AoU TRAINING TOOLKIT
Manual and Slide Decks

Assessing Volunteer Understanding of Informed Consent in Clinical Trials
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Acknowledgement

Many collaborators contributed to the development of the core content of the Mixed-Method AOU.

**AOU pilot studies:**
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Background

The International AIDS Vaccine Initiative (IAVI) and partners worked to develop a way to enhance the assessment of volunteer understanding of informed consent for HIV vaccine clinical trials.

The goal was to:
- Facilitate genuine informed consent (IC)
- Ensure adequate understanding of core trial concepts among participants
- Develop a suitable and adaptable tool
- Empirically assess the tool
- Tweak the tool for optimum use in trials

The first step of this process focused on identifying the more complex and critical concepts of informed consent for trial volunteers to understand before HIV vaccine trial participation. This involved discussions with various stakeholders to determine relative importance of concepts, by asking the question - “what is the consequence of failing to understand each concept?” The process was assessed by gathering feedback from counselors and staff who administered these tools as well as IAVI, HIV/AIDS Vaccine Ethics Group (HAVEG) team and community advisory board (CAB) members at certain research centers. Four critical concepts were identified:

1) False sense of protection.
2) False positive HIV test result due to receipt of study vaccine.
3) Contraception.
4) Possible enhanced susceptibility to HIV infection after receipt of study vaccine if exposed to HIV through high-risk behaviour.

A pilot was designed to test the tool within a hypothetical trial setting. The piloted tool consisted of both open ended questions, using scenarios as well as closed-ended questions, in the form of a true/false questionnaire. The feasibility of administering the tool in a clinical setting and the acceptability of the tool for researchers and volunteers was also reviewed.

The key learning outcomes for this 2 day training are to:
1) Ensure uniform understanding of the informed consent concepts and assessment of understanding (AoU) tool
2) Build familiarity with the new tool
3) Strengthen skills to conduct assessments with the new tool
4) Build understanding on how to develop assessment tools for different types of clinical studies e.g. microbicides.

Guidelines for the Trainer

What follows are some key pointers to follow as you conduct the training.

Trainer Brief

Each session is preceded by a summary box, with the time allocated to the session, the objectives of the session, the materials needed, the training methods used and the complementary materials you will need to refer to during the session.
Trainer Narrative

There is no text for the trainer in this manual. You will need to be very familiar with the content before running the training, so that you can administer the training. There is text that accompanies each PowerPoint slide - this means that you can look at the audience when you are addressing them; this makes sure that you are not reading the slides and looking away from your audience when presenting.

Speaking Clearly

Speaking carefully and writing clearly and pausing to allow your participants to keep up is important. You are not wasting time – you are ensuring that the information you are sharing is being received and processed.

Handling Questions

You may find that questions arise during the course of a session. You won't always have the time to answer the questions as they are asked. We suggest a parking lot for such questions. This is a flip chart with 'Parking Lot for Excellent Questions' written at the top. This is where you can record questions on the training content that you plan to answer later on. You can ask the person who asks the valuable and pertinent question to write it up in the parking lot. At the end of the session you can answer the questions. Once you have the list of questions in the parking lot, you can look at the list and decide which ones are related to each other and which ones to answer first. It is best to go over the questions in order of importance. As you cover each question, check it off the list.

If you don't know the answer, what should you do? Acknowledge the question, mark it in the parking lot and put a star next to it – noting that you will need to make further inquiry to find the answer to this question. As the trainer, you are not expected to know everything, but you are expected to be able to figure everything out eventually. If you start to explain, and realize half way through that you are stuck, it usually pays to stop and admit it. The best strategy is usually to stop before you get confused and to do as suggested above.

Writing on the Flip Chart or the White Board or Black Board

If you write on the flip chart, black board or the white board your writing should be large and clear. Try using markers that have enough ink for the duration of the training or soft chalk if you are writing on a black board. If the room is large make sure the size of your letters is legible from the furthest seat. If you are not a regular trainer – please practice your writing in advance of the training.

Try not to fill a flip chart or a board with too much writing. Don't keep writing in the corners and edges of your old, filled up board. If you need space on the board, try to erase the oldest writing, not the most recent. You and the participants may want to refer back to the most recent writing, so leave it up for a while. If you are using a flip chart – tape the sheets of completed paper on the wall.
Diagrams and Pictures

Sometimes the training manual uses diagrams and pictures – in particular when we are reviewing the critical concepts of the AoU and the points for each critical concept and the sub-concepts. A diagram helps the learners because it can convey relationships that are almost impossible to put into words. Diagrams can help you as the trainer, because you can refer to them over and over. Do not be afraid to revert to the slides with the diagrams to clarify things for your participants. There is no harm in returning to slides you have already presented.

Pre assessment

In Handout #13 ‘Brief Informed Consent Assessment Questionnaire’ is a pre-assessment. You can use this as a separate exercise a few weeks before the training to determine the level of knowledge of the participants. You can also use it as a pre-assessment before the training – but be aware that it might put people in a sensitive/defensive position with their senior investigators, if the level of knowledge is not where it should be.

Top Ten training tips for the trainer

1. Stand to the side of the projector or the projected screen.
2. Talk to the learners (not to the screen).
3. Write clearly and use lots of space.
4. Use simple straightforward language – with no jargon or abbreviations – unless you have clarified what they mean from the start.
5. Give attention to complex questions and give learners the challenge to answer simple ones.
6. Speak clearly (no ums) and at a regular pace.
7. Look up!
8. Smile!
9. Be confident – you have prepared!
10. Encourage your learners!

Timekeeping

Time is a precious resource, and no one wants their time wasted. To ensure you cover all of what needs to be covered you should use the agenda and assign start and finish times – using the allocated time estimate as a guide. The agenda is what you will refer to in order to keep the training running on target and on time.

Catering

Providing beverages and snacks is helpful - it can make a big difference to the mood and energy level of the group!
Agendas

Sites that are training to implement the AOU tool in different clinical trial settings should determine how much time is needed to complete the training. The training agenda for Day 1 describes the AOU training process for HIV vaccine clinical trials, while the training agenda for day 2 describes the process of adapting the AOU tool and training for other clinical trial contexts. You can choose to use more or less time, depending on the previous experience and comfort level of the site staff with administering AOU.

Note to Trainer:
• Trainers can use the table below to complete the start and end times for each training section using the ‘Time Allocated’ in column two as a guide.
• Keeping this agenda visible and as a guide can help keep the training on track and on time.

### Training Agenda – Day 1

<table>
<thead>
<tr>
<th>Topics</th>
<th>Time allocated</th>
<th>Start time</th>
<th>End time</th>
</tr>
</thead>
<tbody>
<tr>
<td>DECK 1: Introduction session</td>
<td>30 minutes</td>
<td></td>
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<tr>
<td>DECK 2: Overview of informed consent &amp; the relevance of the AoU studies.</td>
<td>60 minutes</td>
<td></td>
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</tr>
<tr>
<td><strong>BREAK – 20 minutes</strong></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>DECK 3: The key components of the AoU mixed tool.</td>
<td>90 minutes</td>
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</tr>
<tr>
<td><strong>BREAK – 60 minutes</strong></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>DECK 4: Administering and Scoring the AoU Mixed Tool</td>
<td>90 minutes</td>
<td></td>
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<tr>
<td><strong>BREAK – 20 minutes</strong></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>PRACTICE SESSION Consolidation and Practice</td>
<td>60 – 90 minutes</td>
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</tbody>
</table>

### Training Agenda – Day 2

<table>
<thead>
<tr>
<th>Topics</th>
<th>Time allocated</th>
<th>Start time</th>
<th>End time</th>
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</thead>
<tbody>
<tr>
<td>DECK 5: Adapting the Mixed Tool to other clinical trial contexts</td>
<td>90 minutes</td>
<td></td>
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</tr>
<tr>
<td><strong>BREAK – 20 minutes</strong></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>PRACTICE SESSION</td>
<td>60 minutes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SUMMARY - CLOSING</td>
<td>30 minutes</td>
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</tbody>
</table>
Symbols

- Clock showing time allocated to session
- Handouts
- Steps required
- Summary Points
- Game
- PowerPoint
- Role Play
Deck 1 - Introduction Session

**Total Time:** 30 minutes

**Learning Outcomes:**
By the end of this session participants will:
- Have been introduced to other participants.
- Recognize ground rules and agendas.
- Understand the objectives of the training.
- Understand the critical baseline concepts of informed consent.

**Training methods used:**
- Lecture
- Group Discussion
- Games

**Materials required:**
- Laptop and LCD projector
- Handout 1 (Agendas)
- Introduction Game
- Flip chart or White Board
- Markers & Tape

**Delivery:**
Present the Introduction and Overview Slide Deck # 1 - there are notes in the slides for the trainer that can be found under presenters’ text.

**Trainer Preparation:**
1) Set up the LCD projector for the Slide Deck # 1 and load the session with the welcome slide mounted on your screen.
2) Arrange your manual and supplies and ensure that you have a white board or flipchart to hand.
3) Ensure that you have relevant handouts ready for distribution.
4) Ensure that there are enough chairs for all the participants you are expecting. Ensure there is space for role play and group work.
5) Ensure you have arranged catering for tea break – this helps with motivation and concentration.

**Welcome and Introductions**
- Welcome all participants as they arrive.
- Give each person a name tag and any supplies such as a pen and folder and ask them to take a seat – try to mix the group if they are from different institutions.
- Once all of the participants have arrived, or it is the scheduled time to start the training, begin.
Overview of the Session

The purpose of this session:
• Introductions to co-participants.
• Recognition of ground rules and agendas.
• Review the objectives of the training.
• Review the critical concepts of informed consent.

Introductions - Activity

• Introduce yourself and your assistant.
• Participants to turn to the person on their right and ask for his or her name, his or her current position at the place where her or she works; and the nature of the research work that they are involved in – for example, clinical TB research, clinical malaria research or clinical HIV research and the kind of clinical research – drug, vaccine.
• Give the group 2 minutes for this activity and then ask them to regroup.
• Ask the pairs to very briefly introduce their partners to the group.

Ground Rules

• Address housekeeping
  1) Be on time.
  2) Turn off your mobile phones – you can put them on during breaks and switch them off before returning to the training room.
  3) Support one another and always use constructive feedback throughout the training.

Training Objectives

• Refresh understanding of essential informed consent concepts;
• Develop a full understanding of the purpose of the assessment of understanding (AoU) tool;
• Be very comfortable and familiar with the tool so as to leave the training skilled in administering and scoring the AoU tool;
• For those learning to adapt the tool during Day 2:
  Be able to adapt the tool to your research settings, while retaining the AoU’s key features.
Agenda

Distribute - Handout #1 (Agendas)

Agenda Day 1 – Full day

<table>
<thead>
<tr>
<th>Topics</th>
<th>Time allocated</th>
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</thead>
<tbody>
<tr>
<td>DECK 1: Introduction Session.</td>
<td>30 minutes</td>
</tr>
<tr>
<td>DECK 2: Overview of informed consent &amp; the relevance of the AoU studies.</td>
<td>60 minutes</td>
</tr>
<tr>
<td>DECK 3: The key components of the AoU mixed tool.</td>
<td>90 minutes</td>
</tr>
<tr>
<td>DECK 4: Administering and Scoring the AoU Mixed Tool.</td>
<td>90 minutes</td>
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</tbody>
</table>

PRACTICE SESSION
Consolidation and Practice.

60 – 90 minutes

Agenda Day 2 – Half day

<table>
<thead>
<tr>
<th>Topics</th>
<th>Time allocated</th>
</tr>
</thead>
<tbody>
<tr>
<td>DECK 5: Adapting the Mixed Tool to other clinical trial contexts.</td>
<td>90 minutes</td>
</tr>
</tbody>
</table>

PRACTICE SESSION
60 minutes

SUMMARY - CLOSING
30 minutes

Activity - Defining Informed Consent

- Give each group FIVE minutes to:
  - Come up with their definition of the term 'informed consent'
  - 3 reasons why it is an important part of research ethics.
- Each group should write their answers on a sheet of flip chart paper and tape it to the wall, near where their group is working and to ask one member of the team to read out their definition of informed consent.
- Summarize informed consent for your participants so that one definition prevails:

  INFORMED CONSENT is a process by which potential research participants freely decide whether to participate or not to participate in a research study – having received and fully understood all the information they need to make an informed decision.

