prevent HIV infection. This is why most trials only enrol volunteers who are not infected with HIV.

The decision about whether or not to participate in a trial should be made by the individual volunteer. It is unethical for anyone (family members, trial staff, etc.) to convince or coerce someone else to participate.

All volunteers should continue to use condoms and practice other forms of risk reduction since they cannot count on the experimental AIDS vaccine to protect them against HIV infection, and because they may receive a placebo.

During the trial, a volunteer who becomes HIV infected through sexual or blood exposure will be provided with or linked to available healthcare. He or she will also continue to be followed to find out if the experimental vaccine affects HIV.
Objectives
By the end of the session trainees will be able to provide a general overview of the key concepts and information covered in Chapter 7 of the VaxLit Core Content.

Method
Lecture

Trainee level
Beginner

Estimated time
30 minutes

Materials
PowerPoint® slides on the CD-ROM (or a printed copy of the slides)

Preparation
If you have an LCD projector, your only preparation is to load the PowerPoint® presentation for this session onto a computer. If you do not have a projector, you will need to prepare a lecture based on the slides, using a flip chart.

Delivery
Present the overview lecture contained in the slides.

Closing
Reiterate the key messages of this module found on the previous page.
Can I Participate?

Objectives
By the end of the session, trainees will be able to:

- Describe general eligibility requirements for a vaccine trial.
- Explain the rationale for trial requirements.

Method
Quiz. Participants review personal characteristics of a group of potential trial volunteers and decide if the person is eligible to be enrolled.

Trainee level
Beginner/Intermediate

Estimated time
45 minutes

Materials (click on info sheet title to jump to its page in the back of the book)
Work sheet 19: Can I Participate?

Preparation
Different trials have different eligibility requirements. You may need to adjust the items on the work sheet to be consistent with local requirements in your country and/or the trial phase you want to address.

Make copies of Work sheet 19.

Delivery
Step 1: Distribute Work sheet 19 and ask participants to complete it according to the instructions. They can either do this individually or in small groups.
**Training tip**
With beginner-level trainees, you should review the general requirements for participation at this point. Consult the section entitled “General criteria for participation” in Chapter 7 of the VaxLit Core Content for general information, as well as “Phases of Clinical Vaccine Trials” in Chapter 6 for information about specific phases.

**Step 2:** When everyone has completed the work sheet, go through each role and solicit answers. For each ineligible participant, ask if anyone can explain the reason the person would not have been eligible for the trial. For example, in the case of Volunteer 1, ask if anyone has an idea of why children below a certain age (usually 18 years old) cannot participate in most clinical trials.

**Closing**
Make the following points:
- Trials have strict eligibility requirements to protect volunteers.
- Volunteers must be uninfected with HIV in order to determine whether the vaccine protects against infection.
- Volunteers must continue to protect themselves from risk of HIV infection even if they are enrolled in a trial.

**Answer Key**
Corresponds with Work sheet 19

1. Ineligible—too young
2. Eligible
3. Ineligible—coerced
4. Ineligible—will be leaving the trial area
5. Ineligible—wishes to become pregnant
6. Ineligible—not in good health
7. Eligible
8. Ineligible—HIV-infected
9. Ineligible—not willing to be tested
10. Ineligible—high risk behaviour, likely to get pregnant
11. Ineligible—pregnant
12. Ineligible—high-risk behaviour
13. Ineligible—breastfeeding
Recruiting and Retaining Volunteers

Objectives
By the end of the session, trainees will be able to:

- Describe the various factors that make volunteers ineligible to participate in a trial.
- Explain why it is necessary to recruit many volunteers for a trial.
- Explain why someone might not be eligible to participate in a trial.

Method
Simulation. Trainees role play being screened for trial participation.

Trainee level
Beginner/Intermediate (see notes in Delivery section on recommended trainee levels for different roles)

Estimated time
60 minutes

Materials (click on Work sheet title to jump to its page in the back of the book)
Work sheet 20: Recruiting and Retaining Volunteers
Work sheet 21: What Happens When Someone Is Not Eligible?
Paper, markers

Preparation
Make five banners:
1 Pre-screening
2 Screening
3 Trial participation
4 Trial completion
5 Not eligible

Set up four desks or “stations” in the order of 1–4 above, and tape the appropriate banner at each one. Place the “Not eligible” banner on a separate wall.

Make five copies of Work sheet 20. Cut one copy into 13 strips along the dotted lines that divide the role descriptions, so that each role can be handed out individually (see Step 2 in Delivery).
The 13 individual strips should NOT include the “Eligibility Key” box.

Make copies of Work sheet 21 for all participants.

**Delivery**

**Step 1:** Explain briefly that the purpose of this exercise is to illustrate the stages of being recruited into and retained in a Phase I trial.

**Important!**

If you have not covered information on phases of trials so far during your training workshop, you should give a brief explanation (see pages 77-78 of the *VaxLit Core Content*) at this point in the session.

**Step 2:** Select 13 people and hand them each a role (strips cut from Work sheet 20). Select four more people, one for each station; it is best to select intermediate-level trainees for this role.

**Training tip**

Depending on your trainee number, you can assign more than one person to each role and/or station.

Give each person assigned to a station a copy of Work sheet 20.

Give everyone **5 to 10 minutes** to read over their roles or Work sheet 20. Individuals at the stations should pay particular attention to the roles that will be screened out at their respective stations.

**Step 3:** Give a brief explanation of the scenario – This is a Phase I trial, and individuals are coming forward to find out whether they qualify and can participate in the trial. Explain that the stations mark various points throughout the process of recruitment and participation in the trial, and explain each of these points. This information can be found in Chapter 7 of the *VaxLit Core Content* under, “Trial participation process”.

**Step 4:** Ask the potential volunteers to line up, approach the first station (Pre-screening) one at a time, and read their roles aloud. The person at the station will either rule them ineligible, or tell them to proceed to the next station. If they are ineligible, the person at the station should give a full explanation, and they should stand under the “Not eligible” banner. Note that only six people—roles 8-13—will move to the second station.

**Training tip**

Make sure trainees know that the individuals in this step have only expressed interest in the trial and are simply getting more information about potential participation.

When people get moved to the “Not eligible” station, give them Work sheet 21 and ask them to follow the instructions outlined.
Step 5: Repeat the process in Step 4 for the next two stations, making sure a full explanation is given each time a person is determined to be ineligible. At the end, only two people (Roles 4 and 13) will move to the fourth and final station, “Trial completion”.

**Important!**
Be sure to emphasize that a volunteer’s potential participation is kept completely confidential throughout the process of screening and enrolment.

Step 6: Lead a discussion around the lessons of the session.

Ask the following questions:
- What does this exercise demonstrate about how many people must be recruited and volunteer for a trial in order for there to be an adequate number of participants who complete the trial?
- Did anyone not understand why he/she was eliminated?
- What seemed to be major factors hindering people’s participation?
- Referring to Work sheet 21, what are the implications of being screened out? What are some of the considerations that need to be taken into account?
- Can you think of reasons people might not be able to participate that were not addressed in this exercise?
- How could your community be prepared to recruit a large number of volunteers into a trial? Do you think the eligibility criteria would be an obstacle?

**Closing**
Close with the point that many potential volunteers need to be recruited in order for the trial to end up with enough qualified participants.
Participating in a Trial

Objectives
By the end of the session, trainees will be able to:
- Describe the trial process.
- Identify some of the most common questions community members ask about a vaccine trial.
- Demonstrate the ability to answer questions about the trial process.

Method
Role play. Participants play the role of either a trial staff member or a community member and interact at a community meeting where the trial staff explain trial participation and answer questions from the community.

Trainee level
Beginner/Intermediate (see notes in Delivery section on recommended trainee levels for different roles)

Estimated time
75 minutes

Materials (click on Work sheet or Info sheet title to jump to its page in the back of the book)
Work sheet 22: Trial Participation: Community Members
Work sheet 23: Trial Participation: Trial Staff Members
Info sheet 9: Participating in a Trial
Flip chart and markers

Preparation
Make copies of Work sheets 22 and 23 and Info sheet 9.

Write most or all of the following questions on a flip chart and place in front of the room:
- How do you know the vaccine candidate won’t give us HIV?
- Why can’t female volunteers get pregnant during the trial?
- How can I promise I won’t get pregnant for 18 months?
- Why can’t people who are HIV-positive participate? We’re the ones who need the vaccine.
- Are volunteers encouraged to use condoms during a trial? What happens if we don’t?
- Why might someone test HIV-positive during the trial?
• What happens if a volunteer becomes infected with HIV during the trial?
• People living with HIV need a lot of support. Now all the emphasis is on a vaccine.
• Do volunteers have to get voluntary counselling and testing (VCT) during the trial? I don’t want to be tested for HIV because I will suffer discrimination.
• If I come to the trial centre, people will know. Everybody in this community knows everyone else.
• If I test positive, I will get kicked out of my house.
• How do I know I will stay negative?
• What is a “false-positive test”?
• Why do some people get a placebo? If I get the placebo, the whole thing will be a waste of my time.
• Why can’t people with [name of disease] participate?

Delivery

Step 1: Explain the overall format for the exercise – It will consist of a community meeting where participants will either play the role of a community member or a trial staff member. Select two or three people who are willing to make presentations to play trial staff members; try to pick trainees you consider to be at intermediate level. Assign the remaining participants to play community members, and divide them into small groups of about 4 or 5 people, or as appropriate based on number of trainees. Assign each community member group several roles listed on Work sheet 22, making sure all roles are assigned.

Step 2: Distribute Work sheet 22 to community member groups, and Work sheet 23 to trial staff members. Distribute Info sheet 9 to everyone. Give participants at least 15 minutes to complete the instructions for their roles. Make sure the trial staff members divide up the topic list among the two or three presenters so that each one has the opportunity to address the meeting and answer questions. Provide them with markers and flip chart paper if needed. Community members can reference the prepared flip chart for questions.

Step 3: When everyone is ready, seat the trial staff members at the front of the room, call the meeting to order (acting as the chairperson), introduce the trial staff, and invite them to give their 5 minute presentations. Explain to the audience that they will hold their questions until all presenters have finished.

Step 4: After presentations are complete, invite community members to ask questions. Facilitate the Q&A session for about 15 to 20 minutes, making sure a variety of questions are asked and everyone has the chance to participate. Make sure you leave enough time for the closing exercise, as you will likely need to wrap up a number of issues discussed during Q&A.

Step 5: Lead a concluding discussion, focusing especially on any outstanding issues or questions from the Q&A session.

Discussion prompts

Some wrap-up questions may include:
• What are the most common questions community members will have about a vaccine trial?
• What are the most important points to get across at such a meeting?
• Who should the speakers be at such a meeting? What kinds of people would have the most credibility explaining the trial?
• How can the tough concepts be explained in a way people in the community can understand?
The sessions in this module are based on Chapter 8 of the *VaxLit Core Content* which you should read before you delivering sessions. Remember that you do not have to use every session for your training programme; just choose those that are most appropriate for your audience and the time available.

<table>
<thead>
<tr>
<th>Session</th>
<th>Topics addressed</th>
<th>Estimated time</th>
</tr>
</thead>
<tbody>
<tr>
<td>8.a</td>
<td>Overview Presentation</td>
<td>30 minutes</td>
</tr>
<tr>
<td>8.b</td>
<td>Agree or Disagree: Gender Issues</td>
<td>45 minutes</td>
</tr>
<tr>
<td>8.c</td>
<td>Gender Implications in AIDS Vaccine Trials</td>
<td>30 minutes</td>
</tr>
<tr>
<td>8.d</td>
<td>Overcoming Women’s Barriers to Participation</td>
<td>60 minutes</td>
</tr>
</tbody>
</table>

- All information in the *VaxLit Core Content* Chapter 8
- All gender issues, including trial participation, vaccine issues, and social factors
- Various reasons that women should be included equitably in AIDS vaccine trials
- Why an AIDS vaccine will be an important tool in reducing women’s vulnerability
- Barriers to women’s participation in AIDS vaccine trials
- Action that might be taken in the community to overcome barriers
- Action that might be taken individually by participants to overcome barriers
Although the AIDS pandemic is affecting women at greater rates than men in many places, current HIV prevention options are not feasible for many women. There is an urgent need for new prevention options that women can more easily initiate and control.

Once available, an AIDS vaccine will be an important tool for reducing women’s vulnerability to infection. It is a method that women will be able to use with or without men’s cooperation since it is not tied to the sexual act.

It is important that women participate in vaccine trials in order to find out whether a vaccine works for them. However, women often find it difficult to participate for social, cultural, and logistical reasons. Efforts should be made to support women’s involvement in trials, and to ensure that they make voluntary, independent, and well-informed decisions to participate.
Objective
By the end of the session trainees will be able to provide a general overview of the key concepts and information covered in Chapter 8 of the VaxLit Core Content.

Method
Lecture

Trainee level
Beginner

Estimated time
30 minutes

Materials
PowerPoint® slides on the CD-ROM (or a printed copy of the slides)

Preparation
If you have an LCD projector, your only preparation is to load the PowerPoint® presentation for this session onto a computer. If you do not have a projector, you will need to prepare a lecture based on the slides, using a flip chart.

Delivery
Present the overview lecture contained in the slides.

Closing
Reiterate the key messages of this module found on the previous page.
Agree or Disagree: Gender Issues

Objectives
By the end of the session, trainees will be able to:
- Debate critical gender issues.
- Examine their own biases on gender issues.
- Articulate the importance of separating personal values from professional practice, particularly when working with stigmatised and vulnerable populations.

Method
Group debate. Participants read statements on gender issues, decide whether they agree or disagree, and debate other participants with opposing positions.

Trainee level
Beginner

Estimated time
45 minutes

Materials
Flip chart and markers

Preparation
Make a banner that says AGREE and a banner that says DISAGREE and tape them on opposite walls of the room.

Review the list of statements regarding gender issues in vaccine trials, below. Choose three to five statements to be debated by the trainees (allow 10 to 15 minutes for debate around each statement). Write each statement on a separate sheet of flip chart paper to display during the exercise. Make sure the statements are written where trainees cannot see them ahead of time.

Delivery
Step 1: Explain that the purpose of the session is to explore ideas and possible biases about gender, specifically with respect to conducting AIDS vaccines research.
Step 2: Ask all of the participants to stand in the middle of the space you have prepared, between the AGREE and DISAGREE signs. Reveal the flip chart paper with the first statement for debate. Read the statement aloud. Ask those who agree to move near the AGREE sign, and those who disagree to move to DISAGREE sign.

Step 3: Give each group 3 to 5 minutes to discuss amongst themselves why they chose to agree or disagree.

Step 4: Bring the groups together. First, ask representatives of each group to state their reasons for agreeing or disagreeing. Next, let each group try and convince members of the other group to reconsider their opinion, and switch sides if they do.

**Training tip**
Let the debate happen in a free-form manner, but ensure that each group gets the chance to present its side. Make sure to facilitate effectively so that as many trainees as possible get a chance to join the debate.

Once the discussion has ended, repeat with the next statement. Proceed until all statements have been debated.

Step 5: Once several points have been debated, bring the group together and facilitate a discussion about some of the key issues discussed. Be sure to focus on the trial- and vaccine-specific points.

**Important!**
Be sure to acknowledge the differences in people's values, and emphasize the importance of separating personal values from professional practice, particularly when working with stigmatised and vulnerable populations.

**Closing**
Wrap up any final points that emerged during the discussion.
Agree/Disagree Statement List

The list below contains statements to be used in this exercise. Chose as many statements as you think you will have time for. Four or five statements will most likely be appropriate for a 45-60 minute session.

**Trial Participation Issues**

- A woman should not be allowed to participate in a vaccine trial without getting permission from her husband.
- Women are more likely than men to participate in AIDS vaccine trials.
- Pregnant women should not be allowed to participate in vaccine trials.

**Vaccine Issues**

- An AIDS vaccine will be more beneficial to women than men.
- A vaccine will increase risky behaviour in men.
- A woman should tell her husband when she receives an AIDS vaccine.
- AIDS vaccine distribution should be prioritised for sex workers and young girls.
- An AIDS vaccine should be provided to women and girls for free.

**Social Factors**

- Women's ignorance of sexual matters is a sign of purity.
- It is inappropriate for women to have knowledge of sexual matters.
- Men don’t like to admit their lack of knowledge about sexual matters.
- It is acceptable for men to have multiple sexual partners.
- Men are under social pressure to have many sexual partners.
- Female sex workers are women without morals.
- It is abnormal for men to have sex with men.
- Good women should be modest and remain virgins until marriage.
- Women feel more pressure to be faithful to their partner than men do.
Gender Implications in AIDS Vaccine Trials

Objectives
By the end of this session, trainees will be able to:

- Explain the complex challenges posed in recruiting equitable numbers of women and men in AIDS vaccine trials.
- Explain why it is important to recruit and retain equitable numbers of women and men in trials.

Method
Group discussion. Participants respond to questions about women and AIDS vaccines.

Trainee level
Intermediate

Estimated time
30 minutes

Materials (click on Info sheet title to jump to its page in the back of the book)
Info sheet 10: Including Women in AIDS Vaccine Trials

Preparation
Make copies of Info sheet 10. Prepare flip chart questions (see Delivery).

Delivery
Step 1: State that in conducting AIDS vaccines trials, there are many important reasons for including equitable numbers of men and women. Ask if anyone can help explain this by telling a story from experience, if trainees have had experience with a vaccine trial. If not, have an example prepared for the group.

Step 2: On a flip chart, write the following question: “Is it important to enrol equitable numbers of men and women in AIDS vaccine trials? Why or why not?”
Step 3: Ask each participant to respond to the question. If they have not had hands-on experience with vaccine trials, they can speculate about reasons why. They can also give their views regarding why it is essential or not to enrol women in the trials. Note the affirmative and negative responses on separate flip charts. These responses will help chart the level of agreement and understanding on this issue.

Step 4: Distribute Info sheet 10, which highlights the biological, scientific, ethical, and social factors for enrolling equitable numbers of men and women in a trial.

Step 5: Using this information, ask trainees to comment on their responses to the question.

Closing
Make the following points:
- Equitable numbers of men and women should be enrolled in trials as a measure of ethical trial conduct.
- In order for a trial to give information about women’s responses to the vaccine, a large enough number of women must be enrolled and retained in trials.
- An AIDS vaccine will be an important tool for reducing women’s vulnerability to infection, since they will most likely be able to use it without men’s cooperation.
8d

Overcoming Women’s Barriers to Participation

Objectives
By the end of this session, trainees will be able to:
• Explain potential barriers to women’s participation in trials.
• Identify potential strategies for overcoming barriers.
• Identify actions they can personally take to help eliminate barriers.

Method
Small group discussion, followed by full group discussion. Participants break into small groups to read about women’s barriers to participation and discuss actions that can be taken to overcome barriers to women’s participation, and then share thoughts with the larger group.

Trainee level
Beginner

Estimated time
60 minutes

Materials (click on Work sheet title to jump to its page in the back of the book)
Work sheet 24: Overcoming Women’s Barriers to Participation

Preparation
Make copies of Work sheet 24.

Delivery
Step 1:
Introduce the session as described above in Method. Distribute the work sheet and divide participants into small groups. Give them 20 to 25 minutes to answer the two questions (Part 1 and Part 2). All groups can discuss all seven of the barriers or you can divide the barriers among the groups.

