Integrating Gender Issues Into AIDS Vaccine Clinical Research

A training manual for sub-Saharan Africa
Acknowledgements

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An online version of Integrating Gender Issues into AIDS Vaccine Clinical Research may be found at www.iavi.org/gendertraining

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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 appropriate and sustainable education and training mechanisms.
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The AIDS pandemic continues to devastate the world, affecting people in all regions, of all groups and at every stage in life. However, the disease is particularly destructive in sub-Saharan Africa, which is home to 68 percent of global HIV cases. Women there are particularly hard hit; almost 61 percent of those living with HIV in sub-Saharan Africa are women.¹

Women—young women in particular—are more susceptible to HIV than men. Women’s increased biological vulnerability to HIV, which is a factor based upon their sex, coupled with social and economic inequities, which are related to gender, fuel the epidemic [see box].

Traditional gender roles often result in power imbalances in relationships, affecting women’s ability to control or negotiate the terms of sexual relations and condom use. Poverty and reliance on men for economic support limit women’s power to protect themselves and force some to turn to transactional sex for survival. Also, cultural norms that preclude women’s access to information about sexuality, and the threat of violence or loss of economic support, can impede women’s ability to communicate with their partners about HIV prevention.

In addition to the impact of the disease itself on HIV-positive women, the burden of caring for those with HIV-related illnesses and for children orphaned by AIDS typically falls on women and girls. HIV-affected women and families are increasingly impoverished, further increasing their vulnerability to infectious diseases. Additionally, women who are infected with or affected by HIV often face stigma and discrimination, at times leading to ostracism, abuse and destitution.

Gender plays a prominent role in women’s susceptibility to HIV, but men also face particular vulnerabilities that are related to their gender, including social pressures to take risks, demonstrate their power and prove their manhood. These expectations can lead to behaviours such as having sex with multiple partners and avoiding services for HIV testing, prevention, treatment, care and support. Men are also socialized to be strong and therefore may not seek needed health services.

Furthermore, specific communities of men and women may be at an even higher risk for HIV, such as sex workers and men who have sex with men (MSM). For these vulnerable populations, their sexual identity and/or sexual practices can lead to stigma, discrimination and poverty.

It is important that research practices consider the needs and circumstances of trial volunteers, including married couples, women, MSM, sex workers and others. It is important that the research team conducting clinical trials and other clinical research is aware of how gender might affect volunteers’ participation. They should also understand the importance of enrolling equitable numbers of men and women in the trials, and ethical issues around gender and research. Empowering the research team members with better gender awareness and understanding will help them conduct more-efficient research with better outcomes for volunteers and communities.

This training manual aims to help improve awareness and understanding of the gender issues relevant to AIDS vaccine clinical research. It is intended to serve as a resource for trainers with background knowledge or experience in gender issues, AIDS vaccine research and participatory training. The manual does not include information on general AIDS vaccine literacy. Participants should receive this training separately.\(^2\)

**The objectives of this training are:**

- To equip participants with information on what gender is and its impact on health.
- To help participants understand how gender roles and social factors such as class, race, ethnicity, marital status, disability and age contribute to individuals’ vulnerability to HIV.
- To help participants understand the importance of gender when conducting AIDS vaccine clinical research.
- To support participants in identifying gender-sensitive approaches that can be applied in the conduct of AIDS vaccine research.

**Potential workshop participants include:**

- Staff at clinical research centres, including principal investigators, clinicians, counsellors and others.
- Members of community groups involved in volunteer recruitment and in supporting the conduct of research studies.
- Representatives from other organisations involved in HIV prevention programmes and clinical research.

The training exercises in this manual provide a flexible framework that should guide but not dictate the trainer’s agenda for a particular set of participants. Although agendas are suggested, each trainer should choose the combination of sessions that suits the needs of his or her group. For some sessions, alternate case studies are provided for audiences in Southern Africa or East Africa. However, each trainer should assess the appropriateness of the materials and adjust them accordingly.

The primary goal of this manual is to facilitate training workshops that will improve awareness and understanding among those involved in carrying out AIDS vaccine clinical research of the impact of gender and other social factors on men’s and women’s vulnerability to HIV, their general health and well-being, and their participation in AIDS vaccine clinical research. The secondary goal of this manual is to promote improvements to operations, procedures, materials and messages related to gender in the conduct of AIDS vaccine research.

### Selecting Trainers

The trainers who facilitate this workshop should have experience in the following areas: participatory training, gender and AIDS vaccine clinical research. These skills can be covered by a combination of two or three trainers, or by just one. Gender or participatory training experts without experience in AIDS vaccine research should undergo training in vaccine literacy prior to leading this workshop.

### Recommended Publications


### Recommended Websites


### Workshop Preparation

The workshop group can include both men and women and should not exceed 25 participants. This should help maximize effective participation and dialogue. Participants might include members of the clinical research team, others working in cooperation with the research centre, members of community groups and representatives from civil society organisations or other agencies working on HIV prevention research. The diversity of participants along the spectrums of profession, education, gender, ethnicity, income and social standing should be considered when the trainer is putting together a group and
selecting sessions. Although research centre staff and others at all levels are encouraged to participate fully in the workshop, it may be appropriate to conduct certain sessions in a targeted manner based on participants’ background or roles. Sample workshop agendas with suggested sessions are provided in the following section.

Facilitation Methods
Trainers should utilize principles of adult learning while recognizing the level of experience that participants have in the areas of gender issues and AIDS vaccine research. An effective trainer will draw on the skills and personalities in the group to conduct an engaging and effective workshop. The following participatory training methods might be helpful to the trainer:

Experience Sharing
This involves giving selected participants or invited speakers the opportunity to share parts of their life histories relevant to the topics at hand. This is a way to give a human side to the topics addressed. Care should be taken to ensure that speakers stick to the topic and time allocated.

Presentation by Facilitator
This method is commonly referred to as “lecture method”. Though this method has been criticized for being teacher/facilitator centred and reducing participants to passive listeners, it is nevertheless suitable, especially when introducing topics that may be outside the experience of the participants. However, the facilitator should present the information in a manner that elicits responses from the group, thereby initiating an interactive learning process. The presentation by the facilitator can be enhanced through:

- Use of anecdotes/humour/analogues
- Providing handouts
- Use of PowerPoint or overhead projectors
- Use of audio-visual resources
- Asking questions and eliciting responses from participants

Small Group Discussion
The main objective of small group discussions is to ensure maximum participation of all those involved and to help them develop new insights. Small groups of four or five people are best because participation is maximized and conversations are more meaningful. This is because:

- Participants interact at a more personal level in a small group than in a large group.
- Participants are less intimidated to speak in front of fewer people.
- Participants may more readily exchange and discuss ideas.
The following areas should be considered in group work/discussion sessions:

- The topic
- The objective
- Tasks to be assigned to the groups
- Desired level of participation
- Resources available
- Time management
- Composition of the group, including gender
- Seating arrangements

Each group should have a chairperson and a note taker. The gist of the proceedings should be recorded on a flip chart for ease of reporting. The groups should then report back in plenary using the flip chart, and the facilitator should synthesize and clarify any issues that have come up.

**Role Play**

Another method that facilitates participation and enhances creativity is role play, in which a situation is “simulated”. Participants are given a hypothetical situation and are expected to act as their “character” would in a real situation. Participants who are not acting out roles serve as critics as well as the audience. At the end of the role play, the facilitator guides the group discussion.

*Steps in role play:*

- Choose an appropriate topic.
- Discuss the topic and the experiences associated with it.
- Structure ideas on the flip chart, outlining the theme in an order that can be acted out.
- Decide on who should play which role.
- Establish a time frame for the exercise: 5 to 10 minutes is usually sufficient for a role play.
- Conduct a brief rehearsal to encourage the actors to speak loudly and clearly, to use props, and to make the role play realistic, humorous and engaging.

It is not necessary for the role play to involve scripts, costumes or significant preparation. It should be informal and fun. The group discussion should concentrate on the beliefs, attitudes and biases demonstrated by the characters. The takeaways from the role play should be listed on a flip chart.

**Case Study**

The case study involves a real-life or imaginary case, which is often examined in small groups before it is discussed in plenary. The facilitator presents the facts of the case, and the participants are asked to suggest solutions and give their opinions. The facilitator should not dictate the best solution or criticize the contributions from the group.
Questions to consider when choosing a case study

- Is it relevant to the objectives of the session?
- Is it realistic?
- Is there enough time to review and discuss the case?
- Are the issues to be discussed clear to the reader?
- Are the problems solvable?

Case study methods:

- The facilitator introduces the case and gives clear tasks.
- Participants read and analyse the case.
- Small group discussion.
- Plenary report back and discussions.
- Facilitator summarizes and records key learning points on a flip chart.

Brainstorming

Brainstorming involves quick group discussion about a topic. It encourages creativity and quick generation of ideas. It is effective in building consensus around contentious issues. The issues raised in a brainstorm exercise are often written on a flip chart.

Buzzing

The term “buzzing” is derived from the sound bees make as they go about their chores. As a facilitation method, it has been described as “to whisper or spread secretly” and involves groups of two or three engaged in brief discussion in the middle of a long session or presentation.

Buzzing economizes on time as participants turn to those nearest them for a brief interaction. The facilitator should control reporting to the plenary to avoid repetition and unnecessary elaborations.

Songs and Stories

Songs and stories are rich sources of information about cultural beliefs, practices and attitudes. They help in drawing out stereotypes, arousing interest and encouraging participation. After a brief presentation of a relevant song or narrative, the facilitator should guide participants in identifying learning points from the story.

Resource Persons

Resource persons are usually experts on a certain issue or people with experiences relevant to the workshop. Such resource persons should be chosen carefully and might include people living with HIV; former clinical trial volunteers; survivors of domestic abuse; clinical staff working on HIV preventions, treatment or research; or community leaders. In each case, the facilitator should carefully prepare the resource person and the group so that everyone is aware of the topic to be discussed and the etiquette for the discussion. The facilitator and the group should be especially vigilant about ethical considerations when dealing with individuals representing key populations at higher
risk of HIV. After the resource person’s presentation, learning points should be identified and discussed in plenary.

The methodologies identified here are not exhaustive. Facilitators are encouraged to be as creative as possible in identifying relevant training methodologies to reap maximum benefits.

Guiding Principles for Leading the Workshop

Strong methods alone cannot ensure that the objectives of a given training are achieved. Preparation and skill are also necessary. The following principles will help trainers conduct effective workshops:

- Prepare for the workshop—master the content and the facilitation methods.
- Have an agenda.
- Clearly state the objectives of the overall workshop and each session.
- Be clear and concise.
- Use simple, but not simplistic, language.
- Do not teach—instead, guide the learning process.
- Be interactive and engaging.
- Avoid the temptation to evaluate contributions from participants in terms of correct or incorrect.
- Avoid the temptation to impose personal views—instead, guide the discussion to the important learning points.
- Allow time for the group to respond to presentations, activities, etc.
- Record important discussion and learning points on a flip chart.
- Acknowledge, validate and record each participant’s contributions when appropriate.
This manual is designed to be flexible to meet the particular needs of the organizer and attendees, taking into consideration participants’ backgrounds and expertise and the time and resources available for the workshop. The sample agendas below are suggestions. The workshop organizer and trainer should use these as a guide for selecting the sessions that they deem most suitable for a particular audience and setting.

To complete every session in the manual would require at least a three-day workshop. The manual is designed to be flexible so that shorter workshops and variations on exercises can be used. To create more space in the daily schedule, the organizer and trainer could distribute the Pre-Training Questionnaire to participants in advance of the workshop and ask them to complete it before arriving.

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### One-day workshop agenda

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<th>MODULES/SESSIONS</th>
<th>FACILITATOR</th>
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<td>8:00 to 8:30</td>
<td>Climate setting, Introduction, Expectations, Objectives, Ground rules</td>
<td>Introduction</td>
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<tr>
<td>8:30 to 9:00</td>
<td>Pre-training evaluation</td>
<td>Introduction</td>
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<tr>
<td>9:00 to 9:45</td>
<td>Sex and gender</td>
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<td>9:45 to 10:00</td>
<td>Game handout (page viii)</td>
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<tr>
<td>10:00 to 10:30</td>
<td>Tea break</td>
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<tr>
<td>10:30 to 11:30</td>
<td>Gender-related barriers to participation in AIDS vaccine clinical research</td>
<td>Session 5.4</td>
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<tr>
<td>11:30 to 12:30</td>
<td>Gender and counselling in AIDS vaccine clinical research</td>
<td>Session 5.6</td>
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<tr>
<td>12:30 to 1:30</td>
<td>Lunch</td>
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<td>1:30 to 2:30</td>
<td>Influence of gender and other socio-economic factors on participation in AIDS vaccine clinical research</td>
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<tr>
<td>2:30 to 3:15</td>
<td>Attitudes about gender in AIDS vaccine research</td>
<td>Session 3.4</td>
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<tr>
<td>3:15 to 4:15</td>
<td>Addressing gender issues in AIDS vaccine clinical research</td>
<td>Session 5.5</td>
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<tr>
<td>4:15 to 4:45</td>
<td>Post-training evaluation</td>
<td>Introduction</td>
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<tr>
<td>4:45 to 5:00</td>
<td>Workshop wrap-up</td>
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# Two-day workshop agenda

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<th>FACILITATOR</th>
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</table>
| 8:00 to 8:30 | Climate setting  
Introduction  
Expectations  
Objectives  
Ground rules | Introduction         |             |
| 8:30 to 9:00 | Pre-training evaluation                                                   | Introduction       |             |
| 9:00 to 9:45 | Sex and gender                                                           | Session 2.1        |             |
| 9:45 to 10:30 | Gender and HIV and AIDS                                                   | Session 3.2        |             |
| 10:30 to 11:00 | Tea break                                                                |                    |             |
| 11:00 to 12:15 | Sexuality, sexual health and gender identity                             | Session 4.1        |             |
| 12:15 to 1:00 | Sexual practices and vulnerability to HIV                                 | Session 4.2        |             |
| 1:00 to 2:00 | Lunch                                                                    |                    |             |
| 2:00 to 3:00 | The importance of language                                               | Session 2.5        |             |
| 3:00 to 3:30 | Gender-equitable enrolment in AIDS vaccine clinical research             | Session 5.1        |             |
| 3:30 to 4:30 | Gender-related barriers to participation in AIDS vaccine clinical research | Session 5.4        |             |
| 4:30 to 5:00 | Wrap-up and tea break                                                    |                    |             |

## DAY TWO

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<td>8:30 to 9:00</td>
<td>Definition game</td>
<td>Session 2.4</td>
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<td>Working with stigmatized populations: Participation and social impact</td>
<td>Session 5.3</td>
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<td>Session 3.4</td>
<td></td>
</tr>
<tr>
<td>2:30 to 3:00</td>
<td>Gender-based violence and AIDS vaccine clinical research</td>
<td>Session 5.7</td>
<td></td>
</tr>
<tr>
<td>3:00 to 4:00</td>
<td>Addressing gender issues in AIDS vaccine clinical research</td>
<td>Session 5.5</td>
<td></td>
</tr>
<tr>
<td>4:00 to 4:30</td>
<td>Post-training evaluation</td>
<td>Introduction</td>
<td></td>
</tr>
<tr>
<td>4:30 to 5:00</td>
<td>Workshop wrap-up</td>
<td>Module 6</td>
<td></td>
</tr>
</tbody>
</table>

### Three-day workshop agenda

#### DAY ONE

<table>
<thead>
<tr>
<th>TIME</th>
<th>TOPIC(S)</th>
<th>MODULES/SESSIONS</th>
<th>FACILITATOR</th>
</tr>
</thead>
<tbody>
<tr>
<td>9:00 to 9:30</td>
<td>Climate setting</td>
<td>Introduction</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Introduction</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Expectations</td>
<td></td>
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</tr>
<tr>
<td></td>
<td>Objectives</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Overview of the training programme</td>
<td></td>
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</tr>
<tr>
<td></td>
<td>Ground rules</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9:30 to 10:00</td>
<td>Pre-training evaluation</td>
<td>Introduction</td>
<td></td>
</tr>
<tr>
<td>10:00 to 10:30</td>
<td>Tea break</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10:30 to 11:15</td>
<td>Sex and gender</td>
<td>Session 2.1</td>
<td></td>
</tr>
<tr>
<td>11:15 to 12:00</td>
<td>Gender and HIV and AIDS</td>
<td>Session 3.2</td>
<td></td>
</tr>
<tr>
<td>12:00 to 1:00</td>
<td>Gender-based violence and HIV and AIDS</td>
<td>Session 3.3</td>
<td></td>
</tr>
<tr>
<td>1:00 to 2:00</td>
<td>Lunch</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2:00 to 3:15</td>
<td>Case study: Gender norms and women’s vulnerability</td>
<td>Session 2.6</td>
<td></td>
</tr>
<tr>
<td>3:15 to 4:30</td>
<td>Gender and society</td>
<td>Session 2.2</td>
<td></td>
</tr>
<tr>
<td>4:30 to 5:00</td>
<td>Gender-equitable enrolment in AIDS vaccine clinical research</td>
<td>Session 5.1</td>
<td></td>
</tr>
</tbody>
</table>
### DAY TWO

<table>
<thead>
<tr>
<th>TIME</th>
<th>TOPIC(S)</th>
<th>MODULES/SESSIONS</th>
<th>FACILITATOR</th>
</tr>
</thead>
<tbody>
<tr>
<td>8:30 to 9:00</td>
<td>Review of Day 1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9:00 to 10:00</td>
<td>Sexuality, sexual health and gender identity</td>
<td>Session 4.1</td>
<td></td>
</tr>
<tr>
<td>10:00 to 10:30</td>
<td>Tea break</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10:30 to 11:15</td>
<td>Myths and misperceptions regarding sexuality</td>
<td>Session 4.3</td>
<td></td>
</tr>
<tr>
<td>11:15 to 12:15</td>
<td>Legal and social context of sexuality and sexual practice</td>
<td>Session 4.4</td>
<td></td>
</tr>
<tr>
<td>12:15 to 1:00</td>
<td>Sexual practices and vulnerability to HIV</td>
<td>Session 4.2</td>
<td></td>
</tr>
<tr>
<td>1:00 to 2:00</td>
<td>Lunch</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2:00 to 2:45</td>
<td>Attitudes about gender in AIDS vaccine research</td>
<td>Session 3.4</td>
<td></td>
</tr>
<tr>
<td>2:45 to 3:30</td>
<td>Gender-related barriers to participation in AIDS vaccine clinical research</td>
<td>Session 5.4</td>
<td></td>
</tr>
<tr>
<td>3:30 to 4:30</td>
<td>Influence of gender and other socio-economic factors on participation in AIDS vaccine clinical research</td>
<td>Session 5.2</td>
<td></td>
</tr>
<tr>
<td>4:30 to 5:00</td>
<td>Definition game</td>
<td>Session 2.4</td>
<td></td>
</tr>
</tbody>
</table>

### DAY THREE

<table>
<thead>
<tr>
<th>TIME</th>
<th>TOPIC(S)</th>
<th>MODULES/SESSIONS</th>
<th>FACILITATOR</th>
</tr>
</thead>
<tbody>
<tr>
<td>8:30 to 9:00</td>
<td>Review of Day 2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9:00 to 10:00</td>
<td>Character role-play</td>
<td>Session 2.3</td>
<td></td>
</tr>
<tr>
<td>10:00 to 10:30</td>
<td>Tea break</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10:30 to 11:30</td>
<td>Working with stigmatised populations: Participation and social impact</td>
<td>Session 5.3</td>
<td></td>
</tr>
<tr>
<td>11:30 to 12:30</td>
<td>Gender and counselling in AIDS vaccine clinical research</td>
<td>Session 5.6</td>
<td></td>
</tr>
<tr>
<td>12:30 to 1:00</td>
<td>Gender-based violence and AIDS vaccine clinical research</td>
<td>Session 5.7</td>
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<tr>
<td>1:00 to 2:00</td>
<td>Lunch</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2:00 to 3:00</td>
<td>Addressing gender issues in AIDS vaccine clinical research</td>
<td>Session 5.5</td>
<td></td>
</tr>
<tr>
<td>3:00 to 3:30</td>
<td>Post-training evaluation</td>
<td>Introduction</td>
<td></td>
</tr>
<tr>
<td>3:30 to 4:00</td>
<td>Workshop wrap-up</td>
<td>Module 6</td>
<td></td>
</tr>
</tbody>
</table>
Pre-/Post-Training Evaluation

OBJECTIVE
To assess participants’ knowledge and attitudes regarding HIV and AIDS, gender, sexuality and AIDS vaccine clinical trials and research.

METHODOLOGY
Questionnaire

TIME
30 minutes

MATERIALS

Handouts: Pre-Workshop Questionnaire
Questionnaire Answer Key

PREPARATION
Make copies of Pre-Test Questionnaire and Questionnaire Answer Key for all participants.

INSTRUCTIONS TO FACILITATOR
This questionnaire should be completed by all workshop participants before any sessions are conducted and again after they have completed the workshop. The questionnaire should be given so that participants can respond anonymously. Either names can be left off and the scores can be added up to see if the group as a whole improves, or unique symbols can be written on each pre-test questionnaire and participants can be asked to remember their symbol to match the post-test questionnaire. Participants can then examine and discuss any changes in their responses from the pre-test.

DELIVERY
Step one: Ask participants to create a two-letter, two-number code that they will remember at the end of the workshop. Instruct them to record this code, not their names, on the questionnaire. Explain that this is to keep their responses confidential and anonymous while enabling documentation of the workshop’s impact.

Step two: Distribute the questionnaire to the participants.

Step three: Explain the purpose of the questionnaire: to document the impact of the workshop through before-and-after/pre- and post-workshop questionnaires.

Step four: Collect a questionnaire from each participant before beginning workshop sessions.

Step five: Using the answer key provided, total the number of correct responses in each section. Keep this score for comparison with the post-test questionnaire.