- Each group will take FIVE minutes to discuss ONE thing that might happen if informed consent in research does not happen correctly.
- Each group will then take ONE minute to communicate this through role play to the rest of the group.
Summary - Role Play – Follow Up

Without informed consent, it is possible that the volunteer may:

- Not be fully informed and understand his or her role in the research study.
- Choose to participate in the study without understanding the risks and benefits of participating.

Next Step

- Deck 2 – Overview of informed consent & the relevance of the AoU studies.
Deck 2 – Overview of Informed Consent & the relevance of the AoU Studies

**Total Time:** 60 minutes

**Learning Outcomes:**
By the end of this module participants will:
1) Be able to identify critical concepts of informed consent in a clinical trial.
2) Understand the reason behind the development of the AoU tool.
3) Understand the research basis for a mixed-method approach to measure volunteer understanding of informed consent.

**Materials required:**
- Laptop with PowerPoint
- Flip chart or White Board
- Markers & Tape

**Training methods used:**
- Lecture
- Group Discussion

**Delivery:**
Present the Slide Deck #2 - there are notes in the presentation with detailed explanation for you to follow if you wish.

**Overview of Session**
This session covers:
- The critical concepts of informed consent.
- The reason behind the development of the AoU tool.
- The research basis for the mixed tool approach to assessing levels of understanding of informed consent.

**Reasons for using Informed Consent in research**
- It is an essential ethical requirement for all clinical trials involving human subjects.
- It is necessary to make sure that potential volunteers are not encouraged to take part in research that they have not fully understood.
- It is critical that research with human subjects includes effective Informed Consent to protect people from participating in research that may cause harm without them fully understanding the potential risks.
- Volunteers should be informed to make a clear choice whether to participate or not.
- Obliged based on 4 basic principles in ethical research – autonomy, beneficence, non-maleficence and justice.
Four Basic Ethical Principles

There are 4 basic ethical principles in medical research:

• **Respect** the independence or autonomy of the volunteer – **Autonomy**.
• **Prioritize** the wellbeing or the best interest of the research volunteer - **Beneficence**.
• **First, do no harm** to the volunteers - **Non-maleficence**.
• **Assure fairness and equality** (usually ensured through randomization) - **Justice**.

Of these 4 principles – the most important principle for Informed Consent is **respect for autonomy**. Researchers must respect an individual and their capacity to make decisions about their own life.

Genuine True Authentic

Informed consent has to be "**genuine**" and "**true**" and "**authentic**".

Sometimes, informed consent can be too brief and even rushed or minimalistic and this can compromise ethics when it focuses on making the volunteer cooperate.

Good Clinical Practice Guidelines for Informed Consent

- What are the essential components of Informed Consent
  - Be given all the relevant information – this is also called Information Disclosure
  - Fully understand all the information about the study
  - Have the capacity to make a decision: both legally and mentally
  - Be a volunteer – not paid to participate
  - The individual should give explicit and formal consent – by signing or finger printing to show that the volunteer knows what he or she is doing

Good Clinical Practice (GCP) guidelines require that before a potential research volunteer gives informed consent, she or he must understand:

- Trial methodology
- Personal consequences of trial participation
- Potential consequences or benefits of participation
- The right to withdraw
- Confidentiality
- Product-related information
- That this is research not healthcare
- Alternative available treatments
- Compensation
Good Clinical Practice Guidelines for Informed Consent - continued

- The volunteer must recognize that they are consenting to participation in research.
- Recognise that understanding something does not mean that a volunteer has accepted it. Meanwhile, being informed does not mean that you truly understand everything.
- Sometimes research volunteers sign the consent form without fully understanding the risks and benefits of participation.
- The AOU mixed tool is trying to prevent this from happening!

Rationale for Assessment of Understanding (AoU) of IC

- Assessment of Understanding of IC (AoU) - Why do it?
  - Standard Assessment of Understanding (AoU) tools like a checklist, are generally closed-ended true/false questionnaires.
  
  - **Closed-ended tools:**
    - May overestimate understanding
    - May measure short term memory, but may not measure understanding
    - May be culturally foreign
  
  - **Open ended tools**
    - May give a better opportunity to assess understanding
    - Scenarios could be preferable in certain settings.

A tool consisting of both closed ended and open ended questions was developed and tested by IAVI, HAVEG and partners.

Background of AoU Tool Development

- Background of tool development
  - Development of a mixed-method AOU tool was informed and tested in a series of studies
    - Lindegger et al (2006), UKZN HAVEG study
    - AoU Pilot study
    - Comparative study
  
  - Lindegger et al (2006) examined how well different AOU tools measured understanding of informed consent concepts in an HIV vaccine trial. The study compared:
    - **Self-report:** volunteers were asked to estimate their level of personal understanding of each component as “little/no understanding” or “good enough understanding.”
    - **Narratives:** the volunteers were asked to explain everything they know about the trial as though they were talking to a friend.
    - **Scenarios:** volunteers were presented with story vignettes and associated prompts that probe for knowledge of a particular topic.
    - **True/False questions:** a self-administered questionnaire that asked whether statements about trial participation were true or false.

  - They concluded that it was best to use a mixture of methods, especially to assess understanding of complex concepts.

  - Based on HAVEG findings, 4 key complex concepts were identified for the HIV Vaccine.
Critical Concepts Identified

- Critical Concept 1: False sense of protection.
- Critical Concept 2: False positive HIV test result due to receipt of study vaccine.
- Critical Concept 3: Contraception.
- Critical Concept 4: Possible enhanced susceptibility to HIV infection after receipt of study vaccine if exposed to HIV through high-risk behavior.

• Three AOU methods were compared in pilot studies conducted by multiple clinical research center partners, IAVI, and the HIV/AIDS Vaccine Ethics Group (HAVEG).
  - The three methods compared were: Scenarios, true/false, and narrative. Study staff received in-person training from IAVI and HAVEG trainers on how to administer and score the AOU methods prior to the pilots. Role-playing was encouraged to practice. Volunteers and study staff provided feedback on which method they preferred to use, indicating reasons for their choice.
  • Results from the pilot showed that volunteers answered more True/False questions correctly than the scenarios.
  • In other words, volunteers got the answers to the T & F questions right, more often than they got the answers to the scenarios right.
  • This suggests that True False questions may not detect real levels of understanding.

Reinforcing the HAVEG Study Findings

AOU Pilots reinforced the HAVEG study findings:

• The majority of volunteers scored high on all concepts in the true/false, but the same volunteers could not duplicate those high scores on the scenarios and narrative.
  • T/F may be overestimating understanding, perhaps assessing short-term recall or rote memorization?
  • The scenarios and narrative may be more difficult to complete than the T/F questions?
  • The time to administer the scenarios and true/false questions did not differ significantly. The narrative took a bit longer to administer.
• Issues were highlighted around need for thorough training and practice with administering and scoring tools.
• Some volunteers preferred the T/F because they reported that T/F was easier, but more volunteers and study staff preferred the scenarios because it allowed them to have more dialogue about the trial procedures.
• The need to remove counseling ‘hat’ when administering AoU was highlighted.
• The need to be very familiar with concepts and tools before using them.
• The need to be at ease with real time scoring when administering the tools.
Staff Feedback on the Mixed Method Tool

Staff feedback on the Mixed Method Tool

- Highlights need for counselors to be comfortable with informed consent concepts and AOU tool prior to consenting volunteers.

- Initially, staff did not see the benefit of the tool, there were concerns raised about the tool:
  - Cost of implementing the new tool
  - The skill level required to implement the tool
  - Time required to administer the tool
  - The risk of higher rates of screen out of volunteers not qualifying due to low AoU scores
  - Researchers were also concerned about staff ability to be objective in scoring the open ended questions
  - Despite these concerns, following training and implementation, feedback suggests that the tool was well liked by both staff and volunteers.

Excerpts from Feedback from Staff Administering the Mixed Method Tool

Staff felt that the tool allows volunteers to better demonstrate their understanding.

“Volunteers enjoy the scenarios because they are more interactive and they feel more at ease … an opportunity to exchange ideas.” (Doctor, Rwanda).

“… the scenarios also helped us realize there is a chance that we had been making assumptions about volunteer understanding for example, a person may know what a placebo is but not necessarily why it is given.” (Nurse Counselor, Kenya).

Staff said that volunteers appeared to be less nervous as compared to when closed-ended tools were used.

“Scenarios are much better because when you read them the volunteer feels like they are in a conversation while in the T/F they feel like they are doing an exam and get nervous.” (Nurse counselor, Rwanda).

The tool allows staff to assess their own understanding of trial concepts and therefore make necessary improvements to informed consent process.

“The new tool helped the Counselor realize their own understanding of concepts and their ability to explain them well.” (Nurse Counselor, Kenya).

The staff felt the design of the tool allowed for clear and consistent scoring.

“The use of a marking scheme was very helpful to ensuring all information was captured and scoring was correct.” (Nurse counselor, Uganda).
Post-AOU Pilot- Developing a Mixed-Method AOU tool

- The "mixed method" resulted from the pilot studies, the pilot was testing different methods and it was decided to create a mixed-method with the T/F (true - false questions) and scenarios after the pilot.
- This 'mixed-method' tool means:
  - Part True / False questions - Example of T/F:
    - One of the purposes of this study is to see if the vaccines are safe.
    - If you join this study, you may receive an inactive substance called a placebo instead of the study vaccine.

- Part scenarios - Example of Scenarios:
  - Mr. Simba decides that he will enroll in this vaccine trial. So, he starts attending information sessions/discussion. On the way to attend one of his sessions at the vaccine trial site, he thinks to himself, "Once I am in the vaccine trial, I won’t need to worry about practicing this safe sex stuff anymore."

Summarize AoU Rationale and Development

- Open-ended questions like scenarios may assess volunteer understanding of complex informed consent concepts differently than closed-ended questions like T/F.
- A mixed method tool is a viable option to use within the context of a clinical trial.
- To be successful the tool needs researcher commitment to ensure staff are well trained.
- The AoU process helps counselors realize the gaps in the informed consent process and provides a concrete way to address these gaps.

Key lessons were learned from the AoU studies and apply to how the tool is administered.

- Staff who administer the tool need to be:
  - Very familiar and comfortable with the tool and the concepts.
  - Able to clearly and simply explain each concept in the local language.
  - Able to probe so that the volunteer ‘says’ what he / she means – while not ‘assuming’ a meaning.
  - Able to administer the tool as written without deviating too much from the ideas being expressed in each question.
  - Able to listen carefully and record answers at the same time – realizing that the answers rarely come in the scoring sheet sequence.
  - Willing to practice, discuss and share strategies to improve the tool which is still under development.

Next Step

- Deck 3 – will show the key features of the AoU Mixed Tool so that participants can begin to use it.

Note to Trainer: Break
This is a good time to stop for a refreshment break – 15 to 20 minutes.
Deck 3 – The Key Components of the AoU Mixed Tool

**Total Time:** 90 minutes

**Learning Outcomes:**
By the end of this session participants will:
- Unpack the 4 key concepts for an HIV vaccine trial.
- Understand the sub-concepts within each concept and their rationale.
- Understand the decision trees for each concept including prompts.
- Consider the approach to scoring.

**Materials required:**
- Laptop with PowerPoint
- Handout #2: Scoring Cards; #3: Decision Trees, #4: Summary Deck 3
- Flip chart or White Board
- Markers & Tape

**Training methods used:**
- Lecture
- Group Discussion
- Games

**Delivery:**
Present the Slide Deck #3 contained in the slides - there are notes in the presentation with detailed explanation for you to follow if you wish.

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**Overview of Session**

The purpose of this session is to:
- Unpack the 4 critical concepts that were identified in an HIV vaccine trial informed consent document that are assessed using scenarios.
- Understand the sub-concepts within each concept and their rationale.
- Understand the decision trees for each concept including prompts.
- Consider the approach to scoring.

---

**Review the Critical Concepts of AoU**

The following 4 critical concepts were identified during ranking exercises and consultations as described earlier in the training. These 4 critical concepts were identified as being more complex or carrying more serious personal negative consequences if misunderstood by the volunteer. Each concept includes specific sub-concepts that the volunteer should understand before consenting to participate in the research study.