Step 2: Bring the groups together and solicit their answers to Part 1, on general strategies.
Step 3: Select a few individuals, each one from a different sector or profession, and ask them how they answered Part 2, on personal actions.

Step 4: Lead a 15 minute discussion using the following questions:
- Which barrier do you consider the most difficult or frightening?
- Which stakeholders in the community are in the best position to help women overcome these barriers?

Closing
Make the following points:
- Because of these barriers, creating a supportive environment for female participation must begin far in advance of the trial.
- Reducing the barriers will take action at all levels: local, national, and regional.
The sessions in this module are based on Chapter 9 of the *VaxLit Core Content* which you should read before delivering sessions. Remember that you do not have to use every session for your training programme; just choose those that are most appropriate for your audience and the time available.

In 2007, UNAIDS released updated ethical guidelines entitled “Ethical considerations in biomedical HIV prevention trials,” which should be used as a reference for this module. If you think it is appropriate for your trainees, you may print or request copies from UNAIDS to hand out during sessions in this module. The document can be found at: [http://data.unaids.org/pub/Report/2007/jc1399-ethicalconsiderations_en.pdf](http://data.unaids.org/pub/Report/2007/jc1399-ethicalconsiderations_en.pdf).

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<td>9.a</td>
<td>Overview Presentation</td>
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<td>9.b</td>
<td>The Seven Principles of Ethical Research: Q&amp;A</td>
<td>45 minutes</td>
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<td>9.c</td>
<td>Agree or Disagree: Ethical Issues</td>
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<tr>
<td>9.e</td>
<td>Is This Informed Consent?</td>
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All AIDS vaccine trials follow the same set of international ethical guidelines to ensure that each volunteer’s health, dignity, and well-being are protected.

National and international authorities that are independent of trial researchers and sponsors, such as regulatory authorities and ethics committees, conduct ongoing monitoring of research projects to ensure that they meet ethical standards.

Obtaining each volunteer’s informed consent to participate in a trial is essential to ethical research. The purpose is to ensure that participants fully understand essential information about the trial, and that they can freely decide whether to participate or not.
Objectives
By the end of the session, trainees will be able to provide a general overview of the key concepts and information covered in Chapter 9 of the VaxLit Core Content.

Method
Lecture

Trainee level
Beginner

Estimated time
30 minutes

Materials
PowerPoint® slides on the CD-ROM (or a printed copy of the slides)

Preparation
If you have an LCD projector, your only preparation is to load the PowerPoint® presentation for this session onto a computer. If you do not have a projector, you will need to prepare a lecture based on the slides, using a flip chart.

Delivery
Present the overview lecture contained in the slides.

Closing
Reiterate the key messages of this module found on the previous page.
The Seven Principles of Ethical Research: Q&A

Objectives
By the end of the session, trainees will be able to:
• Answer common questions about ethical research.
• Explain the practical implications of ethical conduct of trials.

Method
Group discussion. Participants practice answering questions from community members about ethical research.

Trainee level
Intermediate

Estimated time
45 minutes

Materials (click on Work sheet title to jump to its page in the back of the book)
Work sheet 25: The Seven Principles of Ethical Research: Q&A

Preparation
Make copies of Work sheet 25 for all participants.

Delivery
Step 1: Distribute Work sheet 25 and divide participants into small groups. Ask them to complete the assignment as described on the work sheet.

Step 2: Call the groups together and go over each question.

Step 3: After each principle has been discussed, ask the group to discuss how all seven principles work together to ensure ethical conduct of trials.
Closing

In conclusion, make the following points:

- The way a trial is designed and conducted will affect how much support it will receive.
- Those involved in a trial should be able to answer the most common questions about trial ethics.
Agree or Disagree: Ethical Issues

Objectives
By the end of the session, trainees will be able to describe and debate aspects of ethical issues in trials such as participant confidentiality, conducting trials in developing countries, delivery of partially effective vaccines, etc.

Method
Group debate. Participants read statements on vaccine trial ethics, decide whether they agree or disagree, and debate other participants with opposing positions.

Trainee level
Intermediate

Estimated time
45 minutes

Materials
Flip chart and markers

Preparation
Make a banner that says AGREE and a banner that says DISAGREE and tape them on opposite sides of the room.

Review the list of statements regarding ethical issues in vaccine trials, on page 134. Choose 3 to 5 statements to be debated by the trainees (allow about 15 minutes for each statement). Write each statement on a separate sheet of flip chart paper for display during the exercise. Make sure the statements are written where trainees cannot see them ahead of time.

Delivery
Step 1: Explain that the purpose of the session is to explore some of the ethical issues in AIDS vaccine research.
Step 2: Ask all of the participants to stand in the middle of the space you have prepared, between the AGREE and DISAGREE signs. Reveal the flip chart paper with the first statement for debate. Read the statement aloud. Ask those who agree to move near the AGREE sign, and those who disagree to move near the DISAGREE sign.

Step 3: Give each group 3 to 5 minutes to discuss amongst themselves why they chose to agree or disagree.

Step 4: Bring the groups together. First, ask representatives of each group to state their reasons for agreeing or disagreeing. Next, let each group try and convince members of the other group to reconsider their opinion, and switch sides if they do.

Training tip
Let the debate happen in a free-form manner, but ensure that each group gets the chance to present its side. Make sure to facilitate effectively so that as many trainees as possible get a chance to join the debate.

Once the discussion has ended, repeat with the next statement. Proceed until all statements have been debated.

Step 5: Once several points have been debated, bring the group together and facilitate a discussion about some of the key issues discussed. Be sure to focus on the trial- and vaccine-specific points.

Important!
Be sure to acknowledge the differences in people’s values, and emphasize the importance of separating personal values from professional practice, particularly when working in clinical research.

Closing
Wrap up any final points that emerged during the discussion.
Agree/Disagree Statement List

The list below contains statements to be used in this exercise. Choose as many statements as you think you will have time for. Four or five statements will most likely be appropriate for a 45 to 60 minute session.

Trial Participation Issues

- A trial volunteer’s participation should be kept confidential from his/her healthcare provider.
- Volunteers should know whether they are receiving the experimental vaccine or placebo during the trial.
- Trial volunteers should receive reimbursement in return for their participation.
- Potential volunteers should discuss participation with family members before deciding to enrol in a trial.
- The trial team should discourage people from participating if they might not be able to stay enrolled throughout the duration of the trial.
- Participating in a trial will cause people to increase risk behaviour.
- Potential volunteers do not need to fully understand every aspect of participation before giving informed consent to participate.

Vaccine Issues

- It is acceptable for vaccines with potentially negative side effects (such as severe fever) to be used in countries or populations where the HIV disease burden is high.
- A partially effective vaccine should be delivered among populations at higher risk of HIV infection.

Trial Design Issues

- It is not necessary for candidate vaccines to be tested in the developing world.
- Vaccines should always be tested in industrialized countries before they are tested in developing countries.
- Ethical standards of running a trial should depend on the standard of living in a given country.
- A vaccine of one clade should only be tested in countries where that clade exists.
- Developing countries do not operate according to the same ethical and regulatory standards as Western countries.
Objectives

By the end of the session, trainees will be able to:

- Describe the topics people need to be informed about before they can consent to participating in a trial.
- Identify what groups and key individuals in the community need to be informed about these topics.
- Identify the best means of informing the various groups and individuals about these topics.
- Identify what they can do personally to further the cause of informing people about the trials.

Method

Group discussion. Participants discuss how to inform individuals and the broader community about a trial in order to improve chances for informed consent.

Trainee level

Beginner

Estimated time

60 minutes

Materials (click on Work sheet title to jump to its page in the back of the book)

Work sheet 26: The Informed Consent Process

Preparation

Make copies of Work sheet 25 for all participants.

Delivery

Step 1: Distribute Work sheet 26 and explain the purpose of the activity, to identify which groups and individuals in a trial site need to be aware of the basic concepts of informed consent and what is the best way to inform them. Invite a volunteer to read the work sheet in plenary.

Step 2: Divide participants into small groups and assign two or three of the eight topics to each group. Allow 15 to 20 minutes for the groups to complete the activity as described in Work sheet 26.
Step 3: Call the groups together and have each one briefly present the highlights of its discussion.

Training tip
You may want to appoint someone to make a master list of all the suggestions, which should then be typed out and made available to all participants as a handout.

Step 4: Lead a discussion of the key issues. Be sure that the discussion emphasizes the importance of having a process of informed consent by discussing how community awareness can lead to a greater understanding among individuals, which equips them with knowledge to make decisions about trial participation.

Discussion prompts
• Why is it important to conduct community outreach around these topics?
• Why do people other than potential volunteers need to know about these topics?
• Why do people need to know about these topics before they come in for pre-screening?
• How do you inform less-educated groups about these topics?

Closing
Make the following points:
• Informed consent is a process that should start at the community level.
• The more everyone knows about these topics, the better potential volunteers will be informed.
• The higher the level of general community awareness, the greater the support for a vaccine trial will be.
Is This Informed Consent?

Objectives
By the end of the session; trainees will be able to:
- Determine how informed volunteers are about the trial process.
- Demonstrate the ability to explain various aspects of the trial to volunteers who are poorly or only partially informed.
- Argue for the need to get accurate information into the hands of potential volunteers and the people they talk to.

Method
Questionnaire and role play. Participants have to decide if certain responses to common questions about a trial indicate the respondent is informed enough to give consent. They then role play how to inform the respondent.

Trainee level
Intermediate/Advanced

Estimated time
75 minutes

Materials (click on Work sheet title to jump to its page in the back of the book)
Work sheet 27: Is This Informed Consent?

Preparation
Make copies of Work sheet 27

Delivery
Step 1: Distribute Work sheet 27, divide participants into groups of two, and ask the groups to complete the assignment as explained on the work sheet.

Step 2: Call the groups together and go over the 15 examples soliciting their responses. (See Answer Key on page 147).
Step 3: Lead a discussion of the key points.

Discussion prompts
- Why is informed consent so important?
- What can happen if someone who is not informed is enrolled in a trial?
- What are some of the most common misconceptions about AIDS vaccine candidates and vaccine trials?
- How can trial teams make sure participants give true informed consent?

Step 4: Ask several pairs to volunteer to perform the role play they prepared during Step 1 for the whole group.

Closing
Reiterate the point that above all, the purpose of insisting on informed consent is to protect the volunteer.

Answer Key
Corresponds with Work sheet 27

1  No. The volunteer does not understand that the trial is for a preventive vaccine. The trial tests to see if the vaccine candidate will prevent HIV infection, it does not test whether someone who is already HIV infected will be cured.

2  Maybe. The volunteer’s participation and HIV status would be kept confidential by the trial team. However, this volunteer should be counselled about the need to discuss HIV testing and any results with her husband. If she refuses to do this, or if it is not possible, she should be counselled about the potential risks of keeping her HIV status from her husband.

3  Yes.

4  Maybe. The counsellor should question the volunteer to find out if he/she truly understands the risks and benefits of participating in the trial. It is important that volunteers do not simply take the word of the doctor, but have a full understanding themselves.

5  No. The person must know the actual trial length; that participants can decide to leave the trial at any time; and that in some instances, their participation could be discontinued.

6  Maybe. The counsellor should find out if the husband is pressuring the volunteer, or if she is truly participating of her own free will.

7  No. A volunteer should have a full understanding of the care that will be provided to him/her during the trial. This volunteer should have a better understanding of issues such as the conditions that apply to receiving healthcare, and the amount of time the site is liable to provide care.

8  No. This person should not use trial participation as an incentive for her husband to use contraception. She cannot guarantee that her husband will agree to use condoms and that she can avoid pregnancy for the duration of the trial.
9 No. Volunteers should have a full understanding of both the risks and benefits of participating, and they should not feel coerced into participating based on the benefits. Volunteers should identify with some motivation to participate, whether altruistic or not.

10 No. Different trials have different requirements in terms of maintaining volunteers’ health conditions while participating (e.g., developing diabetes may require participants to be discontinued from some trials, but not others). In AIDS vaccine trials, volunteers receive care or referrals in most cases of illness. However, potential participants should be well informed of these details before enrolling.

11 No. While it is true that volunteers do not have to disclose their participation, confidentiality also means that this information will be strictly protected by the trial staff as well.

12 No. No one knows if the vaccine candidate will offer protection, and volunteers should have a full understanding of the need to continue prevention practices, such as condom use, while on the trial. They should also have a full understanding of the chance of receiving placebo while participating in the trial. If volunteers become HIV infected while participating in the trial, they will continue to be followed by the trial team (and in some cases will continue trial participation), and they will receive a referral to a local facility for treatment, care, and support.

13 No. A person with HIV infection can be asymptomatic, often for a long time, before showing any signs of AIDS. Further, knowing a partner’s status does not guarantee the individual’s status. The volunteer should be prepared for either a positive or negative result before getting an HIV test as part of screening for the trial.

14 No. The volunteer needs to understand the distinction between developing AIDS and becoming HIV infected. The counsellor should clarify that the vaccine is meant to prevent HIV infection; a vaccine’s potential effect on the progression of HIV infection to developing AIDS is studied in some trials, but is not the primary focus of most vaccine trials. The counsellor should also make sure the volunteer understands that: (1) no one knows how effective a trial vaccine will actually be in preventing HIV infection, and (2) there is always the possibility that a volunteer will receive a placebo instead of the experimental vaccine.

15 No. Some volunteers may think they will never have a reason to leave the trial, but they should understand that such a situation may arise. Volunteers should have a good understanding of the possible reasons for leaving, and of the right to leave the trial at any point.
The sessions in this module are based on Chapter 10 of the *VaxLit Core Content* which you should read before delivering sessions. Remember that you do not have to use every session for your training programme; just choose those that are most appropriate for your audience and the time available.

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<td>• All information in the <em>VaxLit Core Content</em> Chapter 10</td>
<td>30 minutes</td>
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<tr>
<td>10.b Characteristics of Trial Review</td>
<td>• Scientific review • Regulatory review • Ethical review</td>
<td>45 minutes</td>
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<tr>
<td>10.c The Ethical Review Process</td>
<td>• Steps of the ethical review process</td>
<td>20 minutes</td>
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<tr>
<td>10.d Trial Review and Approval in Your Country</td>
<td>• Local review practices</td>
<td>45 minutes</td>
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All clinical trials, including AIDS vaccine trials, are carefully reviewed before they begin to ensure that they are scientifically and ethically sound and safe for volunteers.

Review committees and regulatory authorities are completely independent from the institutions that sponsor and conduct the trial. These authorities conduct additional reviews as a trial is carried out, and have the power to stop a trial at any time.

Clinical trials must be reviewed and approved by appropriate committees in every country and institution where the trial is to be conducted.
Overview Presentation

Objectives
By the end of the session, trainees will be able to provide a general overview of the key concepts and information covered in Chapter 10 of the VaxLit Core Content.

Method
Lecture

Trainee level
Beginner

Estimated time
30 minutes

Materials
PowerPoint® slides on the CD-ROM (or a printed copy of the slides)

Preparation
If you have an LCD projector, your only preparation is to load the PowerPoint® presentation for this session onto a computer. If you do not have a projector, you will need to prepare a lecture based on the slides, using a flip chart.

Delivery
Present the overview lecture contained in the slides.

Closing
Reiterate the key messages of this module found on the previous page.
**Objectives**
By the end of the session, trainees will be able to:
- Describe the three types of review which most trials undergo.
- Distinguish between the three types of trial review.

**Method**
Questionnaire and group discussion. Participants read statements about the trial review process and decide what kind of review each statement is referring to, and then discuss why all three reviews are important.

**Trainee level**
Intermediate

**Estimated time**
45 minutes

**Materials (click on Work sheet or Info sheet title to jump to its page in the back of the book)**
Work sheet 28: Characteristics of Trial Review
Info sheet 11: Characteristics of Trial Review
For Alternate Delivery: banners and tape

**Preparation**
Make copies of Work sheet 28 and Info sheet 11.
On a flip chart, recreate the three-column chart from the work sheet (for Step 1) and write out the questions listed under Step 3.

If you choose the Alternate Delivery, make three banners and tape them to the wall.
Delivery

Step 1: Distribute Work sheet 28 and Info sheet 11, divide participants into small groups, and ask them to complete the activity as instructed on the work sheet. Reiterate aloud the note on Work sheet 28: this exercise addresses the characteristics of various types of review, rather than actual practice (i.e., the distinct committees that review each aspect), since this varies from country to country.

Step 2: Bring the groups together and solicit their answers, recording the numbers in the proper columns on the flip chart.

Step 3: Put participants back into their small groups and ask them to discuss the following questions (which should be written on a flip chart).
- What are the main differences between regulatory, scientific, and ethical reviews?
- Why is each type of review important?

After 5 to 10 minutes, reconvene the group and briefly discuss their answers to the three questions.

Alternate delivery
Tape three banners—REGULATORY, SCIENTIFIC, and ETHICAL—to the wall. Cut the items on Work sheet 28 into 13 strips of paper and give one to each participant. Each participant must decide which type of review the characteristic he/she received describes and tape it under the correct banner.

Be sure to include Step 3 above as part of the session.

Closing
Close with these observations:
- Vaccine trials need close scrutiny from multiple perspectives to guarantee scientific and ethical soundness.
- More scrutiny equals greater safety for volunteers.

Answer Key
Corresponds with Work sheet 28

Regulatory
3 4 6 7 9 11

Scientific
2 5 6 8

Ethical
1 4 5 6 10 12 13
The Ethical Review Process

Objectives
By the end of the session, trainees will be able to:

- Describe the steps in an ethical review of a vaccine trial.
- Explain the authority of independent ethics committees.

Method
Sequencing exercise. Participants unscramble eight steps in the trial review process.

Trainee level
Beginner

Estimated time
20 minutes

Materials (click on Work sheet title to jump to its page in the back of the book)
Work sheet 29: The Ethical Review Process

Preparation
Make copies of Work sheet 29.

Delivery
Step 1: Distribute Work sheet 29 and ask participants to complete it with a partner.

Step 2: When all groups are finished, review the work sheet as a large group, soliciting participant responses and ordering the steps in the proper sequence.

Closing
Close by emphasizing that:

- Ethics committees have the power to order changes in trial design and execution.
- Ethical review is ongoing as the trial is being conducted.
- Ethics committees can shut down a trial.
Answer Key
The correct sequence is:
4 7 3 1 2 6 5

Trainer notes
Objectives
By the end of the session, trainees will be able to:

- Describe the ethical review and approval process in their country.
- Explain why the approval process is important.

Method
Presentation. You or a knowledgeable participant give a presentation on the trial review process in country.

Trainee level
Intermediate

Estimated time
45 minutes

Materials (click on Work sheet title to jump to its page in the back of the book)
Work sheet 29: The Ethical Review Process

Preparation
Gather information on the vaccine review and approval process in your country by consulting with staff from a trial site and/or trial sponsor (e.g. IAVI). Prepare a visual aid (PowerPoint® slides, transparency, flip chart, etc.) describing the process.

Training tip
If you know that one or more participants will be able to describe this process themselves, then you can ask them to prepare a visual aid and execute Step 2.
Delivery

Step 1: Introduce the session and ask participants what they know about the review and approval process in their country.

Step 2: Present the process as illustrated on your visual aid (or have an informed participant conduct this step).

Step 3: Conduct a discussion of the key issues.