CLOSING
Assure participants that it is okay if they were unsure about some of the answers, since the purpose of the training is to clear up their uncertainties. Tell them that they will have the opportunity to complete another questionnaire after the training is finished.
Pre-Workshop Questionnaire

Personal code (please remember this):

Instructions Please create a two-letter, two-number code that you will remember at the end of the workshop. Write this code at the top of this questionnaire. Please DO NOT WRITE YOUR NAME ON THIS DOCUMENT. Please tick the appropriate box to indicate whether the following relate to sex, gender, both or neither.

GENDER OR SEX

1. Biological differences between males and females.
   - SEX
   - GENDER
   - BOTH
   - NEITHER

2. People's ideas about typical male or female characteristics.
   - SEX
   - GENDER
   - BOTH
   - NEITHER

3. Societal expectations about men’s and women’s behaviour.
   - SEX
   - GENDER
   - BOTH
   - NEITHER

4. Men’s and women’s political power.
   - SEX
   - GENDER
   - BOTH
   - NEITHER

5. Social inequalities that can impact or increase exposure to health risk factors.
   - SEX
   - GENDER
   - BOTH
   - NEITHER

6. Women’s vulnerability to HIV.
   - SEX
   - GENDER
   - BOTH
   - NEITHER

7. Ability to give birth and breastfeed children.
   - SEX
   - GENDER
   - BOTH
   - NEITHER

8. Expected roles for men and women in society.
   - SEX
   - GENDER
   - BOTH
   - NEITHER

   - SEX
   - GENDER
   - BOTH
   - NEITHER

10. Ability to produce sperm or eggs.
    - SEX
    - GENDER
    - BOTH
    - NEITHER
Instructions  Please tick (agree/disagree/uncertain) based on your knowledge and perceptions.

GENDER IN GENERAL

11. A woman can protect herself from HIV by simply insisting on safe sex.

   AGREE  [ ]    DISAGREE [ ]    UNCERTAIN [ ]

12. Stigma can make it difficult for men who have sex with men to get accurate information about HIV and AIDS.

   AGREE  [ ]    DISAGREE [ ]    UNCERTAIN [ ]

13. Men who have sex with men never get married.

   AGREE  [ ]    DISAGREE [ ]    UNCERTAIN [ ]

14. Societal expectations of men’s knowledge and sexual behaviour can put them at risk for HIV infection.

   AGREE  [ ]    DISAGREE [ ]    UNCERTAIN [ ]

15. It is inappropriate for women to desire sex.

   AGREE  [ ]    DISAGREE [ ]    UNCERTAIN [ ]

16. Maleness and femaleness are entirely determined by differences in reproductive systems and hormonal variations.

   AGREE [ ]    DISAGREE [ ]    UNCERTAIN [ ]

17. Although in many societies women have less access to economic resources, they usually have equal status with men.

   AGREE  [ ]    DISAGREE [ ]    UNCERTAIN [ ]

18. “Good women” should know little about sexual matters.

   AGREE [ ]    DISAGREE [ ]    UNCERTAIN [ ]

19. Women who carry condoms are “loose”.

   AGREE [ ]    DISAGREE [ ]    UNCERTAIN [ ]

20. Because they have the capacity for motherhood, women are more caring than men.

   AGREE  [ ]    DISAGREE [ ]    UNCERTAIN [ ]

21. Women who have HIV must have done something wrong to become infected.

   AGREE [ ]    DISAGREE [ ]    UNCERTAIN [ ]

22. A married woman should be able to decide not to have sex with her husband.

   AGREE  [ ]    DISAGREE [ ]    UNCERTAIN [ ]

23. It is immoral for women to seek pleasure in sex.

   AGREE  [ ]    DISAGREE [ ]    UNCERTAIN [ ]

24. Female sex workers should be held responsible for spreading HIV.

   AGREE  [ ]    DISAGREE [ ]    UNCERTAIN [ ]
GENDER AND AIDS VACCINE RESEARCH

25. The personal beliefs that AIDS vaccine research staff hold about gender roles can impact the way they treat study volunteers.

AGREE □  DISAGREE □  UNCERTAIN □

26. People who volunteer for AIDS vaccine research should not be worried about negative consequences in their family or community.

AGREE □  DISAGREE □  UNCERTAIN □

27. A married woman who wants to volunteer for AIDS vaccine research should ask her husband’s permission to participate.

AGREE □  DISAGREE □  UNCERTAIN □

28. Research staff should take the same clinical safety precautions when working with married women as when working with female sex workers.

AGREE □  DISAGREE □  UNCERTAIN □

29. Women who have children should not volunteer for AIDS vaccine research.

AGREE □  DISAGREE □  UNCERTAIN □

30. Female and male volunteers face the same obstacles to participating in AIDS vaccine research.

AGREE □  DISAGREE □  UNCERTAIN □

31. Men and women experience the informed consent process in the same way because they consider identical risks and benefits in their decision to participate in AIDS vaccine research.

AGREE □  DISAGREE □  UNCERTAIN □

32. Female volunteers may face difficulty in making an independent decision about whether to participate in AIDS vaccine research because others, such as their husbands, might exert control over them.

AGREE □  DISAGREE □  UNCERTAIN □

33. Volunteers should always share their HIV test results with their partners, no matter what.

AGREE □  DISAGREE □  UNCERTAIN □

34. If a woman is afraid to share her test results with her husband, the clinic or research centre should always do it for her.

AGREE □  DISAGREE □  UNCERTAIN □

35. Women who become pregnant while participating in AIDS vaccine research are irresponsible.

AGREE □  DISAGREE □  UNCERTAIN □

36. A man is always the person infected with HIV in a discordant couple.

AGREE □  DISAGREE □  UNCERTAIN □
Pre-Workshop Questionnaire—Answer Key

GENDER OR SEX

1. Biological differences between males and females.
   - SEX □
   - GENDER □
   - BOTH □
   - NEITHER □

2. People’s ideas about typical male or female characteristics.
   - SEX □
   - GENDER □
   - BOTH □
   - NEITHER □

3. Societal expectations about men’s and women’s behaviour.
   - SEX □
   - GENDER □
   - BOTH □
   - NEITHER □

4. Men’s and women’s political power.
   - SEX □
   - GENDER □
   - BOTH □
   - NEITHER □

5. Social inequalities that can impact or increase exposure to health risk factors.
   - SEX □
   - GENDER □
   - BOTH □
   - NEITHER □

6. Women’s vulnerability to HIV.
   - SEX □
   - GENDER □
   - BOTH □
   - NEITHER □

7. Ability to give birth and breastfeed children.
   - SEX □
   - GENDER □
   - BOTH □
   - NEITHER □

8. Expected roles for men and women in society.
   - SEX □
   - GENDER □
   - BOTH □
   - NEITHER □

   - SEX □
   - GENDER □
   - BOTH □
   - NEITHER □

10. Ability to produce sperm or eggs.
    - SEX □
    - GENDER □
    - BOTH □
    - NEITHER □

Instructions
Please tick (agree/disagree/uncertain) based on your knowledge and perceptions.

GENDER IN GENERAL

11. A woman can protect herself from HIV by simply insisting on safe sex.
    - AGREE □
    - DISAGREE □
    - UNCERTAIN □

12. Stigma can make it difficult for men who have sex with men to get accurate information about HIV and AIDS.
    - AGREE □
    - DISAGREE □
    - UNCERTAIN □

13. Men who have sex with men never get married.
    - AGREE □
    - DISAGREE □
    - UNCERTAIN □

---

Some of the following questions were adapted from: Medical Women’s International Association. 2002. Training Manual for Gender Mainstreaming in Health.
14. Societal expectations of men’s knowledge and sexual behaviour can put them at risk for HIV infection.

AGREE □ DISAGREE □ UNCERTAIN □

15. It is inappropriate for women to desire sex.

AGREE □ DISAGREE □ UNCERTAIN □

16. Maleness and femaleness are entirely determined by differences in reproductive systems and hormonal variations.

AGREE □ DISAGREE □ UNCERTAIN □

17. Although in many societies women have less access to economic resources, they usually have equal status with men.

AGREE □ DISAGREE □ UNCERTAIN □

18. “Good women” should know little about sexual matters.

AGREE □ DISAGREE □ UNCERTAIN □

19. Women who carry condoms are “loose”.

AGREE □ DISAGREE □ UNCERTAIN □

20. Because they have the capacity for motherhood, women are more caring than men.

AGREE □ DISAGREE □ UNCERTAIN □

21. Women who have HIV must have done something wrong to become infected.

AGREE □ DISAGREE □ UNCERTAIN □

22. A married woman should be able to decide not to have sex with her husband.

AGREE □ DISAGREE □ UNCERTAIN □

23. It is immoral for women to seek pleasure in sex.

AGREE □ DISAGREE □ UNCERTAIN □

24. Female sex workers should be held responsible for spreading HIV.

AGREE □ DISAGREE □ UNCERTAIN □

GENDER AND AIDS VACCINE RESEARCH

25. The personal beliefs that AIDS vaccine research staff hold about gender roles can impact the way they treat study volunteers.

AGREE □ DISAGREE □ UNCERTAIN □

26. People who volunteer for AIDS vaccine research should not be worried about negative consequences in their family or community.

AGREE □ DISAGREE □ UNCERTAIN □

27. A married woman who wants to volunteer for AIDS vaccine research should ask her husband’s permission to participate.

AGREE □ DISAGREE □ UNCERTAIN □
28. Research staff should take the same clinical safety precautions when working with married women as when working with female sex workers.

AGREE ✓ DISAGREE □ UNCERTAIN □

29. Women who have children should not volunteer for AIDS vaccine research.

AGREE □ DISAGREE ✓ UNCERTAIN □

30. Female and male volunteers face the same obstacles to participating in AIDS vaccine research.

AGREE □ DISAGREE ✓ UNCERTAIN □

31. Men and women experience the informed consent process in the same way because they consider identical risks and benefits in their decision to participate in AIDS vaccine research.

AGREE □ DISAGREE ✓ UNCERTAIN □

32. Female volunteers may face difficulty in making an independent decision about whether to participate in AIDS vaccine research because others, such as their husbands, might exert control over them.

AGREE ✓ DISAGREE □ UNCERTAIN □

33. Volunteers should always share their HIV test results with their partners, no matter what.

AGREE □ DISAGREE ✓ UNCERTAIN □

34. If a woman is afraid to share her test results with her husband, the clinic or research centre should always do it for her.

AGREE □ DISAGREE ✓ UNCERTAIN □

35. Women who become pregnant while participating in AIDS vaccine research are irresponsible.

AGREE □ DISAGREE ✓ UNCERTAIN □

36. A man is always the person infected with HIV in a discordant couple.

AGREE □ DISAGREE ✓ UNCERTAIN □
1.1 Workshop Objectives and Participant Expectations

**OBJECTIVES**
1. To introduce participants to the purpose and background of the workshop.
2. To create a supportive learning environment.
3. To set appropriate expectations about the information to be covered and outcomes of the workshop.

**METHODOLOGY**
Introduction in pairs and slide presentation

**TIME**
30 minutes

**MATERIALS**
- Flip chart/chalkboard/marker board
- Markers/chalk
- Overhead/PowerPoint projector

*Slides: Workshop Objectives
Learning Objectives*

**PREPARATION**
Prepare slides.

**INSTRUCTIONS TO FACILITATOR**
This session should be adapted based on the amount of time available for the workshop and how well the participants are acquainted with one another. If participants do not know one another well, this session should be incorporated into a three-day workshop. For a one-day session with participants from a single research centre, STEPS TWO through FIVE can be skipped or modified.

**DELIVERY**

**Step one:** Welcome the participants and provide background and context to the training.

**Step two:** Ask participants to stand and pair up with a person close to them.

**Step three:** Instruct the paired-off partners to introduce themselves to each other by stating:

- Their name and title
- Their profession or occupation
- Two expectations they have for the workshop
An interesting fact about themselves (e.g., something no one in the room knows about them, or a favourite musician or dish)

**Step four:** Instruct participants to make a note of their partner’s name and expectations for the workshop.

**Step five:** Ask people to introduce their partner and his or her expectations. If there is time, ask them to share an interesting fact about them as well.

**Step six:** List the expectations on the flip chart.

**Step seven:** Present the following slide:

### Workshop Objectives

1. To equip participants with adequate knowledge and information on what gender is and its impact on health.

2. To help participants understand how gender roles and social factors, such as class, race, ethnicity, marital status, disability and age contribute to individuals’ vulnerability to HIV.

3. To enable participants to understand the importance of gender in the conduct of AIDS vaccine clinical research.

4. To support participants in identifying gender-sensitive approaches that can be applied at each stage in the conduct of AIDS vaccine research.

**Step eight:** Present the following slide:

### Learning Objectives

*By the end of the training, participants should be able to:*

1. Describe the conceptual differences between sex and gender and how gender roles impact men’s and women’s vulnerability to HIV.

2. Identify obstacles to recruitment and retention of volunteers, especially women and MSM and other vulnerable populations, in AIDS vaccine clinical research.

3. Describe how gender—and research staff members’ attitudes about gender— influence a volunteer’s experience participating in AIDS vaccine research.

4. Develop and apply gender-sensitive strategies in recruitment and retention of volunteers and other practices and processes involved in the conduct of AIDS vaccine clinical research.

5. Apply a gender lens to all phases and stages of AIDS vaccine clinical trials.
Step nine: Explain to participants which of their expectations should be met by the workshop and which ones may not. It is important to provide reasons why certain expectations may be outside the scope of the workshop.

Step 10: Introduce and discuss the following points:

- Although some groups, societies or religions may have different beliefs about gender issues than what is presented in this workshop, participants are encouraged to look beyond pre-existing beliefs and, for the benefit of their work in HIV research, to consider the issues presented here with as open a mind as possible.

- Gender issues vary in AIDS vaccine research depending on the target population and the type of study.

- As the participants proceed through the training, they should bear in mind that not all activities and points discussed may be relevant to a particular study.

- Information will be shared during the workshop that will help participants in their work. However, they must apply discretion when determining what and how they communicate with study volunteers.

CLOSING

Describe the structure of the workshop, including the schedule, group norms, sessions to be covered and any appropriate administrative details.
2.0 Background Primer: Information for the Facilitator

INSTRUCTIONS TO THE FACILITATOR
Review this information prior to conducting training Module 2—Understanding Gender.

<table>
<thead>
<tr>
<th>SESSION</th>
<th>TITLE</th>
<th>TOPICS ADDRESSED</th>
<th>TIME</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.0</td>
<td>Background primer</td>
<td>Information for the facilitator</td>
<td>n.a.</td>
</tr>
<tr>
<td>2.1</td>
<td>Sex and gender</td>
<td>Perceptions of gender versus sex</td>
<td>45 minutes</td>
</tr>
<tr>
<td>2.2</td>
<td>Gender and society</td>
<td>Impact of gender roles</td>
<td>75 minutes</td>
</tr>
<tr>
<td>2.3</td>
<td>Character role-play</td>
<td>Societal powers and gender implications</td>
<td>60 minutes</td>
</tr>
<tr>
<td>2.4</td>
<td>Definition game</td>
<td>Gender definitions</td>
<td>30 minutes</td>
</tr>
<tr>
<td>2.5</td>
<td>The importance of language</td>
<td>Appropriate language for discussing HIV and AIDS and gender issues</td>
<td>60 minutes</td>
</tr>
<tr>
<td>2.6</td>
<td>Case study: Gender norms and women’s vulnerability</td>
<td>Impact of gender norms on women’s vulnerability to HIV</td>
<td>75 minutes</td>
</tr>
</tbody>
</table>

TOTAL: 5 hours, 45 minutes

SEX VERSUS GENDER

<table>
<thead>
<tr>
<th>SEX</th>
<th>GENDER</th>
</tr>
</thead>
<tbody>
<tr>
<td>Refers to the biological difference between males and females</td>
<td>Refers to the economic, social and cultural attributes and opportunities associated with being male or female in a particular social setting at a particular point in time</td>
</tr>
<tr>
<td>Physiological differences between men and women</td>
<td>Socially determined characteristics assigned to men and women</td>
</tr>
<tr>
<td>Male versus female</td>
<td>Masculine versus feminine</td>
</tr>
<tr>
<td>Same across all parts of the world and across different times</td>
<td>Culturally and socially determined, therefore variable</td>
</tr>
</tbody>
</table>

The terms gender and sex are not used interchangeably in this manual. Sex refers to the biological and physiological differences between men and women, while gender refers to social norms related to how men and women are expected to behave. Gender relates to the accepted roles, sexual norms and identity that are described as masculine or feminine. Gender roles and norms are specific to a culture and often change over time. While sex—the physical characteristics that differentiate male from female—does not change, gender norms, gender roles and gender relations can be shaped through interventions or through social and political changes.

Gender relationships are personal as well as political. Personal, because the gender roles that we have taken on define who we are, what we do and how we
think of ourselves. Political, because gender roles and norms are maintained and promoted by society. Modifying these often means challenging our own identity and the way society is currently organized.\(^4\)

**INTERACTION OF GENDER AND HEALTH**

*Gender differences in society can influence both women’s and men’s:*

- Health and well-being
- Exposure to health risk factors
- Access to and understanding of information about disease management, prevention and control
- Experience of illness
- Attitudes toward maintaining one’s own health and that of family members
- Patterns of health service use
- Perceptions of healthcare quality\(^5\)

## 2.1 Sex and Gender

### OBJECTIVE

To develop an understanding about the differences between gender and sex.

### METHODOLOGY

Quiz, group work

### TIME

45 minutes

### MATERIALS

Pens or pencils

**Handouts:** Gender Quiz (page H2)

Gender Quiz Answer Key (page H3)

**Slide:** Sex Versus Gender

### PREPARATION

1. Prepare slide.
2. Make copies of the quiz and answer key for all participants.
3. Prepare a flip chart as described in STEP FIVE.

### INSTRUCTIONS TO FACILITATOR

The quiz is not meant to assess participants’ knowledge. Instead, it is a tool intended to facilitate discussion and learning. Try to refrain from focusing on providing correct answers. Instead, use the questions to highlight common

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\(^1\) Adapted from WHO Training Curriculum: Gender and Rights in Reproductive Health—Module 1, Session 2.

misconceptions and address areas of uncertainty. One question that may particularly stump participants is No. 9. The answer key provides both sex and gender as appropriate answers because men have higher levels of the hormone testosterone, which contributes to sexual aggression. At the same time, gender roles and societal expectations of men include sexual assertiveness and dominance. It is helpful for the facilitator to be familiar with vernacular words for sex and gender.

**DELIVERY**

**Step one:** Distribute the gender quiz and ask participants to tick off answers for each statement.

**Step two:** Divide participants into four groups and assign each group three or four of the quiz questions to discuss. While the groups are talking, walk around and listen in on their conversations to gain an understanding of their current knowledge and perceptions. This information will be useful in the facilitated discussion to follow.

**Step three:** Ask a representative of each group to present the outcome of his or her group’s discussion, including rationales for the answers. Allow each group to share questions for which no common answers were found, if applicable.

**Step four:** Lead a brief brainstorm with the whole group. Ask them to discuss questions that were found to be “contentious”. Identify the rationale behind the different opinions. Acknowledge that the difference between gender and sex is not always as straightforward as people might assume.

**Step five:** Ask the group to brainstorm the meaning of sex and gender. Record their responses on a flip chart set up like this:

<table>
<thead>
<tr>
<th>Sex</th>
<th>Gender</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Step six: Present the following slide:

**Sex Versus Gender**

<table>
<thead>
<tr>
<th>SEX</th>
<th>GENDER</th>
</tr>
</thead>
<tbody>
<tr>
<td>Refers to the biological difference</td>
<td>Refers to the economic, social and cultural attributes associated with</td>
</tr>
<tr>
<td>between males and females</td>
<td>being male or female in a particular social setting at a particular</td>
</tr>
<tr>
<td></td>
<td>point in time</td>
</tr>
<tr>
<td>Physiological differences between men</td>
<td>Socially determined characteristics assigned to men and women</td>
</tr>
<tr>
<td>and women</td>
<td></td>
</tr>
<tr>
<td>Male versus female</td>
<td>Masculine versus feminine</td>
</tr>
<tr>
<td>Same across all parts of the world</td>
<td>Culturally and socially determined, therefore variable</td>
</tr>
<tr>
<td>and across different times</td>
<td></td>
</tr>
</tbody>
</table>

Note: The medical community often uses the term gender to refer to biological characteristics. For the purpose of this workshop, we will use the definitions above, which are commonly used in social science.

Step seven: Distribute the Gender Quiz Answer Key handout. Facilitate a brief discussion for each question. Be sure to hear out objections to the provided answer but refer the group back to the definitions provided.

CLOSING

Reiterate that the way the terms sex and gender are used in society are often interchangeable but that the purpose of this workshop is to explore how they are different and why it is important to consider gender implications in the context of conducting AIDS vaccine research (e.g., exclusion criteria for pregnant women, gender differences in decision making about participation in a trial, etc.).
2.2 Gender and Society

OBJECTIVES
1. To examine the impact of gender roles in society.
2. To explore the effect of gender roles on the conduct of AIDS vaccine clinical research.

METHODOLOGY
Review handout, brainstorm and discussion

TIME
75 minutes

MATERIALS
Flip chart/chalkboard/marker board
Markers/chalk
PowerPoint/slide projector

Slides: Gender Stereotypes
Gender as a System

Handout: Gender as a System (page H4)

PREPARATION
1. Prepare slides.
2. Make copies of the handout.
3. Write the questions for STEP ONE on a flip chart.

INSTRUCTIONS TO FACILITATOR
Gender roles impact relationships, occupations, educational opportunities and even how society values men and women. During this session, discuss these ideas by eliciting common stereotypes about men and women and then examining the societal structure in which these roles and stereotypes are embedded.

DELIVERY
Step one: Present the questions below on a flip chart.