The Critical Concepts and Sub-Concepts:

**Critical Concept #1: False Sense of Protection**
- **Sub-Concept 1a:** Some volunteers may not be getting the vaccine but a placebo.
- **Sub-Concept 1b:** The study vaccine may not protect against HIV.
- **Sub-Concept 1c:** Study volunteers must not increase their risk behavior.
Critical Concept 2: False positive HIV test result due to receipt of study vaccine  
**Sub-Concept 2a:** If volunteers get the vaccine they may test positive for HIV on a standard HIV test.  
**Sub-Concept 2b:** Participants should only get tested for HIV at the research center clinic.  
**Sub-Concept 2c:** The positive HIV test may last a short or long time.

Critical Concept 3: Need for Contraception  
**Sub-Concept 3a:** Volunteers must use contraception after the last trial vaccine.  
**Sub-Concept 3b:** This is to protect children from the possible unknown effects of the vaccine.

Critical Concept 4: Possible enhanced susceptibility to HIV infection after receipt of study vaccine if exposed to HIV through high-risk behavior  
**Sub-Concept 4a:** The study vaccine cannot infect someone with HIV.  
**Sub-Concept 4b:** It is not known if the vaccine can increase the chance of contracting HIV through high risk behavior.

**Summary Table of Concepts & Sub-Concepts**

<table>
<thead>
<tr>
<th>CONCEPT 1</th>
<th>CONCEPT 2</th>
<th>CONCEPT 3</th>
<th>CONCEPT 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>False Sense of Protection</td>
<td>False positive HIV test result after receipt of study vaccine.</td>
<td>Contraception must be used after the last trial vaccination, for the amount of time specified by the trial.</td>
<td>The study vaccine cannot infect the volunteer with HIV.</td>
</tr>
<tr>
<td>Some volunteers may not be getting study vaccine; they may be getting placebo.</td>
<td>Volunteers might test positive on a standard HIV test.</td>
<td>Contraception protects children from the possible unknown effects of the study vaccine.</td>
<td>It is not known if the HIV vaccine could increase the risk of getting HIV infected if the volunteer engages in HIV high risk behaviour.</td>
</tr>
<tr>
<td>The study vaccine may not protect volunteers against HIV Infection.</td>
<td>A volunteer should only get tested at the research center and not outside.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Volunteers must not increase their risk behaviour.</td>
<td>A positive HIV test from the study vaccine could last a short time or as long as several years.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Overview of Characters in Scenarios

- Name the four characters in the scenarios and write the selected names in big letters on the flipchart so you can see them clearly so you or the participants can substitute whenever reading the scenario.

  A name for Mr YY = 
  A name for Mrs ZZ = 
  A name for Mr XX = 
  A name for Mrs NN =

Purpose of the Prompts

The purpose of prompts

- These are guides for the administrator to use in case the research volunteer is not forthcoming with an answer.
- They are not the answers to the questions posed. They are another way to ask the question that can help the volunteer to understand the question.
- They should be administered slowly – one at a time and only if the volunteer has not provided the answer already (i.e. use prompts as needed).

Overview of Critical Concept 1

Critical Concept 1 addresses the 'False Sense of Protection' that may result if someone believes he or she has received an HIV vaccine.

Scenario 1 - Administrator reads this to the volunteer:

Mr YY ________ Decides that he will enrol in this vaccine trial. So he starts attending information sessions/discussion groups. On the way to attend one of his sessions at the vaccine trial site, he thinks to himself "Once I am in the vaccine trial, I won’t need to worry about practicing this safe sex stuff anymore".

Then the administrator asks the volunteer:

If Mr YY ________ told you this, what would you say to him?
Discussion of Scenario 1

What do you think is being tested by Scenario 1?

**Note to Trainer:**
Focus on getting the answers on 2 points - (1) Vaccine is being researched and therefore we don’t know if it will protect or not against HIV and some will get vaccine and others placebos and those who get the placebo will definitely not be protected. (2) No one knows who gets what, everybody participating in the trial should protect themselves from HIV infection.

**Distribute**
- Handout 2 - Score Card for Critical Concept 1 – 4
- Handout 3 – Decision Trees

**Introduction to Scoring Card - Critical Concept 1**
- Scoring card for Critical Concept 1 – False Sense of Protection with the sub-concepts.

**SCORING CARD for Critical Concept 1**
**Please read the following scenario out loud to the volunteer.**

Mr. YY _____________decides that he will enroll in this vaccine trial. So, he starts attending information sessions/discussion groups. On the way to attend one of his sessions at the vaccine trial site, he thinks to himself, "Once I am in the vaccine trial, I won’t need to worry about practicing this safe sex stuff anymore."

Then the administrator asks the volunteer:
If Mr. YY ___________told you this what would you say to him?

<table>
<thead>
<tr>
<th>CRITICAL CONCEPT 1 – FALSE SENSE OF PROTECTION</th>
<th>SCORE:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1) Some volunteers may not be getting a study vaccine; they may be getting the placebo.</td>
<td>1 = CORRECT</td>
</tr>
<tr>
<td>If the volunteer does not mention the above, use the following question to get information.</td>
<td>0 = WRONG</td>
</tr>
<tr>
<td>• Do all volunteers in the study get the same injection?</td>
<td></td>
</tr>
<tr>
<td>2) The study vaccine may not protect volunteers against HIV infection.</td>
<td></td>
</tr>
<tr>
<td>If the volunteer does not mention the above, use the following question to get information.</td>
<td></td>
</tr>
<tr>
<td>• What kind of protection do you think this study vaccine gives?</td>
<td></td>
</tr>
<tr>
<td>3) Volunteer must not increase their risk behaviour.</td>
<td></td>
</tr>
<tr>
<td>If the volunteer does not mention the above, use the following question to get information.</td>
<td></td>
</tr>
<tr>
<td>• What should volunteers be doing to help them not get HIV?</td>
<td></td>
</tr>
</tbody>
</table>
False Sense of Protection
Sub-concept 1

Key points to assess:
• Some might not get the study vaccine.
• Some might get the placebo.

Correct answer

Incorrect answer
• No answer
• Appears confused
• Unsure of what is being asked

If volunteer does not mention any correct answers - then administrator can give 2 prompts:

PROMPT
1. Do all volunteers in the study get the same injection?
2. What injections do they get?

Correct answer

RIGHT ANSWER
Score 1

WRONG ANSWER
Score 0
Continue with AOU until all questions have been administered and calculate the score at the end. Depending on the score, you may reeducate and retest understanding.
False Sense of Protection
Sub-concept 2

Key points to assess:
- The study vaccine may not protect volunteers against HIV Infection.
- The vaccine is still being studied, the researchers do not know if it provides any protection against HIV infection.

Correct answer

Incorrect answer
- No answer
- Appears confused
- Unsure of what is being asked

If volunteer does not mention any correct answers - then administrator can give 1 prompt:

**PROMPT**
1. What kind of protection do you think this study vaccine gives?

Right answer
Score 1

Wrong answer
Score 0

Continue with AOU until all questions have been administered and calculate the score at the end. Depending on the score, you may reeducate and retest understanding.
False Sense of Protection
Sub-concept 3

Key points to assess:
• Volunteers must not increase their risk behaviour.
• Volunteers must practice Safe Sex.
  • One sexual partner  • Or use condoms

Correct answer

Incorrect answer
• No answer
• Appears confused
• Unsure of what is being asked

If volunteer does not mention any correct answers - then administrator can give 1 prompt:

PROMPT
1. What should volunteers be doing to help them not get HIV?

Correct answer

RIGHT ANSWER
Score 1

Wrong Answer
Score 0
Continue with AOU until all questions have been administered and calculate the score at the end. Depending on the score, you may reeducate and retest understanding.
Overview of Critical Concept 2

Critical Concept 2 addresses the 'False positive HIV test result due to receipt of study vaccine.

Scenario 2 - Administrator reads this to the volunteer:

"Mrs. ZZ goes to another clinic outside of the research centre because of being sick often. The doctor at the other clinic advises her to have an HIV test. The results come back positive."

Then the administrator asks the volunteer:

What do you think Mrs. ZZ should have done?

Discussion of Scenario 2

What do you think is being tested by Scenario 2?

Introduction to Scoring Card - Critical Concept 2

- Scoring card for Critical Concept 2 – False positive HIV test result after receipt of study vaccine.

<table>
<thead>
<tr>
<th>SCORING CARD for Concept 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Please read the following scenario out loud to the volunteer.</td>
</tr>
<tr>
<td>While participating in this HIV vaccine trial, a volunteer, Mrs. ZZ goes to another clinic outside the research centre because she is sick often. The doctor at the clinic advises her to have an HIV test. The results come back positive.</td>
</tr>
<tr>
<td>Then the administrator asks the volunteer:</td>
</tr>
<tr>
<td>What do you think about Mrs. ZZ going outside of the research centre to get a HIV test?</td>
</tr>
</tbody>
</table>

CRITICAL CONCEPT 2: False positive HIV test result due to receipt of study vaccine. | SCORE: 1 = CORRECT 0 = WRONG |
|---|---|
| 1) If the volunteers get the study vaccine, they may test positive on standard HIV tests even if they are not HIV infected. If the volunteer does not mention the above, use the following question to get information.  
  • If Mrs. ZZ tests outside the study clinic, what does she need to know about the HIV test result? |
| 2) Only get tested at the research center and not outside. If the volunteer does not mention the above, use the following question to get information.  
  • Where should Mrs. ZZ go if she needs to get tested for HIV? |
| 3) A positive HIV test from the study vaccine could last a short time or as long as several years. If the volunteer does not mention the above, use the following question to get information.  
  • How long could Mrs ZZ test HIV positive due to the study vaccine? |
**Decision Tree - Critical Concept 2**

**Decision Tree – Concept 2 – Sub-concept 1,2,3**

**Note to Trainer:** Please allow extra time for review this flow chart. Be sure to move thoroughly through each step of each flowchart.

---

**False positive HIV test result after receipt of study vaccine**

**Sub-concept 1**

Key point to assess:
- If volunteers get the study vaccine they may test positive for HIV on a standard HIV test, even if they are not HIV infected.

- **Correct answer**

- **Incorrect answer**
  - No answer
  - Appears confused
  - Unsure of what is being asked

- **If volunteer does not mention any correct answers** - then administrator can give 1 prompt:

  **PROMPT**
  1. If the volunteer tests for HIV outside the study clinic, what does he or she need to know about the HIV test result.

- **Correct answer**

- **RIGHT ANSWER**
  Score 1

- **WRONG ANSWER**
  Score 0

Continue with AOU until all questions have been administered and calculate the score at the end. Depending on the score, you may reeducate and retest understanding.
False positive HIV test result after receipt of study vaccine
Sub-concept 2

Key point to assess:
• Volunteers must only get tested for HIV at the research center and not outside.
• Volunteers should always try to test at the research center.
• If a volunteer chooses to test elsewhere, must first inform research team.

Correct answer

Incorrect answer
• No answer
• Appears confused
• Unsure of what is being asked

If volunteer does not mention any correct answers - then administrator can give 1 prompt:

PROMPT
1. Where should the volunteer go if he or she needs to get tested for HIV.

Correct answer

RIGHT ANSWER
Score 1

WRONG ANSWER
Score 0
Continue with AOU until all questions have been administered and calculate the score at the end. Depending on the score, you may reeducate and retest understanding.
False positive HIV test result after receipt of study vaccine

Sub-concept 3

Key point to assess:
- A positive HIV test from the study vaccine could last a short time or as long as several years.
- It is not known how long the false positive test result will last.
- It may last a long time.

Correct answer

Incorrect answer

- No answer
- Appears confused
- Unsure of what is being asked

If volunteer does not mention any correct answers - then administrator can give 1 prompt:

PROMPT
1. How long could the volunteer test positive for HIV due to the study?

Correct answer

RIGHT ANSWER
Score 1

WRONG ANSWER
Score 0

Continue with AOU until all questions have been administered and calculate the score at the end. Depending on the score, you may reeducate and retest understanding.
Overview of Critical Concept 3

Critical Concept 3 addresses the need for Contraception while enrolled in the trial.

Scenario 3 - Administrator reads this to the volunteer:

“While participating in this HIV vaccine trial and one month after Mrs. XX ______ received her first injection, she and her spouse want to have another child. She reports that she is thinking of stopping her contraception.”