Discussion prompts

- Why is it important to have a process like this in place?
- Has anyone ever been involved in any aspect of this process? What was your experience?
- Under what circumstances might you need to know about or have to explain this process to others? What questions will people have?
- Have you ever been asked about this topic?
- Does the process in your country seem to have any ethical or safety “loopholes”?
- As far as you know, does the process work most of the time?

Alternate delivery

If trainees from more than one country are present, you may want to have them create a short presentation on the review/approval process in their respective countries and then give this presentation as Step 1 (followed by Q&A). Step 2 could then be a discussion of the similarities and differences between various countries’ processes.

Closing

Close with these points:
- Review committees and regulatory authorities are completely independent from trial sponsors.
- These groups typically carry out follow-up reviews during the trial and can stop the trial at any time.
The sessions in this module are based on Chapter 11 of the VaxLit Core Content which you should read before delivering sessions. Remember that you do not have to use every session for your training programme; just choose those that are most appropriate for your audience and the time available. The content in this module is for intermediate or advanced audiences, and should only be used after sufficient coverage of previous modules, primarily modules 4, 5, 6, and 7.

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<tr>
<td>11.b An Overview of Challenges</td>
<td>• Brief overview of challenges</td>
<td>45 minutes</td>
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<td>11.c The Challenges in Detail</td>
<td>• Global funding, finance mechanisms, and pricing</td>
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<td>• Estimating demand and use</td>
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<td>11.d The Acceptability Question</td>
<td>• Efficacy</td>
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<td>• Stigma</td>
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Historically, vaccines have taken up to 20 years after approval and licensure in developed countries to be available to people in the places where they are most needed. This delay must not happen in the case of an AIDS vaccine.

There are questions about how soon to address access issues for a product that is not yet developed, but these issues should be examined at an early stage, given the history of delayed access to important public health interventions.

Working on eventual access to a vaccine can go hand-in-hand with clinical trials for AIDS vaccines. This may be a very efficient way to address some of the barriers to access.
Overview Presentation

Objectives
By the end of this session, trainees will be able to provide a general overview of the key concepts and information covered in Chapter 11 of the VaxLit Core Content.

Method
Lecture

Trainee level
Beginner

Estimated time
30 minutes

Materials
PowerPoint® slides on the CD-ROM (or a printed copy of the slides)

Preparation
If you have an LCD projector, your only preparation is to load the PowerPoint® presentation for this session onto a computer. If you do not have a projector, you will need to prepare a lecture based on the slides, using a flip chart.

Delivery
Present the overview lecture contained in the slides.

Closing
Reiterate the key messages of this module found on the previous page.
An Overview of Challenges

Objectives
By the end of the session, trainees will be able to:
- Describe the main challenges to access and use of an AIDS vaccine.
- Identify the main challenges in their own setting.

Method
Matching exercise. Participants read five statements about the main challenges to acceptance and use of a vaccine and match each statement to the challenge it refers to.

Trainee level
Advanced

Training tip
For a less advanced exercise focusing on similar content, you may want to use Session 11.c.

Estimated time
45 minutes

Materials (click on Work sheet title to jump to its page in the back of the book)
Make copies of Work sheet 30: An Overview of Challenges

Preparation
Make copies of Work sheet 30

Delivery
Step 1: Distribute Work sheet 30 and explain the purpose of the activity—to familiarize participants with the main challenges to the widespread delivery and use of an AIDS vaccine, especially in developing countries, and to identify challenges in their own settings.
Step 2: Divide participants into groups and have them complete the exercise as described in Work sheet 30.

Step 3: Bring the groups back together and ask for them to volunteer their answers (see Answer Key below).

Closing
Close by pointing out that simply developing a vaccine does not guarantee that people will have access to it or that even those who do have access will automatically want to get vaccinated.

Answer Key
Corresponds with Work sheet 30

<table>
<thead>
<tr>
<th>A</th>
<th>5</th>
<th>11</th>
</tr>
</thead>
<tbody>
<tr>
<td>B</td>
<td>1</td>
<td>4</td>
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<tr>
<td>C</td>
<td>2</td>
<td>9</td>
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<tr>
<td>D</td>
<td>6</td>
<td>13</td>
</tr>
<tr>
<td>E</td>
<td>3</td>
<td>10</td>
</tr>
</tbody>
</table>

Trainer notes
The Challenges in Detail

Objectives
By the end of the session, trainees will be able to:

• Describe the major challenges to access and use of an AIDS vaccine.
• Identify which aspects of this challenge are present in their country/community/setting and how they might be addressed.

Method
Participant presentation. Participants read a fact sheet about one of the challenges to acceptance and prepare a presentation for delivery in plenary.

Trainee level
Intermediate

Estimated time
60 minutes

Materials (click on Work sheet or Info sheet title to jump to its page in the back of the book)
Work sheet 31: The Challenges in Detail
Info sheet 12: The Challenges in Detail
Flip chart paper, markers

Preparation
Make copies of Work sheet 31. Make several copies of the Info sheet 12 and cut them into strips for Step 2 below.

Delivery
Step 1: Distribute Work sheet 31 and explain how the activity works – small groups will be assigned one challenge for which they will prepare and deliver a short presentation in plenary.

Step 2: Divide participants into five groups and assign one challenge to each group. Give all members of that group a copy of the part of the info sheet that describes their challenge. Also give them some flip chart paper and a marker for making a visual aid. Allow each group 10 minutes to prepare its presentation and 5 minutes to practice delivering it.
Step 3: Reconvene the group and have each group give its presentation (5 minutes per group). Allow another few minutes for questions.

Step 4: Lead a discussion of the key issues.

Discussion prompts
- What are the main challenges in your country/setting?
- What is being done to address these challenges?
- Have similar challenges been faced/overcome with regard to other vaccines? What happened? Could this be done with an AIDS vaccine?
- What could you do as an individual to address the challenges?
The Acceptability Question

Objectives
By the end of the session, trainees will be able to:
• Identify key stakeholder groups for the acceptance of an AIDS vaccine.
• Describe the main obstacles to the acceptability of an AIDS vaccine in their country.
• Describe ways to address these obstacles.
• Explain to others what these obstacles are and how to address them.

Method
Brainstorm and small group discussion. Participants are assigned to one of four stakeholder groups and asked to discuss how this group would feel about five challenges to acceptability of an AIDS vaccine.

Trainee level
Intermediate

Estimated time
60 minutes

Materials (click on Work sheet or Info sheet title to jump to its page in the back of the book)
Work sheet 32: The Acceptability Question
Info sheet 13: The Acceptability Question

Preparation
Make copies of Work sheet 32 and Info sheet 13 for everyone.

Delivery
Step 1: Divide participants into four small groups, distribute Work sheet 32 and Info sheet 13, and assign each group one of the four stakeholder groups described in the work sheet.

Step 2: Give participants 30 minutes to answer the two questions on Work sheet 32. Advise them to spend the first 5 to 10 minutes reading through Info sheet 13.
Step 3: Bring the groups together and have them briefly present the answers to their questions or highlights of the discussion.

Step 4: Lead a brief discussion covering some or all of the points listed in the box below.

Discussion prompts
• What do you believe is the biggest obstacle to acceptability in your country?
• What is the biggest obstacle in your community?
• Is anything being done to address acceptability in the country/community? Is it working?
• What is the single biggest thing that still needs to be done?

Closing
Close by making the following points:
• The mere existence of a vaccine does not guarantee that it will be used or viewed favourably.
• Obstacles to acceptability need to be identified and addressed before any vaccine becomes available.
• Many obstacles to vaccine use are similar to obstacles to various prevention approaches. We should look at how these obstacles are presently being addressed and extract key lessons.
This module contains five sessions on topics that are not specific to any one chapter of the *VaxLit Core Content*, but rather address topics in several chapters or next steps for trainees after a *VaxLit* workshop. These sessions will be most effective as final sessions for your workshop.

<table>
<thead>
<tr>
<th>Session</th>
<th>Topics addressed</th>
<th>Estimated time</th>
</tr>
</thead>
<tbody>
<tr>
<td>12.a Myths and Rumours</td>
<td>• Most common misconceptions about AIDS vaccines and research</td>
<td>45 minutes</td>
</tr>
<tr>
<td>12.b Frequently Asked Questions</td>
<td>• Most frequently asked questions about vaccines and trials</td>
<td>45 minutes</td>
</tr>
<tr>
<td>12.c Watch Your Language</td>
<td>• Technical vocabulary from the <em>VaxLit Core Content</em></td>
<td>60 minutes</td>
</tr>
<tr>
<td>12.d Watch Your Language: In Practice</td>
<td>• Technical vocabulary from the <em>VaxLit Core Content</em></td>
<td>45 minutes</td>
</tr>
<tr>
<td>12.e Next Steps: Developing a Personal Work Plan</td>
<td>• Actions participants can personally take in response to what they have learned</td>
<td>60 minutes</td>
</tr>
</tbody>
</table>
**Myths and Rumours**

**Objectives**
By the end of this session trainees will be able to:
- Describe the most common myths and rumours about AIDS vaccines and research.
- Dispel doubts raised by these myths and rumours by correcting inaccurate information.

**Method**
Brainstorm and group discussion. Participants brainstorm a list of myths or misconceptions they personally have heard about an AIDS vaccine. Then they practice answering questions about the eight most common myths.

**Trainee level**
Beginner

**Estimated time**
45 minutes

**Materials (click on Work sheet title to jump to its page in the back of the book)**
Work sheet 33: Myths and Rumours
Fact sheet: Myths & Misconceptions (found in VaxLit Toolkit)
Flip chart paper

**Preparation**
Make copies of Work sheet 33 and the fact sheet for all participants.

**Delivery**
**Step 1:** Divide participants into groups of five, give each group a piece of flip chart paper, and have them brainstorm for about 20 minutes about the following question. What are some of the most common myths, rumours, or misconceptions you have heard about AIDS vaccines in your country or region?
Important!
Groups only need to develop the list of questions and do not need to come up with answers at this time.

Step 2: Have each small group present its list to the other groups. For each myth, they should ask one of the other groups to respond or correct it. Let this be a free-flowing discussion, but also try to ensure that there is equal dialogue between groups.

Step 3: Distribute Work sheet 33 and give participants 5 minutes to read through it. Facilitate a discussion, asking:
- Were any myths listed on the work sheet not mentioned during the group discussions?
- If so, how would participants respond to these myths?
- Which myths were most commonly mentioned, both in group discussion and on the work sheet?

At the end of the session distribute the fact sheet as a resource for participants to take with them.

Closing
Close by pointing out that:
- It is easy for misinformation to circulate about the development of AIDS vaccines and AIDS vaccine research.
- Being empowered with the right responses is crucial to helping dispel myths that may circulate.
Frequently Asked Questions

Objectives
By the end of the session, trainees will be able to:
- Identify the most frequently asked questions about vaccines and trials.
- Answer these questions.

Method
Group discussion

Trainee level
Intermediate

Estimated time
45 minutes

Materials (click on Work sheet title to jump to its page in the back of the book)
Work sheet 34: Frequently Asked Questions
Fact sheet: AIDS vaccine research: FAQs (found in VaxLit Toolkit)

Preparation
Make copies of Work sheet 34 and the fact sheet for all participants.

Delivery
Step 1: Distribute Work sheet 34 and introduce the exercise. Divide participants into five small groups, assign two questions to each group, and have the groups complete the exercise as described on the work sheet.

Step 2: Bring the groups together and ask each group to answer its questions. After each question is answered, invite participants to ask one or two follow-up questions and let group members try to answer.
Step 3: Ask participants if there are any other questions they are frequently asked. Then see if the group can answer these questions. In closing, distribute the fact sheet for participants to take with them.

Alternate delivery
Instead of presenting participants with the “prepared” list on Worksheet 34, you could ask them to compile their own list of the questions they are asked most frequently. Using this list, you can then proceed from Step 1.
Watch Your Language

Objectives
By the end of the session, trainees will be able to:

- Identify technical vocabulary that may be difficult for non-technical people to understand.
- Describe technical concepts using non-technical language.

Method
Questionnaire

Trainee level
Beginner

Estimated time
60 minutes

Materials (click on Work sheet title to jump to its page in the back of the book)
Work sheet 35: Watch Your Language

Preparation
Review Work sheet 35 and add any words you would like to include. Make copies of the work sheet for all participants.

Delivery
Step 1: Distribute Work sheet 35 and begin by explaining the general purpose of the activity – to alert participants to the fact that some technical vocabulary may be difficult for a general audience to understand and to identify alternative vocabulary to use when talking to such listeners.

Step 2: Then lead a short discussion using the following questions:

- How do you feel when someone talks to you using a lot of vocabulary you do not understand?
- What do you usually do in this situation?
- What do you think of that person?
- How does this affect your reaction to their message?
Step 3: Divide participants into small groups and give them **20 to 25 minutes** to complete the exercise as a group. Remind them that they can choose 10 terms (or more if they have time) from the list and they do not need to complete the list in order.

Step 4: Reconvene the groups. Ask each group to present a few answers from their work sheet. If some groups have different suggestions for a common term, discuss which one might be the “best” and make sure everyone writes it in that column of the work sheet.

**Training tip**
Encourage participants to think about country-specific or culturally appropriate ways (words or metaphors) to describe certain technical concepts.

Step 5: Ask the group if they can think of any other words or phrases that should be added to this list and what the substitute or replacement word should be.

**Closing**
Close by reminding people again why it is important to watch their language.

**Trainer notes**
Watch Your Language: In Practice

Objectives
By the end of the session, trainees will be able to:
• Identify technical AIDS vaccine vocabulary that may be difficult for non-technical people to understand.
• Use non-technical language to describe technical AIDS vaccine concepts.

Method
Interactive game

Trainee level
Intermediate/Advanced

Estimated time
45 minutes

Materials (click on Work sheet title to jump to its page in the back of the book)
Work sheet 35: Watch Your Language

Preparation
Review Work sheet 35 and add any words you would like to include. Make copies of the work sheet for all participants.

Delivery
Step 1: Distribute Work sheet 35 and begin by explaining the general purpose of the activity – to alert participants to the fact that some technical vocabulary may be difficult for “lay” listeners to understand, and to practice discussing AIDS vaccines without using technical language.

Step 2: Divide the trainee group into groups of 5 to 10 people, depending on your total number of trainees. Ask each group to sit or stand in a circle.
Step 3: Instruct the groups that they will give a group speech or informal oral presentation about AIDS vaccines, using the information they learned in the rest of the VaxLit workshop. One person will start the speech, stating one or two sentences, and the next person in the circle will follow, continuing where the previous person left off. Everyone in the circle will take a turn.

Groups should focus on using simple language and avoiding terms that are technical or confusing. Encourage groups to think creatively about explanations, and to use metaphors that are relevant to their country, region, or community. All trainees will follow the conversation with Work sheet 35, and will alert each other when any technical or confusing word is used. If a trainee uses a technical term he/she will be eliminated.

The speech continues until only one person is left.

Step 4: Once all groups are finished with the game, lead a plenary discussion asking the following questions:

- Was it difficult to avoid technical terms while explaining AIDS vaccine concepts?
- Did any group come up with a particularly creative and/or simple way to explain a concept?
- How do you feel people would react to explanations that are too technical or complex?
- Are there any drawbacks to using language that is too simple?

Closing
Close by once again reminding trainees why it is important to watch their language.
Next Steps: Developing a Personal Work Plan

**Objectives**
By the end of the session, trainees will be able to:
- Identify areas of vaccine literacy where they would like to become more involved.
- Identify specific actions they could take to become more involved.

**Method**
Brainstorming

**Trainee level**
Intermediate

**Estimated time**
60 minutes

**Materials (click on Work sheet title to jump to its page in the back of the book)**
Work sheet 36: Next Steps: Developing a Personal Work Plan

**Preparation**
Make copies of Work sheet 36 for all trainees.

**Delivery**
**Step 1:** Distribute Work sheet 36 and explain the purpose of the activity— to give participants an opportunity to think about what they might want or be able to do to further the cause of AIDS vaccine literacy based on what they have learned during this training.

**Step 2:** Give participants **15 minutes** to answer the questions on Work sheet 36.
**Training tip**
If you have different types of stakeholders in the audience, you may want to divide them up by type and have them work on this exercise in small groups.

**Step 3:** Reconvene the entire group and ask for several volunteers to describe what they wrote on their work sheet.

**Step 4:** Lead a general discussion on next steps.

**Discussion prompts**
- Who is already involved in/working on improving vaccine literacy?
- What are you doing?
- How did you become involved?
- What are the areas of greatest need?
- Are there people who have thought about becoming involved but have yet to do so?
- What kept you from acting on your interest? What prevents people from becoming more active?

**Closing**
Close by reminding participants that becoming “involved” does not have to mean making a major commitment, and that doing even small things can make a big difference.
Treatment Options

Assignment

Four reasons are often given for why antiretrovirals (ARVs) are not in wider use in developing countries: cost, lack of infrastructure, problems with and limitations of the drugs, and limited uptake of HIV testing (a prerequisite to being treated with ARVs). Try to answer the following questions with your group:

1. What are some of the factors that have helped make antiretrovirals (ARVs) more available and accessible in your country? What are some factors that have hindered ARV access and use?

2. Does the public health infrastructure in your country or setting pose any problems for the distribution or use of ARVs? What are they?

3. What are the obstacles to more people getting tested for HIV in your country or setting?

4. How might wider provision of HIV treatment and increased uptake of voluntary counselling and testing (VCT) in your community be beneficial to the conduct of HIV prevention research?

Notes

Use with session 1c Work sheet 1

Assignment

Four reasons are often given for why antiretrovirals (ARVs) are not in wider use in developing countries: cost, lack of infrastructure, problems with and limitations of the drugs, and limited uptake of HIV testing (a prerequisite to being treated with ARVs). Try to answer the following questions with your group:

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3. What are the obstacles to more people getting tested for HIV in your country or setting?

4. How might wider provision of HIV treatment and increased uptake of voluntary counselling and testing (VCT) in your community be beneficial to the conduct of HIV prevention research?

Notes

Use with session 1c Work sheet 1
A Comprehensive Approach: The Need for Options

Assignment

Discuss the question you have been assigned with your group.

1 How would you answer someone who asked you, “Why should we be working on new HIV prevention methods (vaccines and microbicides) when people aren’t even using the perfectly good prevention options already available?”

2 How would you respond to someone who says: “All the money going into new preventive technologies (such as vaccines and microbicides) should be spent making current prevention efforts work better, especially if we have to wait 10 years for a vaccine”?

3 How would you respond to someone who says: “With antiretrovirals (ARVs) becoming more widely available, we don’t need to worry about prevention anymore”?

4 How would you explain to someone that, even when we have an AIDS vaccine, we will still need to continue all the other forms of HIV prevention, such as using condoms, reducing sexual partners, and using clean needles?

Notes

Use with session 1d Work sheet 2
The Wrong Foot

Assignment

Imagine the following incident: Early one morning, a van marked “AIDS Vaccine Trial” pulls up near a community park in [insert relevant city, country, or region ______________]. Three people in white jackets get out of the van, set up a table, and begin distributing leaflets explaining that they have come on behalf of NAIVE, the government-sponsored National AIDS Vaccine Effort, to recruit volunteers to test a new candidate vaccine against AIDS. The leaflet explains that the “team” will be at this location for the next two days to sign up volunteers to participate in a study to test a possible new AIDS vaccine. There has been no publicity about this effort, and this is the first time most people in the community have ever heard about the possibility of a vaccine against AIDS.