- Which gender stereotypes, beliefs or norms have an impact on how men/boys and women/girls relate in your society? (e.g., in courtship, sex, marriage, decision making, investment, etc.)
- Which roles have been assigned to men/boys and women/girls in your society, and what has been the rationale for such role distribution?
- What do men/boys own and what do women/girls own in your society? (e.g., land, children, inheritance, finances, family income, etc.)

Step two: Divide the group into three smaller groups. Ask each group to discuss the three questions and arrive at answers. Provide 15 minutes for this step.
Step three: Allow each group to present for five minutes, and allow questions and comments from the larger group. Initiate discussions on how society reacts when a man or a woman defies accepted gender norms.

Step four: Present the following slides:

**Gender stereotypes are ...**

...generalizations about males or females.

For example, the assumptions that men like to hold babies less than women do or that women are gossips are derived from gender stereotypes. These tend to reinforce gender norms and obstruct changes to expectations and dynamics of men and women in society. Thus, a father who enjoys cradling his child or a woman who prefers to keep to herself may feel inhibited by gender stereotypes.

**Gender ...**

... Defines beliefs in society about men and women

... Defines norms that shape the behaviour of men and women in society

... Defines roles for men and women

... Defines sexual division of labour

... Defines activities and interests for men and women

... Defines differential access to and control over resources and opportunities

... Defines differential decision making and power

Step five: Using the examples that the group devised in STEP ONE, encourage the group to come up with examples for each line in the system.

Example: For the line “Defines beliefs in society about men and women”, a possible example could be “Society believes that men should be heads of households and women need the direction of men”.

Step six: Have the group brainstorm how the stereotypes and examples discussed affect participation and conduct of AIDS vaccine clinical research.
Step seven: Distribute Gender as a System handouts for participants to keep as a reference.

CLOSING
Historically, gender roles and stereotypes may have been useful in some societies. For example, they could easily help divide labour, resources or power, which could improve productivity or help avoid conflict. In some cultures, women, not men, inherit land and resources.

In contemporary society, traditional gender roles and stereotypes are sometimes harmful to individuals. Children are usually socialised from birth to fulfil their male or female roles, which impacts their place in society and their access to opportunities and resources.

It is important to be aware of gender stereotypes and expectations of gender roles. However, we should be cautious to avoid blaming men or women in our discussions—society as a whole contributes to the norms and dynamics associated with gender. Instead, throughout this workshop we will improve our understanding of the impact of gender in society, on health and in clinical research. We will also aim to develop strategies to attain gender equity in the conduct of AIDS vaccine research.

2.3 Social Power and Vulnerability Role Play

OBJECTIVE
To explore and understand how individuals’ power and vulnerability are affected by gender roles and other social factors, such as race, ethnicity, class, age and marital status.

METHODOLOGY
Role play

TIME
60 minutes

MATERIALS
Flip chart/chalkboard/marker board
Markers/chalk
Facilitator statements

Handouts: Character Roles (page H5)
Power (page H6)
Empowerment (page H7)

PREPARATION
1. Cut character roles into slips from the Character Roles handout or write each role on a separate piece of paper. If necessary, adapt the roles to represent the research volunteer population.
2. Prepare yourself with the Facilitator Statements for the activity.
3. Make copies of the handouts.

**INSTRUCTIONS TO FACILITATOR**
In this exercise, participants are assigned roles to play and participate in a dynamic exercise that demonstrates how social power impacts people's life experiences and vulnerabilities.

**DELIVERY**

**Step one:** Explain that you are going to distribute characters to each participant to role play and that they should keep their role assignment confidential.

**Step two:** Distribute the character slips.

**Step three:** Move participants to a space large enough for everyone to stand in a single line, shoulder to shoulder, and for everyone to take several steps forward and backward. This can be done inside or outside.

**Step four:** Ask participants to line up shoulder to shoulder in the middle of the space.

**Step five:** Explain to participants that you will read them a series of statements (you will find them on the page following this session). As the character, each participant should react to each statement by taking steps forward if the statement describes the character on their slip or steps back if the statement does not.

**Step six:** Proceed by reading statements and allowing participants to react to them. Remind them periodically that they should react as the character they are role playing, not themselves.

**Step seven:** After all the statements have been read, ask those who have moved forward the farthest to share their thoughts on the statements. Then ask those who moved backward what they think.

**Step eight:** Ask the participants to reveal their character identities. Use the flip chart to list the identities of those who moved forward the most. Ask the group to list resources available to those people and put them on the board. Repeat this process for those in the middle and those farthest behind.

**Step nine:** Discuss the following questions:

- What were the factors that led certain characters to move forward while others moved back?
- What was the effect of the visual separation of the group with some moving forward while others moved backward?

**Step 10:** Distribute the handout about power and ask participants to complete the document, considering the communities where volunteers for AIDS vaccine research live.

**Step 11:** Discuss how the systems and power might affect volunteers' decision to participate in and experience of participating in AIDS vaccine clinical research.
Step 12: Ask the participants to read and discuss the handout on empowerment.

CLOSING
Summarise by stating:

- Each individual's power and social vulnerability depends somewhat on society's views on gender, as well as race, class, age and other factors.

- There are various kinds of power. Power can be derived from position, knowledge or expertise.

- Empowerment is a process that allows a person to take charge of his or her own life.

- Gender-related power does not operate by itself. It interacts with other systems of power and authority. For example, a poor man versus a rich woman.

- It is important to remember that the same person can be in a position of power in one situation and vulnerable in another.

FACILITATOR STATEMENTS FOR ROLE PLAY EXERCISE for session 2.3

- If you have completed high school/secondary school, please take two steps forward. If not, take two steps back.

- You need money for a major purpose, and you do not want to ask your partner (husband or wife) for it. If you can arrange a loan from a bank, take one step forward. If you cannot, take one step back.

- If you are free to associate with whomever you choose, take a step forward. If not, take a step back.

- If you have the freedom to volunteer for an AIDS vaccine clinical trial, take two steps forward. If not, take two steps back.

- If you are able to choose whether to try to have a baby during the next six months, take two steps forward. If not, take two steps back.

- You are not well and wish to see a doctor. The clinic is at a distance of four kilometres from your home. If you can get there on your own without anybody's help, take two steps forward. If not, take two steps back.

- If you read the newspaper every day, take one step forward. If not, take one step back.
2.4 Definition Game

**OBJECTIVE**
To review definitions and descriptions related to gender and sex.

**METHODOLOGY**
Game

**TIME**
30 minutes

**MATERIALS**
Prizes (e.g., chocolate bars; sweets; magazines; cards; information, education and communications (IEC) materials; AIDS vaccine advocacy message T-shirt, etc.)

*Handouts: Game Handout (page H8)
Gender Terms Defined (page H9)*

**PREPARATION**
1. Make copies of handouts for all participants.
2. Purchase prizes for all participants.

**INSTRUCTIONS TO FACILITATOR**
This session should be conducted after most terms have been reviewed. It should be a fun and lively exercise. Keep score for the two teams and provide prizes for all participants after the competition is completed.

**DELIVERY**
**Step one:** Divide the participants into two groups.

**Step two:** Distribute the definition handout.

**Step three:** Describe the game: You (the facilitator) will call out a term, and then each team should search for the correct definition for the term on their handout. The first team to provide the correct answer receives a point.

**Step four:** At the end of the game, distribute prizes to all participants, but give the winners theirs first.

**Step five:** Distribute Gender Terms Defined handout for participants to keep.

**CLOSING**
Congratulate all participants on demonstrating their improved understanding of gender. Staff of AIDS vaccine clinical trials, advocates for AIDS vaccines, community advisory board members or members of regulatory bodies need to be fluent in gender terminology and processes of engendering health programmes.
2.5 The Importance of Language

OBJECTIVES
1. To heighten participants’ awareness of their own use of language.
2. To understand the importance of using language that is gender sensitive, empowering and value neutral.

METHODOLOGY
Review and discussion

TIME
60 minutes

MATERIALS
Handout: Appropriate Language Related to HIV and Gender (page H10)

PREPARATION
Make copies of handout for all participants.

INSTRUCTIONS TO FACILITATOR
Become familiar with inappropriate vernacular words used in the handout and be prepared to suggest appropriate language.

DELIVERY
Step one: Explain that terms and phrases often carry positive or negative connotations and that appropriate language will not impart a value judgement and may even help to empower men and women.

Step two: Ask participants’ reactions to the usage of terms and phrases such as promiscuous, high-risk/low-risk persons or groups, prostitutes, AIDS victims, drug addicts, subjects, AIDS positive, weaker sex, AIDS has a woman’s face, mother-to-child transmission, women are emotional beings, men are risk takers and the man is head of the house.

Step three: Distribute Appropriate Language Related to HIV and Gender handout and review it with the group.

Step four: Ask participants to suggest words/terms that exist in their local language that should be avoided.

Step five: Wrap up the session by underscoring the need for using sensitive, non-discriminatory and nonthreatening language.

CLOSING
Language can contribute to building positive relationships or can create barriers between participants and community members. While some of the terms and phrases discussed in this session might be commonly used in the community, it is imperative to start developing awareness of the impact of language and to develop the habit of using better alternative words both at the individual level and at the team level. This may require holding discussions with the particular groups involved in AIDS vaccine clinical research to identify acceptable vernacular terms and phrases.
2.6 Case Study: Gender Norms and Women’s Vulnerability

OBJECTIVE
Examine the case study to analyse the impact that gender norms have on women’s well-being and vulnerability to HIV.

METHODOLOGY
Case studies and discussion

TIME
75 minutes

MATERIALS
Overhead/PowerPoint

Handouts: Chiriku’s Plight (pages H11–H12)
          Case Study Questions (page H13)

PREPARATION
Make copies of handouts for all participants.

INSTRUCTIONS TO FACILITATOR
Ideally, this session should be conducted after discussing the differences between gender and sex (Session 2.1), gender as a system (Session 2.2) and the definition game (Session 2.4) to provide adequate background. The following are some issues that participants may raise during the discussion, or that the facilitator may choose to raise:

- Gender violence/rape
- Low educational status of women and its impact on health
- Lack of access to accurate health information
- High rates of unemployment
- Limited job opportunities for rural men
- Migration to find work
- Subordination of women/male dominance
- Male and female condom use
- Family support systems
- Female biological vulnerability to HIV
- Sex work
- Pregnancy and breastfeeding when a couple has HIV
- Perception of AIDS as a woman’s illness
- Men’s role in the response to gender and HIV

DELIVERY
Step one: Divide participants into small groups, distribute the handouts and allow 30 minutes for the groups to study the case and discuss the questions.

Step two: Lead the groups through the questions and select one group to share its answers for each question. Allow the other groups to contribute to what the selected group shared and discuss the question and responses in plenary.
Step three: Ask the participants if this case study seemed realistic. Ask what aspects seemed like a realistic occurrence in the communities where they work and what aspects were unrealistic in those settings.

CLOSING

Power and stereotypes related to gender, education, family structure, marital status and health come together and interact to impact individuals, families and communities. The webbed structure of societal factors makes approaching gender issues complex, and conducting clinical trials with sensitivity and awareness of these issues becomes complicated. However, as we will see through this workshop, services that adequately integrate power and gender concerns through recruitment, counselling, medical care and community education have the power to effectively and comprehensively approach complex situations like those experienced by Chiriku.
3.1 Social Determinants of Health

OBJECTIVES
1. To explore and analyse the range of factors that determine health.
2. To discuss the concept of social determinants’ impact on health with a specific focus on gender.
3. To examine the importance of gender-specific health issues in AIDS vaccine clinical research.

METHODOLOGY
A brief presentation by the facilitator, group discussions, questioning of each participant’s knowledge of the AIDS epidemic and its gender dimensions

TIME
60 minutes

MATERIALS
Flip chart/chalkboard/marker board
Markers/chalk
PowerPoint/slide projector

Slide: Determinants of Health
Handout: Social Determinants of Health (page H14)

PREPARATION
1. Prepare overheads with the slide information or queue up the PowerPoint presentation.
2. Make copies of handout for all participants.
3. Prepare a flip chart as described in STEP SIX.

INSTRUCTIONS FOR FACILITATOR
This session focuses on the concept that health is not just a medical issue based on biological factors and medical interventions—it is also a social issue. Where and how people live, what they do, and their interactions and relationships all affect health. This session addresses the connections between social factors and health outcomes and highlights the differences between male and female health based on these connections. When both sessions are conducted in the same workshop, this session should be done before session 5.4. Similarities
between the two sessions should be taken into account to avoid duplication and redundancy.

**DELIVERY**

**Step one:** Present the following slide:

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**Determinants of health**

Many factors work together to affect the health of individuals and communities. Whether people are healthy or not is determined by their circumstances and environment. The determinants of health include:

- The social and economic environment
- The physical environment
- The person’s individual characteristics and behaviours

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**Step two:** Review the slide with participants and explain that health is determined by interactions among biology and the physical, socio-cultural and political environments. Elicit examples from the group and discuss together.

If necessary,

- Prompt them to describe how income (social and economic environment) relates to health (e.g., access to quality health services), and then ask about gender differences in income and the connection to health.
- Prompt them to consider how occupation (physical environment) relates to health (e.g., work environment and conditions), and discuss gender division of labour and the impact on health.
- Prompt them to think about how use of alcohol (individual behaviour) impacts health (e.g., can lead to risky behaviours) and how this can lead to different outcomes for women and men.

**Step three:** Explain how the examples they provided described the effect that biological and social factors have on health and how each combination also leads to gender-specific health outcomes.

**Step four:** Divide the participants into several groups. Assign each a factor such as income, education, occupation, gender and biology.

**Step five:** Ask the groups to discuss the following:

- How does this factor contribute to vulnerability to HIV?
- How does this factor influence the conduct of AIDS vaccine research?
Step six: Have the groups report back to the group and record responses on a flip chart set up like this (insert the factors that you assigned across the top):

<table>
<thead>
<tr>
<th>FACTOR</th>
<th>INCOME</th>
<th>EDUCATION</th>
<th>OCCUPATION</th>
<th>GENDER</th>
<th>BIOLOGY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contribution to vulnerability to HIV</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Influence on conduct of AIDS vaccine research</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Allow other groups to contribute to each column. Steer the participants toward describing different ways that each factor contributes to vulnerability to HIV and influences the conduct of AIDS vaccine research. It is okay if ideas from each column overlap.

Step seven: Distribute the Social Determinants of Health handout and discuss the examples in the context of the chart the group created.

CLOSING

Health is a product of the physical and social environments in which each person lives. Differences in health status, including gender differences, are a result of biology as well as differences in social and economic status. It is important to remain aware of the social determinants of health in planning and conducting AIDS vaccine research and especially while interacting with study volunteers.

3.2 Gender and HIV and AIDS

OBJECTIVES
1. To demonstrate that the AIDS pandemic is not only a medical issue but also a developmental and gender issue.
2. To identify areas in which these issues may impact the conduct of AIDS vaccine clinical research.

METHODOLOGY
Discussion

TIME
45 minutes

MATERIALS
Handouts: Factors That Contribute to Men’s and Women’s Vulnerability to HIV and AIDS (pages H15–H16)
Gender and HIV and AIDS (pages H17–H19)
PREPARATION
Make copies of handouts for all participants.

INSTRUCTIONS TO FACILITATOR
Encourage a group discussion based on the handouts. Keep the focus of the discussion on participants’ reactions rather than on analysis of the information. Underline the fact that although HIV and AIDS are medical issues, the epidemic is also a social and gender issue. Get current data on the country where the workshop is being conducted and encourage discussion based on that data.

DELIVERY
Step one: Distribute the handouts and allow the participants time to read them.

Step two: Ask participants what they thought after reading the handouts. Generate a list of reactions from the group. Summarize main points of the discussion from a gender perspective, interpret the statements and correct misconceptions.

Step three: Using the main points of the discussion from STEP TWO as a starting point, discuss how an effective, preventive AIDS vaccine would be an important tool for women, then discuss how it would be so for men.

Step four: Brainstorm how the issues raised in the handouts might arise in the conduct of AIDS vaccine clinical research.

CLOSING
Effective approaches to HIV prevention, treatment and care require awareness of and sensitivity to the many ways in which gender influences men’s and women’s experiences of the disease. Gender is an important factor in HIV acquisition, access to health services and social consequences of the disease. Professionals working on HIV-prevention clinical research and other HIV and AIDS programmes have an important role in improving the situation for those living with HIV through better understanding of these issues. Also, professionals involved in conducting AIDS vaccine clinical research can help ensure that equitable numbers of men and women are enrolled in studies and that they benefit equally from participation.

3.3 Gender-Based Violence and HIV and AIDS

OBJECTIVES
1. To analyse the relationship between gender-based violence and HIV and AIDS.
2. To improve knowledge and skills related to identifying gender-based violence in the context of HIV vaccine clinical research and appropriate methods for handling the situation.

METHODOLOGY
Presentation by the facilitator, group discussions and case studies
TIME
60 minutes

MATERIALS
Flip charts / marker boards / markers

Slide: Gender-Based Violence
Handout: Stop Violence Against Women—Fight AIDS (pages H20–H22)

PREPARATION
1. Make copies of handout for all participants.
2. Write out questions from STEP TWO on a flip chart.
3. Prepare slide (see below).
4. Research the local laws, mandated reporting requirements and referral options related to abuse and assault. Also, identify the persons or organisations (including names, phone numbers, websites) that research centre staff or other participants should contact in case of an instance of abuse. Prepare slides and/or handouts with this information.

DELIVERY

Step one: Ask participants to share what they think the phrase gender-based violence means.

Step two: Show the slide below or write on a flip chart the definition of gender-based violence and the three major forms of gender-based violence: physical, sexual and psychological.

Gender-based violence

DEFINITION:
Any act of violence against a person that results in, or is likely to result in, physical, sexual or psychological harm or suffering, including threats of such acts, coercion or arbitrary deprivation of liberty, whether occurring in public or in private life.

Adapted from The Declaration on the Elimination of Violence Against Women, adopted by the United Nations General Assembly in 1993.

Step three: Divide participants into three small groups for each form of gender-based violence and ask each group to discuss how the form affects women and men in terms of:

- Risk of becoming infected with HIV
- Access to prevention, counselling and testing services
- Access to treatment and care
- Participation in AIDS vaccine research

Step four: Distribute handout.
Step five: Review with the group the local laws related to gender-based violence, such as what constitutes abuse or assault under the law and the requirements for mandated reporting. Also, review local referral contacts, including the police, hospitals, shelters and advocacy groups.

Step six: Brainstorm methods for identifying gender-based violence, especially in the context of AIDS vaccine clinical research, and appropriate steps that can be taken by professionals.

Step seven: Briefly discuss this question: What impact could access to a female-initiated or controlled prevention option have on gender-based violence?

CLOSING
The purpose of this session is to better understand how gender-based violence impacts risk for HIV and to consider how gender-based violence should be handled in the context of AIDS vaccine clinical research. It is important for professionals to be compassionate and sensitive, as well as consistent with the law, when handling these issues and the volunteers who might face violence in their home or community. Understanding these issues will help AIDS vaccine research staff develop strategies and practices that help minimize gender-based violence in the context of AIDS vaccine studies. A future AIDS vaccine will be instrumental in reducing vulnerability of women and young girls to HIV and gender-based violence.

3.4 Attitudes About Gender in AIDS Vaccine Research

OBJECTIVES
1. To trigger critical thinking around gender issues and enable participants to examine biases related to gender.
2. To raise awareness of the importance of separating personal values from professional practice for health workers, particularly when interacting with stigmatised and vulnerable populations.

METHODOLOGY
Ask participants to react to a series of “value statements” by indicating whether they believe that members of their community or the community in which AIDS vaccine clinical research is conducted would agree or disagree. Alternatively, participants can examine their own beliefs during the exercise.

TIME
45 minutes

MATERIALS
One copy of the list of Value Statements for the facilitator

PREPARATION
Create an open space in the room where participants are free to move from one side to the other.
INSTRUCTIONS TO FACILITATOR

Some of the statements you will ask participants to consider are the same as those in the pre- and post-workshop questionnaires. The focus of this exercise is to facilitate a discussion around each of the value statements and to incorporate the topics discussed in previous sessions to better understand attitudes and recognize biases about gender. You do not have to read all of the statements if you have limited time.

DELIVERY

Step one: Explain that the purpose of the session is to explore ideas and views about gender, specifically with respect to the conduct of AIDS vaccine research.

Step two: Explain that you are asking the participants to consider the general views about gender that exist within local communities where AIDS vaccine clinical research volunteers live, work and participate in studies. Participants may choose to represent the views of certain members of the community by playing a role. Alternatively, ask participants to represent their own beliefs.

Step three: Ask all of the participants to stand in the middle of the space you have prepared. Designate one side of the room for “agree” and another for “disagree”.

Step four: Read aloud a statement from the list. Ask those (or those whose views they are representing) who agree to move to the designated area and those who disagree to move to the other.

Step five: Allow members of each group time to discuss briefly amongst themselves why they took the side they did. Ask representatives of each group to describe their reasoning.

Step six: Let each group try to convince members of the other group to reconsider their decision. People are permitted to switch sides.

Step seven: Facilitate a discussion around the issues. Do not try to resolve the issues, but once enough points have been argued, proceed to the next statement. Repeat this process with other statements.

CLOSING

Sum up the session by acknowledging the different values that exist within the community, and emphasizing the importance of separating personal values from professional practice for health workers, particularly when working with stigmatised and vulnerable populations.
VALUE STATEMENTS for session 3.4

Does your community agree or disagree with the following statements?