Then the administrator asks the volunteer:

What do you think about her decision to get pregnant and stop contraception at this time?

Discussion of Scenario 3

What do you think is being tested by Scenario 3?

Introduction to Scoring Card - Critical Concept 3

• Scoring card for Critical Concept 3 – The need for contraception and the sub-concepts.

SCORING CARD for Concept 3

Please read the following scenario out loud to the volunteer.

“While participating in this HIV vaccine trial and one month after Mrs. XX ______ received her first injection, she and her spouse want to have another child. She reports that she is thinking of stopping her contraception.”

Then the administrator asks the volunteer:

What do you think about her decision to get pregnant and stop contraception at this time?

If Mrs. XX _____ told you this what would you say to her?

CRITICAL CONCEPT 3 – CONTRACEPTION

<table>
<thead>
<tr>
<th>SCORE: 1 = CORRECT 0 = WRONG</th>
</tr>
</thead>
</table>

1) Volunteers must use contraception after the last vaccination to prevent pregnancy. The period is specified by the study protocol.

If the volunteer does not mention the above, use the following question to get information.

• What should the volunteer do to prevent pregnancy? And for how long?

2) This is to protect children from possible unknown effects of the study vaccine.

If the volunteer does not mention the above, use the following question to get information.

• Why should Mrs. XX not get pregnant during the vaccination period?
Contraception
Sub-concept 1

Key points to assess:
• A female volunteer must commit to being on contraception until four months after the last trial vaccination to prevent pregnancy.
• Contraception must be used (even if no reference to time).
• The volunteer should not get pregnant (even if no reference to time).
• It is ok to stop using contraception after a set number of months (specified by the trial) after the last vaccination.

Correct answer

Incorrect answer
• No answer
• Appears confused
• Unsure of what is being asked

If volunteer does not mention any correct answers - then administrator can give 2 prompts:

PROMPT
1) What should the volunteer do to prevent pregnancy?
2) And for how long should the volunteer prevent pregnancy while in the trial?

Correct answer

RIGHT ANSWER
Score 1

WRONG ANSWER
Score 0
Continue with AOU until all questions have been administered and calculate the score at the end. Depending on the score, you may reeducate and retest understanding.

Note to Trainer: Please allow extra time for review this flow chart. Be sure to move thoroughly through each step of each flowchart.
Contraception
Sub-concept 2

Key point to assess:
• This is to protect the child from possible unknown effects of the study vaccine.
• It is not known what the effect of the vaccine could be on the child.

Correct answer

Incorrect answer
• No answer
• Appears confused
• Unsure of what is being asked

If volunteer does not mention any correct answers - then administrator can give 1 prompt:

PROMPT
1) Why should the volunteer not get pregnant during the vaccination period?

Correct answer

RIGHT ANSWER
Score 1

WRONG ANSWER
Score 0
Continue with AOU until all questions have been administered and calculate the score at the end. Depending on the score, you may reeducate and retest understanding.
Overview of Concept 4

Critical Concept 4: Possible enhanced susceptibility to HIV infection after receipt of study vaccine if exposed to HIV through high-risk behavior.

Scenario 4 - Administrator reads this to the volunteer:
"Mr. NN tests HIV positive at the research center clinic. The laboratory test at the research center show that he is really infected with HIV. He is very angry and says to the counselor – ‘I knew this vaccine would infect me with HIV’ – Then he adds ‘Even if the vaccine did not give me the HIV, it is part of the problem.’"

Then the administrator asks the volunteer:
What do you think about what Mr. NN said?

Discussion of Scenario 4

What do you think is being tested by Scenario 4?

Note to Trainer:
Focus on getting the answers on 2 points being tested here. Focus on getting the answers on the sub-concepts - (1) The study vaccine cannot infect a volunteer with HIV; (2) It is not known if the vaccine can increase the risk of getting HIV from high-risk behaviour.

Introduction to Scoring Card - Concept 4

• Scoring card for Critical Concept 4 – Possible enhanced susceptibility to HIV infection after receipt of study vaccine if exposed to HIV through high-risk behavior.

SCORING CARD for Critical Concept 4

Please read the following scenario out loud to the volunteer.
"Mr. NN tests HIV positive at the research center clinic. The laboratory test at the research center show that he is really infected with HIV. He is very angry and says to the counselor – ‘I knew this vaccine would infect me with HIV’ – Then he adds ‘Even if the vaccine did not give me the HIV, it is part of the problem.’"

Then the administrator asks the volunteer:
What do you think about what Mr. NN said?

<table>
<thead>
<tr>
<th>CRITICAL CONCEPT 4 - Possible enhanced susceptibility to HIV infection after receipt of study vaccine if exposed to HIV through high-risk behavior.</th>
<th>SCORE:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1) The study vaccine cannot infect the volunteer with HIV. If the volunteer does not mention the above, use the following question to get information. Can Mr NN get HIV from this vaccine? Why/why not?</td>
<td>1 = CORRECT 0 = WRONG</td>
</tr>
<tr>
<td>2) It is not known whether the HIV vaccine could increase a volunteer’s risk of getting HIV infected if the volunteer gets the HIV vaccine during the study and engages in HIV risky behaviour. If the volunteer does not mention the above, use the following question to get information. Can the study vaccine make it more likely that Mr. NN might get HIV infection if he is exposed to HIV through risk personal behaviour? Why not?</td>
<td></td>
</tr>
</tbody>
</table>
### Possible Enhanced Susceptibility to HIV

**Sub-concept 1**

**Key point to assess:**
- The study vaccine cannot infect or cause HIV in a volunteer.

- **Correct answer**
  - If volunteer mentions the correct answer, continue with AOU.

- **Incorrect answer**
  - **No answer**
  - **Appears confused**
  - **Unsure of what is being asked**

- **If volunteer does not mention any correct answers** - then administrator can give 1 prompt:
  ```
  PROMPT
  1) Can the volunteer get infected with HIV from the study vaccine?
  2) Why/why not?
  ```

- **Correct answer**
  - If prompt is answered correctly, continue with AOU.

- **Wrong answer**
  - **Score 0**
  - Continue with AOU until all questions have been administered and calculate the score at the end. Depending on the score, you may reeducate and retest understanding.
Possible Enhanced Susceptibility to HIV
Sub-concept 2

Key point to assess:
• It is not known whether the HIV vaccine could increase a volunteer’s risk of getting HIV infected if the volunteer gets the HIV vaccine during the study and engages in HIV high risk behavior.

**Correct answer**

**Incorrect answer**
• No answer
• Appears confused
• Unsure of what is being asked

If volunteer does not mention any correct answers - then administrator can give 1 prompt:

**PROMPT**
1) Can the study vaccine make it more likely that the volunteer might get HIV infection if he is exposed to HIV through risky personal behavior?

**RIGHT ANSWER**
Score 1

**WRONG ANSWER**
Score 0
Continue with AOU until all questions have been administered and calculate the score at the end. Depending on the score, you may reeducate and retest understanding.
The AoU Funnel

- During the AoU the volunteers may share a lot of information with the person administrating the AoU – the task of the administrator is to listen and sieve through the information.

How to SIEVE through the information a trial volunteer may share?

- The job of the person administering is to LISTEN to what is being said; determine if the answers are correct or incorrect and score these; identify which sub-concepts have not been addressed and ask probing questions to determine if the volunteer knows or does not know the correct answer.

- The administrator should use the scoring sheet not only to score the answers but also to keep track of what has been answered and what remains to be answered.
Linking Game - A group game and energizer to reinforce the concepts and sub-concepts

Note to Trainer:
Please prepare yourself for the Linking Game before the session.

After you have given the explanations described below, you can give out the cards and tape or safety pins for the participants to attach to their chests described below. You will have prepared these prior to the session. Do not give the cards out until you have explained the instructions. Set a clock or timer so that the group that finishes first and links up in the correct order is given a time, as well as the runner up teams. When the linking game is complete review the links and make sure that all the pieces are in the right place.

- Prepare participants to play a game – that involves moving around.
- Clear a space.
- Show a box full of concepts, scenarios and the key points.
- Invite each training participant in the training to take one card and stick it to his/her shirt with tape. You will try to find all the other people who have the other cards that fit together with your concept.
- Each person will need to find 3 - 4 or 5 other people depending on which concept they have received!
- When a training participant finds all the pieces of her team, they should line up with a Concept – Scenario and each Key Point in the correct order and SHOUT AoU.
- The team that does this first and has all the pieces in the right place is the Winner!
  - Remind the training participants that Critical Concept 1 is 'False Sense of Protection' and it has 1 scenario, 3 sub-concepts that the trial volunteer will need to grasp.
  - Remind the participants that Critical Concept 2 is 'False positive HIV test result due to receipt of study vaccine' and it has 1 scenario, 3 sub-concepts that the trial volunteer will need to grasp.
  - Remind the training participants that Critical Concept 3 or 'Contraception' has 2 sub-concepts and 1 scenario that the trial volunteer will need to grasp.
  - Remind the training participants that Critical Concept 4 is 'Possible enhanced susceptibility to HIV infection after receipt of study vaccine if exposed to HIV through high-risk behavior.' It has 1 scenario and 2 sub-concepts that the trial volunteer will need to grasp.
The Linking Game - Feedback

Ask each team to sit down with their 'linked u' team to discuss how The Linking Game went!

One member of each team can write the feedback on the chart or board.

Start with Critical Concept 1 'False Sense of Protection'
- Did you find all sub-concepts for your concept?
- Did you find it easy or challenging?
- Why did you find it easy? (IF easy) Why did you find it difficult (IF challenging)
- What could help you to remember the components of this Critical Concept next time?

Move to Critical Concept 2 'False positive HIV test result due to receipt of study vaccine'
- Did you find all sub-concepts for your concept?
- Did you find it easy or challenging?
- Why did you find it easy? (IF easy) Why did you find it difficult (IF challenging)
- What could help you to remember the components of this Critical Concept next time?

Move to Critical Concept number 3 'Contraception'
- Did you find all sub-concepts for your concept?
- Did you find it easy or challenging?
- Why did you find it easy? (IF easy) Why did you find it difficult (IF challenging)
- What could help you to remember the components of this Concept next time?

Finally, how did it go for Critical Concept 4 'Possible enhanced susceptibility to HIV infection after receipt of study vaccine if exposed to HIV through high-risk behavior.'
- Did you find all sub-concepts for your concept?
- Did you find it easy or challenging?
- Why did you find it easy? (IF easy) Why did you find it difficult (IF challenging)
- What could help you to remember the components of this Concept next time?

Summary
- The summary exercise
- Handout # 4 – Summary of Deck 3

Note to Trainer:
Give out the Handout – and ensure the class is quiet so that participants can concentrate on the assignment. When they are complete, you can replace the final slide with Slide 39.

Next Step
- Deck 4 – will further explore the scenarios and how to engage the volunteer in the process. How to listen and process the responses for scoring and complete the scoring form.
Deck 4 – Administering and Scoring the AoU Mixed Tool

Total Time: 90 minutes

Learning Outcomes:
By the end of this session participants will:
• Understand the concepts and sub-concepts.
• Understand the scenarios.
• Know how to read the scenarios in an engaging, unbiased way.
• Know how to explain the process to the volunteer.
• Know how to listen to the volunteer responses and analyze the responses for scoring.
• Know how to ask questions and to be objective.
• Know how to complete the scoring from the volunteers’ responses.

Materials required:
• Laptop with PowerPoint
• Handout #5
• Game # 4 Pre-cut puzzle pieces, with the 24 pieces in an envelope, one envelope per participant
• Game # 5 Scoring Exercise
• Flip chart or White Board, Markers & Tape
• Glue Stick
• Blank pieces of paper on to which jigsaw pieces can be stuck
• Clock or timer

Training methods used:
• Lecture
• Group Discussion
• Games

Delivery:
Present the Deck 4 slides - there are notes in the presentation with detailed explanations for you to follow if you wish.

Overview of Session
The objectives for this Session are to:
• Thoroughly understand the scenarios.
• Know how to read the scenarios in an engaging unbiased way.
• Know how to explain the process to the volunteer.
• Know how to listen to the volunteer response and process the responses for scoring.
• Know how to complete the scoring from the volunteers responses.
• Know how to trouble shoot when scoring does not go to plan.
Activity - Solitary Jigsaw Game

This concept summary game is a solitary game. It is a jigsaw puzzle. It will clarify any questions from Handout #4.