Now imagine that you are one of the people and answer the questions at the end of this list from the point of view of that person:

- A local religious leader
- A nurse in the provincial hospital
- A man who has tested positive for HIV
- A mother who has tested positive for HIV and does not know his/her status
- Someone who works in HIV and AIDS prevention for a local nongovernmental organisation (NGO)
- A journalist who covers this province for a national daily newspaper
- A provincial-level Minister of Health (MOH) official

1. Do you think somebody in your position would understand what a “vaccine trial” is?
2. When you see the van pull into town with the words “AIDS Vaccine Trial” written on it, what is your immediate reaction? What do you think “AIDS Vaccine Trial” means?
3. Would you volunteer for this trial? Would you advise others to volunteer? If yes, why? If no, why not?

Notes

Use with session 2c Worksheet 3
# The Vocabulary of the Immune System

## Assignment

Match each definition from the column on the right with the word it describes from the column on the left. Write the letter of the definition in the blank next to the word it defines.

<table>
<thead>
<tr>
<th></th>
<th>Pathogens</th>
<th></th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>B</td>
<td>They direct the production of antibodies.</td>
</tr>
<tr>
<td>2</td>
<td>C</td>
<td>They recognise antigens and coordinate the response of the immune system, also called “helper” cells.</td>
</tr>
<tr>
<td>3</td>
<td>D</td>
<td>They start the immune response whenever a pathogen reappears in the body.</td>
</tr>
<tr>
<td>4</td>
<td>E</td>
<td>Foreign, rotten, harmful organisms that cause disease in the human body.</td>
</tr>
<tr>
<td>5</td>
<td>F</td>
<td>A piece or fragment of a pathogen.</td>
</tr>
<tr>
<td>6</td>
<td>G</td>
<td>They coat the pathogen by attaching to antigens, marking the pathogen (for killer cells) and making it inactive.</td>
</tr>
<tr>
<td>7</td>
<td>H</td>
<td>They kill cells that have been infected with the pathogen.</td>
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</table>

Notes
Understanding the Immune System

Assignment

Your assignment is to work with your group to design a five-minute presentation on the concept you have been assigned, using the info sheet you have been provided. This presentation should:

- Define the concept
- Explain the relationship of this concept to HIV and AIDS

If you would like, you may create a visual aid to use in your presentation. Info sheet 1 may be helpful for this.

After the group has designed the presentation, someone should be chosen to present it to the other groups. This person should now practice giving this presentation to the small group.

List of concepts

1. Pathogen
2. Antigen
3. Antibody
4. B-cells
5. T-cells

Notes
How a Vaccine Works

Assignment

Imagine that you have been asked to attend a community meeting on how a vaccine works. Working from the info sheets you have been given, design a presentation on this subject (no more than five minutes) that would be suitable for such an audience (i.e., people with no medical background).

Suggestions for the presentation:

- Try to incorporate a visual aid that is appropriate and understandable for the audience.
- Try to think of a metaphor that uses an aspect of everyday life that a lay audience could understand to explain the immune system and how it responds to a pathogen.

For example: If the immune system is like the fence that protects a farmer's goats; the goats are like healthy cells; a wolf on the outside of the fence is like _____; etc.

After your group has designed the presentation and visual aid, select someone to deliver it to the other groups and have this person practice the presentation at this time.

Try to think of questions you can ask the other presenters when the large group reconvenes.

Notes
Vaccine Design Analogies

Assignment

Your community is losing its citizens to deadly snake bites. Despite many efforts and strategies put together by the Snakebite Prevention Agency to exterminate the snake population, their number keeps increasing, their bites become incurable, and they become more and more dangerous. The Agency realizes that the best way to protect your citizens is to empower them with skills to identify, attack, and kill snakes before they have a chance to bite.

The community leaders ask the Head of Snakebite Prevention to come up with different techniques or strategies that the citizens might use. Three techniques were identified: (1) Identify the snake before it bites, and suffocate the snake with a fire; (2) Kill the snake by using poison, arrows, or a gun; or (3) Use technique 1, and then technique 2.

After a few months of theoretical discussions, the Head of Snakebite Prevention asks his officers to equip citizens with skills and techniques suggested in real situations. Each of his five officers proposes a strategy and brags that it is the most excellent method.

1 Officer #1 suggests first teaching the self-defence skills to people, and then capturing a living snake and throwing it into a room for people to exercise these skills. The snake’s venom would be removed so that it’s not dangerous when it is thrown into the room. She believes this is the most effective way for people to practice skills and have an effective response when they encounter a snake in the community. She calls it “live-attenuated” strategy.

2 Officer #2 has a different idea, saying the most important thing is for citizens to recognise snakes and develop the ability to kill them as fast as possible. If they can recognise a dead snake and practice killing it now, they will be able to kill a live snake. He argues that we cannot expose our precious population to the risk of a live-attenuated snake. He points out that even if the snake has no venom, it is dangerous, because who knows the speed with which the snake produces new venom? A dead snake is safe for all citizens to practice on. He calls his strategy “whole-killed” strategy.

3 Officer #3 replies with a local saying: “Even a dead snake is dangerous.” He suggests using only the head and tail of the snake and fixing them into a pipe, which would be attached to a cord so a snake’s movements can be simulated. “This way, there would be no danger of exposing the population to a snake,” he says, “but we still have something that resembles a snake so the people can develop their response skills”. He calls it “subunit” strategy.

4 Officer #4 nods her head in appreciation of Officer #3’s strategy, but then offers a new suggestion: “I am afraid that only using the head and tail will not get to the root of the problem. We only need to see the outside skin of the snake to be able to recognise it and to develop a response against the entire snake. We have many artists in this community. Why can’t we just ask them to make an identical snake skin using plastics and cover a snake puppet with the plastic skin?” She calls it “DNA” strategy.

5 Officer #5 agrees with #4, but he recommends a slight change. “I agree we should use a manmade skin that looks like a snake’s. But instead of using a plastic puppet, we should use a live lizard, covered with the skin of a snake. In this case, citizens will gain skills on an animal that is similar (including its movements and escaping tactics), but that is less dangerous than the snake”. He calls his strategy “recombinant vector” strategy.
If you were one of the citizens in this community, trying to gain skills and practice for snake protection, which strategy would you prefer? Why?

Once you have decided, move to the appropriate sign to join the other participants who chose that strategy. You will have about 15 minutes to discuss your reasons as a group. Select one or two people to present your group’s ideas with the other participants when you are all called back together.

Notes
Understanding Vaccine Types

Assignment

You have been assigned either to the presentation group or the question group.

If you are in the presentation group, consult the info sheet you have been given and design a short presentation about the vaccine type assigned to your group, covering all the key points. Design this presentation so that it can be delivered to any type of audience, and try to include a visual aid if possible. Remember to be careful of your vocabulary and not use too many technical terms, or be able to explain them if you do.

If you have been assigned to the question group, consult your info sheet and think of questions people might ask about each type of vaccine. You will be invited to pose these questions at the end of the small group presentations.

Notes
# Vaccine Facts

## Assignment

Match each definition from the column on the right with the word or phrase it describes from the column on the left. Write the letter of the definition in the blank next to the word it defines. You will probably need to refer to the info sheets you have been given, but you may want to try finishing as much of the exercise as you can without them.

### Part 1: Vaccine types

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<table>
<thead>
<tr>
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<tbody>
<tr>
<td>1</td>
<td>Whole-killed/whole-inactivated vaccine</td>
<td>A Uses copies of single or multiple genes of the pathogen to stimulate an immune response.</td>
</tr>
<tr>
<td>2</td>
<td>Live-attenuated vaccine</td>
<td>B Uses the entire dead pathogen to stimulate an immune response; not being used for HIV.</td>
</tr>
<tr>
<td>3</td>
<td>Subunit vaccine</td>
<td>C Uses a weakened form of the pathogen to stimulate an immune response; not being used for HIV.</td>
</tr>
<tr>
<td>4</td>
<td>DNA vaccine and recombinant vector vaccine</td>
<td>D Uses only a small part of the pathogen to stimulate an immune response.</td>
</tr>
</tbody>
</table>

### Part 2: Key qualities

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<table>
<thead>
<tr>
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<tbody>
<tr>
<td>5</td>
<td>Preventive vaccine</td>
<td>E Stops or destroys a pathogen after it has infected the body; a treatment vaccine.</td>
</tr>
<tr>
<td>6</td>
<td>Therapeutic vaccine</td>
<td>F Describes how people who are not vaccinated may be protected.</td>
</tr>
<tr>
<td>7</td>
<td>Efficacy</td>
<td>G Like the classic vaccines (polio, measles, hepatitis) that prevent infection.</td>
</tr>
<tr>
<td>8</td>
<td>Effectiveness</td>
<td>H Refers to how successful a vaccine has been in preventing infection in a clinical trial.</td>
</tr>
<tr>
<td>9</td>
<td>Herd immunity</td>
<td>I Refers to how well a vaccine will reduce disease in the overall population.</td>
</tr>
</tbody>
</table>

### Part 2: An ideal vaccine

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<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>10</td>
<td>A safe vaccine</td>
<td>J Those who need it the most can afford it.</td>
</tr>
<tr>
<td>11</td>
<td>An available vaccine</td>
<td>K Without serious side effects.</td>
</tr>
<tr>
<td>12</td>
<td>A stable vaccine</td>
<td>L A vaccine that can last a long time in different environments.</td>
</tr>
<tr>
<td>13</td>
<td>An affordable vaccine</td>
<td>M Can be produced in large quantities and delivered easily.</td>
</tr>
</tbody>
</table>
Facts About the Development of AIDS Vaccines

Assignment

1  **True or False:** At the present time, no vaccine has been proven safe and effective in clinical trials to prevent HIV infection.

2  Researchers have been trying to develop an AIDS vaccine since:
   a  The year 2000
   b  The 1980s
   c  The 1970s

3  **True or False:** Developing a vaccine against HIV infection may take longer than for other diseases because there are many unique scientific challenges to understanding the virus and humans’ immune response to it.

4  A preventive AIDS vaccine could work by:
   a  Blocking infection, so the vaccine recipient does not become HIV infected if exposed after receiving the vaccine
   b  Delaying the progression of HIV infection to AIDS if the vaccine were not successful in preventing infection in an individual vaccine recipient
   c  Both of the above

5  Which one of the following types of vaccines has NOT been tested as a candidate AIDS vaccine in human trials?
   a  DNA vaccine
   b  Vector vaccine
   c  Whole-killed vaccine
   d  Subunit vaccine

6  As of 2007, how many vaccine candidates had been tested in clinical trials?
   a  Over 100
   b  Around 30
   c  Less than 5

7  **True or False:** If a vaccine trial does not show that the candidate vaccine is working, then researchers have not learned anything from the trial.

8  Which of the following is NOT considered one of the scientific challenges to developing an AIDS vaccine?
   a  The inability to use whole pathogens in developing a vaccine
   b  The limitations of predictions from an animal model
   c  The inability to create effective scientific partnerships between countries involved in research
   d  Problems associated with mutation and virus subtypes
   e  The inability to understand how some people’s immune systems naturally fight the virus
9 How many major clades or subtypes of HIV have been identified worldwide?
   a  5
   b  7
   c  9
   d  11

10 True or False: The AIDS vaccines now being developed cannot cause HIV infection because they use copies of small pieces of the virus but not the virus itself.

Notes
AIDS Vaccines Cannot Cause HIV Infection

Assignment

One of the most common questions people have about a vaccine is: Is there a chance the experimental vaccine could cause HIV infection? It is extremely important to be able to answer this question clearly.

In this activity, pretend that you write a weekly health column for a national newspaper and a reader has written you with this question:

I am a member of the local governing council in my community. We have been approached by an AIDS research team who want our community to participate in a vaccine trial. The news has gotten around and many people have come up to me and asked me if they will get infected with HIV if they take the experimental vaccine. The research team assured us that the candidate vaccine has no chance of causing HIV infection, but I did not understand their explanation. Can you please explain why? I need to have an explanation that the local people will accept and be able to understand.

Sincerely,
Nelson Munduku

You have decided to answer this question in your next column. Working from the info sheet you have been given, compose a short column that answers this reader’s question.

When you have finished writing your text, transfer it to the piece of flip chart paper. Write large enough so the paper can be seen by everyone in the session.

Notes
Overcoming Challenges in AIDS Vaccine Development

Assignment

Developing an AIDS vaccine has posed four unique challenges to researchers, challenges that have not been encountered in developing other vaccines.

Working from your info sheet, develop a presentation that explains the particular challenge you have been assigned. In designing your presentation, imagine that someone has asked you to explain why it is taking a long time to develop a vaccine. Be as creative and non-technical as possible.

After the group has designed the presentation, select someone who will deliver it in the plenary session. This person should practice by giving the presentation to the small group.

Notes
Ask the Experts: Common Questions About Vaccines

Assignment

This session reviews the information you have learned about vaccines. Read all of the role descriptions, so you understand how the activity will proceed, and then follow the instructions for your role.

**Role 1:** You are the host of a popular radio talk show in your country. Today you have invited a panel of five experts on AIDS vaccines to appear on the show to answer questions about this topic from your national audience. Your task is to take calls from community members (the people in Role 3 below) and generally facilitate the interaction between the people on the phone and the experts in the studio. As you take each call, make sure the experts understand the question, give them time to answer, ask the caller if he/she understands the answer or has a follow-up question, ask your own questions of the panel, etc. Try to have fun with the audience and with the experts.

While the two groups are preparing, make a list of any questions you might want to ask, in case the audience does not ask these questions. You will also need to prepare your introductory remarks: what you will say in welcoming your audience, how you will introduce the topic, how you will introduce the panel, and any other explanations you will give. At the signal from the facilitator, you will begin the show!

**Role 2:** You are five panellists appearing on a popular radio talk show in your country today:

1. **Principal investigator of the vaccine trial or other site staff.** The principal investigator is the physician in charge of running the clinical vaccine trial and providing clinical attention to volunteers. You could also play a study coordinator or nurse counsellor, who performs similar functions.
2. **Ethicist.** This is an expert in ethical issues. This person will speak on any issues with ethical implications, such as how volunteers are protected and cared for during trials.
3. **VCT counsellor.** This is an individual who conducts voluntary counselling and testing. You may decide if this person is part of the actual clinical trial team, or works at a VCT centre in the trial community. This person might comment on the type of individuals who qualify for a vaccine trial, common misconceptions that community members have about trials, etc.
4. **Community Advisory Board (CAB) member.** This is a person who acts as a liaison between the community and the researchers conducting the vaccine trial.
5. **Epidemiologist.** This is a person who studies issues related to trends in diseases, such as how often people become infected with certain diseases, and the sources of diseases in large populations. This expert might comment on why the trial is being conducted in the particular community or country.

When the talk show begins, you will “take calls” from people around the country (the people in Role 3 below) who have questions about AIDS vaccines. As a group, spend this time trying to anticipate the most likely questions and prepare your answers. A list of possible topics is given below, along with background information on the topic; audience members have been asked to limit their questions to these topics.

**Note:** If you do not know the answer to a question, it is always fine to say that you do not know, and that you need to refer back to a different expert. In this case, you may ask the trainer to help answer the question.

**Role 3:** You are part of the listening audience for a popular radio talk show in your country. The guests on today’s show are five professionals in the HIV field, and you have some questions about vaccines that you want to ask. The assignment for your group is to try to think of questions various types of people in your country (politicians, religious leaders, medical professionals, community groups, etc.) might have about AIDS vaccines. Make a list of these questions and be prepared to “call in” to the talk show when the activity starts.
A list of topics is given below; try to limit your questions to these topics. When the show starts, the host will invite questions. You should decide who in your group is going to ask which question, and that person should be prepared. Prioritise the most important questions that your group has come up with and ask them first. Also try to ensure that a variety of questions gets asked. You may assign one person to be the facilitator to organise the group.

**Topic list for audience members**

You can ask questions about any of the following topics. Remember that people from different groups and different walks of life in your country may have different questions about the same topic. Also see Info sheet 7 for some of the most common questions and answers.

- How a vaccine works
- Therapeutic vaccines
- Preventive vaccines
- Efficacy
- Herd immunity
- Side effects and vaccine safety
- Why you can’t get HIV infection from the vaccine candidate
- Why vaccines should be tested in developing countries
- The four challenges, or why it’s taking so long to develop a vaccine:
  - How to make the vaccine
  - Animal models
  - Correlates of protection
  - HIV mutation

**Notes**
## Phases of Clinical Vaccine Trials

### Assignment

Below you will find a list of characteristics of the three phases of trials. Read through the items on the list, decide which phase each item describes, and check the appropriate box. Remember that some items may apply to multiple phases, so you can check more than one box for each item. **CAUTION:** There is one item which is *not true for any phase*; see if you can find it (and just circle the number of the item).

<table>
<thead>
<tr>
<th>Assignment</th>
<th>Phase I</th>
<th>Phase II</th>
<th>Phase IIb</th>
<th>Phase III</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 This phase could involve 2,000 or more people.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2 This phase assesses safety of the vaccine.</td>
<td></td>
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</tr>
<tr>
<td>3 The primary purpose of this phase is to measure safety and immunogenicity in a small number of healthy volunteers.</td>
<td></td>
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<tr>
<td>4 The purpose of this phase is to measure effectiveness.</td>
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<tr>
<td>5 As of 2008, only three candidate AIDS vaccines had reached this phase.</td>
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<tr>
<td>6 This phase can enrol less than 100 volunteers.</td>
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<tr>
<td>7 The primary purpose of this phase is to find the best dose and regimen of the experimental vaccine.</td>
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<tr>
<td>8 This phase usually involves volunteers who are likely to be at risk for the disease the vaccine is meant to protect against.</td>
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<td>9 This phase usually involves 50-500 volunteers.</td>
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<tr>
<td>10 A goal of this phase is to learn about the efficacy of the vaccine.</td>
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</tbody>
</table>

### Notes
Volunteer Questions

Assignment

In this exercise you will be participating in or watching a demonstration of the concepts of placebo, blinding, and randomisation as they apply in a trial setting. The person playing the doctor will give those playing volunteers mock injections which may either be the candidate AIDS vaccine or a placebo, but volunteers will not be told which one they are receiving.

Working from the info sheet, your assignment at this stage is to discuss among yourselves what questions trial participants might ask a trial doctor when they get an injection. Make a list of these questions below. If you have trouble thinking of questions, your facilitator will come around and make some suggestions.

Questions volunteers might ask the doctor

1. 
2. 
3. 
4. 
5. 
6. 
7. 
8. 

Notes
Doctor and Assigner Roles
(For doctor and assigner only)

Assignment

Doctor

Initial Role Play:
When the role play starts, call a volunteer to the front of the room for his “appointment”. Welcome the volunteer, thank him for volunteering, refer to the fact that he has been through a process of education and counselling about the trial and has signed the informed consent form. Say that he is healthy, HIV-uninfected and qualifies to be in the trial, and now it is time for his first injection. Ask him if he has any questions (the trainer will help you with any questions you are not able to answer).

When questions are answered, get the syringe from the assigner and give the injection to the volunteer. Remind him that you do not know if he has received the experimental vaccine or placebo and he needs to continue preventive behaviour. Ask him if he has any further questions or concerns, and then send him to the room where he will be observed for a while before leaving the clinic.