- It is inappropriate for women to have knowledge of sexual matters.
- Men don’t like to admit their lack of knowledge about sexual matters.
- Health workers find it easier than other people to discuss sexual matters.
- Men and women experience equal social pressure to have children.
- It is acceptable for men to have multiple sexual partners.
- Female sex workers are women without morals.
- Men having sex with men is abnormal.
- Good women should be modest and remain virgins until marriage.
- A woman should not be allowed to participate in AIDS vaccine clinical research without getting permission from her husband.
- An AIDS vaccine will be more beneficial to women than men.
- An AIDS vaccine will increase risky behaviour in men.
- A woman should tell her husband when she receives an AIDS vaccine.
- Distribution of an AIDS vaccine should be prioritized for sex workers and young girls.
4.0 Background Primer: Information for the Facilitator

INSTRUCTIONS TO FACILITATOR
Review this information prior to conducting workshop Module 4—Understanding Sexuality and Gender. Module 4 focuses on improving understanding of sexuality and sexual health with the goal of improving the conduct of AIDS vaccine research. A good understanding of sexuality is important to ensure effective recruitment strategies, sensitive and ethical practices, and appropriate evaluation and treatment—resulting in better research and better outcomes for volunteers and communities.

READ
Sexual Practices and Risk of Exposure to HIV*

VERY LOW RISK—No reported cases due to these behaviours:
- Masturbation—mutual masturbation
- Touching—massage
- Erotic massage—body rubbing
- Kissing
- Oral sex on a man with a condom
- Oral sex on a woman with dental dam or plastic wrap

LOW RISK—Rare reported cases due to these behaviours:
- Vaginal intercourse with correct, consistent use of a male or female condom
- Anal intercourse with correct, consistent use of a male condom
- Oral sex without dental dam/plastic wrap or without condom

HIGHER RISK—Millions of reported cases due to these behaviours:
- Vaginal intercourse without a condom
- Anal intercourse without a condom

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4.1 Sexuality, Sexual Health and Gender Identity

OBJECTIVES
1. To discuss the concepts of sexuality and sexual health.
2. To emphasise the importance of understanding sexuality and sexual health in the conduct of AIDS vaccine clinical research.

METHODOLOGY
Discussion, question and answer

TIME
60 minutes

MATERIALS
Flip chart/chalkboard/marker board
Markers/chalk

Handout: Sexuality Terms (pages H23-H24)
Slide: Working Definitions

PREPARATION
1. Prepare overheads with the slide information or queue up the PowerPoint presentation.
2. Make copies of Sexuality Terms handout for all participants.

INSTRUCTIONS TO FACILITATOR
Be aware that some participants may be uncomfortable discussing issues related to sexuality, especially those that are related to behaviours that are often stigmatized or groups such as sex workers or men who have sex with men. It will be important to maintain a productive discussion and engage participants, allowing them to express their opinions while reinforcing the separation between personal beliefs and professional behaviour. Emphasize the concept that sexual health does not just mean absence of sexually transmitted infections or the ability to reproduce, but that it also includes freedom from coercion, discrimination or stigma associated with sexual behaviours or sexual identity.

DELIVERY
Step one: Introduce this module by explaining that sexual health requires awareness and appreciation of sexuality, gender roles and power. In previous sessions, participants discussed gender roles and issues of power. In this session, the focus is on understanding sexuality and some of the concepts that will be relevant to working with certain populations at risk for HIV and conducting AIDS vaccine clinical research.

Step two: Ask participants to brainstorm definitions of the terms sexuality and sexual health. Record their responses on a flip chart set up like this:
<table>
<thead>
<tr>
<th>Sexuality</th>
<th>Sexual Health</th>
</tr>
</thead>
</table>

**Step three:** Present the following slide and discuss the breadth of ideas included in these terms:

**Working definitions**

**Sexuality**

Sexuality is a central aspect of being human and encompasses sex, gender identities and roles, sexual orientation, eroticism, pleasure, intimacy and reproduction. Sexuality is experienced and expressed in thoughts, fantasies, desires, beliefs, attitudes, values, behaviours, practices, roles and relationships. While sexuality can include all of these dimensions, not all of them are always experienced or expressed. Sexuality is influenced by the interaction of biological, psychological, social, economic, political, cultural, ethical, legal, historical, religious and spiritual factors.

**Sexual Health**

Sexual health is a state of physical, emotional, mental and social well-being as it relates to one's sexuality; it is not merely the absence of disease, dysfunction or infirmity. Sexual health requires a positive and respectful approach to sexuality and sexual relationships, as well as the possibility of having pleasurable and safe sexual experiences free from coercion, discrimination and violence. For sexual health to be attained and maintained, the sexual rights of all persons must be respected, protected and fulfilled.⁷

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⁷ These working definitions were developed through a consultative process with international experts beginning with the Technical Consultation on Sexual Health in January, 2002. They reflect an evolving understanding of the concepts and build on international consensus documents such as the ICPD Programme of Action and the Beijing Platform for Action. These working definitions are offered as a contribution to advancing understanding in the field of sexual health. They do not represent an official position of WHO.
Step five: Distribute the Sexuality Terms handout and review it as a group. Be sure to read through and define each term, perhaps providing examples. Encourage the participants to ask clarifying questions. Be aware of stigmatising language and value judgements about sexual practices. Encourage participants to use appropriate language.

Step six: Re-examine the list of behaviours and characteristics that the group brainstormed. Ask the participants to try to use the new terminology to describe some of the things they listed.

CLOSING
Understanding and respecting the way that individuals identify and behave sexually is important to ensuring their health. Using appropriate terminology that avoids stigma and discrimination is an important way to ensure that we provide good services to volunteers in our AIDS vaccine studies. Understanding sexuality without stereotyping will also help us develop effective strategies for recruiting volunteers from key populations at higher risk for HIV, and for counselling them on ways to reduce their risk.

4.2 Sexual Practices and Vulnerability to HIV

OBJECTIVES
1. To identify sexual practices associated with an increased risk of exposure to HIV and to promote safer sex practices.
2. To promote understanding of the difference between sexual orientation (e.g., gay male) and sexual practice (e.g., oral sex) with the goal of avoiding negative judgements and discrimination.
3. To highlight how value judgements about sexual practices and identities can hinder the provision of health services and promotion of safer sex practices.

METHODOLOGY
Brainstorming in groups, discussion in plenary

TIME
60 minutes

MATERIALS
Flip chart/chalkboard/marker board
Markers/chalk
PowerPoint/slide projector

Slide: Sexual Practices

PREPARATION
Prepare overheads with the slide information or queue up the PowerPoint presentation.
INSTRUCTIONS TO FACILITATOR

Be aware that some participants may be uncomfortable discussing sexual practices. Remind them that as AIDS vaccine clinical research professionals, it is important for them to fully understand these issues. Encourage them to ask questions and try to explain terms and concepts in detail, since some may not have a complete understanding but may be reluctant to ask. You should be well versed in national or local penal codes on different sexual practices.

If you have conducted Session 4.1 with the participants involved in this session, skip STEP ONE of this session and use outcomes from STEP FOUR in Session 4.1 for STEP TWO below.

DELIVERY

Step one: Present the following slide and ask the group to identify other sexual practices that they know about. Allow time for questions about the practices listed below, and encourage the group to provide answers and to clarify myths and misconceptions before you do.

**Some sexual practices**

- Kissing
- Masturbation
- Massage
- Sexual stimulation using one’s hand on another person
- Oral sex on a man who is wearing a condom
- Oral sex on a woman using a dental dam or plastic wrap
- Vaginal sex using a latex or polyurethane male or female condom
- Oral sex without a condom
- Vaginal sex without a condom
- Anal sex without a condom
- Sex under the influence of drugs or alcohol
- Sex work
- Coercive or forced sex

Step two: Divide the group into three small groups and assign each group one of the following questions to answer in 15 minutes:

1. **GENDER:** What are some gender issues related to each practice? (e.g., gender preferences, gender power, gender norms, etc.)

2. **SEXUALITY:** Which practices belong to which sexual orientation or gender identity? (e.g., homosexuals, heterosexuals, transsexuals, etc.)

3. **RISK OF EXPOSURE:** Which practices are considered high risk, low risk and no risk with respect to HIV transmission or infection?
Step three: Ask each group to report back.

- As the groups present their answers, highlight the overlap and differences among sex, gender, sexuality and risk of exposure to HIV with respect to sexual practices.

- Highlight the idea that sexual orientation and gender identity do not necessarily determine sexual practices (e.g. heterosexual women may practice anal sex, bisexual or homosexual men may not practice anal sex, transsexuals may or may not practice any sexual activity) and sexual practices are not an indication of sexual orientation.

- Be sure to discuss that stereotypes can arise when people consider these topics. There are often gender stereotypes regarding sexual preference. Gender norms and power imbalances often impact the ability to practice safer sex.

- Explain that although certain sexual practices are associated with increased exposure to HIV, a person’s sexuality (sexual identity) is not.

- Explain that although sex and gender are associated with risk of exposure to HIV, individuals should be empowered to reduce their risk through education about HIV and safer sex practices.

- Point out that the topics of sex work, sex under the influence and forced sex are not “practices” in the same way that kissing or vaginal sex are, but that they are important to discuss since they illustrate the complexity of these issues.

Step four: Revisit the list of sexual practices. Engage the group in a discussion about the list using the following questions:

- Which sexual practices/behaviours have legal implications in this country?

- Which of these behaviours may be objectionable to some people but are not a violation of human rights?

- Which of these behaviours may be considered a violation of human rights?

- Why do health workers sometimes have difficulty helping people reduce their risk of exposure to HIV when their clients/patients/volunteers are practicing behaviours the workers find objectionable?

- Is it illegal to provide health services or HIV-risk-reduction counselling to, or to enrol into AIDS vaccine studies, individuals who engage in the sexual practices we discussed? (Encourage participants to reference specific laws or human rights standards in order to support their argument.)
CLOSING
The purpose of this session was to discuss the relative risk of exposure to HIV associated with various sexual practices, and to clarify the difference between sexual orientation and sexual practices. It is critical to avoid judgement or discrimination against any volunteer participating in AIDS vaccine clinical research because of this sexual orientation, gender identity or sexual practices. This is an important aspect of the ethical and professional conduct of clinical research.

Understanding the variations in people’s behaviours and preferences, and avoiding judgement, will help us respond to the challenges involved in recruiting and working with different populations of men and women—and help volunteers reduce their risk of infection.

4.3 Myths and Misconceptions Regarding Sexuality

OBJECTIVES
To identify and improve understanding of common myths related to sex, sexuality, HIV and sexually transmitted infections (STIs).

METHODOLOGY
Question and answer, discussion, quiz

TIME
45 minutes

MATERIALS
Handout: Quiz: Myths on Sex and Sexuality (page H25)

PREPARATION
1. Make copies of the quiz handout for each participant.
2. Review Notes for the Facilitator for this exercise.

INSTRUCTIONS TO FACILITATOR
This session is intended to raise awareness of and to debunk common myths and misconceptions about sex and sexuality. Care and sensitivity must be taken to avoid passing judgement about participants’ feelings or beliefs.

DELIVERY
Step one: Distribute the quiz sheet Myths on Sex and Sexuality to each participant.

Step two: Ask participants to take turns reading the statements aloud. Ask for a volunteer to state whether he or she believes the statement to be a myth or a fact. You may also give participants the option to provide their opinion about each statement, instead of stating fact or myth.
Step three: Encourage a discussion among the participants about whether each statement is a myth or a fact. Ask them to provide the rationale for their judgements. The facilitator can refer to the explanations given in the notes below to guide the discussion.

Step four: Ask the group to discuss the ways in which they encounter myths and misconceptions in their work.

CLOSING
Explain that many of the statements in this exercise are difficult to answer, even for those with expertise in the field of HIV and AIDS. This exercise was meant to improve the participants’ understanding of many of the fallacies about sex and sexuality that are prevalent within our communities and among our study volunteers, and to help participants improve their own understanding and sensitivity.

NOTES FOR THE FACILITATOR
1. Sexually transmitted infections (STIs) can be cured if an infected man has sex with a virgin.
   Myth: There is no cure for HIV. Sex with a virgin does not cure any sexually transmitted infection.

2. Condoms help prevent the spread of sexually transmitted infections.
   Fact: Correct and consistent use of latex male condoms or female condoms helps prevent STIs, including HIV.

3. Homosexuality is a mental illness.
   Myth: Homosexuality implies no impairment in judgement, stability, reliability, or general social or vocational capabilities. Homosexuality exists across all cultures, geography and time.

4. Most homosexuals are men.
   Myth: Both men and women identify as gay or lesbian. In some cultures, homosexual men may be more visible than homosexual women because of societal norms about sexual openness.

5. Many men who have sex with men are married and have children.
   Fact: Men who have sex with men often marry women to hide their sexual identity or because they do not consider themselves to be homosexual. For example, many male clients who regularly visit male sex workers do not consider themselves to be homosexual or even bisexual. The fact that they have a wife confirms their gender identity as a heterosexual.

6. Foreigners introduced homosexuality into this region.
   Myth: Homosexuality is a human phenomenon that has nothing to do with nationality. Many communities, including some African communities, have taboos forbidding same-sex relationships, indicating the possibility of homosexual practices in the past.
7. *Most women with HIV are sex workers.*
   **Myth:** Increasingly, women in monogamous relationships are infected with HIV. In fact, in some regions, being a married woman is considered a risk factor for HIV. Married women are often infected by their husbands who have had sex with others.

8. *A man can only become infected with HIV from an infected woman, not if he has sex with an infected man.*
   **Myth:** HIV is transmitted through anal sex with men or women and through vaginal sex. The possibility of transmission is higher during anal sex because the chance of minor abrasions or tearing is higher.

9. *Having a sexual relationship with only one partner will prevent HIV and other sexually transmitted infections (STIs).*
   **Myth:** This would be true if two people were monogamous with each other and neither had sex with anyone else for the duration of their sexual lives. The reality is that extramarital sex, either before marriage or during marriage, is common. If one marriage partner remained monogamous but the other did not, the faithful partner would also be at risk for HIV or other STIs. Women who are married are increasingly at risk for HIV.

10. *Girls do not have sex before marriage.*
    **Myth:** Although it may not be socially acceptable to discuss premarital sex, it is common among women and men.

11. *Contraceptive services are not necessary for unmarried adolescents.*
    **Myth:** Since premarital sex is common and adolescents are at particular risk of sexual coercion, gender violence and risky behaviours, it is important that they have access to information and methods to prevent unwanted pregnancy and STIs, including HIV. However, professionals should be aware of local regulations about service provision to minors.

12. *All materials or pictures that are sexually explicit should be banned.*
    **Myth:** Materials that provide information on female and male anatomy, reproductive health and sexual transmission of infections such as HIV are important tools for educating individuals on how to protect their health. Such resources help to empower men and women, and girls and boys, to make safe and healthy choices for themselves and their families.

13. *People should only have sex in order to produce children.*
    **Myth:** Men and women should be able to have satisfying and safe sex lives, the capability to reproduce, and the freedom to decide if, when and how often to do so.
4.4 Legal and Social Context of Sexuality, Sexual Practices and Sexual and Reproductive Health

OBJECTIVES
1. To examine the legal and social context of sexuality, sexual practices and sexual and reproductive health and their implications for the conduct of AIDS vaccine clinical research.
2. To devise strategies for improving the conduct of AIDS vaccine clinical research that effectively integrate the needs of participants who may have practices outside of legal or traditional social norms.

METHODOLOGY
Brainstorming in groups, discussion in plenary

TIME
45 minutes

MATERIALS
Flip chart/chalkboard/marker board
Markers/chalk

PREPARATION
1. Research relevant local and national laws/policies related to marriage (e.g., legal age, status of polygamy, status of same-sex unions, status of extramarital sex), sex work, homosexual intercourse, HIV and AIDS policies (e.g., HIV-disclosure law, government provision of treatment and care, etc.), reproductive health policies (e.g., limits on abortion, contraception, health services, etc.).
2. Prepare a flip chart as described in STEP TWO.

INSTRUCTIONS TO FACILITATOR
This session is mostly instructional. You will present the public policies relevant to conducting AIDS vaccine research. It is important for you to consider the locations in which the participants conduct their work, as well as upcoming research projects in order to address all relevant issues. Care must be taken to sensitively discuss participants’ concerns about working with populations that may transgress legal boundaries and social norms. It will be important to identify mechanisms for handling challenging situations.

DELIVERY
Step one: Introduce this session by discussing the importance of understanding and considering public policy and social acceptability of sexuality and sexual practices in conducting AIDS vaccine clinical research. For example, describe how an AIDS vaccine study might require recruitment from a community of sex workers. If sex work is illegal in the country, the research study and staff need to understand and address issues such as confidentiality and barriers to recruitment. If the society is hostile to sex workers, the research study staff must consider the safety of these volunteers and the impact on others attending the
same clinic or research centre. Tell the group that you will discuss relevant legal and social issues.

**Step two:** Present the following flip chart:

<table>
<thead>
<tr>
<th>Topic</th>
<th>Legal considerations</th>
<th>Social considerations</th>
<th>Implications for AIDS vaccine research</th>
<th>Strategies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Marriage/union</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sex work</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Homosexuality</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HIV and AIDS</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reproductive health</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Step three:** Present the law/public policy associated with each of the following and record the points most relevant to conducting AIDS vaccine clinical research under the appropriate column of the flip chart.

- Marriage (legal age, status of polygamy, status of same-sex unions, status of extramarital sex)
- Sex work (brothel-based, street-based, condom use)
- Homosexuality (intercourse, identity, association)
- HIV and AIDS policies (HIV-disclosure law, government provision of treatment and care)
- Reproductive health policies (limits on abortion, contraception, health services)

**Step four:** Ask the group to discuss the social context for each of the above and record their main responses in the appropriate column of the flip chart.

**Step five:** As a group, brainstorm how the legal and social issues associated with sexuality directly affect the conduct of AIDS vaccine clinical research. Record the main responses in the appropriate column of the flip chart.

**Step six:** Brainstorm appropriate strategies or operating procedures that centres conducting AIDS vaccine clinical research should put into place to address the identified implications. Record the group’s main responses in the appropriate column of the flip chart.

**Step seven:** Allow some time for participants to share their personal experiences (successes and challenges) or concerns about reconciling legal and social considerations in their work.

**CLOSING**

The purpose of this session was to learn about local public policies and social context of such issues as marriage, sex work, homosexuality, HIV and AIDS, and reproductive health as they relate to AIDS vaccine clinical research. It is important for research centres and staff to prepare to address the impact of the legal and social context on the conduct of research and support of volunteers.
Gender-Equitable Enrolment in AIDS Vaccine Clinical Research

**OBJECTIVE**
To explain the importance of enrolling equitable numbers of men and women in AIDS vaccine clinical research.

**METHODOLOGY**
Presentation and discussion

**TIME**
30 minutes

**MATERIALS**
Flip chart/chalkboard-marker board
Markers/chalk

Handout: Understanding the Recruitment and Retention of Women in Clinical Trials (pages H26–H27)

Slide: Rationale for Enrolling Equitable Numbers of Men and Women in AIDS Vaccine Clinical Trials

**PREPARATION**
1. Prepare overheads with the slide information or queue up the PowerPoint presentation.
2. Make copies of handout for all participants.
3. Prepare a flip chart as described in STEP THREE.

**INSTRUCTIONS TO FACILITATOR**
The development of a safe and effective AIDS vaccine depends on the...
willingness of both women and men to participate in clinical trials. It is important that an AIDS vaccine is tested on adequate numbers of women and men to ensure licensure and to extend the benefits of participation (e.g., education, counselling and care) to them. Biological distinctions between women and men, such as differences in viral load and rates of male-female versus female-male transmission, may impact the effect of a vaccine. In addition, gender-related social and economic factors will impact women’s and men’s participation in trials, as well as future access to and use of a vaccine.

However, enrolling and retaining female volunteers in AIDS vaccine trials can be challenging in some settings. While recent trials in East Africa have met targets for recruitment of female participants (approximately 35 percent), the ratio of female-to-male participants in earlier clinical trials in Kenya and Uganda declined from one-to-one at initial contact to one woman for every eight male participants upon enrolment. While more women than men have been enrolled in some epidemiology studies in East Africa, it is unknown whether the experience of recent or earlier trials will carry forward to larger-scale efficacy trials. Conversely, in some regions, including Southern Africa, enrolling men has been more difficult. As the field moves toward test-of-concept and efficacy trials, the trials will focus on populations at higher risk for HIV, who often are stigmatized. Sociocultural factors combined with exclusion criteria may also limit participation. For example, a large proportion of women of childbearing age, who would otherwise be eligible for participation in a trial, are either excluded or unwilling to participate because they are planning to become pregnant, are pregnant or are lactating.

DELIVERY

Step one: Ask the group about their experiences with AIDS vaccine clinical research, specifically considering the ratio of male-to-female trial participants. Explain that in some settings, it has been difficult to recruit women for trials, while in others (in Southern Africa, for instance) women seem to be more easily recruited.

Step two: Introduce the following definitions:

- **Equity**—Freedom from bias or favouritism.
- **Equality**—Of the same measure, quantity, amount or number as another, as for each member of a group, class or society.

Step three: Discuss the difference between “equality” and “equity”. Then ask participants to brainstorm reasons why it is important to have equitable numbers of women and men in clinical trials. Record their responses on a flip chart set up like this:

<table>
<thead>
<tr>
<th>Why is it important to enrol equitable numbers of men and women in AIDS vaccine clinical trials?</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
</tr>
<tr>
<td>2.</td>
</tr>
<tr>
<td>3.</td>
</tr>
<tr>
<td>4.</td>
</tr>
</tbody>
</table>

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Prompt additional ideas by mentioning biological differences, differences in effect, licensure and ethics.

**Step four:** Present and discuss the following slide:

---

**Rationale for enrolling equitable numbers of men and women in AIDS vaccine clinical research**

- To study the efficacy of the candidate vaccine in both women and men.
- To detect the effects of the candidate vaccine and how they differ between men and women.
- To ensure that there is sufficient data for licensing the vaccine for use by both women and men.
- On ethical grounds—both women and men should have access to the benefits of participating in AIDS vaccine clinical research.