Note to Trainer:

- The goal of the game is to reinforce that the training participants know each critical concept, scenario and sub-concept.
- Each training participant should receive an envelope with 24 pieces of the jigsaw puzzle.
- Each participant will need to create 4 jigsaw puzzles - one jigsaw has 5 pieces per concept.
- Give each participant a glue stick for this exercise and Game # 4 with the frame where he or she will stick the pieces of each jigsaw puzzle.
- The one to finish first with 4 complete jigsaw puzzles is the winner!
- There is 1 extra piece in each envelope that does not match or fit into the puzzle.

You can ask your assistant to hand out the envelopes to each participant with 24 pieces of puzzle mixed together in each envelope, along with the jigsaw puzzle, there are 6 blank sheets with a frame into which to stick the pieces.

Once the game is over:

- Review the jigsaw puzzles and be sure everyone completed them correctly.
- Receive feedback from the participants - from the ones who managed and the ones who struggled.
- Write key elements on the board or flip chart.
Solitary Jigsaw Puzzle Game - Feedback

- Critical Concept 1 - False Sense of Protection
- Critical Concept 2 - False positive HIV test result due to receipt of study vaccine
- Critical Concept 3 - Contraception
- Critical Concept 4 - Possible enhanced susceptibility to HIV infection after receipt of study vaccine if exposed to HIV through high-risk behavior

Draw attention to the extra tiles that do not belong to any of the puzzles.

Completed Jigsaw Puzzle for Critical Concept 1

- False sense of protection
- The study vaccine may not protect against HIV infection
- I won’t need to worry about practicing this safe sex stuff any more
- Volunteers must not increase their risk behaviour
- Some volunteers may receive the vaccine, some may receive the placebo
- Volunteers receiving the vaccine are safe than those receiving the placebo

Completed Jigsaw Puzzle for Critical Concept 2

- Only get tested at the research centre
- False positive HIV test
- If the volunteers get the study vaccine they may test positive on standard HIV tests even if they are not HIV infected
- A positive HIV test from the study vaccine may last a short time or as long as several years
- The doctor at the clinic outside of the research centre advises her to have an HIV test
- A positive standard HIV test means that the trial volunteer has HIV.
Completed Jigsaw Puzzle for Critical Concept 3

What should the volunteer do to prevent pregnancy?

Volunteers must use contraception for a period specified by the trial, after the last trial vaccination.

She reports that she is thinking of stopping her contraception.

Protect children from possible unknown effects of the vaccine.

It is okay if the volunteer gets pregnant while receiving injections in the trial.

Completed Jigsaw Puzzle for Critical Concept 4

I knew this vaccine would infect me with HIV. Even if the vaccine didn’t give me HIV, it’s part of the problem.

Vaccine will increase risk of infection if the volunteer has unprotected sex.

No one knows if the risk will increase, decrease or stay the same.

The laboratory test at the research centre clinic shows that he is really infected with HIV. He is very angry.

The vaccine does not cause HIV.

The vaccine suppresses your immune system and you can get HIV.
Scoring Scenarios - Section 1 of the Mixed-Method AOU

OVERVIEW OF SCORING

- Study volunteers get points “correct” for each sub-concept they correctly describe or address. Note: They are not asked specific questions as is the case with the T/F assessment.
- You will need to add up the total number of T/F questions answered correctly PLUS the points earned for the sub-concepts in the scenarios to arrive at a total score for the AOU True/False + Scenario Points = Total Score.

WHEN SCORING

- Add up the total number of questions answered correctly in both true/false and scenarios.
- If ALL Correct (100%) = You ENROLL the participant if they give consent.
- If the allowable number of questions are answered incorrectly = you RE-EDUCATE them on the ones they get wrong.
- If the allowable number of questions are answered incorrectly = you RE-CONSENT & repeat the AoU.
- Allowable number of correct or incorrect questions is usually stipulated by the trial.

Emphasize

- The percentage of allowable questions answered incorrectly will depend on the total # of questions in AOU. Requiring that 80% of questions are correct as the “passing rate” can work well.
- The number answered incorrectly will depend on the total number of questions for the particular AoU.

Scoring Card Formalities

- Before practicing scoring, review what the AoU Mixed tool looks like.
- Complete the Volunteer ID number as appropriate for the study.
- Complete the sex of the trial volunteer.
- Complete the date of the assessment.

Assessment of Informed Consent Understanding

Volunteer ID No.: □□□□  Sex: Male □  Female □

Date of Assessment: □□/□□□/□□□□

Date/Month/Year
### Scoring Scenarios - Example of Concept 1

- When scoring the scenario section of the tool, the person administrating the AoU should mark the response – 1 or 0 in the right hand column.
- A hypothetical example for Concept 1 – False Sense of Protection shows how the scores are entered.

| CONCEPT 1 – FALSE SENSE OF PROTECTION | SCORE:  
1 = CORRECT  
0 = WRONG |
|---------------------------------------|---------------|
| **1) Some volunteers may not be getting a study vaccine; they may be getting the placebo and will not be protected against HIV infection.**  
*If the volunteer does not mention the above, use the following question to get information.*  
• Do all volunteers in the study get the same injection?  
• What injections do they get?  
• What kind of protection against HIV do you think these injections provide? | 1 |
| **2) The study vaccine may not protect volunteers against HIV infection.**  
*If the volunteer does not mention the above, use the following question to get information.* §  
• What kind of protection against HIV do you think this study vaccine provides? | 0 |
Trouble Shooting when Scoring Scenarios

- If the one administrating the AoU is not sure how to score a volunteer’s response he or she needs to mark the query and continue with the other questions.
- Then contact a supervisor to repeat the section where she or he is uncertain.
- If this is not possible – it is best to be safe and re-educate the volunteer, re-administer the tool.

Emphasize
NO ONE SHOULD BE ENROLLED IF THERE IS ANY REASON TO BELIEVE THE TRIAL VOLUNTEER HAS NOT GRASPED ALL THE CONCEPTS AND CRITICAL POINTS.

Distribute
- Handout #5 - An exercise in scoring.
- Give 20 minutes to complete the exercise.

Activity - Exercise in Scoring

Review
- Critical Concept 1: Hypothetical Response for Scoring of Scenarios.
- Responses to handout in detail to see whether there are parts that were found to be challenging.
- Make sure all contribute, to identify which part of the text represents a critical point for Critical Concept 1.

Read
- Critical Concept 1 Scenario and hypothetical reply for analysis.

Ask
- Participants to raise their hands to suggest if there are parts of the response that represent a sub-concept that can award the volunteer 1, 2 or 3 of the scores needed for each concept or if there is a wrong response.

The Scenario: Critical Concept 1

Mr. YY___________decides that he will enroll in this vaccine trial. So, he starts attending information sessions/discussion groups. On the way to attend one of his sessions at the vaccine trial site, he thinks to himself, “Once I am in the vaccine trial, I won’t need to worry about practicing this safe sex stuff anymore.”

What the volunteer asks:
If Mr. YY___________told you this what would you say to him?
Hypothetical Response for Scoring of Scenarios:

Critical Concept 1 - FALSE SENSE OF PROTECTION

“I would say to Mr. YY ____________ remember this is a research thing they are doing - you know it is not a hospital giving out real vaccinations that work, this vaccine it may not even work to protect us from HIV. It may do as much as taking a panadol to stop HIV – it may not even work. I would tell him safe sex stuff is important if you’re not getting the vaccine, but then it is always better to be safe than sorry. Also, it is hard to know if you’re on the vaccine - safe sex in this day and age is the only way and he is a man so that is easy for him, if he was a woman, like me, then safe sex is not always in her court – it is usually up to the man to decide how safe the sex is going to be, do you know what I mean!

So I'd say, ummm be careful, he must remember he may be unlucky and he'll be getting the fake vaccine, the one that does nothing! They call that one the Play vaccine – playcbo, and if you get that one, then you're just going to get HIV out there, unless you're safe. But then maybe Mr YY should remember that he must not go crazy out there and get risky, thinking he's on this magic thing that protects him and he can go and taste all the women out there! No! He must not do that without many condoms– otherwise that can make things worse and he can be unlucky and get HIV.

Discuss Score for Hypothetical Response

• So what score does this volunteer get for Critical Concept 1?

The volunteer responded correctly to all three sub-concepts, so he earned 3 points for this (3/3).

Demonstrate How to Complete the Score Card

• How to complete the score on the score card - for Concept 1 – False Sense of Protection.

<table>
<thead>
<tr>
<th>CONCEPT 1 – FALSE SENSE OF PROTECTION</th>
<th>SCORE:</th>
</tr>
</thead>
</table>
| 1) Some volunteers may not be getting a study vaccine; they may be getting the placebo.  
*If the volunteer does not mention the above, use the following question to get information.*  
• Do all volunteers in the study get the same injection? | 1 |
| 2) The study vaccine may not protect volunteers against HIV infection.  
*If the volunteer does not mention the above, use the following question to get information.*  
• What kind of protection do you think this study vaccine gives? | 1 |
| 3) Volunteer must not increase their risk behaviour.  
*If the volunteer does not mention the above, use the following question to get information.*  
• What should volunteers be doing to help them not get HIV? | 1 |
**Activity - Exercise in Scoring**

- Critical Concept 2: Hypothetical Response for Scoring of Scenarios.

**Ask**

Training participants to raise their hands to suggest if there are parts of the response that represent a correct sub-concept that can award the volunteer 1, 2 or 3 of the scores needed for each critical concept or if there is a wrong response.

**The Scenario: Critical Concept 2**

"Mrs. ZZ___________ goes to another clinic outside of the research centre because of being sick often. The doctor at the other clinic advises her to have an HIV test. The results come back positive."

**You ask the volunteer:**

What do you think about Mrs. ZZ______going outside the research centre to get tested for HIV infection?

**Hypothetical Response for Scoring of Scenarios:**

**Concept 2 - FALSE POSITIVE HIV TEST**

"Perhaps she went there because she was ashamed. I understand. She wanted to keep that she was feeling sick a secret – maybe she had did not want the research people to know in case they told her to leave the study. It is ok. She is allowed to get care – it is a private matter. I would reassure her. Tell her it is ok."

**Prompt posed to the volunteer:**

If Mrs. ZZ___________ tests outside the study clinic, what does she need to know about the HIV test result?

**Hypothetical Response for Scoring of Scenarios:**

"She needs to know that it will be positive or negative and if it is positive then she will be excluded from the research that is why she went to the clinic outside, away from the researchers. Now she will need to go and tell them that she has the disease and that will be difficult for her. I will tell her to have courage and go to the research clinic and to tell the truth. Yes – that will be the best for Mrs. ZZ______".

**Discuss Score for Hypothetical Response**

- So what score does this volunteer get for Critical Concept 2?
- The score for this volunteer is zero for sub-concept 1,2,3,4.
- The score is 0/4.
Demonstrate How to Complete the Score Card

• How to complete the scenario score card for Critical Concept 2 - False positive HIV test result due to receipt of study vaccine.

Please read the following scenario out loud to the volunteer.

While participating in this HIV vaccine trial, a volunteer, Mrs. ZZ goes to another clinic outside the research centre because she is sick often. The doctor at the clinic advises her to have an HIV test. The results come back positive. What do you think she should have done?

CRITICAL CONCEPT 2 - False positive HIV test result due to receipt of study vaccine

| Score | 1 = CORRECT  
| 0 = WRONG |
|-------|------------------|
| 1) If the volunteers get the study vaccine, they may test positive on standard HIV tests even if they are not HIV infected.  
The volunteer does not mention the above, use the following question to get information.  
• Mrs. ZZ tests outside the study clinic, what does she need to know about the HIV test result | 0 |
| 2) Only get tested at the research center and not outside.  
If the volunteer does not mention the above, use the following question to get information.  
• Where should Mrs. ZZ go if she needs to get tested for HIV? | 0 |
| 3) A positive HIV test from the study vaccine could last a short time or as long as several years.  
If the volunteer does not mention the above, use the following question to get information. | 0 |
| 4) How long could Mrs ZZ test HIV positive due to the study vaccine?  
If the volunteer does not mention the above, use the following question to get information. | 0 |
Activity - Exercise in Scoring


The Scenario: Critical Concept 3

"While participating in this HIV vaccine trial and one month after Mrs. XX ______ received her first injection, she and her spouse want to have another child. She reports that she is thinking of stopping her contraception."