Follow-Up Role Play:
Call each of the volunteers forward according to their numbers. Say something along the lines of the following:

“Thank you for participating in the AIDS vaccine trial. The trial is over now, and we know which volunteers got the placebo and which got the experimental vaccine. As you know, since you have had HIV tests throughout the trial, we know which volunteers have become HIV-infected during the course of the trial and which have remained HIV-uninfected. During the trial, you received [placebo/experimental vaccine] and, as you know, you are now [HIV-uninfected/HIV-infected]."

Volunteer 1: Received experimental vaccine, is HIV-uninfected at end of trial
Volunteer 2: Received placebo, is HIV-uninfected at end of trial
Volunteer 3: Received placebo, is HIV-infected at end of trial
Volunteer 4: Received experimental vaccine, is HIV-infected at end of trial

Ask each volunteer if he has questions or concerns, and answer them with the help of the trainer.

Assigner

Initial Role Play:
You will stand behind a screen, curtain, or flip chart. When the doctor is ready to give an injection to a volunteer, you will draw a syringe out of the hat or box. Make it clear to the audience that you are drawing randomly, and not looking at the syringes. When you pick the syringe, remove the label that says ‘vaccine’ or ‘placebo’. Place the label on the roster next to the volunteer’s number. Hand the unlabeled syringe to the doctor.

Following the role play, fill in the full Volunteer Roster according to the attached handout. You will do this while the trainer is leading the Q&A session after the initial role play.

Notes
Volunteer Roster
(For assigner only)

Assignment

Assigner:
During the Question and Answer session (Part 2 of the session), you will complete the volunteer roster on the prepared flip chart as follows.

<table>
<thead>
<tr>
<th>Volunteer #</th>
<th>Vaccine</th>
<th>Placebo</th>
<th>HIV-uninfected</th>
<th>HIV-infected</th>
</tr>
</thead>
<tbody>
<tr>
<td>01</td>
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<tr>
<td>Volunteer #</td>
<td>Vaccine</td>
<td>Placebo</td>
<td>HIV-uninfected</td>
<td>HIV-infected</td>
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<td>32</td>
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</tbody>
</table>

Notes
Assignment

When prompted by your trainer, please answer the following questions with your group.

Think about the experience in your community with vaccines. Do you think that every baby who receives vaccines is fully protected? For example, is every baby who receives the polio vaccine completely protected from polio infection? Why or why not?

________________________________________________________________________

________________________________________________________________________

Do you know of any cases where someone has become sick with a disease they were supposed to be vaccinated against? If so, please describe below.

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

In your own words describe below what the term “partial efficacy” might mean when referring to vaccines.

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

Notes
Can I Participate?

Assignment

In this exercise you will practice applying eligibility criteria for volunteers in a low risk Phase I or II trial calling for participants 18 to 60 years old. Below you will find a brief profile of 12 possible trial participants; for each one, decide whether this person might be eligible to participate and should continue on to the screening stage.

<p>| Volunteer 1 | You are a 17-year-old young man. You don’t know your HIV status. You are here of your own free will. You have no serious diseases. You do not engage in behaviours that may put you at risk of HIV infection. ___ Eligible ___ Not eligible |
| Volunteer 2 | You are a 20-year-old man. You are in good health. You do not engage in behaviours that may put you at risk of HIV infection. You do not know your HIV status. You agree to take an HIV test. ___ Eligible ___ Not eligible |
| Volunteer 3 | You are an 18-year-old woman, unmarried. You don’t know your HIV status. Your father (or mother) told you that you must volunteer for this trial. You are willing to take an HIV test. You are not pregnant. You have no serious illnesses. You do not engage in behaviours that may put you at risk of HIV infection. ___ Eligible ___ Not eligible |
| Volunteer 4 | You are a 45-year-old married man. You do not engage in behaviours that may put you at risk of HIV infection. You have recently accepted a promotion and will be moving out of the area in a few months. You don’t know your HIV status. You are willing to take an HIV test. ___ Eligible ___ Not eligible |
| Volunteer 5 | You are a 25-year-old married woman. You are not pregnant. You do not engage in behaviours that may put you at risk of HIV infection. You do not know your HIV status. You are willing to be tested for HIV. Your husband wants to have another child in the next two years. ___ Eligible ___ Not eligible |</p>
<table>
<thead>
<tr>
<th>Volunteer</th>
<th>Description</th>
<th>Eligibility</th>
</tr>
</thead>
<tbody>
<tr>
<td>6</td>
<td>You are a 30-year-old married man. You are HIV-uninfected. You do not engage in behaviours that may put you at risk of HIV infection. You have diabetes.</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>You are a 45-year-old woman. You are in good health. You are not pregnant. You do not engage in behaviours that may put you at risk of HIV infection. You are HIV-uninfected.</td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>You are a 30-year-old married woman. You are HIV-infected. You are not pregnant. You do not engage in behaviours that may put you at risk of HIV infection. You do not have any illnesses.</td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>You are a 40-year-old man. You do not engage in behaviours that may put you at risk of HIV infection. You are in good health. You do not know your HIV status. You are not willing to be tested for HIV.</td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>You are a 35-year-old woman. You are not pregnant. You do not know your HIV status. You are in good health as far as you know. Your husband refuses to use condoms and you don’t use any contraception.</td>
<td></td>
</tr>
<tr>
<td>11</td>
<td>You are a 24-year-old woman. You are HIV-uninfected. You are pregnant. You do not engage in behaviours that may put you at risk of HIV infection. You are in good health.</td>
<td></td>
</tr>
<tr>
<td>12</td>
<td>You are a 50-year-old man. You are in good health. You do not know your HIV status. You are willing to take an HIV test. You live away from your family and often visit sex workers.</td>
<td></td>
</tr>
<tr>
<td>13</td>
<td>You are a 35-year-old woman. You are HIV negative. You are not pregnant. You are breastfeeding. You have no illnesses.</td>
<td></td>
</tr>
</tbody>
</table>
## Recruiting and Retaining Volunteers

### Assignment

Each of the four participants sitting at Stations 1-4 should have a copy of this work sheet. The participants playing the parts of volunteers will only receive individual description boxes (middle column of the chart); make a fifth copy of the work sheet and cut along the dotted lines.

<table>
<thead>
<tr>
<th>Description</th>
<th>Eligibility Key</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ROLE 1</strong></td>
<td>Eliminated at Station 1. Too young to participate.</td>
</tr>
<tr>
<td>You are a 17-year-old young man. You are HIV-uninfected. You are here of your own free will. You have no serious diseases.</td>
<td></td>
</tr>
<tr>
<td><strong>ROLE 2</strong></td>
<td>Eliminated at Station 2. Cannot advance to Station 3 because she cannot give independent informed consent (her father is trying to force participation).</td>
</tr>
<tr>
<td>You are an 18-year-old woman, unmarried. You don’t know your HIV status. Your father told you that you must volunteer for this trial. You are willing to take an HIV test. You are not pregnant. You have no serious illnesses. You do not engage in behaviour that may put you at risk for HIV infection.</td>
<td></td>
</tr>
<tr>
<td><strong>ROLE 3</strong></td>
<td>Eliminated at Station 1. Cannot advance to Station 2 because he will not be within travelling distance of the study centre for the duration of the trial.</td>
</tr>
<tr>
<td>You are a 45-year-old married man. You do not engage in behaviour that may put you at risk for HIV infection. You have recently accepted a promotion and will be moving out of the area in a few months. You don’t know your HIV status. You are willing to take an HIV test.</td>
<td></td>
</tr>
<tr>
<td><strong>ROLE 4</strong></td>
<td>Not eliminated. Advances to Station 4.</td>
</tr>
<tr>
<td>You are a 25-year-old married woman. You are not pregnant. You do not engage in behaviour that may put you at risk for HIV infection. You do not know your HIV status. You are willing to be tested for HIV. You and your husband have agreed that you can wait until the trial is complete for your next pregnancy.</td>
<td></td>
</tr>
</tbody>
</table>

1 In most cases of AIDS vaccine trials, behaviour considered to be at-risk for HIV infection will be determined individually for each trial, based on characteristics of the community in which the trial takes place.
<table>
<thead>
<tr>
<th>Description</th>
<th>Eligibility Key</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ROLE 5</strong></td>
<td>Eliminated at Station 2. Cannot advance to Station 3 due to the medical condition (diabetes) found during screening.</td>
</tr>
<tr>
<td>You are a 30-year-old married man. You are HIV-uninfected. You do not engage in behaviour that may put you at risk for HIV infection. Medical tests show that you have diabetes.</td>
<td></td>
</tr>
<tr>
<td><strong>ROLE 6</strong></td>
<td>Eliminated at Station 2. Cannot advance to Station 3 due to HIV-infected status.</td>
</tr>
<tr>
<td>You are a 30-year-old married woman. Tests show that you are HIV-infected. You are not pregnant. You do not engage in behaviour that may put you at risk for HIV infection. You do not have any illnesses.</td>
<td></td>
</tr>
<tr>
<td><strong>ROLE 7</strong></td>
<td>Eliminated at Station 1. Cannot advance to Station 2 due to unwillingness to be tested for HIV.</td>
</tr>
<tr>
<td>You are a 40-year-old man. You do not engage in behaviour that may put you at risk for HIV infection. You are in good health. You do not know your HIV status. You are not willing to go through HIV testing.</td>
<td></td>
</tr>
<tr>
<td><strong>ROLE 8</strong></td>
<td>Eliminated at Station 2. Cannot advance to Station 3 due to behaviour.</td>
</tr>
<tr>
<td>You are a 35-year-old woman. You are not pregnant. You do not know your HIV status. You engage in behaviour that may put you at risk for HIV infection according to risk assessment surveys. You are in good health as far as you know. You test negative for HIV.</td>
<td></td>
</tr>
<tr>
<td><strong>ROLE 9</strong></td>
<td>Eliminated at Station 3. Cannot advance to Station 4 because he did not complete trial participation.</td>
</tr>
<tr>
<td>You are a 20-year-old man. You meet the health requirements of the trial. You do not engage in behaviour that may put you at risk for HIV infection. You are HIV-uninfected. During the trial, you take a job in another part of the country and cannot travel for your clinic visits.</td>
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<tr>
<td><strong>ROLE 10</strong></td>
<td>Eliminated at Station 3. Cannot advance to Station 4 because he cannot complete participation due to TB infection.</td>
</tr>
<tr>
<td>You are a 20-year-old man. You are in good health. You do not engage in behaviour that may put you at risk for HIV infection. You are HIV-uninfected. During screening you meet all the requirements of the trial. After you are enrolled, you remain HIV-uninfected but you develop tuberculosis.</td>
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<tr>
<td>Description</td>
<td>Eligibility Key</td>
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<tr>
<td><strong>ROLE 11</strong> You are a 45-year-old woman. You are in good health. You are not pregnant. You do not engage in behaviour that may put you at risk for HIV infection. You are HIV-uninfected. During screening you meet all the other requirements of the trial. After one of the first injections, one of your HIV tests shows that you are infected with HIV.</td>
<td>Eliminated at Station 3. Cannot advance to Station 4 due to becoming infected with HIV. NOTE: It is important to explain that even though this volunteer reported no high-risk behaviours, she became infected during the time of the trial due to sexual or blood exposure. This may have happened due to circumstances she could not control, (e.g., rape or becoming infected by her partner).</td>
</tr>
<tr>
<td><strong>ROLE 12</strong> You are a 24-year-old woman. You are HIV-uninfected. You are not pregnant. You do not engage in behaviour that may put you at risk for HIV infection. You are in good health. You become pregnant after receiving one of the trial injections. You meet the health requirements of the trial.</td>
<td>Eliminated at Station 3. Cannot advance to Station 4 because she became pregnant and cannot complete the trial injections.</td>
</tr>
<tr>
<td><strong>ROLE 13</strong> You are a 35-year-old man. You are in good health. You do not engage in behaviour that may put you at risk for HIV infection. You do not know your HIV status. During screening you meet all the requirements of the study. You remain HIV-uninfected and in good health during the trial.</td>
<td>Not eliminated. Advances to Station 4.</td>
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**Notes**
What Happens When Someone Is Not Eligible?

Assignment

This work sheet is for trainees who get screened out at any point during the exercise and sent to the “Not Eligible” station.

While waiting for others to complete the process of recruitment and retention in the trial, think about your experience with getting screened out of participation. You can either answer the questions below individually, or nominate someone in the group to lead a discussion, involving all trainees as they join throughout the exercise.

Questions:

Were you able to enrol in the trial, or were you determined ineligible during pre-screening?

How did getting screened out of the trial make you feel? What questions did you have about the reason you were screened out?

What considerations should be made for people who get screened out?

Should the services offered to trial participants be the same for the people who were screened out before enrolment?

If you were found ineligible at screening, could the site have done anything prior to your visit to help avoid this?

Notes
**Trial Participation: Community Members**

**Assignment**

In this exercise, you will imagine that you are at a community meeting that has been called to discuss an AIDS vaccine trial. Members of the trial staff will come before the community to explain the trial and answer questions from the people.

You have been selected to either play the role of a community member or a trial staff member. Read and follow the instructions for your role.

Your role: **community member**

You have heard about the AIDS vaccine trial soon to be started in your community and have decided to attend this meeting to learn more about it.

Think about the most common questions a community member might have if he/she heard about the trial. Similar questions on general issues will be asked by many different types of people. However, certain people may have very specific questions or concerns. You have been assigned several of the roles listed below. In consultation with your group members, prepare your specific questions based on the role you have been assigned.

To prepare, consult the info sheet you have been given.

**Roles:**
- Person living with HIV
- Nurse/doctor at the local health clinic (or HIV testing site)
- Religious leader
- Community leader
- School teacher
- Pregnant woman
- Man who is HIV-infected
- Woman who is HIV-infected
- Man who is HIV-uninfected
- Woman who is HIV-uninfected
- Someone who does not know his/her HIV status
- Unmarried teen
- Someone who works in an HIV support group
- Treatment advocate
- Member of the media

**Notes**
Trial Participation: Trial Staff Members

Assignment

In this exercise, you will imagine that you are at a community meeting that has been called to discuss an AIDS vaccine trial. Members of the trial staff will come before the community to explain the trial and answer people’s questions.

You have been selected to either play the role of a community member or a trial staff member. Read and follow the instructions for your role.

Your role: trial staff member

You and the other trial staff members will explain the details of the trial process, including:

- Eligibility requirements
- The screening process, including HIV testing and medical tests
- Informed consent
- The trial process (after enrolment), including the responsibilities of participants
- Placebo
- Blinding
- Falsely testing positive
- Confidentiality and protecting volunteers
- Contraception and pregnancy
- Characteristics of the vaccine/how it is made

After you and your colleagues present these topics, you will be asked questions by members of the community.

At this time, divide the topics above among the trial staff members. Each person should plan a five-minute presentation, consulting the info sheet you have been given. Try to be creative and present the information in a way that will be interesting to your audience, using visual aids or metaphors that are relevant to your audience.

To prepare your presentation, ask yourself the following questions:

- Of the information that I will present, what is the “take-home” or key message for the audience? Or, what is the most relevant information for their interests?
- How can I present this information in an interesting way? Is there a metaphor or a personal story I could use to make the information interesting?
- What questions might the audience ask after my presentation is over?

Use the back of this work sheet to prepare your presentation.

Notes
Overcoming Women’s Barriers to Participation

Assignment

Below you will find a list of factors that discourage or prevent women from participating in AIDS vaccine trials.

Part 1:
With your group discuss what can be done in general, in the community and elsewhere, to help women overcome these barriers.

1. Women’s household duties, such as housework, childcare, and looking after elderly parents, make it difficult to attend meetings (to hear about a trial) and to make trips to the trial site for medical tests, etc.

2. Women may feel they have to get the permission of their husband to participate, and the husband may refuse.

3. Women are afraid to get tested for HIV because of concerns about stigma, spousal abuse, or abandonment if they test positive.

4. Women may live far from the site and have difficulty with transportation, or may not be able to travel without a family member.

5. Family or social pressure to bear children keeps women from participating.

6. Women know their partner will not use a condom, so there is no point in volunteering for a trial.

7. Women are worried about the confidentiality of their participation; they may not want other people to know they are participating.

Part 2:
Now that your group has discussed general strategies for helping women overcome these barriers, try to think of actions that you personally (or someone in your profession or sector) could take to help eliminate these barriers. Think about your experience in the field of gender in regards to the barriers discussed around women’s participation in AIDS vaccine trials.

Notes
Imagine that you are members of the Community Advisory Board (CAB) in a community that has been chosen for an AIDS vaccine trial. You are holding a public meeting to inform people about the trial and to answer questions. Some of these questions may relate to the ethics of the trial, and you should be prepared to answer them. Below you will find a list of the seven principles of ethical research. For each principle, there is a typical question you might be asked. With your group members, try to answer the questions. You may not be able to answer some of them, or be able to answer very well. In those cases, decide among yourselves where you would go or who you would talk to in order to find the answer.

1 Value. The study should answer a question that will enhance health or provide useful knowledge in the health field.
   Will a safe and efficacious vaccine, once available in our community, be helpful to people like us?

2 Validity. The study should have an appropriate, careful, practical design and methodology.
   How do you know this trial has been well designed?

3 Fair participant selection. Volunteers should be selected in a fair manner, based on scientifically and ethically sound factors.
   How are you selecting people to participate in this trial?

4 Favourable risk-benefit ratio. Participating in any trial involves both benefits and risks; neither factor should greatly outweigh the other.
   How do you know that there is a relative balance between the risks and benefits for volunteers? What if one outweighs the other?

5 Independent review. Independent ethical and regulatory committees must review and give approval for the study.
   Has the design of this study been reviewed by any experts or committees? Who?

6 Informed consent. There must be an adequate process to make sure that volunteers fully understand all aspects of the trial and are enrolling based on their own free will.
   How do you know volunteers understand the trial and are not just being pressured to participate?

7 Respect for participants. The rights and welfare of participants must be upheld and protected throughout the entire trial, and its conclusion and follow-up.
   What steps have you taken to protect the rights and welfare of participants? What are the rights of the participants?

Notes
The Informed Consent Process

Assignment

One of the most important ethical considerations in a trial is getting the informed consent of trial volunteers. For their consent to be truly informed, volunteers need to understand the eight topics listed below:

1. Why the research is being done
2. What researchers want to accomplish and who is responsible for the trial
3. What will be done during the trial and for how long
4. What are the benefits and the risks of participating
5. What is expected of trial participants
6. The system in place for the care and support of participants
7. What other interventions are available
8. Participants’ right to leave the trial at any time

Information on these topics can be made available to people in two ways: through community outreach (i.e., disseminating information in the broader community), and by individual outreach. Your group has been assigned to work on several of these topics. For each topic, try to answer the following two questions:

• What groups, organisations, institutions, and key individuals should be informed about these topics?
• For each group, organisation, institution, and individual identified above, what is the best method of informing them about your topics?

After you have answered the two questions as a group, each group member should take a moment to consider what role he/she could personally play in disseminating information about the trial and thereby advancing the cause of informed consent.

Notes
Is This Informed Consent?

Assignment

For the exercise, pretend you are a counsellor working on an AIDS vaccine trial. Listed below are questions you might ask a potential participant who is considering whether or not to enrol in the trial. Read the person’s answer to your question and decide if the person truly understands the issue in order to give consent regarding this particular topic. Would you accept this answer? If not, what would you say to better inform the person on this topic?