*However,*

- Although it is recommended to enrol men and women in equitable numbers, the total number of participants in a Phase I clinical trial is not sufficient to detect differences between men and women.
- It might be possible to make some comparison between men and women in Phase II trials for safety and immunogenicity.
- Equitable numbers of men and women are critical for Phase III trials, which have enough total volunteers to be able to compare the response of men versus women to the vaccine candidate.

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**CLOSING**

There are biological, scientific, ethical and regulatory issues, as well as issues related to access and acceptability, that make enrolling equitable numbers of men and women essential for high-quality AIDS vaccine clinical research.
Influence of Gender and Other Socio-Economic Factors on Participation in AIDS Vaccine Clinical Research

OBJECTIVE
Identify how gender, socio-cultural and economic factors are related to participation in AIDS vaccine clinical research.

METHODOLOGY
Discussion and brainstorming in plenary

TIME
90 minutes

MATERIALS
Flip chart, markers

PREPARATION
Prepare a flip chart as described in STEP FOUR.

INSTRUCTIONS TO FACILITATOR
You should be aware of similarities between this session and Sessions 5.4 (Gender-Related Barriers to Participation in AIDS Vaccine Clinical Research) and 5.5 (Addressing Gender Issues in AIDS Vaccine Clinical Research). Ideally, this session should be followed by Session 5.5.

DELIVERY
Step one: Present the following list:

Key elements of AIDS vaccine clinical research:
- Recruitment and enrolment
- Informed consent
- Education and counselling
- Healthcare
- Blood drawing and laboratory tests
- Research environment (hours, location, facilities, staff, etc.)
- Community engagement

Step two: Divide the participants into smaller groups.

Step three: Ask each group to answer the following questions. When responding, they should consider the key elements of clinical research that were presented.

- What are the social and economic factors, including those that are gender-related, that might impact a volunteer’s decision to participate in AIDS vaccine clinical research?
What are the social and economic factors, including those that are gender-related, that might impact a volunteer’s experience participating in AIDS vaccine clinical research?

**Step four:** Ask each group to present its main responses to the questions. Record the responses on a flip chart set up like this:

<table>
<thead>
<tr>
<th>Clinical research element</th>
<th>Gender-related factors</th>
<th>Other social factors</th>
<th>Economic factors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recruitment and enrolment</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Informed consent</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Education and counselling</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Health care</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blood drawing and laboratory tests</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Research environment (hours, location, facilities, staff, etc.)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Community engagement</td>
<td></td>
<td></td>
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</tbody>
</table>

**CLOSING**

Note that many factors influence a volunteer’s decision to enrol in AIDS vaccine clinical research and their experience of participation. Professionals involved in such research should be aware of these issues so that they can devise strategies to address them.
OBJECTIVES
1. Identify the particular barriers to enrolment and the potential benefits and harms of participation that are relevant to stigmatised populations and volunteers.
2. Brainstorm strategies to enhance benefits, minimise harm and address barriers to participation.

METHODOLOGY
Brief presentation by facilitator, group discussions, brainstorming

TIME
90 minutes

MATERIALS
Flip chart/marker board/index cards/markers/tape

Handout: Understanding the Benefits and Risks of Participating in Clinical Research (pages H28–H29)

Slide: Volunteers in AIDS Vaccine Clinical Research

PREPARATION
1. Prepare overheads with the slide information or queue up the PowerPoint presentation.
2. Prepare small pieces of tape made into loops.
3. Prepare flip chart as described in STEP THREE.
4. Prepare flip chart as described in STEP THREE.

INSTRUCTIONS FOR FACILITATOR
Be aware of similarities between this session and Sessions 5.2 (Influence of Gender and Other Socio-Economic Factors on Participation in AIDS Vaccine Clinical Research 5.4 (Gender-Related Barriers to Participation in AIDS Vaccine Clinical Research) and 4.2 (Sexual Practices and Vulnerability to HIV).
Step one: Introduce the session by presenting the following slides:

Volunteers in AIDS vaccine clinical research

Efficacy trials for AIDS vaccines are generally conducted with populations that have a high incidence of HIV infection. This minimizes the length of the trial and the size of the study population.

Epidemiological and other clinical studies are often conducted prior to efficacy trials to help determine the feasibility of conducting a trial in a particular location and for a particular population. For example, incidence studies will help determine if the HIV incidence in the population is appropriate for conducting an efficacy trial for an AIDS vaccine.

Volunteers in AIDS vaccine clinical research

Populations that tend to have higher incidence of HIV infection include:
- Sex workers—women and men who engage in transactional sex (including transgender individuals in some settings)
- Men who have sex with men
- Sero-discordant couples (i.e., couples with one HIV infected partner and one uninfected partner)
- Injecting drug users

Certain populations that have a high incidence of HIV infection tend to be socially marginalized and may experience stigma and discrimination aside from their risk for HIV. Therefore, it is important to ensure that their involvement in AIDS vaccine clinical research does not inadvertently contribute to or exacerbate existing stigma and discrimination or other forms of social harm.

Step two: Briefly discuss with the group some of the social vulnerabilities (unrelated to participation in AIDS vaccine clinical research) of:
- Women who engage in transactional sex
- Men who have sex with men (MSM)

For example, they might say that a group may face discrimination in pursuing employment, may experience exclusion or violence in social settings, or may resort to higher-risk behaviours for survival. Include any additional key populations that are involved in local AIDS vaccine clinical research.

Step three: Brainstorm some of the reasons each of these groups may find it difficult to participate in AIDS vaccine clinical research. Record participants’ responses on a flip chart set up like this:
Step four: Distribute two index cards and a marker to each participant.

Step five: Ask participants to write one potential benefit of participating in AIDS vaccine clinical research on an index card and one potential social harm on another (if the group is small, participants can write more than one benefit and more than one harm, each on a separate card).

Step six: When they are finished, ask them to tape the cards with benefits on one wall and the cards with social harms on another wall.

Step seven: With the help of participants, move the cards around to group similar ideas together. Discuss the ideas posted and add in others from the list below, as appropriate. Ask the group to discuss the ways in which volunteers’ concerns about social harms could impact participation.

Some possible social harms associated with participation in clinical research or perception of HIV infection:

- Inadvertent disclosure of HIV status
- Identification with a stigmatised group (MSM, sex worker)
- Members of the community learning about a volunteer’s participation
- Judgement or discrimination from family members or others about a volunteer’s participation
- Social stigma or exclusion from social events
- Loss of business or economic opportunities
- Loss of employment
- Loss of property
- Negative impact on an intimate relationship
- Ostracism from family or community
- Abuse or violence
- Loss of respect or status
- Gossip
- Curiosity from others about their participation
Some possible benefits of trial participation:

- Altruism (feels good to help)
- Compensation for travel
- Information and education about HIV and AIDS
- Information and education about risk reduction
- Healthcare services
- HIV testing
- Counselling

Step eight: Brainstorm with the whole group a list of actions that a research team, community advisory board or others can undertake to enhance benefits, minimise social harm and minimise barriers to enrolment for these key populations. List the strategies on one side of the flip chart and who might be involved in implementation on the other. Set up the flip chart like this:

<table>
<thead>
<tr>
<th>Strategy</th>
<th>Implementation</th>
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</thead>
<tbody>
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Step nine: Distribute Understanding the Benefits and Risks of Participating in Clinical Research handout.

CLOSING
Participation in clinical trials could have both social harms and benefits. Some of the social harms and benefits are deeply rooted in gender norms and stereotypes. Research centres can develop strategies to enhance social benefits and minimize, to the best extent, social harms by integrating a gender-sensitive approach to AIDS vaccine clinical research.
OBJECTIVES
1. Examine gender-related barriers to participation for men and women.
2. Identify strategies to overcome the challenges presented in the cases.

METHODOLOGY
Brief presentation by facilitator, group discussions and brainstorming

TIME
60 minutes

MATERIALS
PowerPoint/slide projector

Handouts: Understanding Informed Consent (pages H30–H31)
Understanding Couples Voluntary Counselling and Testing
(pages H32–H33)

Slides: Case 1
Case 2

PREPARATION
1. Prepare overheads with the slide information or queue up the
   PowerPoint presentation.
2. Distribute handouts with case studies.
3. Prepare flip chart as described in STEP ONE.

INSTRUCTIONS FOR FACILITOR
Be aware of similarities between this session and Session 5.3 (Working With
Stigmatized Populations: Participation and Social Impact) to avoid duplication.
You should be familiar with the basic enrolment processes used by the research
centres, basic volunteers’ rights (e.g., the right to informed consent and to
withdraw at anytime) and basic research centre policies on reparation for any
harms related to participation.
**Step one:** Brainstorm some reasons why men and women would and would not want to participate in AIDS vaccine clinical research. Record responses on two separate flip chart sheets as shown:

<table>
<thead>
<tr>
<th>Women</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Why women would want to participate in AIDS vaccine research</td>
<td>Why women would NOT want to participate in AIDS vaccine research</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Men</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Why men would want to participate in AIDS vaccine research</td>
<td>Why men would NOT want to participate in AIDS vaccine research</td>
<td></td>
</tr>
</tbody>
</table>
Step two: Present the following slides and give handouts with the cases to the group:

**Case 1**

A woman decided to participate in an AIDS vaccine trial after attending several information sessions and discussing it with her friends. She completed the screening procedures and was considered eligible for trial participation. The trial team handed over some trial-related educational material to her, including the study brochure. She was asked to return within the next 42 days for study enrolment. Three days later, she telephoned to report that when her husband learnt of her decision to enrol in the trial, the couple quarrelled, and he threatened to send her back to her parents’ home if she participated.

*Exercise:*
- Consider the potential volunteer’s decision-making process up until she informed the research staff of her decision not to participate.
- Brainstorm strategies for handling situations like this.

**Case 2**

A 30-year-old man decided to participate in an AIDS vaccine clinical trial because after witnessing several friends and family members suffer and die from the disease, he wanted to contribute to the search for a preventive vaccine. However, he had concerns about how the vaccine candidate might impact his ability to perform sexually, and any potential birth defects that a vaccine might cause if he decided to father a child. He decided to discuss his concerns with the counsellor at the research centre, however, when he arrived, he was too embarrassed to raise the issues of impotency and safety. He did go through with the informed consent process, and after discussing the potential risks and benefits of participating as outlined in the informal consent document, he decided to enrol.

*Questions:*
- As a professional, what concerns do you have about this man’s decision to participate in the study?
- What could have been done differently by the research team and counsellors to improve the situation?

Step three: Divide participants into four groups and assign Case #1 to two groups and Case #2 to two groups. Have them answer the two questions.

Step four: Ask the groups to present their answers to question one in each case. Encourage the exchange of ideas amongst participants. Brainstorm with the group about the role of gender in the decision-making process in each case.
Step five: Ask participants to present their responses to question two in each case. Prompt participants to consider the following issues if they were not brought up in the group discussion:

- Availability of information and resources to volunteers and community members
- Gender-sensitive counselling for volunteers
- How to support volunteers with effective strategies for disclosure of participation
- Counselling supervision for staff
- Staff training/meetings
- Role of community education and support

Step six: Distribute handouts Understanding Informed Consent and Understanding Couples Voluntary Counselling and Testing.

CLOSING
The purpose of this session was to understand the complexity of the decision-making process for many potential volunteers. Understanding potential volunteers’ concerns throughout the recruitment and enrolment process helps develop effective strategies for recruitment and retention.

5.5 Addressing Gender Issues in AIDS Vaccine Clinical Research

OBJECTIVE
Develop strategies and action plans for implementing gender-sensitive practices and procedures in AIDS vaccine clinical research.

METHODOLOGY
Brainstorm in groups and discussion in plenary

TIME
60 minutes

MATERIALS
Handout: Addressing Gender Issues in AIDS Vaccine Research  
(pages H34–H36)

PREPARATION
Make copies of the handout for all participants.

INSTRUCTIONS TO FACILITATOR
Ideally, this session should be conducted after Session 5.2 (Factors That Impact Volunteers’ Participation in AIDS Vaccine Clinical Research) if they are conducted in the same workshop. Key points raised in Session 5.2 could be used in this session as a basis for integrating gender-sensitive practices. You should facilitate
a group discussion and lead the group in devising actions and strategies for integrating gender issues in clinical research that can be implemented both in the short- and long-term. The action plans should be documented and used as a basis for follow-up after the training.

DELIVERY

Step one: Distribute the handout Addressing Gender Issues in AIDS Vaccine Research. Review and discuss any points that were not already covered in previous sessions.

Step two: Inform the group that this exercise will focus on identifying the mechanisms that a research centre can put into place to ensure a gender-sensitive research process.

Step three: Divide the participants into small groups (ensure a mix of participants in each group) and assign one (or two) of the following categories to each:

- Recruitment and enrolment processes
- Informed consent process
- Voluntary counselling and testing (VCT) process
- Strategies to address confidentiality, stigma and discrimination
- Strategies to prevent or mitigate social harm
- Research centre environment

Step four: Ask each group to come up with a list of actions that it would take to ensure a more gender-sensitive process in the assigned category. Handouts can be used for reference, but the groups should not feel limited to the information in the handouts.

Step five: Return to plenary and ask each group to present its ideas. Following each presentation, ask the larger group:

- Are there any elements that you would like to add that were not included?
- What stumbling blocks might you encounter despite putting mechanisms in place?

CLOSING

Integrating gender issues in AIDS vaccine clinical research involves a thorough analysis of study processes and appropriate action points at all stages. A team approach to the integration of gender issues is required to effectively provide gender-sensitive clinical trial services. A continuous process of monitoring and evaluation of the gender action plan is needed to determine successes, challenges and areas that require further improvements.
Gender and Counselling in AIDS Vaccine Clinical Research

OBJECTIVE
To practice applying key issues addressed throughout the workshop.

METHODOLOGY
Role play and case scenarios

TIME
75 minutes

MATERIALS
Handout: Counselling Case Studies (pages H37–H39)

PREPARATION
Make copies of handout for each participant.

INSTRUCTIONS TO FACILITATOR
These role play and case scenarios should be helpful not only for the research centre staff who are responsible for counselling and education but for other staff as well. They focus on counselling issues related to decision making, values and beliefs, gender-based violence, ethics, stigmatised groups, confidentiality, recruitment and self-awareness. The exercise can be done as a large group or in small groups. The aim of this session is not to develop in-depth counselling skills but to provide the opportunity for participants to discuss major issues related to gender in counselling.

DELIVERY
Step one: Distribute copies of the case studies and questions to participants. Ask them to read the case studies and jot down their responses to the questions (explain that these are notes for themselves, not to hand in). Allow 30 minutes.

Step two: Ask for a volunteer to read Case #1 to the group and to facilitate a group discussion around the questions. Ask for a second volunteer to do the same for Case #2 and so on. If you don’t have enough time to go through all of the cases, divide the group in two and ask each to take half of the cases.

Step three: Ask group members to share their relevant experiences counselling for AIDS vaccine clinical research or their thoughts on how to approach the situations presented in the cases.

CLOSING
While there is not time within the context of this particular training to develop in-depth counselling skills, these case scenarios and the group discussion aim to provide insights into some of the more challenging gender aspects of providing counselling to AIDS vaccine research participants.
Case 1: Aisha and Kamau

Question: What are the issues facing Aisha during her visit?

Discussion: Aisha has likely been raped and is suffering from the trauma. Survivors of rape often avoid discussing the incident soon afterward and may be unresponsive to questions or concerns. They may mistrust and feel hostility toward all men.

Facing a male counsellor after her rape may have exacerbated Aisha's suffering and inflated her feeling of animosity toward men.

Sex workers often face stigma related to their work. Also, they are often not believed when they report rape cases. Rape might affect how they interact with male clients and contribute trauma to their future work. Unfortunately, sex workers are often left to deal with the psychological and physical consequences of rape on their own.

Because Aisha was avoiding discussing her rape experience, she may have been asking for treatment to prevent HIV infection because she was concerned about exposure to HIV, but also to provide a clue to the counsellor about what she experienced without revisiting painful memories.

Question: What are Kamau's issues?

Discussion: Kamau's issues are related to his expectations of how a sex worker should behave and portrays a lack of understanding of the traumatic injustice and sexual abuse that many women face. His lack of sensitivity may have contributed to his failure to recognize Aisha's behaviour and request for post-exposure prophylactic treatment to prevent HIV, and may have impaired his response as a counsellor.

Question: What would you have done if you were in Kamau's shoes?

Discussion: Each counselling situation requires the counsellor's personal judgement. In some cases, a female rape survivor might feel more comfortable with a female counsellor. The issue of gender-matching volunteers to counsellors should be considered at each research centre. Policies should be in place for the rapid treatment of rape survivors. Of course, it is important that counsellors and other clinical staff are prepared to identify situations that signal a rape may have occurred.
Case 2: Zandile and Bongani

Question: What are the issues?

Discussion: There is a power issue between the husband and wife. He seems to control the household decision making, including the finances, even though he does not work.

It seems that the woman does not want to continue her participation in the study but her husband is pressuring her. His presence at her visit to the centre implies that he may be threatening her.

Question: How would you help Zandile?

Discussion: Zandile could be counselled to communicate her feelings about participation in the trial with her partner. She needs to be reassured of her right to withdraw at any time without penalty and be given the option for couples counselling.

Case 3: Doreen and Kizito

Question: What are the issues in this counselling session?

Discussion: There is a likelihood that the relationship between the counsellor and volunteer has shifted from professional to personal. Not only may the counsellor be struggling with personal beliefs but also with the possibility of losing a friend if the volunteer stops coming. Personal relationships between counsellors and volunteers must be avoided.

The volunteer might have picked up on the belief pattern of the counsellor and used it to counter the counsellor’s effort to empower her. It is difficult for a counsellor to help a volunteer if he or she is going through the same issues.

Counsellors need to evaluate and deal with their own gender biases, religious and cultural beliefs, and relationship issues.

Question: How could Doreen be counselled?

Discussion: It is advisable to refer a volunteer to another counsellor if personal issues get in the way of providing quality counselling. Both the counsellor and Doreen need assistance in exploring gender issues and biases.
Case 4: Banda and Mwabi

**Question:** How will you handle this situation?

**Discussion:** Meeting a volunteer in a social setting poses difficulties for counsellors. However, it is critical that counsellors maintain confidentiality in such cases.

**Question:** How might your reaction change if you knew Mwabi’s HIV status?

**Discussion:** Sometimes we might be biased toward protecting our relatives or friends if we know they are HIV negative. We may try to protect the volunteer if we know the volunteer is HIV negative and the friend or relative is HIV positive. In any event, the right to confidentiality for both individuals prevails over all. Furthermore, adults have the right to their own associations and are able to make the best decisions to protect themselves against HIV. Counsellors should empower their relatives and friends on safer-sex practices to prevent HIV.

Case 5: Maureen

**Question:** What are the possible issues?

**Discussion:** Recruitment and follow-up strategies need to be gender sensitive with policies and procedures in place that consider challenging situations.

**Question:** What could have been done differently?

**Discussion:** The counsellor could have established with the volunteer, at the point of enrolment, whether and how to contact her for follow-up.

Case 6: Counsellor

**Question:** What are the issues with this counsellor?

**Discussion:** The counsellor is struggling with the sexuality of the volunteers. The counsellor demonstrates an interest in knowing the details of their sexual practices, which may be inappropriate if not handled professionally and within the context of issues such as risk-reduction counselling. Perhaps the counsellor’s discomfort with men who have sex with men is apparent to volunteers and to the counselling supervisor.

**Question:** How should the counselling supervisor handle the situation?

**Discussion:** The supervisor should provide the opportunity for the counsellor to express his fears, concerns and conflicting beliefs through counselling supervision, and then discuss training or other options for ensuring that the volunteers receive appropriate, high-quality counselling.
Gender-Based Violence and AIDS Vaccine Clinical Research

OBJECTIVES
1. To discuss how gender violence could impact AIDS vaccine clinical research.
2. To discuss strategies for addressing gender-based violence in the context of AIDS vaccine research.

METHODOLOGY
Group discussion

TIME
30 minutes

MATERIALS
None

PREPARATION
None

INSTRUCTIONS TO FACILITATOR
Ideally, this session should be done after Session 3.3 (Gender-Based Violence and HIV and AIDS) if both sessions are conducted within the same workshop. You should be aware that they are similar and that you can combine the sessions if time is limited.

DELIVERY
Step one: Discuss with the group their research centre’s policy on gender-based violence and if they have an effective referral system.

Step two: Divide the participants into small groups and ask them to:

1. Discuss the effects of domestic violence on women’s decisions to volunteer for AIDS vaccine clinical trials and studies.

2. Suggest ways in which the research team could effectively deal with issues of gender violence among the study population.
OBJECTIVE
To enable participants to articulate what they need to change and what they’re doing well in both their professional work and their personal lives.

METHODOLOGY
Reflection

TIME
30 minutes

MATERIALS
Slips of paper—8”x11” in two colours
Sketch pens, flip chart

DELIVERY
Step one: Discuss with participants the changes that have to happen at both the professional and personal levels. In order to ensure that the entire team conducting AIDS vaccine clinical research feels empowered and can sustain what has been learnt in the workshop without feeling intimidated or helpless, there has to be accountability at the institutional level. In other words, gender-sensitive attitudes and behaviours have to be upheld throughout the institution.

Step two: Tell participants that they should make some personal and professional commitments.

Step three: Distribute two slips of paper (one of each colour—e.g., pink and blue) to each participant.

Step four: Ask participants to write one thing they would like to change in their personal life on the blue slip and one thing they would like to change in their professional life on the pink slip.

Step five: Collect the commitments and redistribute them to other participants.

Step six: Ask the participants to read the two commitments they received.

Step seven: Congratulate the group for making these commitments and express faith that the participants will use these as concrete steps toward change in their own lives and their professional work.

Step eight: Circulate a copy of the Pre-Training Questionnaire and ask participants to mark their responses. The post-training responses, when compared with the pre-training responses, will be a good indicator of the change in knowledge, attitudes and beliefs that may have occurred during this training.
Gender Quiz

Instructions: Please tick (SEX/GENDER) based on your perception of whether the following items can be attributed to sex (biological) or gender (social).