Prompt posed to the volunteer:
What do you think about her decision to get pregnant and stop contraception at this time?

Hypothetical Response for Scoring of Scenarios:
Critical Concept 3 - CONTRACEPTION

"Perhaps it is the right time for her to have a child and she did not realize this when she started the trial – it is a shame. I think the timing is not good for her. She should reconsider. It depends maybe she is suddenly feeling pressure, that she did not feel before. I would tell her this is a difficult decision."

Prompt posed to volunteer
What should the volunteer do to prevent pregnancy? And for how long?

Response from the volunteer after the prompt
"Oh my, I would tell this lady she must be careful – the counselor told me they don’t know if the vaccine may damage the baby, so if she got pregnant, she may have this problem. It is best now, if she wants to have a baby, that she stops being in the study and then she can get pregnant…..oh! But she must wait four months now, she must stay on the pill for 4 months before she can get pregnant. The vaccine they will give us, it can stay in the blood – 4 months she must wait. But perhaps it is better she stay in the research and then after the research she has her baby. But that is for her to decide."

Discuss Score for Hypothetical Response

- So what score does this volunteer get for Critical Concept 3?
- The score for this volunteer is 1 for sub-concept 1 and sub-concept 2.
- The score is 2/2.
**DECK 4 - ADMINISTERING & SCORING THE AoU MIXED TOOL**

### Demonstrate How to Complete the Score Card

- How to complete the score on the score card - for Critical Concept 3 – Contraception scenario.

**Please read the following scenario out loud to the volunteer.**

“While participating in this HIV vaccine trial and one month after Mrs. XX ________ received her first injection, she and her spouse want to have another child. She reports that she is thinking of stopping her contraception.”

**Then the administrator asks the volunteer:**

What do you think about her decision to get pregnant and stop contraception at this time?

If Mrs. XX ________ told you this what would you say to him?

<table>
<thead>
<tr>
<th>CRITICAL CONCEPT 3 – CONTRACEPTION</th>
<th>SCORE: 1 = CORRECT 0 = WRONG</th>
</tr>
</thead>
</table>
| 1) Volunteers must use contraception for a trial specified period of time after the last vaccination to prevent pregnancy. The volunteer does not mention the above, use the following question to get information.  
• What should the volunteer do to prevent pregnancy? And for how long? | 1 |
| 2) This is to protect children from possible unknown effects of the study vaccine. If the volunteer does not mention the above, use the following question to get information.  
• Why should Mrs XX not get pregnant during the vaccination period? | 1 |
**Activity - Exercise in Scoring**

- Critical Concept 4: Hypothetical Response for Scoring of Scenarios.

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**The Scenario: Critical Concept 4**

After participating in the vaccine trial for one year, Mr. NN, _______ tests HIV positive at the research center clinic. The laboratory test at the research center clinic shows that he is really infected with HIV. He is very angry and says to the counselor: "I knew this vaccine would infect me with HIV". Then he adds: "Even if the vaccine didn’t give me the HIV, it is part of the problem."

**Prompt posed to the volunteer:**
What do you think about what Mr. NN _______ said?

**Hypothetical Response for Analysis: Concept 4**

- POSSIBLE ENHANCED SUSCEPTIBILITY TO HIV INFECTION after receipt of study vaccine if exposed to HIV through high-risk behavior.

"I think this volunteer is very angry! I too would be very upset – even though there are medicines for this disease, it is not easy. He thinks the vaccine has infected him, maybe he thinks the vaccine is alive with the virus but then it seems that he sees that maybe it is not the vaccine that has infected him but that it has made his situation worse. I would say – yes, this is true the vaccine has not caused him to be infected, it cannot do this!"

**Prompt posed to volunteer:**
Can the study vaccine make it more likely that Mr. NN _______ might get HIV infection if he is exposed to HIV through risky personal behavior? Why/why not?

**Response from the volunteer after the prompt:**
"No – no it is sure the vaccine cannot cause infection – if he got HIV it is because he was sleeping with someone with HIV and he was not safe. It is sure that the vaccine cannot cause HIV! This is what he must know. His infection is of his doing."

---

**Discuss Score for Hypothetical Response**

- So what score does this volunteer get for Critical Concept 4?
- The score for this volunteer is 1 for sub-concept 1 and zero for sub-concept 2.
- The score is 1/2.
Demonstrate How to Complete the Score Card

- How to complete the score on the score card - for Concept 4 – Possible Enhanced Susceptibility to HIV Infection with High Risk Behaviour.

<table>
<thead>
<tr>
<th>CONCEPT 4 - POSSIBLE ENHANCED SUSCEPTIBILITY TO HIV INFECTION after receipt of study vaccine if exposed to HIV through high-risk behavior</th>
<th>SCORE: 1 = CORRECT 0 = WRONG</th>
</tr>
</thead>
</table>
| 1) The study vaccine cannot infect the volunteer with HIV. 
*The volunteer does not mention the above, use the following question to get information.* 
• Can Mr NN get HIV from this vaccine? Why/why not? ? | 1 |
| 2) It is not known whether the HIV vaccine could increase a volunteer’s risk of getting HIV infected if the volunteer get the HIV vaccine during the study and engages in HIV risk behaviour. 
*If the volunteer does not mention the above, use the following question to get information.* 
• Can the study vaccine make it more likely that Mr. NN might get HIV infection if he is exposed to HIV through risk personal behaviour? Why not? | 0 |

Processing Information through the AoU Funnel

- As illustrated in the hypothetical response the volunteers will provide information in different sequences - not necessarily the way it is listed in the scoring sheet.

  - It is important that you listen and know what you are looking for and score it off so that you don’t end up repeating questions and know when each aspect is answered - either correctly or incorrectly.

  - As the administrator and scorer your job is to listen as an objective person.

  - If you are unclear whether the volunteer does not understand or has not clearly demonstrated understanding of a sub-concept PLEASE make sure you ask for clarification.

  - DO NOT GUESS OR ASSUME YOU HAVE UNDERSTOOD THE VOLUNTEER’S ANSWER.
Some volunteers may not be getting study vaccine; they may be getting placebo.

The study vaccine may not protect volunteers against HIV Infection.

Volunteers must not increase their risk behavior.

If volunteers get the study vaccine, they may test positive on standard HIV tests even if they are not HIV infected.

Volunteers must get tested at the research center and not outside.

A positive HIV test from the study vaccine could last a short time or as long as several years.

Volunteers must use contraception until four months after the last trial vaccination to prevent pregnancy.

This is to protect children from the possible unknown effects of the study vaccine.

The study vaccine cannot infect the volunteer with HIV.

It is not known whether the HIV vaccine could increase a volunteers risk of getting HIV infected if the volunteer gets the HIV vaccine during the study and engages in HIV high risk behavior.

Volunteer UNDERSTANDS critical concepts & sub-concepts

ENROLL in STUDY if volunteer gives INFORMED CONSENT

Volunteer DOES NOT UNDERSTAND critical concepts & sub-concepts

CONTINUE THROUGH THE AoU REEDUCATE - RETEST and ENROLL if volunteer gives INFORMED CONSENT at the end, as per green!

Investigator decision NOT TO ENROLL if INFORMED CONSENT CANNOT BE OBTAINED for various reasons.
Overview of Scoring

WHEN SCORING
The person adding up the score should add up the total number of questions answered correctly in both true/false and scenarios.

**All Correct (100%) = ENROLLED**

**Less than 3 questions = ENROLL AND RE-EDUCATE ON MISSED QUESTION(S)**

**3 or more questions = REEDUCATE AND AOU REPEATED**

If the allowable number of questions are answered incorrectly

**= RE-EDUCATE THEM ON THE QUESTIONS THEY GOT WRONG**

If the allowable number of questions are answered incorrectly

**= RE-CONSENT AND REPEAT THE AOU**

WHEN SCORING

It is the responsibility of the person administrating the AoU to protect the potential volunteers who have not fully understood the information.

If the trial volunteer understands all concepts 100% the administrator enrolls them.

Depending on the trial the volunteer will get a number of tries (usually two total) to take the AOU. Either they pass on first or second attempt and can be enrolled, or they fail AOU both times and don’t enroll. Note there is always room for investigator discretion not to enroll the volunteer - despite the AOU results. Otherwise, the AoU administrator must consider the other options.
Scoring True and False Questions - Section 2 of the Mixed-Method AOU

- There are True and False questions that should accompany the scenarios.

<table>
<thead>
<tr>
<th>Question</th>
<th>True</th>
<th>False</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. One of the purposes of the study is to see if the study vaccines are safe.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. If you join this study, you may receive an inactive substance called a placebo instead of the study vaccine.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. One purpose of this HIV vaccine trial is to see if the study vaccine protects against HIV infection.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. If you drop out of this study, you will lose health care benefits that you had before joining the study.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. You are free to withdraw from the study at any time.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. The study doctors and nurses at the research center know who is getting the study vaccine or the placebo.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. Participation in the study will last for 12 months from the first vaccination.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8. One of the vaccines will be given using a device that has an electrical symbol.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Additional True and False Questions

<table>
<thead>
<tr>
<th>Question</th>
<th>True</th>
<th>False</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. There is a possibility that you can become infected with HIV from the study vaccines.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. These vaccines have been shown to be safe in pregnant women and a woman may become pregnant at any time during the study, if she wishes.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. One purpose of this HIV vaccine trial is to see if the study vaccine protects against HIV infection.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Because you are participating in an HIV vaccine trial, you do not have to practice safe sex.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. There is no way to test if someone is testing positive from the vaccine or real HIV infection.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. It is not known whether the HIV vaccine could increase your risk of getting HIV-infected, if you have sex without a condom.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. If you participate in the trial, you should get regularly tested outside of the research centre.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8. Volunteers who get the vaccine will definitely be safer from HIV infection than those who get the placebo.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9. Women must use an effective form of birth control until at least four months after the last vaccination.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Optional questions to select from:

<table>
<thead>
<tr>
<th>Question</th>
<th>True</th>
<th>False</th>
</tr>
</thead>
<tbody>
<tr>
<td>8. You may feel some discomfort when the mucosal samples are being collected.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9. One of the vaccines will be given using a device that produces an electrical signal.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Direction to counselor:** if volunteer is female, please ask question 10a, if volunteer is male, please ask question 10b.

<table>
<thead>
<tr>
<th>Question</th>
<th>True</th>
<th>False</th>
</tr>
</thead>
<tbody>
<tr>
<td>10a. If you agree, samples may be taken from different parts of your body including your nose, mouth, rectum and vagina, to learn what happens in the body when a vaccine is given.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10b. If you agree, samples may be taken from different parts of your body including your nose, mouth, and rectum to learn what happens in the body when a vaccine is given.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Demonstrate True & False Scoring**

- True and False Scoring.

**Section 1: True/False Questions**

Ask the volunteers the following questions. If the volunteer thinks the answer is true, put a cross beside True and if False, crosses F.

<table>
<thead>
<tr>
<th>Question</th>
<th>True</th>
<th>False</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. One of the purposes of the study is to see if the study vaccines are safe.</td>
<td>✔</td>
<td></td>
</tr>
<tr>
<td>2. If you join this study, you may receive an inactive substance called a placebo instead of the study vaccine.</td>
<td>✔</td>
<td></td>
</tr>
<tr>
<td>3. One purpose of this HIV vaccine trial is to see if the study vaccine protects against HIV infection.</td>
<td></td>
<td>✔</td>
</tr>
<tr>
<td>4. If you drop out of this study, you will lose health care benefits that you had before joining the study.</td>
<td>✔</td>
<td></td>
</tr>
<tr>
<td>5. You are free to withdraw from the study at any time.</td>
<td>✔</td>
<td></td>
</tr>
<tr>
<td>6. The study doctors and nurse at the research center know who is getting the study vaccine or the placebo.</td>
<td>✔</td>
<td></td>
</tr>
<tr>
<td>7. Participation in the study will last for 12 months from the first vaccination.</td>
<td></td>
<td>✔</td>
</tr>
<tr>
<td>8. One of the vaccines will be given using a device that uses an electrical symbol.</td>
<td></td>
<td>✔</td>
</tr>
</tbody>
</table>

= correct answer
Optional questions to select from;

1. There is a possibility that you can become infected with HIV from the study vaccines.  
2. These vaccines have been shown to be safe in pregnant women and a woman may become pregnant at any time during the study, if she wishes.
3. One purpose of this HIV vaccine trial is to see if the study vaccine protects against HIV infection.
4. Because you are participating in an HIV vaccine trial, you do not have to practice safe sex.
5. There is no way to test if someone is testing positive from the vaccine or real HIV infection.
6. It is not known whether the HIV vaccine could increase your risk of getting HIV-infected, if you have sex without a condom.
7. If you participate in the trial, you should get regularly tested outside of the research centre.
8. Volunteers who get the vaccine will definitely be safer from HIV infection than those who get the placebo.
9. Women must use an effective form of birth control until at least four months after the last vaccination.