1. Do you understand why this trial is being conducted?
   “It has something to do with curing people with AIDS.”

2. Are you willing to undergo testing to determine your HIV status?
   “Yes. But you can’t tell my husband about this.”

3. Do you understand how the trial works?
   “We will be given the vaccine at certain times and you will then take blood samples, to see if the vaccine helps the body develop an immune response against HIV.”

4. Are you aware of the risks involved in taking this vaccine?
   “Yes. But my doctor told me it was safe to participate.”

5. Do you understand how long you will be required to participate in this trial?
   “Until you tell us it is finished.”

6. Are you here of your own free will?
   “My husband and I talked and we agreed that I could participate.”

7. What do you believe about the medical care we will provide you during the trial?
   “If we get sick, you will take care of us.”

8. Do you understand that you are not supposed to get pregnant while you are in this trial?
   “Yes. I am here because my husband wants more children and I do not. This will make him use condoms.”

9. Are you aware of any benefits of this trial for you?
   “I don’t think there are any benefits.”

10. Do you realize that if you get sick on this trial—for example, if you get TB or diabetes—you will not be able to continue?
    “Yes. And you will treat me.”

11. Do you understand what confidentiality means?
    “It means I don’t have to tell anybody I am involved in this trial.”
12 Do you understand you will have to leave the trial if you test positive for HIV?
   “Yes. But I was told the vaccine will probably protect me. And that you will take care of me if I get infected with HIV.”

13 How would you feel if you tested positive for HIV as part of the screening?
   “I won’t because I don’t have any symptoms of AIDS, and my husband tested negative.”

14 What do you think this vaccine is supposed to do?
   “It will protect me from getting AIDS.”

15 Do you realize you can leave the trial at any time?
   “I don’t want to leave. I want to stay in.”

Once you have finished reading through the questions, you and your partner should choose one and develop a role play based on the scenario presented, expanding on the information and explanation that should be given to the potential participant. If you wish, you can offer to perform your role play when the trainer brings the group back together.

Notes
Characteristics of Trial Review

Assignment

Below you will find a list of characteristics of the three types of trial review. Read each characteristic and place the number of that characteristic under the type of review it describes.

Note that this exercise addresses the characteristics of the various types of review, rather than actual practice. Depending on the systems that exist in a given country, one committee may conduct multiple types of review. Given this overlap, a few characteristics may fall under more than one type. If you need to, you can use your Info sheet to help you with this activity.

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<tr>
<th>Regulatory</th>
<th>Scientific</th>
<th>Ethical</th>
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<tr>
<td>1 Community experts are often involved in this type of review.</td>
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<td>2 This type of review looks at how well the trial is designed.</td>
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<tr>
<td>3 This type of review focuses mainly on information about the product.</td>
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<td>4 These reviewers look at whether or not the vaccine is safe.</td>
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<td>5 This type of review may look at the trial protocol.</td>
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<td>6 In most cases, this committee would study the informed consent document.</td>
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<td>7 These reviewers look at how the product is made.</td>
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<td>8 This type of review considers whether the trial is asking a legitimate medical question.</td>
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<td>9 These reviewers would study previous trials done on this vaccine in other places.</td>
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<td>10 These reviewers want to be sure that no one is coerced to participate in the trial.</td>
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<td>11 This type of committee is responsible for approving the product and the trial.</td>
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<td>12 These reviewers want to make sure the trial design protects the human rights of volunteers.</td>
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<tr>
<td>13 These reviewers look at all the documents—print and media ads, brochures—which the public receives about the trial.</td>
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Notes
The Ethical Review Process

Assignment

Below you will find, in scrambled order, seven key steps in the trial review process. Put a one (1) in the blank next to the first step, two (2) next to the second step, etc., until you have all eight items numbered. Many names are used to describe ethical review groups—-independent ethics committees (IEC), institutional review boards (IRB), and ethical review committees (ERC); this session uses the generic term “ethics committee”.

1. The ethics committee recommends changes in the protocol to trial investigators and/or sponsors.
2. The ethics committee receives ongoing reports on the conduct of the trial, including information on any serious adverse events.
3. The ethics committee reviews all trial materials.
4. The ethics committee reviews the qualifications of the trial investigator(s).
5. Trial-related materials are submitted to an IEC.
6. The ethics committee reviews the amended trial protocol.
7. Investigators/sponsors make changes to the protocol or trial documents suggested by the ethics committee.

Notes
An Overview of Challenges

Assignment

There are a number of different challenges to the future widespread distribution and use of an AIDS vaccine, especially in developing countries. These challenges fall into five main categories:

a. Funding and pricing
b. Acceptability
c. Delivery
d. Regulatory approval and licensure
e. Manufacturing

Each of the following statements explains in some detail an aspect of one of these challenges. Match the statement to the challenge it refers to by writing the number of the statement on the line next to that challenge.

1. Early AIDS vaccines will probably have low-to-moderate efficacy (will not offer full protection to many people).
2. Storage facilities will need to be available.
3. Companies may need financial incentives to produce the vaccines.
4. The vaccines may have to be taken in multiple doses and/or over an extended period.
5. Advance purchase commitments from funders may be necessary to encourage investment in vaccine development.
6. Vast amounts of trial data are required to meet approval requirements.
7. Stigma surrounding vaccines may discourage some people from seeking vaccination.
8. People may have heard rumours about the vaccines, such as that they cause sterility or even HIV infection.
9. Arrangements may be needed for transportation to and from a clinic where someone receives vaccination.
10. Large-scale production facilities will have to be built.
11. Billions of dollars may be needed to purchase and deliver the vaccines globally.
12. Doctors may not recommend a partially effective vaccine to their patients.
Approval in developing countries usually depends on approval in wealthy countries.

People may not think they need to be vaccinated because they do not have multiple sexual partners or do not use drugs.

Bioprocesses have to be developed to produce large quantities of the vaccines.

Additional health workers may be needed to administer the vaccines.

The approval process and type of data needed varies from country to country, and a global coordination process may be needed.
The Challenges in Detail

Assignment

Five challenges to future access and use of an AIDS vaccine have been identified:

1. Global funding, finance mechanisms, and pricing
2. Estimating demand and use
3. Delivery
4. Regulatory approval and licensure
5. Manufacturing

Your group will be preparing and presenting a short presentation on one of these challenges, using the Info sheet you have been given. Your presentation should:

- Briefly describe the elements or different aspects of this challenge.
- Describe any general strategies you can think of for how these elements could be addressed in your country/community/setting. Include the role of various stakeholder groups in your country (NGOs/CBOs, political leaders, medical professionals, etc.).

You will have 10 minutes to prepare your presentation. Then you should select one group member to deliver it to the larger group. That person should practice delivering the presentation.

Notes
The Acceptability Question

Assignment

There are four key groups whose support will be needed for the widespread acceptance of an AIDS vaccine in most settings:

• Policymakers/political leaders
• The medical community
• The NGO community
• Individuals who will receive the vaccine

Should these groups decide to “accept” an AIDS vaccine, if and when one becomes available, then a vaccination effort would probably be successful. But there are five common obstacles to the acceptance of a vaccine, as described on the fact sheet you have been given:

• Efficacy level of the vaccine
• Behaviour change of vaccine recipients
• Product characteristics
• Stigma and risk perception
• Myths and rumours about the vaccine

Your assignment is to look at the obstacles to acceptability from the perspective of the key stakeholder group you have been assigned from the list above. Answer the following two questions with your group members:

1 How would each obstacle be relevant for my stakeholder group?
2 How could these problems be resolved?

Notes
Myths and Rumours

Assignment

Here are eight common myths or misconceptions about AIDS vaccines. How would you respond to these myths?

**Myth 1:** An AIDS vaccine exists, but it is only available in places where people can afford it.

**Myth 2:** Western scientists are unfairly using people in developing countries to test AIDS vaccines.

**Myth 3:** The experimental AIDS vaccine might cause HIV infection in trial volunteers.

**Myth 4:** While participating in a trial, volunteers will be exposed to HIV to see if the vaccine really works.

**Myth 5:** Trial volunteers do not need to continue HIV risk-reduction practices.

**Myth 6:** Once an AIDS vaccine is available for the general population, people will be able to revert back to risky behaviour.

**Myth 7:** AIDS vaccine efforts are taking resources away from other efforts to respond to the HIV and AIDS pandemic.

**Myth 8:** An AIDS vaccine will benefit only people who are not already infected with HIV.

Notes
Frequently Asked Questions

Assignment

Below you will find a list of some of the most frequently asked questions about vaccines. From what you have learned in your training, prepare an answer to the questions assigned to your group and be prepared to present your answers when the session starts up again.

1 What is a vaccine?

2 What is an AIDS vaccine?

3 Is an AIDS vaccine currently available?

4 What is a clinical trial?

5 Who can participate in a clinical AIDS vaccine trial?

6 Why are scientists testing AIDS vaccines in developing countries?

7 Can candidate AIDS vaccines cause HIV infection when they are tested in people?

8 Is it possible for volunteers to become infected with HIV while participating in a trial?

9 When someone participates in a trial, does he or she still need to use condoms or other forms of prevention?

10 Why is it taking so long to develop an AIDS vaccine?

Notes
Watch Your Language

Assignment

When you talk to other people about topics such as HIV and AIDS, the immune system, and vaccines, you may use a lot of technical terms. But many people will not be familiar with these topics and may not understand these terms. One skill you will need is to be able to describe technical, scientific subjects in simple language that can be understood by the average person.

Below you will find a list of some of these technical terms. Working with your group members, choose 10 of the words below (or more, if you have time) and try to think of another way of saying this word or phrase. Think creatively about common terms used in your country or community. The chapters listed refer to VaxLit Core Content chapters where the topic is discussed.

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Now look back at this list and try to think of any words or phrases you think should be added. Write them down here, along with substitute wording.

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Notes
Next Steps: Developing a Personal Work Plan

Assignment

Step 1 Below is a list of general activities that are instrumental in supporting the vaccine development process in most countries or communities. Go through the list and put a check mark next to the activities where someone in your position or someone with your expertise could possibly make a contribution.

- Raising awareness about HIV and AIDS
- Encouraging voluntary counselling and testing (VCT)
- Helping to reduce stigma for those who are HIV positive
- Helping to reduce stigma of those who participate in clinical trials
- Helping to change and develop policies around AIDS vaccines
- Creating awareness of and support for the trial in the local community
- Managing expectations and countering misconceptions related to an AIDS vaccine
- Educating people about all aspects of the trial, including how it will be conducted, participant responsibilities, ethical safeguards, benefits to the community, etc.
- Mobilizing and supporting trial volunteers and minimizing dropouts
- Participating/enrolling in a vaccine trial
- Supporting and/or promoting the need for research at local, national, regional and international levels
- Supporting local researchers and regulatory institutions
- Advocating for gender rights and rights to voluntarily participate in a trial

Step 2 For those activities you have checked, now decide which ones really interest you or that you would very much like to become involved in. You may rank these in order of priority if you wish.

Step 3 For those activities in which you would like to become involved, brainstorm a list of actions you could take and things you could do in support of that activity.
The immune system is a complex mechanism that enables the body to recognise agents that are foreign to or different from its own cells and tissues and that could be harmful. The immune system creates defences against these invaders, which are called **pathogens**.

1. **A pathogen enters the body.**
   A pathogen may be a virus, bacteria, or parasite and is potentially harmful.

2. **Immune cells, called macrophages and dendritic cells, recognise the pathogen as foreign and engulf it.** The immune cells present small pieces of the pathogen, called **antigens**, on their outer surfaces. Antigens that initiate an immune response are called **immunogens**.

3. **Other immune cells, called **lymphocytes**, see the immunogens presented on the outer surface of the macrophages or dendritic cells. Lymphocytes recognise the antigen as foreign to the body, which causes them to initiate an immune response. Lymphocytes include B-cells and T-cells.

4. **B-cells response**
   B-cells produce antibodies. Antibodies bind to the outer surface of pathogens, making them inactive and unable to infect the body’s cells. Antibodies can also bind to cells that have been infected with the pathogen, marking them to be killed.

   **T-cells response**
   Helper T-cells, also called CD4⁺ T-cells, regulate the rest of the immune response, directing other cells such as killer T-cells. Killer T-cells, also called CD8⁺ T-cells, recognise the pathogen and body cells that have been infected by the pathogen and kill them.

5. **Memory B-cells and memory T-cells remain in the body after infection has been cleared and start a much more rapid immune response if the body encounters the same pathogen in the future.**
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<th>Concept</th>
<th>Explanation/Definition</th>
<th>How the concept relates to HIV</th>
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<tr>
<td>Pathogen</td>
<td>A foreign, potentially harmful organism that infects the human body and causes disease. The most common pathogens are viruses (such as HIV), bacteria, and parasites (such as worms).</td>
<td>HIV is a pathogen that invades the body. It attacks and weakens the immune system, making it difficult for the body to fight the virus and any other pathogens that may infect the body.</td>
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<tr>
<td>Antigen</td>
<td>A piece or fragment of a pathogen (usually a protein) that is picked up by certain immune cells and then presented to the rest of the immune system to initiate an immune response.</td>
<td>One way a vaccine might work is by producing antibodies which would attach to HIV antigens. This would either make the virus inactive or mark it so that it could be attacked and destroyed by other immune cells. HIV presents a particular challenge, because certain crucial antigens seem to remain hidden from antibodies, which then cannot mark or inactivate the virus.</td>
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<td>T-cells</td>
<td>T-cells are the immune cells, or lymphocytes, that can recognise a foreign pathogen, (or a body cell that has been infected with the pathogen) and can kill it. There are two types of T-cells: CD4+ T lymphocytes and CD8+ T lymphocytes.</td>
<td>HIV needs to be inside human cells – or to infect them – to make more copies of itself. T-cells can recognise and attack these infected cells.</td>
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<tr>
<td>CD4+ T-cells</td>
<td>CD4+ T-cells are the types of T cell that recognise an antigen from a pathogen when it is presented to the immune system. CD4+ T-cells coordinate the rest of the specific immune response against that antigen. They are also called “helper T-cells”.</td>
<td>HIV specifically targets CD4+ T-cells to kill them, which is why people living with HIV and AIDS have to pay attention to their CD4+ count. A low count means HIV has already killed a large number of cells and weakened the immune system.</td>
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<tr>
<td>CD8+ T-cells</td>
<td>These T-cells kill pathogens or cells that have been infected with a pathogen, which is why they are called “killer T-cells”. They do this by releasing a specific substance, which kills the infected cell or pathogen.</td>
<td>CD8+ cells can kill HIV-infected cells. However, because the immune system of a person living with HIV is weakened, it usually cannot keep up with the virus activity. Most candidate AIDS vaccines are aimed at producing CD8+ cells.</td>
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**B-cells**

The B cell response fights the pathogens that have not yet infected a human cell. Soon after infection, B-cells direct the production of antibodies, which attach to the outer surface of pathogens and inactivate them. There are two main types of B-cells: plasma B-cells and memory B-cells.

B-cells begin to produce antibodies against HIV shortly after infection takes place. However, many of these antibodies fail to attach to HIV or to effectively inactivate it because of the virus’ ability to evade immune defenses.

**Antibody**

An antibody is designed to attach to a specific antigen. When antibodies lock or bind to the antigens on the surface of a pathogen, they coat the pathogen, inactivating it and marking it so other immune cells can easily recognise and kill it. Antibodies can also prevent viruses from getting into cells, which is where they must be to reproduce.

HIV protects itself with a coating, which makes it hard for antibodies to find and attach themselves to the virus. This is one of the reasons it has been hard to identify antibodies that will protect a person against HIV infection.
Vaccines “trick” the immune system into thinking the body is being infected by introducing something that is similar to a particular pathogen, the disease-causing organism, but that is not harmful to the person. The immune system learns and remembers how to combat the pathogen. Therefore, it is armed and ready to fight if the actual bacteria or virus ever enters the body.

1. The vaccine introduces safe forms or fragments of a pathogen, called immunogens, into the body. Immunogens resemble the actual pathogen and cause the body to develop an immune response against it.

2. Presence of the immunogens causes the immune system to initiate B-cell and T-cell responses.

3. **a:** B-cells produce antibodies that are specifically shaped to bind to the immunogen
   **b:** Later, if the actual pathogen ever enters the body, large amounts of these antibodies will be rapidly produced and will bind to the pathogen since it is similar to the immunogen. When antibodies bind to the pathogen or to cells infected with the pathogen, they are either inactivated or marked to be killed by other immune cells.

4. An “army” of memory B-cells and memory T-cells is formed through this process. If the actual pathogen ever enters the body, these memory cells will quickly recognise it and react to initiate strong immune responses to avoid or lessen infection.

   **a:** T-cells known as helper T-cells and killer T-cells are also activated by the presence of the immunogen in the blood.
   **b:** Later, if the pathogen ever enters the body, helper T-cells will prompt the killer T-cells to recognise and kill the pathogen or any cells that get infected with the pathogen.

**REMEMBER:** A preventive vaccine is NOT a cure for someone who has already been infected or developed a disease.
Common Vaccine Types

Strategies not used for AIDS vaccines

- Whole inactivated
- Live-attenuated

Strategies used for AIDS vaccines

- DNA alone
- Vector
- Recombinant
- Protein subunit
Strategies not used to develop AIDS vaccine candidates for clinical testing

1 Whole-killed/whole-inactivated vaccines
These vaccines use a form of the entire pathogen (the disease-causing virus, bacteria, or parasite). The pathogen is killed or made inactive so that it is harmless and cannot cause infection. The body will then “remember” the pathogen and activate an immune response if the pathogen ever enters the body.

Examples: injectable polio vaccine (Salk), cholera vaccine, injectable influenza vaccine

This strategy is NOT being used for AIDS vaccine development to avoid the possibility that the vaccine would cause HIV infection.

2 Live-attenuated vaccines
These vaccines are made from an altered form of the pathogen. The pathogen is weakened so that it is not harmful to humans. However, the pathogen is still alive and will mimic true infection when introduced into a human body. Because the pathogen is weakened, it will not cause disease, but it will cause the body to produce an immune response. The body activates the response if the pathogen ever enters the body again.

Examples: measles vaccine, oral polio vaccine (Sabin), nasal influenza vaccine

This strategy is NOT being used for AIDS vaccine development to avoid the possibility that the vaccine would cause HIV infection.

Strategies used to develop AIDS vaccine candidates for clinical testing

3 Subunit/protein vaccines
Subunit vaccines use only a small part of the pathogen. Most contain a small protein (also known as a subunit) from the pathogen. The immune system sees this small piece and produces protective molecules, called antibodies, which match the subunit. When the actual pathogen enters the body, these antibodies attach to the outer surface of the pathogen, coating it and making it inactive (referred to as “neutralizing” the pathogen).

Examples: Hepatitis B vaccine, tetanus vaccine

The first AIDS vaccines developed and tested in large-scale trials used the subunit concept. But this approach has proved to be very challenging for developing an AIDS vaccine. Scientists do not fully understand why the subunit strategy has not produced a good immune response in an AIDS vaccine.

4 DNA and vector vaccines
DNA vaccines use copies of the genes of a pathogen to generate an immune response. (A gene is a small piece of DNA that contains the instructions to create a protein). These genes code for a small piece of the pathogen that will not cause disease, but will most likely produce an immune response against the pathogen. The immune system remembers the response if the pathogen ever enters the vaccinated person’s body.