1. Women are usually the primary caretakers of children.  
2. Women breastfeed babies.  
3. Only women wear dresses.  
4. Women often have less power than men to make decisions or become leaders.  
5. Male voices break at puberty.  
7. More men than women become soldiers.  
8. Men tend to be more sexually aggressive than women.  
9. Women’s illnesses are often considered psychosomatic.  
10. Men are physically stronger than women.  
11. Real men are not supposed to cry.  
12. A woman’s place is in the kitchen.  
13. More men are heads of households than women.
Gender Quiz
(answer key)

Instructions: Please tick (SEX/GENDER) based on your perception of whether the following items can be attributed to sex (biological) or gender (social).

1. Women are usually the primary caretakers of children. (SEX/GENDER)
2. Women breastfeed babies. (SEX/GENDER)
3. Only women wear dresses. (SEX/GENDER)
4. Women often have less power than men to make decisions or become leaders. (SEX/GENDER)
5. Male voices break at puberty. (SEX/GENDER)
6. Women menstruate. (SEX/GENDER)
7. More men than women become soldiers. (SEX/GENDER)
8. Men tend to be more sexually aggressive than women. (SEX/GENDER)
9. Women’s illnesses are often considered psychosomatic. (SEX/GENDER)
10. Men are physically stronger than women. (SEX/GENDER)
11. Real men are not supposed to cry. (SEX/GENDER)
12. A woman’s place is in the kitchen. (SEX/GENDER)
13. More men are heads of households than women. (SEX/GENDER)
Gender as a System

GENDER ...

... DEFINES BELIEFS IN SOCIETY ABOUT MEN AND WOMEN
   Example: Men are strong, women are weak; men are rational, women are emotional

... DEFINES NORMS THAT SHAPE THE BEHAVIOUR OF MEN AND WOMEN IN SOCIETY
   Example: Men should express themselves and be articulate in public; women should remain quiet and avoid drawing attention

... DEFINES ROLES FOR MEN AND WOMEN
   Example: The role of elder or chief is traditionally given to men; the role of medium or servant is given to women

... DEFINES SEXUAL DIVISION OF LABOUR
   Example: Income-generating roles are assigned to men (formal work outside of the home); reproductive roles are assigned to women (bearing and raising children)

... DEFINES ACTIVITIES AND INTERESTS FOR MEN AND WOMEN
   Example: Public domain is for men, private is for women. Women’s tasks within the home, such as cooking and craft making, are often undervalued and less visible, while men’s roles in the public domain, such as political leadership and athletics, are highly valued

... DEFINES DIFFERENTIAL ACCESS TO AND CONTROL OVER RESOURCES AND OPPORTUNITIES
   Example: Women often have less access to resources like money, land, technology, knowledge, education, space and time; men traditionally control these resources

... DEFINES DIFFERENTIAL DECISION MAKING AND POWER
   Example: Power and control is largely invested with men, while women are the objects of domination
### Character Roles

<table>
<thead>
<tr>
<th>Male truck driver</th>
<th>Wife of a truck driver</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male sex worker</td>
<td>Female sex worker</td>
</tr>
<tr>
<td>Male professor</td>
<td>Female professor</td>
</tr>
<tr>
<td>Male nurse</td>
<td>Female nurse</td>
</tr>
<tr>
<td>Illiterate man</td>
<td>Illiterate woman</td>
</tr>
<tr>
<td>Urban man</td>
<td>Urban housewife</td>
</tr>
<tr>
<td>Newly married man</td>
<td>Newly married woman</td>
</tr>
<tr>
<td>Poor rural man</td>
<td>Poor rural woman</td>
</tr>
<tr>
<td><strong>Single man</strong> (20 years old)</td>
<td><strong>Single woman</strong> (20 years old)</td>
</tr>
<tr>
<td>HIV-positive man</td>
<td>HIV-positive woman</td>
</tr>
<tr>
<td>Elderly man</td>
<td>Elderly woman</td>
</tr>
<tr>
<td>Male doctor</td>
<td>Female doctor</td>
</tr>
<tr>
<td>Male vaccine trial volunteer</td>
<td>Female vaccine trial volunteer</td>
</tr>
<tr>
<td>Physically disabled man</td>
<td>Physically disabled woman</td>
</tr>
</tbody>
</table>
Power

There are many social factors that affect an individual’s freedom, autonomy and control of resources. Higher levels of independence and empowerment reflect greater power. On the other hand, lack of power is characterized by reliance on others for basic needs and an inability to care for one’s own well-being or safety. Power is associated with personal happiness and well-being. Social systems affect power for groups and individuals.

The purpose of the chart below is to help you consider how systems in society, such as gender, ethnicity or education, impact power for individuals living in the communities that host AIDS vaccine clinical research. Complete the chart, describing how the system impacts power. For example, for gender, you might write female/feminine near “less” and male/masculine near “more” if men typically have more power in the community.

<table>
<thead>
<tr>
<th>Systems in society</th>
<th>POWER IN SYSTEM</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender</td>
<td></td>
</tr>
<tr>
<td>Class</td>
<td></td>
</tr>
<tr>
<td>Race</td>
<td></td>
</tr>
<tr>
<td>Ethnicity</td>
<td></td>
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<tr>
<td>Family structure</td>
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<tr>
<td>Education</td>
<td></td>
</tr>
<tr>
<td>Marital status</td>
<td></td>
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<tr>
<td>Sexual orientation</td>
<td></td>
</tr>
<tr>
<td>Religion</td>
<td></td>
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<tr>
<td>Age</td>
<td></td>
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<tr>
<td>Politics</td>
<td></td>
</tr>
<tr>
<td>Language</td>
<td></td>
</tr>
<tr>
<td>Health</td>
<td></td>
</tr>
</tbody>
</table>
Empowerment

EMPOWERMENT
Empowerment involves challenging all forms of oppression, exploitation and discrimination. These social ills lead to inequality, harm and even deprivation of basic human rights. An effort toward empowerment for groups, communities and individuals requires those who believe that society should be based on equality and equity to challenge existing power relationships.

Gender empowerment is about men and women recognizing their own role in society, whether as a person who discriminates or exploits, or as a person who is abused, or subjugated and making steps toward change. Gender empowerment involves a process whereby women and men express their own needs and interests and proactively work to impact their own situation and society.

Indicators of Gender Empowerment

- Access to and control over resources both within and outside the house
- Right to one’s own work and earnings
- Right to mobility and the freedom of association
- Ability and freedom to engage in autonomous decision making
- Freedom to participate in political decisions
- Access to and control over knowledge and information
- Equality and equity in legal matters
- Developing the collective strength to pose challenges to established norms and power structures
- Control over one’s body, sexuality and reproduction
- Opportunities to develop one’s self-confidence and earn the respect of society
- Social recognition of the role and participation of women in domestic work, child care and the care of the aged and the sick
- Social norms that recognize the role and responsibility of men in advocating for women’s security and freedom from physical and sexual violence
- Social norms that reinforce men’s role and responsibility in matters relating to reproduction
- Social norms that discourage gender-based discrimination, including those linked to religious, cultural and traditional beliefs and practices
Refers to the economic, social and cultural attributes and opportunities associated with being male or female in a particular social setting at a particular point in time.

Refers to the biological difference between males and females.

The culturally and politically defined functions and responsibilities that men and women are socialized into conforming to.

Equal treatment of women and men in laws and policies, and equal access to resources and services within families, communities and society at large.

Fairness and justice in the distribution of benefits and responsibilities between men and women. It often requires women-specific programmes and policies to end existing inequalities.

When cultural beliefs and societal structural arrangements favour men over women. For example, when women and men are treated differently in the family or in the workplace, resulting in women’s inequality and subordination to men.

All accepted opinions and norms, which are related to the current situation of men and women and to the behavioural norms, motives and requirements that society dictates to them.

The process by which women strengthen their capacity, individually and collectively, to identify, understand and overcome gender discrimination, thus acting to take control of their lives.

The result of how each society divides work among men and women according to what is considered suitable or appropriate for each gender.

The understanding that there are socially determined differences between men and women based on learned behaviour that affect their ability to access and control resources.

The ability to perceive existing gender differences, issues and inequalities and to incorporate these into strategies and actions.

A strategy and process for making women’s and men’s concerns and experiences an integral dimension of the design, implementation, monitoring and evaluation of policies and programmes so that women and men benefit equally and inequality is not perpetuated—the ultimate goal is to achieve gender equality.

Examines the power relationship between men and women and its consequences on their lives, including how the social roles and identities they have been given influence their sexual behaviour and their health and how the social system, from public policy and health services to private intimacy, incorporates inequalities of power between women and men.
<table>
<thead>
<tr>
<th><strong>Gender</strong></th>
<th>Refers to the economic, social and cultural attributes and opportunities associated with being male or female in a particular social setting at a particular point in time.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sex</strong></td>
<td>Refers to the biological difference between males and females.</td>
</tr>
<tr>
<td><strong>Gender roles</strong></td>
<td>The culturally and politically defined functions and responsibilities that men and women are socialized into conforming to.</td>
</tr>
<tr>
<td><strong>Gender equality</strong></td>
<td>Equal treatment of women and men in laws and policies, and equal access to resources and services within families, communities and society at large.</td>
</tr>
<tr>
<td><strong>Gender equity</strong></td>
<td>Fairness and justice in the distribution of benefits and responsibilities between men and women. It often requires women-specific programmes and policies to end existing inequalities.</td>
</tr>
<tr>
<td><strong>Gender discrimination or gender bias</strong></td>
<td>When cultural beliefs and societal structural arrangements favour men over women. For example, when women and men are treated differently in the family or in the workplace, resulting in women's inequality and subordination to men.</td>
</tr>
<tr>
<td><strong>Gender stereotypes</strong></td>
<td>All accepted opinions and norms, which are related to the current situation of men and women and to the behavioural norms, motives and requirements that society dictates to them.</td>
</tr>
<tr>
<td><strong>Empowerment of women</strong></td>
<td>The process by which women strengthen their capacity, individually and collectively, to identify, understand and overcome gender discrimination, thus acting to take control of their lives.</td>
</tr>
<tr>
<td><strong>Gender division of labour</strong></td>
<td>The result of how each society divides work among men and women according to what is considered suitable or appropriate for each gender.</td>
</tr>
<tr>
<td><strong>Gender awareness</strong></td>
<td>The understanding that there are socially determined differences between men and women based on learned behaviour that affect their ability to access and control resources.</td>
</tr>
<tr>
<td><strong>Gender sensitivity</strong></td>
<td>The ability to perceive existing gender differences, issues and inequalities and to incorporate these into strategies and actions.</td>
</tr>
<tr>
<td><strong>Gender mainstreaming</strong></td>
<td>A strategy and process for making women's and men's concerns and experiences an integral dimension of the design, implementation, monitoring and evaluation of policies and programmes so that women and men benefit equally and inequality is not perpetuated—the ultimate goal is to achieve gender equality.</td>
</tr>
<tr>
<td><strong>Gender analysis</strong></td>
<td>Examines the power relationship between men and women and its consequences on their lives, including how the social roles and identities they have been given influence their sexual behaviour and their health and how the social system, from public policy and health services to private intimacy, incorporates inequalities of power between women and men.</td>
</tr>
</tbody>
</table>

Appropriate Language Related to HIV and Gender

The language that we use to discuss, describe and address others impacts those people and the judgements that are formed about them. HIV and AIDS is a sensitive topic charged with the potential for stigma and harm. Societal power structures and norms associated with gender are often reflected in vernacular language and can contribute to disempowerment and even vulnerability to disease. Furthermore, using technical language can create barriers and power imbalances between those conducting AIDS vaccine clinical research and volunteers or community groups. Appropriate language respects the dignity and rights of all concerned. As a professional, you should avoid contributing to the stigmatisation of those affected by HIV. Instead, assist in creating the social changes required to overcome discrimination. The following are some issues to keep in mind:

- Language should be inclusive and not create or reinforce an “us versus them” mentality. For example, try to use terms such as “working with communities” rather than “intervention”. A term like “intervention” places the speaker outside of the group of people with whom he or she is working. Words such as “control” may distance the speaker from the participants. Words such as “subjects” portray volunteers as instruments for research and not participants in the search for an AIDS vaccine. Care should be taken with the use of the pronouns “they”, “them”, etc.

- Descriptive terms should be those preferred by the persons described. For example, “sex worker” is often preferred to “prostitute”. The term “commercial sex worker” is discouraged on the basis that other professionals, such as lawyers, are not referred to as “commercial”. “People living with HIV” or “HIV infected” are preferred for people who are HIV positive rather than “victims” or “sufferers”.

- Language should be value neutral, gender sensitive and empowering. Terms such as “promiscuous”, “drug abuse”, “weaker sex” and all derogatory terms alienate rather than create the trust and respect required in service provision. Terms such as “victim” or “sufferer” suggest powerlessness; “haemophiliac” or “AIDS patient” identifies human beings by their medical conditions alone. “Injecting drug users” is used rather than “drug addicts”. Terms such as “living with HIV” recognize that an infected person may continue to live well and productively for many years. Phrases such as “women are the weaker sex” or “men are risk takers” reinforce stereotypes and may increase vulnerability of both men and women. A phrase such as “women are emotional beings” might alienate women from approaching risk reduction in a rational way and might also alienate men from being in touch with their feelings, which can impede efforts to counsel volunteers on risk reduction.

- Terms used must be accurate. For example, AIDS is not an infection. The infectious agent is HIV. AIDS is a syndrome of opportunistic infections and diseases that can develop as immunosuppression deepens along the continuum of HIV infection from primary infection to death.

- The terms used need to be adequate to inform accurately. For example, the modes of HIV transmission and the options for protective behaviour change need to be explicitly stated so that they are clearly understood within all cultural contexts.12

Chiriku’s Plight

Chiriku is a 21-year-old mother of two children aged four and eight months, and she lives 300 kilometres outside of a city with her mother-in-law and father-in-law in a poor, rural area. She does not have a regular income. Her husband, Mazumbuko, sends monthly income from his work in the city to his mother.

Chiriku must ask her mother-in-law for money for her needs. She has not attended secondary school and has never been a wage earner. Her mother works as a farm labourer on a nearby coffee plantation, and her father died when she was 10. Her family has a home in a nearby village where three of her five siblings live and have no employment.

There is awareness in the community of an illness that has resulted in an increase in people coming home sick from the urban areas. They have heard of HIV but do not understand how it is transmitted or that AIDS-related illnesses and death are caused by HIV. There is a rumour that HIV is spread with tuberculosis. Locally, there has been an increase in the number of orphans in the village, and some homes do not have an adult family member. As is customary, women are charged with caring for the sick.

Chiriku’s first sexual experience occurred when she was 15 years old. She was taken into the fields by an uncle aged 40 and was forced to have sexual intercourse with him. He had recently come home from the city after receiving an HIV diagnosis and had heard that one can cure the illness by having sex with a virgin. He warned her that if she told the family about his actions, he would say she encouraged him and she would be severely punished. She knew this to be true.

Shortly after that incident, she met Mazumbuko and has not had sex with any other man since. As he paid a bride price for her, he considers her his property. She is obligated to care for their children, be available to have sexual relations when he wishes and remain faithful to him.

As there is little available work in their village, Mazumbuko left to find employment in the city. He lives in a room shack in a city slum.

While separated from his wife, Mazumbuko occasionally has sex with sex workers. There is a high rate of unemployment amongst women in the city. Some sex workers are drawn to their work by the flexible hours, which allow them to care for their young children, and the remuneration, which is better than wages for domestic work. Most sex workers have heard about HIV and AIDS and know that they must use condoms to prevent it.

A local NGO supplies free condoms to sex workers. However, men prefer sex without a condom and often will pay more if a sex worker agrees not to use one.

Mazumbuko is able to go home twice a year. When at home, he has sex regularly with his wife and does not consider using a condom. Though Chiriku is aware that her husband is unfaithful, she obliges as she fears emotional or physical abuse from him if she does not comply with his demands. She knows that if he ever thought she had been unfaithful to him, she would be chased out of the village.

Chiriku has two children. She notices that the younger child, eight-month-old Bahati, has frequent diarrhoea and is not gaining weight like her previous child. She is still breastfeeding and will continue, as she did for her first child, until the age of two. Chiriku’s parents-in-law insist that she
visit a traditional healer, who gives her herbs to feed Bahati. When the child fails to improve, Chiriku decides to travel to her husband in the city and seek treatment at the local clinic. Before she can do this, she must get permission from her father-in-law, since he is the patriarch of the family.

Mazumbuko is pleased to see Chiriku when she and their daughter arrive, but he is worried about the baby’s health. The next day, on the way to work, Mazumbuko takes them to the nearby church primary-care clinic (which provides free services). Bahati is weighed and found to be below average weight for a child her age. Chiriku feels guilty and responsible for her baby’s illness. She thinks she may have displeased her ancestors and that is why the baby is ill. Traditionally, mothers are responsible for the health of their children, and success as a mother means having a fat and thriving baby. As the mother of this underweight, sickly child, Chiriku feels as though she is a failure and fears the anger of her mother-in-law.

The doctor suspects that Bahati may have HIV and counsels Chiriku about the disease. With so much new information, Chiriku feels overwhelmed and confused, but she agrees to allow the doctor to test her and Bahati for HIV because it seems the doctor wants to conduct the tests before proceeding with making Bahati better.

When Chiriku tells Mazumbuko that she and their daughter are HIV positive, he says that HIV is a woman’s disease. Mazumbuko becomes abusive and accuses her of infidelity. He blames her for their child’s illness and chases her away.
Case Questions

What were some of the health risks that Chiriku and Mazumbuko faced? How did gender norms impact their risk for HIV?

How did gender affect decisions about work? What did this mean for gender differences in access to economic resources?

Describe the power structures in Chiriku’s family and community. How did this structure impact the health of female characters in the case?

In this case, there were a few examples of ignorance and misinformation about HIV and AIDS. What were some of these? What factors led to a lack of understanding about HIV and AIDS?
Social Determinants of Health

Poor men and women tend to have inadequate access to healthcare services and poor-quality services when they do access them. This leads to a higher burden of illness and earlier death among poor people as compared to the more affluent.

Better education, especially for women, leads to better health outcomes for them and their children.

Sexual gender norms sometimes imply that women should not have the power to decide whether or when to have sex. When men and women conform to this idea, women are placed at risk for emotional and physical illness.

Women often haul water and firewood as part of their household duties. This often requires them to travel by foot, sometimes through dangerous areas, putting them at risk for assault or injury. Their cooking duties could lead to health problems associated with hazardous smoke inhalation and exposure to open flames.

Often boys are favoured over girls when a family has limited resources and must decide which children to send to school. Gender roles for girls include helping with household chores and caring for younger siblings. Since some poor families believe that their sons will have better career opportunities than their daughters, they might send boys to school and put girls to work at home. This results in a double burden of poverty and lack of education for women, confirming the gender stereotype that men are better wage earners and that they should support women. It also leads to poorer health for women and their families.

Men are traditionally expected to provide for their families. If they live in a region suffering from unemployment, they may decide to migrate to seek work, often leaving their families in their home community. Separation from wives or girlfriends might lead men to seek the services of sex workers, putting them—and upon their return home, their partners—at risk for sexually transmitted infections, including HIV and AIDS.

Men are often expected to be strong. This may impact their willingness to seek testing or treatment for a health condition. Instead, they might deny illness or avoid seeking necessary services.
Factors that Contribute to Men’s and Women’s Vulnerability to HIV and AIDS

WOMEN’S BIOLOGICAL VULNERABILITY
Women are more susceptible to HIV infection through vaginal or anal sex than heterosexual men because:

- The vagina and anus have larger areas of exposed and sensitive skin.
- The virus can survive for longer in the vagina and the anus than on the surface of the penis.
- There is a higher viral load of HIV in semen than there is in the fluids of the vagina or anus.
- The vaginal and anal walls are much more likely to be ruptured or suffer microlesions (very small tears) during vaginal or anal sex, especially if the sex is violent or coercive. Cuts, scrapes and bruises allow easy access for HIV into the bloodstream.
- Women may have asymptomatic sexually transmitted infections or difficulty accessing treatment for symptomatic infections. If left untreated, sexually transmitted infections increase the risk of HIV transmission.

SOCIAL AND ECONOMIC VULNERABILITY
Socioeconomic factors are based on gender inequality:

- Women may be unable to negotiate safer sex or the use of condoms in relationships.
- Women often lack the power to demand fidelity in a relationship.
- Women may fear physical violence, abandonment or the loss of economic support if they try to negotiate condom use, discuss fidelity with their partners or leave a relationship.
- Marriage does not protect women from HIV infection. In some places throughout Africa, married women are identified as the group most at risk for HIV infection as most new infections in women result from sex with their husbands or primary partners.
- In some communities, girls marry at a young age, very often to older men who may have had other sexual partners and thus be more likely to have been infected.
Many women and young girls are forced to or choose to engage in sex with men for economic reasons—using sex as a commodity in exchange for goods, services, money, accommodation or even status. This transactional sex often takes place between young women and older men, called intergenerational sex, and renders women vulnerable to HIV.\textsuperscript{13, 14}

Cultural norms often limit women's access to information related to sex and sexual health, and to related healthcare.

Social pressure to bear children may affect women's choices about protecting themselves against HIV infection. They may fear the social consequences of not becoming pregnant if they use condoms to protect themselves against HIV.

Women are at greater risk of being raped, sexually coerced or forced into sex work.

**MEN’S VULNERABILITY**

Men are also subject to gender-specific vulnerabilities:

- Men are affected by gender norms that encourage risky behaviour, increasing women's vulnerability as well as their own risks.

- In many societies, men are not expected to remain monogamous and may even be encouraged to have multiple partners.

- Men are expected to marry and produce children, especially male heirs to carry on the family name.

- Men are expected to be experienced and knowledgeable about sexuality, which might prevent them from seeking information regarding sexual health and protection. More importantly, there is still a lack of accessible information.