Alternative questions to select from;

8. You may feel some discomfort when the mucosal samples are being collected.
9. One of the vaccines will be given using a device that produces an electrical signal.

Direction to counselor: if volunteer is female, please ask question 10a, if volunteer is male, please ask question 10b.

10a. If you agree, samples may be taken from different parts of your body including your nose, mouth, rectum and vagina, to learn what happens in the body when a vaccine is given.
10b. If you agree, samples may be taken from different parts of your body including your nose, mouth, and rectum to learn what happens in the body when a vaccine is given.
Summary of Scoring - Scenarios and True/False

- Show the summary form for AoU Scoring to determine the final score and next steps.

**Administrator:** Complete this section below after administering the Assessment of Understanding Questionnaire.

<table>
<thead>
<tr>
<th>Tick one:</th>
<th>First Attempt: _____</th>
<th>Second Attempt: _____</th>
</tr>
</thead>
</table>

**Results Of Attempt**

**Section 1: Scenarios**

Volunteer answered _____ correct out of 10 Scenario sub-concept points.

**Section 2: True/False Questions**

**Section 3: Total for Section 1 and Section 2**

Volunteer answered _____ correct Scenarios + _____ correct True/False.

Divide the total by the denominator or total of all questions.

- To determine the score, use the scoring exercises above to practice calculating the score.

**Summary Table for Scoring Scenarios and T/F**

**Administrator:** Complete this section below after administering the Assessment of Understanding Questionnaire.

<table>
<thead>
<tr>
<th>Tick one:</th>
<th>First Attempt: _____</th>
<th>Second Attempt: _____</th>
</tr>
</thead>
</table>

**Results Of Attempt**

**Section 1: Scenarios**

Volunteer answered _____ correct out of 10 Scenario concept points.

**Section 2: True/False Questions**

Volunteer answered _____ correct out of ______ True/False questions.

Total for Section 1 and Section 2:  ______

_____ correct out of  ______

<enter number of T/F questions>
Summarize

End of Day 1 Summary – Before Practice & Consolidation Session

- You need to be very familiar with the concepts!
- You need to be very familiar and comfortable with the tool!
- You need to be able to clearly and simply explain each concept in the local language!
- You need to be systematic and organised and ensure that all the components have been covered!

This means practice now and/or throughout most of Day 2.

Next Step

- Deck 5 – will focus on adapting the mixed AoU tool to other clinical trial contexts.

Note to Trainer:
This is a good time to stop for a lunch break – 60 minutes.
Consolidation and Practice Session – End of Day 1

**Total Time:** 60 minutes

**Learning Outcomes:**
By the end of this session participants will:
- Practice and Role Play of Scenarios.
- Summarize the AoU process.
- Plan for Day 2 if appropriate.

**Materials required:**
- Scenarios and Handouts given to date.

**Training methods used:**
- Role Play in Rotating Pairs – with observers.

**Note to Trainer:**
This session is guided entirely by you and is an opportunity to work through scenarios that the participants create in pairs and then practice in order to consolidate the learning to date.

Role Play is the ideal method for this. Rotating pairs and using different scenarios can be helpful. Make sure each role play is being observed by another pair – who can comment and assist in critiquing their peers constructively.
Day 2

**Training Agenda – Day 2**

<table>
<thead>
<tr>
<th>Topics</th>
<th>Time allocated</th>
<th>Start time (trainer to complete)</th>
<th>End time (trainer to complete)</th>
</tr>
</thead>
<tbody>
<tr>
<td>DECK 5: Adapting the Mixed Tool to other clinical trial contexts</td>
<td>90 minutes</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>BREAK – 20 minutes</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PRACTICE SESSION</td>
<td>60 minutes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SUMMARY - CLOSING</td>
<td>30 minutes</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Deck 5 – Adapting the Mixed AoU Tool to other clinical trial contexts

**Total Time:** 60 minutes

**Learning Outcomes:**
By the end of this session participants will:
- Apply the Tool Development Process to the MalVac Trial Information Sheet.
- Develop a new AoU tool.
- Practice and Role Play administration of the new tool.
- Work through other information sheets and informed consent examples.

**Materials required:**
- Laptop with PowerPoint
- Handout # 6 - Steps to Adapt the AoU; Handout # 7 MalVac Trial; Information Sheet, Handout # 8 Empty Decision Trees
- Highlighters
- Index cards

**Training methods used:**
- Lecture
- Group Discussion

**Delivery:**
Present slide Deck 5, there are notes in the presentation with detailed explanation for you to follow if you wish.

**Overview of Session**

The objectives for this session:
- Apply the Tool Development Process to the MalVac Trial Information Sheet.
- Develop a new AoU tool.
- Practice and Role Play administration of the new tool.
- Work through other information sheets and informed consent examples.

**Review of AoU Goals**

- The Goal of AoU before adapting the AoU to other contexts:
  - To facilitate genuine informed consent.
  - To ensure adequate understanding of core trial concepts.
  - To develop a suitable tool that measures understanding effectively.

**Adapting the Tool - Requirements**

- Adapting the tool to other clinical trial contexts means:
  - Identifying the most complex and critical concepts of trial participation that need to be understood.
  - Test these with mixed methodology – meaning combining the scenario with a true and false questionnaire.
  - Test other critical concepts using the 9 step process.
The 9 Step AoU Development Process

Explain - the steps in developing an AoU Mixed Method tool

9 Step Process to Adapt Mixed Method AOU to Another Clinical Trial Context:

Step 1: Free List
Step 2: Group the similar issues/points together
Step 3: Prioritize most important concepts
Step 4: Identify core study concepts
Step 5: Identify sub-concepts
Step 6: Develop scenarios
Step 7: Develop prompts
Step 8: Assign scores and develop score card
Step 9: Develop true and false statements

Breaking down the 9 Steps

Step 1: Free List exercise
- Bring together a group of investigators, researchers, counselors, nurses and other relevant people.
- Distribute the informed consent document that will be used in the clinical trial to the group and review it together.
- Each person should identify 5-6 aspects that are within the trial's informed consent document that they think are important, complex, and often misunderstood by volunteers.
- Each person should write out the points - one issue per card.

Step 2: Group the similar issues/points together
- Group the similar issues/points together.
- Count the number of cards for each issue and rank them accordingly.
- The one with the most cards should be listed first.

Step 3: Prioritize most important concepts
- Ask the group if the issues listed are what they feel are the ones that might pose the greatest personal risk to the volunteers if the concepts are misunderstood.
- Which concepts could create a negative outcome for the volunteer if the concepts are not understood well? These complex concepts with the greatest potential for negative outcome to the volunteer if misunderstood are the concepts that could be developed into scenarios in the mixed-method AOU.
- Work through the first 4 or 5 on the rank list of concepts and begin to prioritize them.
- Ask the group if the issues listed are what they feel are the critical issues that every trial volunteer needs to understand.

Step 4: Identify core concepts
- Some of these identified in Step 3 will now serve as the critical "CONCEPTS" that will feature in the scenarios.
- The 4-6 core concepts should be similar across these groups. If not, identify the ones that are unique to the group and talk with your team about whether these should be included or not.
- Working with different stakeholders will ensure a more valid set of concepts.
Step 5: Identify sub-concepts
- Once the main concepts have been identified, in the group, break down the concepts into key aspects for the volunteer to know.
- Note that not all concepts will have sub-concepts. Identify which concepts have sub-concepts as part of the main idea. For example, if contraception use is a requirement, there may be a few sub-concepts that volunteers should understand about using contraception. When a concept has multiple sub-concepts, it’s more complex and could be considered for development into a scenario.

Step 6: Develop scenarios and identify correct and incorrect answers
- The scenarios should illustrate a misunderstanding or confusion around a key concept and match with the correct and incorrect answers.
- In a group think through what are the ‘correct’ and ‘incorrect’ answers for each sub-concept.
- These will serve as the guide for the answers and the probes for the scoring guide.

Step 7: Develop Prompts
- Having developed the scenarios think through the prompts that can remind the respondent about the key concepts and sub-concepts without giving the answer.

Step 8: Assign scores and develop score card
- Adapt the score sheet from previous modules by inserting the concept and sub-concepts and a place for the score.

Step 9: Develop true and false statements
- In a group review what has been identified in the earlier steps in particular the concepts that were not short listed in the first stages.
- Think about common misunderstandings. Use these to craft the ‘false’ statements and use some that can serve as ‘true’ statements.
- Keep the true and false statements simple and very clear and make sure they are highlighting only ONE point.

Involving Different Groups
Importance of conducting the development of the AoU with various groups.
- Consult different groups at different time - such as CAB members, previous trial participants, researchers, peer educators and so on.
- Compare and contrast the results obtained from these different groups.

Tailor Making the AoU Tool
**Distribute** – Handout # 7 Malvac Information Sheet & Handout # 8 Empty Decision Trees (4 – 8 per group) and 10 index cards per group.

**Note to Trainer:**
If this information sheet does not meet the needs of the group, the researchers can replace it with an information sheet from another trial and adapt the exercises accordingly.
Note to Trainer:
Give each group the time to carry out each step.
Once they have come up with the output, you can present an example.

Reviewed the Information Sheet
- Take time now to review this information sheet on your own with the highlighters.
- Highlight those complex concepts with one color and the possible critical points with another color.
- Focus on:
  - What is the consequence of failing to understand this piece of information?
  - If the consequence of not understanding could result in harm to the volunteer/family/community – then it may be a 'critical concept.'
  - The complex concept will have sub-concepts that are critical for the volunteer to recall.

Using the 9 Steps

STEP 1 – Free List
Groups of 3 develop the free list.
a) Develop a list that is based on the informed consent document - since the AOU is testing understanding of the ICD.
b) Identify 5-6 aspects of the trial (product and trial procedure) that you think are important.
c) Each person should write out the points - one issue per card.

STEP 2 - Group the similar issues/points together
Groups of 3 group the issues together.

<table>
<thead>
<tr>
<th>Placebo</th>
<th>Child</th>
<th>Procedures</th>
<th>Side Effects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Some will get placebo others will not.</td>
<td>Child may experience some discomfort from the injections. Or a slight hardening from needle stick.</td>
<td>A small amount of blood, equal to about a teaspoon will be taken from the child's arm.</td>
<td>The new vaccine that has no known side effects.</td>
</tr>
<tr>
<td>No one can know who is getting placebo until after the study is over.</td>
<td>Child may also be fussier than usual or more tired.</td>
<td>Caregiver will need to stay at the research clinic with the child for 4 hours, 1 day every 3 months.</td>
<td>The vaccine may cause unreported signs or symptoms so caregiver should be aware of any usual signs.</td>
</tr>
</tbody>
</table>
**STEP 3 - Prioritize the concepts in order of importance**

The malaria vaccine cannot infect your child with malaria. But your child may still get malaria while in the study.

Some will get placebo others will not. No one can know who is getting placebo until after the study is over.

You will be reimbursed for your lost time and travel expense and offered food during the clinic visit.

**STEP 4 - Identify the Core Study Concepts**

What are each of the groups' concepts?

Each group should take time to come up with their concepts and then present them.

---

**Note to Trainer:**

Please do not show Slide # 24 and # 25 until the groups have come up with their list.

---

**Possible Examples of Critical Concepts**

**Critical Concept 1**

THE MALARIA VACCINE CANNOT INFECT YOUR CHILD WITH MALARIA. BUT YOUR CHILD MAY STILL GET MALARIA WHILE IN THE STUDY. You must be alert to the symptoms of malaria – and report any fever to the clinic.