Vector vaccines use the same strategy as DNA vaccines, but in this case the gene copy is introduced into humans by a vector. A vector is a bacterium or virus that will not cause disease in humans. The gene copies insert themselves into the vector, which carries the genes into human cells. Using a vector may make a vaccine more effective than using DNA alone.

The few genes contained in DNA and vector vaccines can in no way cause HIV infection in vaccine recipients. These are common strategies being used to develop AIDS vaccine candidates.
Additional Vaccine Facts

**Preventive vs. Therapeutic Vaccines.** The most common type of vaccine is a preventive vaccine. This type of vaccine is intended for people who have not yet been infected with the particular pathogen the vaccine is designed to protect against. It prepares the immune system to respond in case of future exposure to the pathogen. Common examples include the polio, measles, hepatitis B, and tetanus vaccines. Most of the AIDS vaccine candidates currently being tested throughout the world are preventive vaccines.

Another way that vaccines might work would be by administering and starting an immune response after a person has been infected (after the pathogen enters the body). This approach would be called a therapeutic or “treatment” vaccine.

All of the currently available vaccines (e.g., polio, measles) are preventive vaccines. Some therapeutic vaccines are currently in development for some forms of cancer.

**Efficacy.** A vaccine’s efficacy refers to how successful it is in preventing infection or disease in a clinical trial. Efficacy is shown by comparing the rate of infection in the vaccine group versus the rate in the placebo group. (A placebo is an inactive substance that looks exactly like the vaccine.) This is done by monitoring the incidence of infection and disease of the two trial groups over a long period of time (two to three years in the case of AIDS vaccine trials).

**Effectiveness.** Effectiveness refers to how well a vaccine reduces disease in the general population when it is distributed. A vaccine’s efficacy in a clinical trial is meant to predict its effectiveness in the overall population.

**Ideal Characteristics of a Vaccine**
- **Safety.** Does not cause any serious side effects in people (e.g., fever, headache, soreness at injection site) that may outweigh the benefits of receiving the vaccine.
- **Effectiveness.** Significantly reduces the incidence of infection or disease in the general population (see above).
- **Availability.** Can be produced in large quantities, and deliverable to everyone who needs it.
- **Stability.** Is strong or durable enough to last for a long time in different environments.
- **Affordability.** Is affordable to those who need it most.

**Herd immunity.** When many people in a community are vaccinated against a disease, even those who are not vaccinated in that community may be partially protected due to a phenomenon known as *herd immunity.* If enough people in a community are vaccinated, there is less chance of the infection spreading from person to person. Therefore, unvaccinated individuals may be less likely to become infected because there is lower risk of exposure.
AIDS Vaccine Candidates Cannot Cause HIV Infection

The most common type of AIDS vaccine candidate currently being developed is known as a vector or recombinant vaccine. These vaccines contain copies of genetic material of HIV. This diagram shows how the vaccines are made and why there is no chance that they can cause HIV infection.

1. Genes or parts of genes that code for individual proteins of an HIV particle are taken from a virus. Researchers select genes and proteins that will generate an immune response against HIV. The selected genes are harmless and cannot make a whole virus; therefore, there is no way they can cause HIV infection.

2. The gene or genes are copied in a laboratory. This process is comparable to making a photocopy of a famous painting: the copy would look the same but not have the same value as the original because it is not authentic. The gene copies look like 'real' HIV genes and will have the same effect, but are not "authentic".

3. Many AIDS vaccine candidates currently being developed use a vector as a delivery vehicle. A vector is a virus that is unrelated to HIV and will not cause disease in humans. It transports the copies of HIV genes into the body and makes the vaccine more effective than using the gene copies alone.

4. Scientists mix the gene copies and the vector together, prompting the gene copies to insert themselves into the vector and combine with its genetic material. This process is sometimes referred to as "recombining," thus the term recombinant vaccine.

5. The AIDS vaccine candidates contain only copies of individual, non-harmful HIV genes. There is NO POSSIBILITY that such vaccines can cause HIV infection.
HIV is a virus. This means that it survives by invading a host (i.e. the human body) and making many copies of itself inside that host. As the virus continues to make copies of itself, it often makes mistakes, and the copies become different from the original virus. This process is called mutation.

HIV has a high rate of mutation. As different versions of the virus have been transmitted between people, different forms of HIV have evolved all over the world. The forms have been broadly classified into different clades or subtypes. It is not yet known whether one vaccine will protect against different HIV subtypes. Therefore, many different vaccines need to be tested against different subtypes.

Correlates of protection

When a person naturally recovers from a disease, or when a vaccine successfully protects a person against a disease, scientists can measure immune responses that were effective against the pathogen. This enables researchers to determine the immune responses that correlate with protection, called the “immune correlates of protection”.

Because there is currently no effective AIDS vaccine, and because no human has ever naturally recovered from HIV infection, these correlates are currently unknown. However, scientists are learning from unique individuals who do not become infected despite repeated natural exposure to HIV, as well as individuals who are infected yet naturally do not progress to AIDS. Learning the correlates of protection will give scientists important clues about what is required for an effective AIDS vaccine.

How to make the vaccine

Vaccine development strategies that worked well for other diseases (such as measles) use weakened forms of the virus in the vaccines. This strategy is NOT used in AIDS vaccine development due to concern that the weakened form could change back into the disease-causing form of HIV.

Most AIDS vaccines candidate currently being developed use only copies of bits of genetic material from HIV; science shows that these bits cannot cause HIV infection. Researchers are working to identify which bits of genetic material will cause the body to successfully generate a strong immune response against HIV.

Animal models

Before being tested in humans, all vaccines go through testing in animals. These animal models usually give scientists a good idea of what effect a vaccine may have in humans.

Testing AIDS vaccine candidates in animals has not yet accurately predicted how they will work in humans. This makes vaccine research and human trials more difficult to design. However, researchers are constantly learning about the human immune response to HIV through animal testing. This should help develop more promising vaccine candidates.
Cheat Sheet for Asking the Experts

The following information can serve as a reference for coming up with your own questions or answers. Remember that both questions and answers about AIDS vaccines and research will vary greatly depending on the audience. This sheet lists some of the most common questions from a general audience, but you will need to give extra consideration based on the audience you are representing or responding to.

1 What is a vaccine?
A vaccine is a substance that can help protect a person from a particular infection or disease in the future. The vaccine prepares the body to recognise a certain pathogen (a disease-causing virus, bacteria, or parasite) and defend against it by creating an immune response. In general, vaccines are given to healthy individuals who may be at risk of being exposed to the pathogen in the future.

Currently available vaccines save millions of lives each year. A few examples are vaccines against polio, tetanus, and measles, but there are many others. Many vaccines are designed to be given to infants, but vaccines can also be given to adults.

2 What is an AIDS vaccine?
An AIDS vaccine is a substance given (most likely by injection) to people who are not infected with HIV, to prevent them from becoming infected or getting AIDS if they are exposed to the virus in the future.

3 Is an AIDS vaccine currently available?
Right now, NO AIDS vaccine is available. Many possible vaccines, called candidate vaccines, are being developed in laboratories and tested in clinical trials.

4 What is a clinical trial?
A clinical trial is a study done in humans to find out if a new vaccine or drug will be safe and effective.

5 Who can participate in an AIDS vaccine trial?
For any clinical trial, volunteers must fully understand the key facts about the trial and independently give informed consent to participate.

For AIDS vaccine trials, volunteers must not be infected with HIV and should be generally healthy (specific requirements differ from trial to trial). Women cannot be (or become) pregnant while participating. Volunteers must also agree to receive HIV testing and risk-reduction counselling throughout the trial.

6 What is involved in participating in a clinical AIDS vaccine trial?
Participation in an AIDS vaccine trial usually involves:
- Visits to the trial site to receive medical check-ups
- HIV testing and risk-reduction counselling
- Laboratory tests on the volunteer’s blood and urine
- Receiving either the candidate vaccine or a placebo (an inactive substance used for comparison), by injection or other route
- Follow-up visits after all injections are complete

Before joining a trial, potential volunteers receive extensive counselling from trial staff to help them understand what the trial will involve.
7 Are AIDS vaccine trials conducted in an ethical way?

All clinical trials, including AIDS vaccine trials, are carefully reviewed before they receive approval to begin, to make sure that they are scientifically and ethically sound and safe for participants. AIDS vaccine trials follow strict international ethical guidelines to ensure that they protect each volunteer’s health, dignity, and well-being.

Obtaining volunteers’ informed consent to participate in a trial is essential to conducting ethical research and protecting participants. When someone is deciding whether or not to participate in a trial, that person must fully understand essential information about the trial, in order to make an informed choice about participation. Participants must never be unfairly influenced to participate by anyone—friends, family, or trial site staff.

Participating in a trial involves risks and inconveniences that a person may not encounter in normal daily life. Therefore, researchers and ethics committees make sure to protect volunteers and offer them benefits to balance out the risks. Examples of volunteer protection include ensuring that volunteers’ participation is kept confidential and that volunteers have the right to leave the trial at any time. Volunteers also receive appropriate reimbursement to cover time and any travel expenses they may have paid out-of-pocket, as well as access to quality services that are associated with trial participation.

8 Why are scientists testing AIDS vaccines in developing countries?

The search for an AIDS vaccine is a global effort. Vaccine research must occur in both the industrialized and developing world, particularly in countries with high HIV prevalence. The best way to determine if a vaccine will be safe, effective, and accessible for a particular population is to include members of that population in vaccine trials.

Partnership between countries is vital. In-country researchers often play a primary role in conducting trials. Partnering researchers, sponsors, and other groups, often from industrialized countries, look to resident researchers to ensure that studies are relevant to the region. Only through such partnerships can trials be conducted in a locally appropriate way.

Trial communities are often left better off as a result of trials. Communities may experience such benefits as improved health care and voluntary counselling and testing (VCT) services, as well as increased knowledge about HIV and AIDS and vaccines.

9 Can AIDS vaccines cause HIV infection when they are tested in people?

AIDS vaccine candidates currently in human trials cannot cause HIV infection or transmission, because they do NOT contain the entire virus in any form. The vaccines contain only copies of small bits of genetic material from HIV. Scientists know that these small pieces cannot cause HIV infection.

10 Is it possible for volunteers to become infected with HIV while participating in a trial?

Trial volunteers will not become HIV-infected from the candidate vaccine (see question 9). Additionally, candidate volunteers are never exposed to HIV to see if the candidate vaccine prevents infection.

However, it is possible for people to become HIV-infected during the time that they are participating in a trial. These infections are not caused by the vaccine, but rather by exposure to HIV through sex or blood (for example, through unprotected sex or injecting drug use). Even though volunteers are counselled about how to prevent HIV, some people might still take risks and become exposed. In cases where a volunteer becomes infected during the time he or she is participating in the trial, he or she will receive medical services or referrals to services as agreed with local and national stakeholders.

When a person receives an experimental AIDS vaccine, his or her body may produce antibodies against HIV. This response indicates that the immune system has developed antibodies that hopefully would protect the person from HIV infection. These may be the same types of antibodies that standard HIV tests look for. If volunteers in an AIDS vaccine trial test HIV positive on an antibody test at a clinic not affiliated with the trial, it is likely to be a false positive result, meaning the test has responded to antibodies from the candidate vaccine.
Biological markers are referred to by scientists as correlates of protection.

Will candidate AIDS vaccines protect trial volunteers from HIV infection?
People who join a clinical trial should NOT count on the trial vaccine to protect them against HIV infection! In fact, the point of research is to find out if the vaccine works at all, so there is the chance that the vaccine may not prevent HIV infection. Researchers do not know for sure how a candidate vaccine might affect a volunteer’s risk of HIV infection if exposed through such means as sexual transmission – the level of risk might be less, the same, or more than if the volunteer had not received the experimental vaccine. Volunteers MUST continue to practice safe sex, and they are continuously counselled to use condoms and practice other forms of HIV prevention.

Why is it taking so long to develop an AIDS vaccine?
The process of testing any vaccine or drug takes many years. Once scientists develop a possible vaccine, the process of testing it in animals and humans takes a minimum of 10 years. Many vaccines have to be tested before one or more are proven to be effective. AIDS vaccines are particularly hard to develop for several reasons, including:

Making a vaccine that is both safe and effective: First and foremost, researchers must make sure there is no chance of the vaccine causing HIV infection. This means that they cannot use some of the scientific strategies used to develop vaccines for other diseases. Most candidate AIDS vaccines only include artificial copies of either a protein or individual genes from HIV. Scientists know that these small molecules cannot cause infection, so they are safe to use in vaccines. However, it has been hard to produce strong immune responses that protect against HIV infection using these strategies.

Lack of a predictive animal model: Second, scientists have had a hard time predicting from animal data how a vaccine will work in humans. This makes it hard to predict exactly which vaccine candidates are the most promising in the laboratory and should move forward into human trials.

Not enough knowledge about how the body indicates it is protected: Third, scientists do not clearly understand which “biological markers”\(^1\) (such as antibodies or killer T-cells in the blood) indicate that a person is protected against HIV. This makes it hard to determine which markers to measure in the blood of candidate vaccine recipients, making clinical trials hard to design.

Virus mutations and subtypes: Fourth, HIV is a highly mutating virus, which means its genes change frequently. Different forms of the virus can circulate within an individual, and different forms can spread throughout populations. More than nine major forms of HIV, referred to as clades or subtypes, have been identified throughout the world. No one knows if one vaccine will protect against the different forms of the virus.

These challenges have made clinical trials difficult to design, and the overall process of AIDS vaccine research very slow. Despite the challenges, however, experts agree that development of an AIDS vaccine is possible.

What is the difference between preventive and therapeutic vaccines?
The traditional type of vaccine is a preventive vaccine. They are intended for people who have not yet been infected by a particular pathogen. They prepare the immune system to respond in case of future exposure. Common examples include polio, measles, hepatitis B, and tetanus vaccines. All vaccines now marketed throughout the world are preventive vaccines, although a few can work if given immediately after exposure (for example, if a rabies vaccine is administered right after a dog bite or a tetanus “booster” vaccine is given after a wound). Most of the AIDS vaccine candidates now being tested are preventive vaccines.

\(^1\)Biological markers are referred to by scientists as correlates of protection.
Another type of vaccine is a *therapeutic vaccine*. This type of vaccine would start an immune response after a person has been infected. It may also be called a “treatment” vaccine. Right now, there is no AIDS candidate vaccine that works this way, although some scientists are trying to develop one. Scientists are also trying to develop therapeutic vaccines for cancer.

**14 What is efficacy?**

A vaccine’s efficacy refers to the rate of protection from infection and/or disease in a carefully designed clinical trial.

The efficacy level in preventing infection is measured by comparing the rate of infection in the vaccine group to the rate of infection in the placebo group. A lot of people are in the trial, but some will become infected through unprotected sex or exposure to contaminated blood, even though the volunteers are counselled to reduce their risk of infection. The trial monitors volunteers for a long time, usually two to four years, to see how many people become infected in each group, and if they become infected how well they control their virus infection. If a significantly lower number of people in the vaccine group have acquired infection than in the control group, this is an indication that the vaccine protects against infection, and it is said to have efficacy or to be efficacious. If people get infected but don’t have much HIV in their blood, they may stay healthy longer or they may not pass the virus on to other people.

The degree of efficacy may be important as well. No vaccine has 100% efficacy. Regulators and researchers agree on the minimum efficacy rate that will be acceptable for approval and distribution in the general population. The level of efficacy that researchers want to find affects how the trial is designed.

There is a great deal of discussion about how high the efficacy rate of an AIDS vaccine must be in order to have an effect on the disease in the community. Experts agree that, even with a relatively low level of efficacy, an AIDS vaccine would have a significant impact, especially in areas of high HIV incidence.

**15 What is herd immunity?**

When many people in a community are vaccinated against a disease, there is less chance of the infection spreading from person to person, and unvaccinated individuals may be less likely to get infected because there is a lower risk of exposure. This protection afforded to even those who are not vaccinated in a community is called *herd immunity*. For example, measles and rubella vaccines protect vaccinated people and also help cut down on spread of the disease to people who are not vaccinated.

It is important for people to receive vaccines against common diseases that are licensed and available in their communities. If too many people choose not to be vaccinated, herd immunity will not have any effect in the community.

**16 What does the term “safety” mean in the context of AIDS vaccine trials?**

The term “safety”, as used in clinical trials, means that researchers are testing to make sure the vaccine does not cause side effects in a significant number of people or to a significant or severe degree in any person. Therefore, safety simply means that the vaccine itself is not harmful.

Testing for safety does not mean researchers are testing to make sure vaccines cannot cause HIV infection. *No candidate AIDS vaccine can cause HIV infection.* Before a vaccine goes into clinical trials, researchers already know that there is no chance it will cause HIV infection in humans because of the way the vaccines are designed.

During the trial, the researchers do not know what effect the vaccine will have. They do not know if it is completely safe (but they know it cannot cause HIV infection all by itself). They do not know how it will affect the risk of HIV infection or AIDS if a person becomes exposed to HIV through other means, such as sexual transmission or contact with contaminated needles – the level of risk may be less, the same, or more than if the individual did not receive the candidate vaccine.
# Understanding Placebo, Blinding, and Randomisation

<table>
<thead>
<tr>
<th>Concept</th>
<th>Explanation</th>
<th>Role play</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Placebo</strong></td>
<td>A placebo is a harmless, inactive substance that looks like a vaccine. Often, saline solution is used as the placebo. Sometimes a placebo is called a “blank”. The placebo is given to one group of volunteers while the candidate vaccine is given to another group. The group receiving the placebo is usually called the control group. It is only through the comparison of the vaccine and control groups that researchers can evaluate how well the vaccine works. Many clinical trials involve the use of a placebo. Since there are no vaccines against HIV that are effective, placebos are needed for the comparison.</td>
<td>Some of the syringes in the role play contain the placebo, while others contain the “vaccine”. On the outside, they look exactly the same, but the placebo syringes only contain a saline solution, which is inactive and will not cause any reaction in the volunteer’s body.</td>
</tr>
<tr>
<td><strong>Randomisation</strong></td>
<td>Participants in a trial are divided into the vaccine and placebo groups by chance. Neither the researchers nor the participants can decide if a participant gets the vaccine or placebo. Randomisation is the best way to make sure that the different testing groups have the same characteristics. If researchers or participants could choose which group to go into, the groups might be unfairly divided and not be comparable. If the groups were not comparable, the effects of the vaccine could not be measured accurately.</td>
<td>When the assigner picks a syringe for a volunteer, he/she picks it by chance. The assigner does not choose which volunteers get a placebo or the vaccine.</td>
</tr>
<tr>
<td><strong>Blinding</strong></td>
<td>Participants do not know whether they have received the experimental vaccine or the placebo. Therefore, they are “blind” to what was administered to them when they received an injection as part of the trial. The purpose of blinding is to make sure that side effects are not interpreted differently, based on whether someone has received the vaccine or the placebo. This decreases bias (unfairness) in the trial. For example, if people in the trial knew they got the experimental vaccine, they might report more side effects.</td>
<td>The volunteers do not know whether they receive the vaccine or a placebo.</td>
</tr>
<tr>
<td>Concept</td>
<td>Explanation</td>
<td>Role play</td>
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<tr>
<td>Double-blind</td>
<td>In many trials, neither the researchers nor the participants know who is getting the vaccine. This is called double-blinding. Double-blind ensures that researchers are not biased. If researchers know if a participant received the vaccine or a placebo, they may over- or under-report side effects. The individuals responsible for randomisation (usually statisticians, but never anyone on the clinical trial staff) keep the information in a safe location until the end of the study. Most clinical trials are double-blinded.</td>
<td>Even the doctor does not know which volunteers receive vaccine or placebo.</td>
</tr>
</tbody>
</table>
Participating in a Trial

Use the following information to prepare for your role. You may also reference Chapter 7 of the VaxLit Core Content for full details.