- Men are socialized to be self-reliant and not to seek help, and therefore may not seek health information or services.

- Men who have sex with men are biologically vulnerable to HIV during penetrative sex when they are the receptive partner due to microlesions that may occur in the anal tissue.

- Some men and boys have sex with other men for reasons other than homosexuality: economic necessity (sex work), coercion or violence.


Gender and HIV and AIDS

Two and a half decades into the AIDS pandemic, the disease continues to outpace the global response. According to new data released by the Joint United Nations Programme on HIV/AIDS (UNAIDS), an estimated 33.2 million people are now living with HIV worldwide with infections among women continuing to rise in many parts of the world. In 2007, women represented 46 percent of HIV-infected adults worldwide. Regionally, they comprised 61 percent of HIV-infected adults in sub-Saharan Africa, 26 percent in Eastern Europe and Central Asia, and 29 percent in Asia. Among young people ages 15 to 24 in sub-Saharan Africa, the difference in rates of infection is striking: nearly three out of four infections are among young women.

Increased biological vulnerability, coupled with social and economic inequities, fuel the global epidemic in low- and middle-income countries. Entrenched gender norms and inequalities result in power imbalances in relationships, affecting women’s ability to control or negotiate the terms of sexual relations and condom use. Poverty and reliance on men for economic support also limit women’s power to protect themselves and force some to turn to transactional sex for survival. Also, cultural norms that preclude women’s access to information about sexuality, and the threat of violence or loss of economic support, can impede women’s ability to communicate with their partners about HIV prevention. In addition to the impact of the disease itself on HIV-positive women, the burden of caring for those with HIV-related illnesses and for children orphaned by AIDS typically falls on women and girls. HIV-affected women and families are increasingly impoverished, further increasing their vulnerability to infectious diseases. Additionally, women who are infected with or affected by HIV often face stigma and discrimination, at times leading to ostracism, abuse and destitution.

How do pregnancy and childbearing affect the risk of HIV?

- Studies from higher-income countries indicate that pregnancy does not affect the progress of infection in HIV-positive women who show no symptoms, or in those in the early stages of infection. Care should be taken, however, not to generalize these results to low- and middle-income countries, since there has been little research on this topic in such settings. A recent study indicates that in lower-income countries, there is a high risk of infant death associated with maternal HIV infection.

- Pregnancy-related complications, such as haemorrhage, expose women to the risk of infection related to blood transfusions.

- Since HIV can be transmitted through breast milk, breastfeeding presents a dilemma for many women. Those who decide to discontinue breastfeeding in favour of infant formula may reduce the risk of HIV transmission to their child yet may expose the infant to diseases resulting from an unclean water supply, as well as to malnutrition. The use of infant formula can alert others to the mother’s HIV status and lead to stigma and discrimination.

16 UNAIDS. 2006. Keeping the Promise: An Agenda for Action on Women and AIDS. Geneva: UNAIDS.
What role do gender norms play?

- Early initiation of sexual activity among girls is directly related to the practice of early marriage for girls in many lower-income countries. Early marriage may expose girls to an increased risk of STIs and HIV infection, especially if their partners are older and have had more sexual exposure.

- Gender norms around decision making and autonomy may affect access to healthcare. For example, while men often make independent decisions to seek voluntary counselling and testing (VCT) services, women are often obliged to discuss VCT with their partners before accessing the services.

- Men may be under pressure to keep their HIV infection status secret for fear of dismissal from work and therefore being unable to fulfill their traditional gender roles as breadwinners.

- The role of same-sex relations among young men in enhancing the risk of HIV infection is often ignored in settings where sex between men is socially stigmatized and/or illegal. The limited availability of data contributes to the invisibility of this issue.

How does gender violence impact risk of HIV infection?

- Some women experience the threat of or actual physical violence when attempting to negotiate safer sex through the use of condoms.

- Violence in the form of coerced sex or rape may also result in the acquisition of HIV, especially as coerced sex may lead to the tearing of delicate tissues. Studies in adolescents from several countries found that a significant proportion report that their first intercourse was forced, particularly for young women. Sexual minorities, such as homosexual men, might also face sexual coercion and are similarly at risk of HIV infection.

- Conflict situations aggravate a number of factors that fuel the HIV and AIDS crisis. These include the breakdown of families and communities, forced displacement, poverty, the collapse of health services, and physical and sexual violence. Women more than men are at risk of rape and sexual assault in conflict situations, and consequently of HIV infection.

Health programme and service issues

- The cost of HIV and AIDS treatment renders it unaffordable for most families in lower-income countries. While the price of treatment affects both sexes, women’s lack of economic power as compared with men may make access to treatment particularly difficult.

- Much of the resistance to condom use encountered by condom promotion programmes is gender related. A number of studies report that young women are reluctant to carry or suggest using condoms for fear of being seen as promiscuous. Many young men dislike condoms for their perceived interference in the enjoyment of sex.
It is estimated that perfect use of the female condom may reduce the annual risk of acquiring HIV by more than 90 percent among women who have intercourse twice weekly with an infected male. However, the price of the female condom (4 to 10 times that of male condoms) makes it inaccessible to most women.

Stand-alone services related to STIs and HIV and AIDS may deter women and young people from accessing care since, in such cases, use of services may be seen as tantamount to an admission of having a sexually transmitted infection, thus leading to stigmatisation.

Health providers need to be aware of and sensitive to the possibility that women can be subjected to violence and other serious consequences within households or communities as a result of revealing an HIV-positive status.

In many countries, HIV and AIDS information and services are provided primarily through family planning, prenatal and child health clinics, which are typically not designed to reach men. As a result, men may be less likely than women to receive HIV and AIDS information, counselling and treatment services.

What research is needed?

More research is needed on gender and HIV and AIDS issues for men, such as the impact of masculinity on vulnerability to HIV, as well as gender-related factors that impede men’s access to HIV and AIDS testing and treatment.

Increased investment must be put into research and development of effective female-controlled methods of preventing HIV transmission that do not prevent pregnancy and do not involve the use of a condom, such as vaccines and microbicides.

Research on gender differences in risk perception and behaviour across different age groups and in different settings would help design more relevant information, education and communication (IEC) interventions in HIV-prevention programmes.

The role of nonconsensual sex in increasing the risk of HIV infection in adolescent girls and boys is an important area for further research.

More research is needed on the response of health systems to HIV-infected adolescents, and on gender differences regarding the barriers adolescents face in gaining access to health services. Effective interventions should be designed to overcome these barriers.

There is limited research on women’s and men’s perspectives on the design and delivery of HIV treatment and care. These include, for example, opinions on individual versus couples counselling, disclosure and partner notification processes, location of services, and differences among all of these by gender, age and setting.

The ways in which different service delivery settings (e.g., prevention of mother-to-child transmission, voluntary counselling and testing) influence the process of disclosure of HIV-infected status to one’s partner, and the consequences of this for women and men, need to be better understood. This is necessary in order to design programmes that minimize adverse consequences, such as intimate partner or family violence against HIV-infected women.
Stop Violence Against Women—Fight AIDS

The Global Coalition on Women and AIDS: A UNAIDS Initiative
Adapted from Issue #2

What’s Real
Violence against women is a global health crisis of epidemic proportions and often a cause and consequence of HIV. Violence and the threat of violence dramatically increase the vulnerability of women and girls to HIV by making it difficult or impossible for women to abstain from sex, to get their partners to be faithful or to use a condom. Violence is also a barrier for women in accessing HIV prevention, care, treatment and support services. That is why the UNAIDS-led Global Coalition on Women and AIDS has made stopping violence against women a top priority.

High rates of violence make women more vulnerable
Growing evidence from around the world shows that a large proportion of women and girls are subjected to violence by family members, acquaintances and strangers.

Violence against women is a fundamental violation of their human rights and is often fuelled by longstanding social and cultural norms that reinforce its acceptability in society—by both men and women. In some societies, women and men agree that it is acceptable for a man to beat his wife for various reasons, including if she refuses to have sex with him.

Violence against women increases their risk for HIV infection
Numerous studies from around the globe show the growing link between violence against women and HIV. These studies demonstrate that HIV-infected women are more likely to have experienced violence, and that women who have experienced violence are at higher risk for HIV.

Violence impedes access to essential AIDS services
Violence, or fear of violence, makes it difficult for women and girls to disclose their HIV status or to access essential HIV and AIDS services. Some women are powerless to access HIV and AIDS services because their husbands physically attack, threaten or intimidate them.

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19 The Global Coalition on Women and AIDS is a worldwide alliance of civil society groups, networks of women living with HIV and AIDS, governments and UN organisations supporting AIDS strategies that work for women and girls. This brief is the second in a series that will explore a range of key issues that particularly affect women and girls in the global fight against AIDS. The first briefing, Educate Girls, Fight AIDS, can be found at: http://womenandaid.unaids.org.
What Works
A range of promising programmes are already working to prevent violence against women and HIV infections among women and girls.

- The Chelstone Clinic in Lusaka, Zambia, provides free HIV and AIDS treatment to women who test positive in the antenatal clinic. Still, some 60 percent of clinically eligible women decide to opt out of treatment due in part to their fears of violence and abandonment that might result from disclosing their HIV status. A counsellor at the clinic explained that many women who disclose their status, or try to encourage their partners to be tested, “were beaten and withdrew from the programme”. Despite the programme’s success in treating some 750 women, violence continues to present challenges to its work.24

- By fostering greater community dialogue, Stepping Stones workshops in 29 countries—mostly in sub-Saharan Africa, but increasingly in Asia and Europe—have helped to reduce the acceptability and prevalence of violence and to promote discussion and awareness about HIV. By changing attitudes and behaviour related to violence against women, and reducing stigma and discrimination in the community, these programmes work to lower HIV vulnerability for women.25

- The Intervention with Microfinance for AIDS & Gender Equity (IMAGE) programme in Limpopo Province, South Africa, integrates HIV prevention and violence training into its microfinance programmes for rural women.26 The aim: to provide women with small loans to start a business and gain greater economic independence. When combined with training on HIV prevention, the programme empowers women to stand up to violence and stay safe from HIV and changes the way they are perceived by their families and communities.27

- Also in South Africa, the Men as Partners (MAP) programme uses community-based workshops to challenge the attitudes and behaviours that perpetuate violence against women and increase their vulnerability to HIV. Through frank discussions of gender stereotypes and power dynamics, the programme engages men and boys as positive forces for change in reducing violence, particularly as it contributes to the spread of HIV. A preliminary evaluation showed that workshop participants were more likely to believe that men and women should have equal rights and that wife-beating was wrong.28

- With funding from the UN Trust Fund to End Violence Against Women, the Soma Development Organisation in Puntland, Somalia, conducts psychosocial training of peer counsellors on violence and HIV. Counsellors, who include traditional birth attendants and other health workers, are taught to recognize and respond to the signs of violence, and to provide appropriate referrals to HIV and AIDS services.29

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29 The UN Trust Fund to End Violence Against Women, established by the UN General Assembly within UNIFEM in 1996, has supported innovative programs to address violence against women in nearly 100 countries. In 2005, it began a small grants programme to address the intersection of violence against women and HIV. Information on this project was provided by UNIFEM.
Other programmes provide essential services for survivors of violence, particularly given their increased risk for HIV:

- The Nairobi Women’s Hospital Gender Violence Recovery Centre in Kenya provides specialized medical and psychological treatment, including HIV and AIDS services, to survivors of domestic violence and sexual abuse. To date, the centre has provided medical assistance and counselling to more than 3,000 women, including basic lab tests and medical examinations, post-exposure prophylaxis (PEP), HIV tests and interventions to prevent mother-to-child transmission (pMTCT).

- The Cambodian Women’s Crisis Center (CWCC) assists abused and trafficked women through its crisis shelters, drop-in centre and counselling programme, which includes information on HIV. CWCC also provides referrals for HIV testing and, when appropriate, for HIV and AIDS care, including antiretroviral (ARV) treatment.

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30 Where the risk of HIV infection is high, post-exposure prophylaxis (PEP), a 28-day course of antiretroviral therapy to begin within 72 hours of rape or other exposure, has been used to reduce risk of HIV infection. Unfortunately, information about and access to PEP is still not widespread in countries most highly affected by AIDS, and it must be better integrated within a broader, more comprehensive response to rape.


32 Duvvuri, N. p. 22.
**Sexuality Terms**

In previous sessions, we demonstrated how the terms male and female can be used to describe the biological characteristics of individuals and to describe gender-related characteristics or the sociological roles and expectations of individuals. The following are some terms that will help clarify concepts associated with sexuality.

<table>
<thead>
<tr>
<th>TERM</th>
<th>DEFINITION</th>
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<tbody>
<tr>
<td>Sexuality</td>
<td>Involves giving and receiving sexual pleasure, as well as enabling reproduction. Sexuality is a total sensory experience, involving the whole mind and body—not just the genitals. A reflection of the total expression of who we are as human beings, sexuality is shaped by our values, attitudes, behaviours, physical appearance, beliefs, emotions, personality, likes and dislikes, and spirituality, as well as all the ways in which we have been socialized.</td>
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<tr>
<td>Gender identity</td>
<td>Refers to an individual’s own sense of identification as male or female. The term distinguishes this psychological association from the physiological and sociological aspects of gender.</td>
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<tr>
<td>Heterosexual</td>
<td>A person who is emotionally, romantically and/or sexually attracted to people of another gender.</td>
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<td>Homosexual</td>
<td>A person who is emotionally, romantically and/or sexually attracted primarily to people of the same gender.</td>
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<tr>
<td>Bisexual</td>
<td>A person who is emotionally, romantically and/or sexually attracted to both men and women.</td>
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<tr>
<td>Gay</td>
<td>Men or women who feel romantic, emotional or sexual attraction to members of the same sex.</td>
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<tr>
<td>Lesbian</td>
<td>A woman who feels romantically, emotionally and sexually attracted to other women.</td>
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<tr>
<td>Men who have sex with men (MSM)</td>
<td>This term is used to refer to all men who have sex with other men regardless of their sexual identity. A man may have sex with other men but still consider himself to be a heterosexual or may consider himself to be gay or may not have any specific sexual identity at all.</td>
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<tr>
<td>TERM</td>
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<tr>
<td>Transgender/ism</td>
<td>Describes those whose gender identity is neither male nor female. They defy binary gender categorization and blur the roles typically assigned to either males or females. In contemporary usage, “transgender” has become an umbrella term that is used to describe a wide range of identities and experiences, including but not limited to: preoperative, postoperative and nonoperative transsexual people; male and female cross-dressers (sometimes referred to as “transvestites”, “drag queens”, or “drag kings”); people with both male and female biological organs and/or genitals; or men and women, regardless of sexual orientation, whose appearance or characteristics are perceived to be gender atypical. (A male-to-female transgendered person is referred to as a “transgender woman”, and a female-to-male transgendered person is referred to as a “transgender man”).</td>
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<tr>
<td>Transexual/ity</td>
<td>Describes members of the transgender community who undergo their gender transition to live full time in the gender that corresponds to their identity (typically the opposite of their birth sex). There are male-to-female and female-to-male transsexuals. A transsexual may or may not have had sex reassignment surgery and thus could be a preoperative transsexual, a postoperative transsexual or a nonoperative transsexual. (A male-to-female transsexual person is referred to as a “transsexual woman”, and a female-to-male transsexual person is referred to as a “transsexual man”).</td>
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<tr>
<td>Intersex/ed</td>
<td>Describes those who have both male and female biological organs and/or genitals (formerly called “hermaphrodites”).</td>
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Quiz: Myths on Sex and Sexuality

Instructions: State whether the following statements are myths or facts. Provide reasons for your responses.

1. Sexually transmitted infections (STIs) can be cured if an infected man has sex with a virgin.
2. Condoms help prevent the spread of sexually transmitted infections.
3. Homosexuality is a mental illness.
4. Most homosexuals are men.
5. Many men who have sex with men are married and have children.
6. Foreigners introduced homosexuality into this region.
7. Most women with HIV are sex workers.
8. A man can only become infected with HIV from an infected woman, not if he has sex with an infected man.
9. Having a sexual relationship with only one partner will prevent HIV and other sexually transmitted infections.
10. Girls do not have sex before marriage.
11. Contraceptive services are not necessary for unmarried adolescents.
12. All materials or pictures that are sexually explicit should be banned.
13. People should only have sex in order to produce children.
Understanding the Recruitment and Retention of Women in Clinical Trials

What are some of the considerations regarding recruitment and retention of women in AIDS vaccine clinical trials?

To determine the safety and efficacy of an AIDS vaccine candidate, it must be tested in populations that are most affected by the disease. This requires conducting AIDS vaccine clinical trials in countries with the highest HIV infection rates.

The best way to know if a vaccine will be safe and efficacious for a particular population is to include that population in vaccine research and development from the beginning. In addition, in order to ensure licensure of a vaccine, it must be tested in the populations in which it will be used. Given the fact that women are at increasingly high risk of infection, particularly in sub-Saharan Africa where women represent the majority of infections and would therefore be among the populations that would benefit most from a vaccine, it is critical that AIDS vaccine candidates are evaluated in female volunteers.

Including adequate numbers of women and men in efficacy trials will ensure that any differences in effect of the vaccine that may be caused by biological differences between men and women can be detected, and will help ensure licensure. In addition, principles of health equity imply that women and men should both have the opportunity to receive the benefits of trial participation.

Reaching the Target

Specific targets are often set for the number of women who will be enrolled in an AIDS vaccine clinical trial. If the percentage of women participating is too low, researchers may be unable to draw conclusions about the safety or efficacy of the vaccine candidate in women.

During an efficacy (Phase III) or preliminary efficacy trial, such as a Phase IIb test-of-concept trial, it is also important to include volunteers at higher risk of HIV infection in order to evaluate whether or not the vaccine candidate works, as well as to conduct the trial in the shortest time frame possible and with the fewest volunteers possible. This issue was highlighted in the recently conducted STEP trial, testing Merck's AIDS vaccine candidate. The majority of volunteers enrolled in the trial in North and South America, Australia and the Caribbean were men who have sex with men. One-third of the participants were women, but during the course of the trial only a single HIV infection occurred in a female volunteer. As a result, those conducting the data analysis could not draw any conclusions about how well the vaccine worked in women. For the Phambili trial, a companion study to the STEP trial that was conducted in South Africa, investigators planned to enrol mostly women, but this study was stopped early by the trial's data safety monitoring board based on the lack of efficacy found in the STEP trial.

Recruiting Women

Recruiting women for AIDS vaccine trials can be challenging. In some places it is difficult for women to participate because they are the primary caregivers for their families and are therefore unable to make regular clinic visits. To make it easier for women to participate, some clinical trial centres alter their hours or offer supervised child-care services and encourage women to bring their children along on clinic visits.

In other situations women are hesitant to participate without the permission of their husbands or male partners. One strategy used to encourage participation in this case is to offer couples voluntary counselling and testing for HIV. At many clinical trial centres where couples cohorts are established, researchers have been able to recruit higher numbers of female volunteers for AIDS vaccine trials.

**Pregnancy and Participation**

Women may also be unwilling to participate in a trial if they wish to become pregnant. Pregnant women are not allowed to enrol in AIDS vaccine clinical trials because of safety concerns regarding the effect of the product on the woman or the foetus. If a woman becomes pregnant during the course of an AIDS vaccine trial, she is not allowed to receive further vaccinations. Women who become pregnant during an AIDS vaccine trial, as well as their babies, are usually followed beyond the end of the trial to monitor any potential adverse effects of the vaccine. During microbicide or pre-exposure prophylaxis trials—where antiretrovirals are administered to women to try to prevent HIV infection—women must discontinue use of the product for the duration of their pregnancy.

In all HIV-prevention trials, women are counselled to use some form of contraception to prevent pregnancy. Some trials require that women use hormonal contraception, either oral or injectable, in addition to a barrier method such as condoms, to prevent pregnancy. Although some studies have suggested that hormonal contraceptives can increase a woman’s risk of HIV infection, this association has not been proven, and the WHO continues to include hormonal contraceptives as recommended forms of contraception. Whether or not hormonal contraception is required, female volunteers are usually offered it free of charge. These services, however, are not always provided at the clinical trial centres. Instead, women may be given a referral to a clinic in the area that provides hormonal contraception.

Despite efforts to provide access to contraceptives, pregnancy rates during some HIV-prevention trials have been quite high. All women are tested for HIV infection before enrolment, and researchers speculate that some women who find out they are not infected may choose that time to become pregnant. In a microbicide trial conducted in Nigeria, 7 percent of women who were screened for participation in the trial were already pregnant, and during the trial 30 percent of the participants became pregnant. In a trial testing pre-exposure prophylaxis, the total pregnancy rate at all sites in Cameroon, Nigeria and Ghana was 56 percent during the trial. If such a high percentage of women are excluded from the trial for an extended period of time, the trial can lose its statistical power. This limits the ability of investigators to interpret the data and draw conclusions about the safety and efficacy of the intervention being tested.

Many trial centres are now offering on-site female planning services and are focusing on the quality of those services to reduce pregnancy rates in trials and to meet volunteer needs.
What are the major considerations influencing the decision to volunteer for an AIDS vaccine trial?
Making the decision to participate in an AIDS vaccine clinical trial is a complex and personal process, and it is important that all potential volunteers fully understand what is involved in the trial when making this choice. Researchers and staff conducting AIDS vaccine trials take several measures to ensure that, to the best of their ability, any possible benefits and risks of trial participation are identified. These are then reviewed before the trial begins by local and independent groups known as ethical review committees (ERC) or institutional review boards (IRB) and sponsors to ensure the list is complete. The ERC is committed to ensuring that the trials are run to the highest safety and ethical standards. All of the possible benefits and risks are also explained carefully to each interested volunteer during the informed consent process.