Eligibility requirements

Every trial has different requirements. In general, to join a preventive AIDS vaccine trial, a volunteer must meet the following criteria:

- Fully understand the trial and be willing to give informed consent
- Be healthy, as determined by medical history and physical examination
- Not be infected with HIV
- Match the protocol for age and health requirements
- Be willing to stay in the study for the amount of time required by the trial, generally up to 18 months for Phase I/II trials and up to four years for efficacy trials
- Women must not be pregnant and must use an effective contraceptive method for the period defined in the protocol
- Agree to risk-reduction counselling to prevent HIV, as well as HIV testing until a certain time has passed after the last injection

The screening process

Before a volunteer can enter into a trial, he/she must be screened. In most cases, a potential volunteer signs the informed consent form for the trial before entering the screening process.

In most cases, screening involves:

- Medical examination and history
- HIV counselling and testing
- Other blood tests, (e.g., checking the amount of iron in the blood or checking for diabetes)
- Urine tests
- Pregnancy test
- Questionnaire to check how well the potential volunteer understands the trial

The informed consent process

Each trial participant must give voluntary, informed consent before he/she enters into the screening process and trial.

Researchers must ensure that the individual has a full understanding of all aspects of trial participation, which involves extensive education for the individual. Other important aspects of supporting trial volunteers include conducting outreach with the broader community, particularly community leaders, to build general understanding and preparedness among the community at large. Building general education in a community about AIDS vaccine trials enhances individual knowledge and decreases any stigma that may exist around such research. Educating both potential volunteers and the greater community helps ensure that individuals are free and able to give true informed consent, should they decide to participate.
Responsibilities of participants during enrolment
Volunteers will have the following responsibilities while they are participating:
• Regularly visiting the trial centre to receive injections of the test vaccine or a placebo
• Undergoing regular drawing and testing of blood (only a small amount is taken)
• Receiving HIV counselling and testing
• Receiving risk-reduction counselling and practicing corresponding behaviours, such as practicing safer sex
• Agreeing not to get HIV tests outside of the trial
• Agreeing not to become pregnant and to use effective contraception

Placebo
A placebo is a harmless, inactive substance that looks like a vaccine. Often, saline solution is used as the placebo. A placebo is sometimes referred to as a “blank”.

The placebo is given to one group of volunteers, while the candidate vaccine is given to another group. The group receiving the placebo is usually called the ‘control group’. It is only through the comparison of the vaccine and control groups that researchers can evaluate how well the vaccine works.

Blinding
Participants do not know whether they have received the experimental vaccine or the placebo. Therefore, they are “blind” as to what was administered when they received an injection as part of the trial. A double-blinded trial is a trial in which neither the volunteers nor the researchers know who has received the vaccine or placebo. Most clinical vaccine trials are double-blinded.

The purpose of blinding is to make sure that side effects are not interpreted differently, based on whether someone has received the vaccine or the placebo. This decreases bias (unfairness) in the trial. For example, if people in the trial knew they got the experimental vaccine, they might report more side effects.

Falsely testing positive
When a person receives an experimental AIDS vaccine, his or her body may produce antibodies against HIV (see Chapter 3 of the VaxLit Core Content for further information). This response indicates that the immune system has developed antibodies that hopefully would protect the person from HIV infection. These may be the same types of antibodies that standard HIV tests look for.

There are several important points for volunteers to remember about this:
• Candidate vaccines used in humans cannot cause HIV infection.
• If volunteers in an AIDS vaccine trial test HIV positive on an antibody test, it does not necessarily mean that they are HIV-infected. If needed, more tests will be performed to distinguish between vaccine-induced antibodies and antibodies due to true HIV infection.
• While in the trial, volunteers should not have an HIV test outside the trial clinic. The researchers can tell the difference between vaccine-induced antibodies and true HIV infection, but a testing centre probably cannot.
• If a volunteer gets an HIV test outside the trial clinic that shows a positive result, this may be a false-positive result, meaning that the volunteer is not infected. Sometimes researchers refer to this as being “antibody positive” because the person is producing antibodies against HIV, but is not actually infected with the virus. In this case, it is important for the person to get an additional HIV test at the trial clinic.
• If volunteers need an HIV test for health or life insurance, travel or employment, they should get tested at the study site, not at another health clinic.
Confidentiality and protecting volunteers
The confidentiality of volunteers’ participation and their medical information is strictly upheld by the doctors conducting the trial.

Other ways that researchers ensure volunteers are fully protected when they participate in the trial include:
- Providing treatment for vaccine-related effects, such as sore arm or fever
- Helping volunteers avoid stigma and discrimination. For example, researchers may provide special ID cards or letters for insurance purposes in the case of false-positive HIV tests after vaccination (see section on previous page). Not all trials will provide this service in the same way.
- Consistent risk-reduction counselling for participants and partners, (in cases where partners give consent).
- Providing referral for available care in the case of someone becoming HIV-infected during the time that they are participating.

Contraception and pregnancy
Researchers do not know if a test vaccine will have any effects on a foetus if it is given to a pregnant woman. For this reason, female volunteers cannot be or become pregnant and are required to use a reliable form of contraception for at least four months after receiving the last vaccination. Female volunteers will have pregnancy tests at the time of screening, before each vaccination, and at some additional times. Male volunteers should also use condoms for at least four months after receiving the last vaccination to avoid pregnancy in a spouse or partner.

If a female participant becomes pregnant during the trial, she will not receive any further injections as part of the study. She will be monitored until the end of the trial and until the end of the pregnancy, and her baby will be examined during the first month of life to ensure that he or she is healthy.
Including Women in AIDS Vaccine Trials

Scientific reasons: Detecting differences in effect of a candidate AIDS vaccine

- Any one particular trial may not be able to conclusively determine whether the vaccine works differently for men than for women, but it can detect trends in the effect of vaccines.
- Past clinical trials have not always included enough women participants and sometimes have been unable to distinguish such trends.
- The VaxGen study in the US (2003), for example, claimed that the women in their study had lower rates of infection than men. But they also acknowledged that they did not have enough numbers of women in their trials to make significant conclusions.
- Generally, fewer women than men have volunteered in trials. The male-to-female ratio has varied according to the recruiting site and the initial population contacted.
- There are biological differences between men and women in risk of infection, which may correspond to a differential effect of the vaccine.
- The biological differences in vulnerability to HIV infection appear to be exacerbated based on age. Young women may be much more vulnerable to infection than their male counterparts, though we do not know how much of these differences are due to biology and how much to social and behavioural conditions.
- There are also conflicting reports on whether women taking hormonal contraceptives have an increased susceptibility to HIV infection, and if the vaccine has a different effect on women taking contraceptives.
- Viral loads (the amount of virus in the blood) following infection appear to differ between men and women. This could possibly have an impact on the effects of a vaccine, but there is no conclusive information yet.
- Progression of HIV may vary between men and women.

Ethical and social reasons

- The principles of health equity require that women be involved in all appropriate clinical research.
- Evidence shows that AIDS vaccine research programmes usually benefit all participants – those receiving the test vaccine and those receiving a placebo – because the education, counselling, and care components of these trials reduce every participant’s risk of contracting HIV. Excluding women from trials deprives them of these benefits.
- Nearly half of all new HIV infections worldwide now occur among women. Ethical principles of health equity therefore demand that women are enrolled in sufficient numbers in AIDS vaccine trials.

Licensure

- Regulatory authorities require that a product be tested in the populations in which it will be used.
- Enrolment of women is critical to assure that there is sufficient data for licensing the vaccine for use by both women and men.

However:

- Although it is recommended to enrol both men and women and, if possible, in equitable number, the total number of participants in Phase I are not sufficient to detect differences between men and women.
- It might be possible to make some gender comparison in Phase II trials for safety and immunogenicity.
- The gender comparison is critical for Phase III trials conducted in populations which may include injecting drug users, men who have sex with men, and sex workers.
## Characteristics of Trial Review

### Summary of types of review

In general, there are three types of review processes for any given trial: regulatory, scientific, and ethics.¹ Certain review committees may be involved in one or more of these areas depending on the structure and function of the committees in countries and institutions involved in a given trial protocol. The table below lists some of the characteristics of these three types of review.

<table>
<thead>
<tr>
<th>Focus</th>
<th>Regulatory</th>
<th>Scientific</th>
<th>Ethics</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Focus</strong></td>
<td>Reviews all relevant information about the product, including all previous tests (preclinical and clinical) done on the product and how it will be tested in humans, including protocol for testing the product, and the investigator's brochure.</td>
<td>Ensures that the trial is asking legitimate scientific questions and that the study is well designed to answer these questions.</td>
<td>Reviews all relevant information about the protocol, focusing on one study of the product to be conducted at a specific institution. Some also include review of the product, usually based on the investigator's brochure.</td>
</tr>
<tr>
<td><strong>Level of committee</strong></td>
<td>National, appointed by government, sometimes regional</td>
<td>Institution/university or country/national</td>
<td>Institution/university in most cases, national in some cases</td>
</tr>
<tr>
<td><strong>Materials reviewed</strong></td>
<td>Product-specific materials: entire package of information on preclinical and clinical testing of the product; its safety and biological effects; rationale for specific details of testing. Trial-specific materials (such as the protocol) are also reviewed.</td>
<td>Product- and trial-specific materials</td>
<td>Trial-specific materials: study protocol (including the informed consent document) and advertisements for study recruitment</td>
</tr>
<tr>
<td><strong>Examples</strong></td>
<td>United States Food and Drug Administration (FDA); National Council of Science and Technology of Government of Kenya</td>
<td>Institutional review board at an academic institution involved in the trial</td>
<td>Kenyatta National Hospital Ethical and Research Committee, a joint committee between the University of Nairobi and Kenyatta National Hospital</td>
</tr>
</tbody>
</table>

¹ In some cases, additional types of review in some countries may include biosafety or “genetically modified organism” committees, in which case trials must also be reviewed by existing committees.
The Challenges in Detail

This fact sheet should be copied and then cut into strips along the dotted lines for distribution to the five groups.

Global Funding, Finance Mechanisms, and Pricing

Financial mechanisms must be set up to ensure that vaccines are affordably priced and that there are sufficient funds in place to purchase and deliver vaccines as soon as a product is licensed. A large sum of money—likely billions of dollars—will be needed to purchase and deliver AIDS vaccines globally. Most of this funding will need to come from governments, especially in wealthy countries, as well as multinational funding bodies like the Global Fund to Fight AIDS, TB, and Malaria, and organisations like the World Bank.

To help guarantee sufficient funding, mechanisms for purchase and delivery can be put into place including, for example, “advance purchase commitments” from funders. If such commitments are made, governments will likely be more willing and able to create systems for delivery. Ensuring demand may also encourage investment by pharmaceutical and biotech firms who may be reluctant to invest in developing a product that might only have a small profit.

Tiered Pricing

Tiered pricing is one solution to the potentially high cost of an AIDS vaccine once it is on the market. This is when a vaccine is offered at different prices in different countries, based on a country’s ability to pay. Developing countries would receive the vaccine at a lower price, made possible by higher prices paid by developed countries. The system allows developing countries to receive favourable prices, but will also provide commercial firms with a reasonable profit on vaccine production.

Estimating Demand and Use

In order to plan for manufacturing and delivery of a vaccine it is important to predict the number of people who will be willing to be vaccinated as well as the number of people who will actually be vaccinated.

Potential factors that need to be taken into account in predicting demand and use include:

- The predicted level of efficacy of the vaccine
- Length of time a vaccine offers protection
- Number of doses required for protection
- Acceptability and likelihood of use (see above)
- Affordability and predicted price of the vaccine
- Country capacity for vaccine or service delivery

Information about the demand for an AIDS vaccine can help plan for production, delivery, education programmes, and financial needs.
Delivery

Unlike current vaccination programmes, most of which benefit children, AIDS vaccines will first be available for adults and adolescents who may be difficult to reach through current vaccine delivery systems. Efforts to reach populations at the greatest risk of infection, such as sex workers or injecting drug users, may be even more difficult. Strategies for delivery should be well planned and placed within broader national AIDS prevention agendas. They should also be compatible with national vaccine programmes.

A delivery strategy should address:

- Transportation
- Human resources
- Appropriate venues for delivering vaccines (e.g. clinics, community settings)
- Storage facilities and conditions
- Education and social marketing appropriate to specific populations
- Linkages with voluntary counselling and testing (VCT) systems

Regulatory Approval and Licensure

In order to make a vaccine available in a country, it must be licensed or approved by national regulatory authorities, such as a country’s Ministry of Health or the Food and Drug Administration (FDA) in the United States. Historically, there have been delays of several years between initial licensure in an industrialized country and widespread approval in developing countries. Vaccine developers often seek approval first in those places where there is a more profitable market, which is usually in industrialized or developed countries.

Approval of a new product requires review of a detailed record that presents the safety and efficacy of the vaccine. Since the approval process and the type of data needed for approval may vary between countries, vaccine developers may be required to prepare and submit multiple applications for approval. It is important to work with regulatory authorities when designing the clinical trials to ensure that the trial will provide the necessary data to support eventual licensure. Working with the appropriate authorities in advance may prevent unnecessary delays and assure a smoother approval process. Efforts to better coordinate and standardize regulatory processes across regions and internationally may facilitate approval.

Approval in some developing countries usually relies on prior approval by regulatory agencies in industrialized countries. Stronger regulatory review mechanisms are needed in developing countries, and should be better coordinated internationally. One potential approach is to pool expertise and resources across regions and link with more experienced regulatory bodies for technical support.

Manufacturing

Manufacturing an AIDS vaccine will require hundreds of millions of dollars (US) and entails two costly elements: building a large-scale manufacturing facility, and developing biological processes (“bioprocesses”) to produce large quantities of the vaccine.

It is likely to take at least five years to build sufficient capacity for manufacturing, so work should begin well in advance of vaccine availability. Policy action is needed to create incentive for large companies to work on scaling up manufacturing or to provide small biotechnology companies or academic developers with the resources to do this work. One effective way to achieve these goals is by creating partnerships between the public and private sectors.
Acceptability of an AIDS vaccine is important on various levels. If it is acceptable to policymakers and other influential people, they may be more willing to approve and license the vaccine, introduce the vaccine in-country and integrate it into the national health programme. If it is acceptable to the medical community and NGOs, they may be more willing to support and promote use of the vaccine. If it is acceptable to individuals and communities, they may be more willing to be vaccinated. Acceptability therefore affects accessibility and uptake of a vaccine. A number of factors may affect the level of acceptability of any particular AIDS vaccine:

**Efficacy level of the vaccine**

Just as no vaccine that is currently available for other diseases provides absolute protection to everyone who receives it, an AIDS vaccine will not offer full protection for everyone (see Chapter 4 of the VaxLit Core Content for more information on efficacy). The first generation of AIDS vaccines to be licensed and made available to the public may be of low-to-moderate efficacy in comparison to some vaccines that are available for the prevention of other diseases. The level of efficacy may influence acceptability on all levels. For example, the vaccine’s efficacy levels may be considered: by governments when deciding whether to make vaccines a public health priority; by medical providers in their decisions to promote and/or recommend their use; and by individuals in their decisions to use a vaccine. It is critically important that stakeholders at all levels understand the benefits of a partially effective vaccine when making decisions. Even an AIDS vaccine with relatively low efficacy would have a significant impact on the epidemic in high incidence countries if given to a large segment of the population.\(^1\)

An AIDS vaccine, as with any vaccine, must be combined with other prevention efforts and treatment programmes.

**Behaviour change**

Even though a partially effective vaccine can have a strong public health impact, the benefits could be diminished or lost if people’s risk behaviour increases. Some policymakers or medical providers might be concerned that if partially effective vaccines or microbicides\(^2\) are available, people who receive them will think they no longer need to practice other preventive behaviours. For instance, people may stop using condoms (sometimes referred to as **condom substitution**), they may not practice partner reduction, or they may begin needle sharing or other use of contaminated needles. Such behaviour change will potentially increase their risk for both HIV and other sexually transmitted infections (STIs). It is therefore essential that programmes continue to promote the existing prevention and risk-reduction strategies and integrate vaccines and microbicides into these programmes.

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\(^1\) BCG, the vaccine against tuberculosis, has proven to be only partially effective. The vaccine, however, is recommended for countries where TB is endemic since it will at least reduce the incidence of TB in the population. Another example of a common vaccine that is partially effective is the influenza vaccine.

\(^2\) You may need to assess your training audience to decide whether or not to address the issue of microbicides, since certain groups or individuals may not have any previous knowledge about them. Microbicide research is a complex topic and may be too confusing or distracting from vaccines. Please refer to the VaxLit Core Content for information on microbicides, as well as other sources for further information.
Product characteristics

The characteristics of any vaccine product are strong determinants of its acceptability to the end user. A vaccine that requires one or two doses will likely be more acceptable than a vaccine that requires multiple doses; an oral vaccine might be more acceptable than an injected vaccine for some people. Unfortunately, it is unlikely that scientists will have control over the vaccine characteristics given the difficulty of developing a vaccine.

Stigma and risk perception

As with other AIDS interventions, stigma and perceived risk are likely to affect access to and use of AIDS vaccines. First, stigma can affect risk perception. People often believe that only certain stigmatised groups (e.g., people who engage in “dangerous” sexual activities or drug use) are at risk of infection. They may not believe they are at risk or need to be vaccinated. Second, even if people do understand their risk of HIV infection and the benefits of vaccination, they might fear that they will be stigmatised or judged if they seek vaccination. Women in particular might fear that they will be accused of unfaithfulness, and they might experience violence from or abandonment by partners. These issues need to be addressed within vaccine delivery plans.

Myths and rumours

Undue fears, myths, and rumours about the vaccine may have a negative impact on acceptability at all levels. Some common concerns based on myths and rumours include:

- Worry that the vaccine may cause HIV infection
- Concern that any illness following vaccination is due to the vaccine
- Fear that the vaccine could cause sterility

Knowledge of AIDS vaccines and their potential benefit will have an impact on whether governments make vaccines a public health priority. It is important that AIDS advocates, community groups, and vaccine developers increase awareness and support among government officials to help ensure vaccine access.

In addition, to make sure that vaccines are accepted, supported, and used by the public, education campaigns should build knowledge among communities and societies about the characteristics, advantages, risks, and limitations of AIDS vaccines.

Delivering risk reduction education along with a vaccine

Since an AIDS vaccine will most likely be partially effective, it will be very important not to create a false sense of security among people who receive it. If people think they are fully protected against HIV infection, they may return to risky behaviour, increasing their vulnerability to HIV, the opposite of the vaccine’s intended effect.

It is therefore critical to promote risk-reduction behaviour along with an AIDS vaccine. Information on existing prevention methods, such as the use of condoms and clean needles, partner reduction, and abstinence, should be delivered with administration of the vaccine and will need to be incorporated into community AIDS education programmes. Stakeholders at all levels will need to understand the implications of efficacy and the importance of continued risk reduction, even after a vaccine is available to the general population.