Benefits
There are several ways that clinical research, including AIDS vaccine trials, can benefit the countries and communities in which the trials take place even if the vaccine candidate being tested is eventually found to be ineffective. Before AIDS vaccine trials are conducted, educational campaigns take place to raise awareness within the community about HIV transmission and prevention, and these can benefit all community members, not just those who choose to volunteer for the trial. Many of these outreach programmes also promote voluntary counselling and testing (VCT) for community members to find out if they are HIV infected, which can influence future decisions about their health and help reduce the stigma associated with HIV testing.

There are also several possible benefits for those who decide to participate in an AIDS vaccine clinical trial. They include the VCT services and risk-reduction counselling that the volunteers will receive regularly throughout the course of the trial. Volunteers will also have continual access to the best available prevention measures in their community, including male and female condoms. Participants in AIDS vaccine trials also benefit from the rewarding feeling of being involved in medical research that may benefit others. Altruism, or concern for the welfare of others, is one of the most common reasons trial volunteers give for participating.

Other possible benefits include the basic medical care that volunteers receive during the trial. People interested in volunteering for AIDS vaccine trials who are found to have malaria or tuberculosis can receive referrals to treatment programmes in their community, thereby improving their overall health. This is also true for people who are found to be HIV infected or who become HIV infected during the course of the trial through exposure in their community. These individuals can be referred to treatment programmes as well as to support groups.

Volunteers in AIDS vaccine trials might also receive reimbursement for transportation to and from the trial centre or for food if they are expected to be at the centre during a mealtime. A reasonable amount is determined, with input from the community advisory board, before the trial begins and is reviewed and approved by the ERC.

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Researchers and the ethics committees take these considerations seriously because they don’t want the compensation or the healthcare provided at the trial centres to be the reason that people join the study. All trial organizers and approval bodies work carefully to avoid undue inducement. To prevent this, some trial centres may strive to provide a level of care that is consistent with what is available in the broader community. Other centres try to extend some basic healthcare services as much as possible to the wider community, which can be difficult at urban locations.

Volunteers should not feel pressured by the trial staff into enrolling in a trial but should make a decision only after weighing all of the potential benefits and risks. Ethicists are also studying how to ensure that adolescents fully understand the risks and benefits of participation in medical research before agreeing to enrol. This may be an important issue in the future as researchers consider the possibility of testing AIDS vaccine candidates in this age group.

**Risks**

It is equally important that all volunteers understand the potential risks of participating in AIDS vaccine clinical trials. All vaccine candidates are tested extensively before they enter human clinical trials, but there is still the possibility that there will be side effects or adverse reactions caused by the vaccine candidate. These are often mild and can include headaches, fever and inflammation at the injection site, but these effects should be explained to all volunteers clearly during the informed consent process. However, researchers can’t predict each individual’s response to the vaccine.

It is also critical for volunteers to understand that there is a possibility that the vaccine candidate will not be effective or that they will be randomly selected at the start of the trial to receive an inactive substance known as a placebo. Either way, the volunteers won’t be protected against HIV infection by participating in the trial, emphasizing the need to practice risk-reduction behaviours.

Other potential risks include the possibility of receiving a false-positive HIV test result in the future (this is when the HIV test detects antibodies in the blood due to the immune response to the vaccine, but there is no HIV infection), being unable to donate blood after participation in the trial and social risks such as facing possible stigma or discrimination.

Despite these inherent risks, researchers and trial staff are dedicated to making sure that AIDS vaccine trials are run safely and ethically and that these trials contribute to the overall health and welfare of the communities that participate in AIDS vaccine research, especially in lower-income countries.
How does the informed consent process work in vaccine trials?
AIDS vaccine candidates must be tested on human volunteers to evaluate their safety and efficacy. A vaccine trial can only be successful if people in the community are willing to volunteer for the trial, receive the vaccination and return to the trial site for follow-up visits. An essential part of running ethical research is assuring that the rights of these volunteers are protected.

To ensure that the volunteer enrolment in vaccine trials meets high ethical standards there is a process known as “informed consent”. During this process, trial investigators must fully explain the details of the trial and the vaccine candidate that will be tested make sure that the volunteer understands the information and allow the potential volunteer to freely decide if he or she wishes to participate. The informed consent process must be completed for each person before he or she can enter the screening process for the trial. During the screening process, all volunteers undergo research voluntary counselling and testing for HIV infection, because only people who are not infected with HIV can enrol in a preventive-vaccine trial.

At the end of the informed consent process, everyone who chooses to join the trial is asked to sign the informed consent document that has all of this information in writing. The document shows that they want to participate in the trial, but informed consent involves much more than simply signing a paper. The United Nations Joint Programme on HIV/AIDS (UNAIDS) established a set of guidelines that recommends cooperation among researchers, community representatives in the form of Community Advisory Boards (CAB) and regulatory bodies to design and implement the informed consent process at AIDS vaccine trial centres throughout the world. The protocol for a vaccine trial, including the informed consent document, must receive approval from a local ethics committee and national regulatory authority before that trial can begin.

Information
Community outreach is the first step of the informed consent process and aims to prepare a community for a vaccine trial. All of the educational materials about HIV and AIDS vaccines are a necessary first step in getting people informed and interested in participating in a trial. This general information includes what HIV is, how it is transmitted and how an AIDS vaccine might work. When members of the community who may be interested in volunteering come to the trial centre, they are educated about the trial and the vaccine candidate being tested.

The nurse or counsellor at the trial centre begins by explaining any general background information about HIV and then explains why the vaccine candidate is being tested, what participation in the trial involves and how the trial is being conducted. For example, in some trials, not every person in the trial will receive the vaccine candidate. Some volunteers will receive an inactive substance known as a placebo, so that the researchers can compare the vaccine being tested to something they know will have no effect. In most trials, neither the volunteers nor the researchers will know who receives the vaccine candidate or placebo until the end of the trial (this is called a “double-blinded” study). The nurse or counsellor explains that the person can’t be infected with HIV from the vaccine candidate and also emphasizes that the vaccine being tested may not provide any protection against HIV infection, so all volunteers must avoid risk behaviours.

The information provided also includes specifics about the trial process, including the length of

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the trial, the number of visits to the trial centre and what medical tests (such as the collection of blood samples) will be required. Potential volunteers will also be informed about the type of general healthcare they will receive during the trial, any reimbursement they will receive for travelling to the site and, most importantly, their right to leave the trial at any time.

The way this information is provided varies based on the trial centre, but informed consent documents used in both lower- and higher-income countries are very similar. At some centres, the informed consent process can extend over several visits, allowing the volunteers to take the information home and discuss it with their family. Once the trial centre staff is trained, it is their responsibility to carry out the informed consent process according to international and local standards.

Researchers may use videos or flip charts to explain complex issues like the benefits and risks of participation in the trial. The possible benefits include the medical attention that volunteers receive, as well as the rewarding feeling of participating in research that will benefit the community. Potential risks of participating in a vaccine trial include the possibility of side effects of the vaccine candidate or the possibility of temporarily having a false positive HIV test in the future, even though they are not HIV-infected. A false positive can occur because the vaccine may cause the person’s immune system to make antibodies to HIV, which is what the standard tests measure.

Cultural Considerations

Investigators at the site do their best to explain terms in a way that is easy for the individual to understand and should try to answer all questions to the best of their ability. This is an important part of obtaining “true” informed consent. Researchers must be able to explain complicated terms to potential volunteers in a way that is relevant to the community and can easily be understood, sometimes even in languages that have no translations for these words.

The local ethics board and community advisory boards have input into the informed consent process before the trial protocol is implemented and can therefore influence this process. Leaders in the community can provide the investigators with culturally specific ways to explain key concepts. But it is still very important that researchers uphold the standards of the informed consent process, while trying to make it more sensitive to the beliefs of the community.

Understanding

The final step of the informed consent process involves ensuring that each individual fully understands the information provided. At some centres, investigators may use written tests to verify their understanding. The investigators also try to ensure that each person’s decision to participate is truly voluntary. The potential volunteer must not be pressured into enrolling by anyone at the trial centre, or by anyone in their family or community. This can be difficult in some cultures where, for example, women are unable to make decisions without consulting their husbands or community leaders. The nurses or counsellors at the trial centres should do their best to find out if each person’s decision was made independently.

After they are certain the choice was made independently and based on a firm understanding of the trial, the informed consent document can be signed. If the volunteer cannot write, he or she may be identified in another way, such as a thumbprint. Volunteers who complete this step can enter the screening process, where they are examined and tested to see if they are eligible for the trial.
Understanding Couples Voluntary Counselling and Testing

Why is voluntary counselling and testing for couples an important process for recruiting women into vaccine trials?

Voluntary counselling and testing (VCT) is the process used by community-based clinics and trial centres to offer HIV testing, education and counselling to individuals who want to know whether they are HIV infected or not. The VCT process involves learning about how HIV is transmitted and what behaviours put a person at risk for infection, in addition to the meaning and implications of the individual’s test results.

There are several different types of VCT depending on whether the service is administered at a community clinic, as an initial screening for participation in an AIDS vaccine trial or before joining a research study. There are also different types of VCT used to target specific populations. One involves testing and counselling couples that are married or living together, rather than individuals, and is therefore referred to as couples VCT (CVCT).

What is different about a CVCT session?

During a traditional VCT session, a person is given information on what can put him or her at risk for HIV infection. In a couples session, the counsellor works with the couple to find out how their behaviours work together to influence their risk. This involves opening a dialogue between partners about their sexual activities and empowering them to communicate their shared risks, which can be complicated in countries where such discussion may be taboo. Nurse counsellors encourage each person to take responsibility for their behaviours and inform them about ways they can limit their risk, such as by using condoms. CVCT is a complex process because counsellors are working with the needs and emotions of two people whose risk for HIV infection can involve others outside of their relationship.

A couple will go through the entire process together, including completing the consent documents, pre-test counselling, HIV testing and post-test counselling. The consent for participation in CVCT requires that the partners agree to receive their HIV test results together, but these results remain confidential outside of the couple.

Dependent on their test results, the nurse or counsellor will work with the couple during the post-test counselling to help them make a plan for the future. In testing and counselling couples, there are three scenarios: both partners are HIV-infected, both are uninfected or one is infected and the other is uninfected. This last case is what researchers refer to as a discordant couple. Counsellors can work closely with discordant couples to create an atmosphere where the partners support each other, both through this process and in the future, while limiting the uninfected partner’s risk of becoming HIV-infected.

Working with couples rather than individuals has been shown to have many positive effects, including increased condom use and a lower rate of new HIV infections between partners.

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Why is CVCT an important recruitment tool for AIDS vaccine trials?
To find out if an AIDS vaccine candidate is effective at blocking HIV transmission, researchers must administer the vaccine candidate to groups or cohorts of people who are at high risk of becoming infected with HIV. This requires testing the vaccine in countries or communities where there is a high prevalence of infection. In sub-Saharan Africa, couples are at the highest risk for HIV infection, and researchers estimate that between 60 and 70 percent of HIV transmission occurs within couples that are married or living together.

African couples are therefore an important cohort for evaluating the efficacy of AIDS vaccine candidates, and CVCT is one way to enrol volunteers that are at high risk for HIV infection from heterosexual transmission. This may not be true on other continents like Asia, where HIV transmission is still mainly occurring in the more traditional high-risk groups, such as sex workers or injecting drug users.

How can CVCT be used to recruit women for vaccine trials?
CVCT is an important way for researchers to reach out to more women about accessing counselling and testing services as well as possibly joining a vaccine trial. In recent years, the number of people utilizing VCT services in some areas of sub-Saharan Africa has increased dramatically, mainly because of new treatment programmes that offer people life-saving drugs if they are found to be HIV infected. Despite being more vulnerable to infection, women remain underrepresented at many VCT sites.

Counselling and testing partners together can empower women to access VCT services while avoiding discrimination or even possible violence from their husbands or communities. At some sites, counsellors will invite couples who have received CVCT to come for focus groups to see how they feel about possibly enrolling in a trial. Couples can learn about the vaccine candidate being tested and find out what it is like to volunteer for an AIDS vaccine trial.

One of the earliest centres to implement CVCT was a clinic in Kigali, Rwanda, run by Project San Francisco and Susan Allen, a researcher from Emory University who has established one of the largest couples counselling centres in Africa. This research centre started screening couples because women requested that their husbands also be tested. Of the original 1,500 women who were seen at the Kigali centre, 1,000 were able to convince their husbands or partners to join them.
Addressing Gender Issues in AIDS Vaccine Research

**VOLUNTEER CONCERNS**

**Fear and misinformation:** Men and women may have concerns about the vaccine candidate and HIV testing.

**Autonomy:** Women may lack the freedom to make independent decisions about HIV testing or participating in a study.

**Domestic violence:** Women may fear the consequences of potential violence if they enrol in a study or test positive for HIV at the screening or at any time during the study.

**Time commitment:** Women bear a heavy burden of work in and outside of the home. Therefore, they may not be able to attend education sessions/clinic visits.

**Travel/location:** Women may not be allowed to travel alone or may not have the resources to make trips to the study site.

**Fertility:** Many women and families value fertility and family size very highly. The requirement that female volunteers avoid pregnancy during the course of the trial may affect their choice to participate. Also, women may fear that a vaccine candidate will impact their future fertility. Still, others fear that the vaccine candidate will harm a developing foetus. Lack of control regarding reproductive matters puts women in a vulnerable position regarding the decision to join and/or continue in studies.

**Contraception:** Women may not be able to negotiate contraceptive use with their husbands/partners, which is necessary for enrolment. Others may fear that the vaccine candidate will interfere with their hormonal contraceptive, or that contraceptives themselves are not safe. They may also worry that the supply of contraceptive commodities may not be guaranteed.

**Stigma:** Men and women may fear that they will be stigmatized if they participate because people will think they are infected or at higher risk, or if they are members of astigmatized group, that such stigma will be exacerbated due to their participation.

**ADDRESSING RECRUITMENT**

Trial teams must tailor their messages carefully when recruiting volunteers to minimize the risk of stigma and discrimination for specific groups.

Those contacting volunteers may be close to the community, so the trial team has to bear in mind the possibility of disclosure or pressure that could be exerted on volunteers.
The name and location of the research study should be under a neutral, nonthreatening name since visits to an HIV and AIDS or STI clinic may be stigmatizing, particularly for women.

Women’s groups and NGOs working on women’s health issues could help in mobilizing husbands and families to understand the importance of women’s participation in trials. Members of community advisory boards and opinion makers within the community could also be part of this process.

ADDRESSING CONFIDENTIALITY

All trial personnel (those who are recruiting, conducting trials and assessing) should be trained to handle issues of confidentiality in a gender-sensitive manner.

Maintaining confidentiality of high-risk groups is critical. It is particularly important to be aware of risks for women, who often face violence; for partners of migrant workers, who are often alone and vulnerable to abuse; and for female sex workers. Men who have sex with men may also face high levels of stigma and discrimination or violence.

Each individual’s diagnostic test results should be confidential and shared only with him or her. Support can be provided if the participant wishes to share results with his or her family.

A woman’s need for confidentiality should be respected, and she should be allowed to determine whether or not she wishes to share information with her family or spouse.

Volunteers can be offered the option to leave confidential papers regarding the trial with the investigator if they wish to do so.

The name and site of the research study should be under a neutral, nonthreatening name since visits to an HIV and AIDS or STI clinic can be stigmatizing, particularly for women.

If a woman is known to be a participant in a trial, it may be perceived that she is engaging in risk behaviour, or protecting herself from the risk behaviour of her partner, so confidentiality should be handled in a gender-sensitive manner.

ADDRESSING INFORMED CONSENT

Individual consent must be directly sought from volunteers and not from family members, spouses or partners.

Trial team members should be aware of the possibility of coercion by family or other community members. Women in particular may be subject to coercion or influence of family members.

It is important to ensure that all volunteers make their own decisions at every stage of the trial. An interactive process throughout the trial can help to ensure “meaningful consent”.
ADDRESSING COUNSELLING AND OTHER INTERACTION BETWEEN STAFF AND VOLUNTEERS

Content and approach to counselling must be gender sensitive, and counsellors must be trained accordingly.

Counselling must be tailored to specific trial groups based on gender, social status and education levels.

Gender-matched counsellors may be more appropriate in many cultural contexts.

Researchers should obtain medical history and conduct clinical assessment in a gender-sensitive manner.

For individuals who have difficulty negotiating safer sex practices, counselling must empower them to protect themselves from becoming infected.

Counselling on contraceptive use should take into account issues such as women’s own desire to have children, as well as pressures on women to bear children; women’s level of support from their partners in using contraceptives; their ability to procure contraceptives or access contraceptive services (if not supplied on-site); their preferences and need for contraceptive options such as “non-coitally dependent” methods, non-hormonal methods and barrier methods; and the need to continue using contraceptives throughout the course of the trial.

ADDRESSING THE RESEARCH ENVIRONMENT

Convenient location to enable volunteers, especially women, to attend.

A reception area and space that would be non-intimidating, welcoming and participant-friendly.

Privacy—both in terms of not being seen or heard—when interviews are conducted.

A waiting area with general space for families and a specially designated area for women and children; child care during medical examinations or counselling sessions.

Clean toilets, drinking water, a canteen, appropriate audio-visual material and educational literature are necessary for an overall quality environment.

Gender balance in terms of staff who work with volunteers (e.g., doctors, laboratory assistants and technicians).

Clinic hours and days to suit work schedules of women and men.
Counselling Case Studies

CASE 1: Aisha and Kamau
Aisha, a 24-year-old sex worker, is a volunteer in an AIDS vaccine clinical trial. She has a two-year-old boy. She has come to the research centre on an unscheduled visit. She seems unstable, restless and unusually impatient. She became more restless when she was told that a male counsellor, Kamau, is available for her. She entered the room and could not talk to Kamau at all for 15 minutes despite his prompting her to talk. She started crying and shouting that she wanted treatment to prevent HIV infection. She said, “I do not want to talk to you; you are all the same…. I hate you and I hate even my boy”. Kamau could not understand at all why Aisha, who has been visiting the centre for three years, could react in such a way.

Case Questions:
- What are the issues facing Aisha during her visit?
- What are Kamau’s issues?
- What would you have done if you were in Kamau’s shoes?

CASE 2: Zandile and Bongani
You are a counsellor for a Phase I AIDS vaccine clinical trial. Zandile, a 35-year-old woman who sells vegetables for a living, and Bongani, her 45-year-old husband who does not have a job, have been attending education seminars to learn more about participating in the study. They have both qualified to participate. They have four children and do not intend to have any more. After a week of thinking through the informed consent document, they decided that Zandile would be the one to volunteer for the trial. Once Zandile was enrolled in the trial, Bongani accompanied her to each study visit, staying outside of the site grounds. One day, Bongani did not come with Zandile for her visit. You noticed that she was eager to talk and talked even more about their personal issues. She said that participation in the trial was affecting the upbringing of their children and she wanted to stop coming, but she also understood the benefits of participating in the trial. She said that her husband had repeatedly told her that if she stopped she would have to look for money for healthcare and family-planning costs. She needs your help.

Case Questions:
- What are the issues?
- How would you help Zandile?

CASE 3: Doreen and Kizito
You are a female counsellor at a hospital site for AIDS vaccine clinical research. Doreen is a 35-year-old volunteer in a Phase I clinical trial, and you have been counselling her in the context of the study for 12 months. You also happen to attend the same church every Sunday. Doreen is also a doctor at the hospital, as is her 30-year-old husband, Kizito.

On Doreen’s most recent visit, she came to tell you that her husband does not want her to participate in the trial any longer, but that she prefers to continue. You understand the importance of independent decision-making. You remind her that she is an independent adult (you are thinking...
about the fact that Doreen is older than Kizito) and an intelligent woman who should be able to make her own decision. However, in your personal life, you too struggle with similar issues with your own husband.

Throughout your conversation with Doreen, she repeatedly mentioned that the “husband is the head of the house”.

**Case Questions:**
- What are the issues in this counselling session?
- How could Doreen be counselled?

**CASE 4: Banda and Mwabi**

You counsel volunteers participating in a Phase III AIDS vaccine clinical trial. You have been counselling Banda, a good-looking 26-year-old man, for 12 months. He poses as a rich young man in pubs, but actually, he is a sex worker. He has told you in the past that he avoids using condoms because he does not like the way they feel and because he can charge higher fees for sex without a condom. Still, he acknowledges your effort to encourage him to practice safer sex when you have your counselling visits with him.

You went out to dance with your 24-year-old cousin, Mwabi, to celebrate her graduation. Banda sees you and poses as your colleague. You notice that Mwabi is into Banda and that she has been drinking throughout the evening. Later, Mwabi tells you that she and Banda will go to another club and that she will see you tomorrow.

**Case Questions:**
- How would you handle this situation?
- How might your reaction change if you knew Mwabi’s HIV status?

**CASE 5: Maureen**

You are a male counsellor working with volunteers in an AIDS vaccine research study. You have not heard from Maureen since she missed her scheduled study visit. You decide to call her, and her husband answers the phone. When he hears your male voice on the phone, he threatens you, so you hang up. The next day, you pass Maureen on the street and see that she has bruises on her face. You feel guilty and blame the call you made for the violence she experienced.

**Case Questions:**
- What are the possible issues?
- What could have been done differently?

**CASE 6: Counsellor**

You are a counsellor at a clinical research centre that is recruiting a cohort of men who have sex with men for an AIDS vaccine clinical trial. However, based on your personal values, you disapprove of homosexuality. Because you will be working with these men, you are working on your attitude toward them. However, you realize that you understand very little about their lifestyle, and since you have
never met an openly gay man before the study, you are curious. For example, when you counsel the men, you often wonder how they have sex and who is the “female” or “male” in their relationships. You are fascinated by how some behave in feminine ways. After considering these things, you find it important to discuss homosexuality with your children in order to caution them not to follow suit. You, in your opinion, are doing the best for these male volunteers, and the retention rate for the study is good. However, you feel as if the counselling supervisor has an issue with your approach to working with men who have sex with men.

*Case Questions:*

- What are the issues with this counsellor?
- How should the counselling supervisor handle the situation?