**Critical Concept 2**

NO ONE KNOWS WHO IS GETTING THE VACCINE OR THE PLACEBO UNTIL AFTER THE TRIAL.

**Critical Concept 3**

THERE ARE NO KNOWN SIDE EFFECTS BUT BE AWARE OF ANY UNUSUAL SYMPTOMS.

**Critical Concept 4**

A FALSE POSITIVE MALARIA TESTS CAN OCCUR AT NON RESEARCH CLINICS.
Critical Concept 1: THE MALARIA VACCINE WILL NOT INFECT YOUR CHILD BUT YOUR CHILD MAY STILL GET MALARIA DURING THE TRIAL

Sub-Concept 1: The malaria vaccine cannot infect your child with malaria.
Sub-Concept 2: The malaria vaccine may not work to protect your child against malaria and the placebo will not protect your child against malaria.
Sub-Concept 3: You must still use the mosquito net and other precautions to protect your child from malaria.

Critical Concept 2: NO ONE KNOWS WHO IS GETTING THE VACCINE OR THE PLACEBO UNTIL AFTER THE TRIAL

Sub-Concept 1: There is no way of knowing who is getting which vaccine.
Sub-Concept 2: Know one knows if the vaccine will protect the child until after the research is complete.

Critical Concept 3: THERE ARE NO KNOWN SIDE EFFECTS BUT BE AWARE OF ANY UNUSUAL SIGNS AND SYMPTOMS

Sub-Concept 1: There is a possibility that vaccine may cause unreported signs or symptoms in your child.
Sub-Concept 2: You must come to the research clinic immediately if you see any signs of sickness in your child or call the hotline for collection at your home.

Critical Concept 4: FALSE POSITIVE MALARIA TESTS CAN OCCUR AT NON RESEARCH CLINICS

Sub-Concept 1: The malaria vaccine cannot infect your child with malaria.
Sub-Concept 2: The trial vaccine may cause the malaria test used in non research clinics to be positive even if your child does not have malaria.
Sub-Concept 3: You should only seek treatment for your child at the research clinic.
Possible Scenarios

STEP 6 - Develop the scenarios and consider correct and incorrect answers for each sub-concept

Examples of Scenarios

Note to Trainer:
Please do not show next slides until scenarios have been presented

Critical Concept No. 1: THE MALARIA VACCINE WILL NOT INFECT YOUR CHILD BUT YOUR CHILD MAY STILL GET MALARIA DURING THE TRIAL

The Scenario:
Granny John is little Johns' guardian and she has enrolled little John in the MalVac trial. She has received the free mosquito net but decides that the other 4 children in the family need the net more than little John, because he is getting the vaccine that will protect him. The four children sleep under the net and she sleeps with John, without a net.

*You ask the potential trial volunteer*

What do you think about Granny Johns' choice?

Critical Concept 2: NO ONE KNOWS WHO IS GETTING THE VACCINE OR THE PLACEBO UNTIL AFTER THE TRIAL

The Scenario:
"Baba Ellen is a widower, his wife died of malaria and he is raising 3 children alone. Since his wife died of malaria he has decided to enroll his youngest daughter in the Malvac trial, to try to protect her from suffering from malaria. He wants to be sure that his daughter is getting the 'real vaccine' and not the 'placebo' – so he goes to the traditional healer to ask him to divine whether she is getting the real vaccine or not. But instead of telling him the answer, the healer tells Baba Ellen to withdraw his child because the vaccine can give Ellen malaria."

*You ask the potential trial volunteer*

What advice would you give to Baba Ellen?
Critical Concept 3: THERE ARE NO KNOWN SIDE EFFECTS BUT BE AWARE OF ANY UNUSUAL SYMPTOMS

The Scenario:
"Mama Gloria has had to travel to see her sick mother – she leaves her daughter with an aunty for 10 days. While she is away her daughter loses her appetite, becomes lethargic but because she has no fever, the aunty does not contact the research clinic. When the day to take the child to the research clinic comes around, the aunty doesn’t take the child because she finds the child too tired and restless to travel. When her mother returns she finds her child sick and very thin."

You ask the potential trial volunteer
What do you think Mama Gloria should have done?

Critical Concept 4: FALSE POSITIVE MALARIA TESTS CAN OCCUR AT NON RESEARCH CLINICS

The Scenario:
"Mama Simba takes her daughter to a clinic down the road from her house, because she is coughing and has high fever. The doctor at the clinic notes that she is weak and advises her to test her daughter for malaria is his lab. The results come back positive."

You ask the potential trial volunteer
What do you think Mama Simba should have done?

Developing Prompts

Possible prompts

STEP 7 - Develop Prompts
Example prompts

• Do all trial volunteers in the study get the same injection?
• What injection do they get?
• Do these vaccines offer any protection?
• If the trial volunteer tests outside the research clinic what does he or she need to know about the test result?
• Where should she or he go if the child needs a malaria test?
• What should the volunteers do to prevent malaria?
• Can the child in the trial get malaria from the vaccine – why or why not?
Decision Trees and Scoring

How to Assign a Score

**STEP 8 - Assign Scores and Develop the Score Card**

Assign a score with the algorithm Decision Tree! One point for each sub-concept and begin to complete your decision trees.

**Developing a Score Sheet**

![Critical Concept Diagram]

**RIGHT ANSWER**

Score 1

**WRONG ANSWER**

Score 0

Continue until the end of AoU and re-educate and depending on score you may retest.

Total No. of Scenario Questions

Total No. of T/F Questions

\[ \text{_____________} \]

\[ = \text{Denominator} \]
Developing True and False Statements

How to develop true and false statements

STEP 9 - Develop the true and false statements
Think about common misunderstandings. Use these to craft the ‘false’ statements and use some that can serve as ‘true’ statements.

Examples of True and False Questions for MALVAC Hypothetical Trial.

<table>
<thead>
<tr>
<th>QUESTION</th>
<th>TRUE OR FALSE</th>
</tr>
</thead>
<tbody>
<tr>
<td>On the first visit, a small amount of blood, equal to about a teaspoon</td>
<td>□ True □ False</td>
</tr>
<tr>
<td>will be taken from your child’s arm.</td>
<td></td>
</tr>
<tr>
<td>This study will carry on for 1 year and you will need to come in for</td>
<td>□ True □ False</td>
</tr>
<tr>
<td>4 hours every 4 months.</td>
<td></td>
</tr>
<tr>
<td>Your child is guaranteed not to experience any side effects from this</td>
<td>□ True □ False</td>
</tr>
<tr>
<td>vaccine.</td>
<td></td>
</tr>
<tr>
<td>Apart from quality medical care and food on the clinic day, there are</td>
<td>□ True □ False</td>
</tr>
<tr>
<td>no other benefits to you from participating in this study.</td>
<td></td>
</tr>
<tr>
<td>The information that will be collected from this research project will</td>
<td>□ True □ False</td>
</tr>
<tr>
<td>be kept confidential. No-one but the researchers will be able to see it.</td>
<td></td>
</tr>
<tr>
<td>Once enrolled in this study you may not withdraw your child until the</td>
<td>□ True □ False</td>
</tr>
<tr>
<td>end of the first year.</td>
<td></td>
</tr>
</tbody>
</table>

Next Step

The next step is to practice adapting other information sheets using the 9 steps and role playing new tools.
Consolidation and Practice Session
– Day 2

**Total Time:** 60 minutes

**Learning Outcomes:**
By the end of this module participants will have:

- Practice adapting information sheets from other trials
- Role play the Scenarios from MalVac or other trials
- Summarize training.

**Materials required:**
- Scenarios and Handouts given to date
- Handout # 11 – Handouts 6, 7, 8, 9, 10, 11

**Training methods used:**
- Group work
- Role Play in Rotating Pairs – with observers
- Discussion

**Delivery:**
Guided entirely by trainer.

**Note to Trainer:**
This session is guided entirely by you and is an opportunity to work through new information sheets as well as the MalVac scenarios in pairs and to practice and consolidate the exercises.

Once the adaptation steps have been carried out, concepts, sub-concepts, scenarios, possible answers and prompts as well as scoring sheets have been developed, the scenarios can be role played.

Role Play is the ideal method for this. We suggest rotating pairs and using different scenarios and making sure each role play is being observed by another pair – who can comment and assist in critiquing their peers constructively.

**Summary and Closure (30 minutes)**
This is an opportunity for you to review the parking lot questions, summarize the approach and address any pending issues.

End the training with an explanation that the AoU mixed tool is a new approach to informed consent and their feedback and comments as they apply the lessons learned to their work settings - are welcome. Provide contact details as appropriate.
Handouts
HANDOUT # 1 – Agendas

Training Agenda – Day 1

<table>
<thead>
<tr>
<th>Topics</th>
<th>Time allocated</th>
</tr>
</thead>
<tbody>
<tr>
<td>INTRODUCTION SESSION</td>
<td>30 minutes</td>
</tr>
<tr>
<td>MODULE 1</td>
<td>60 minutes</td>
</tr>
<tr>
<td>Overview of informed consent &amp; the relevance of the AoU studies.</td>
<td></td>
</tr>
<tr>
<td>MODULE 2</td>
<td>90 minutes</td>
</tr>
<tr>
<td>The key components of the AoU mixed tool.</td>
<td></td>
</tr>
<tr>
<td>MODULE 3</td>
<td>90 minutes</td>
</tr>
<tr>
<td>Administering and Scoring the AoU Mixed Tool</td>
<td></td>
</tr>
<tr>
<td>PRACTICE SESSION</td>
<td>60 – 90 minutes</td>
</tr>
<tr>
<td>Consolidation and Practice</td>
<td></td>
</tr>
</tbody>
</table>

Today’s training will start at _____:_____               Today’s training will end by _____:_____

Training Agenda – Day 2

<table>
<thead>
<tr>
<th>Topics</th>
<th>Time allocated</th>
</tr>
</thead>
<tbody>
<tr>
<td>MODULE 4</td>
<td>90 minutes</td>
</tr>
<tr>
<td>Adapting the Mixed Tool to other clinical trial contexts</td>
<td></td>
</tr>
<tr>
<td>PRACTICE SESSION</td>
<td>60 minutes</td>
</tr>
<tr>
<td>SUMMARY - CLOSING</td>
<td>30 minutes</td>
</tr>
</tbody>
</table>
Please read the following scenario out loud to the volunteer.
Mr. YY _____________ decides that he will enroll in this vaccine trial. So, he starts attending information sessions/discussion groups. On the way to attend one of his sessions at the vaccine trial site, he thinks to himself, “Once I am in the vaccine trial, I won’t need to worry about practicing this safe sex stuff anymore.”

Then the administrator asks the volunteer:
If Mr. YY ___________ told you this what would you say to him?

<table>
<thead>
<tr>
<th>CONCEPT 1 – FALSE SENSE OF SECURITY</th>
<th>SCORE: 1 = CORRECT 0 = WRONG</th>
</tr>
</thead>
<tbody>
<tr>
<td>1) Some volunteers may not be getting a study vaccine; they may be getting the placebo.</td>
<td>If the volunteer does not mention the above, use the following question to get information.</td>
</tr>
<tr>
<td>If the volunteer does not mention the above, use the following question to get information.</td>
<td></td>
</tr>
<tr>
<td>• Do all volunteers in the study get the same injection?</td>
<td></td>
</tr>
<tr>
<td>2) The study vaccine may not protect volunteers against HIV infection.</td>
<td>If the volunteer does not mention the above, use the following question to get information.</td>
</tr>
<tr>
<td>If the volunteer does not mention the above, use the following question to get information.</td>
<td></td>
</tr>
<tr>
<td>• What kind of protection do you think this study vaccine gives?</td>
<td></td>
</tr>
<tr>
<td>3) Volunteer must not increase their risk behaviour.</td>
<td>If the volunteer does not mention the above, use the following question to get information.</td>
</tr>
<tr>
<td>If the volunteer does not mention the above, use the following question to get information.</td>
<td></td>
</tr>
<tr>
<td>• What should volunteers be doing to help them not get HIV?</td>
<td></td>
</tr>
</tbody>
</table>
### Scoring Card: Critical Concept 2 - False Positive HIV Test

Please read the following scenario out loud to the volunteer:

While participating in this HIV vaccine trial, a volunteer, Mrs. ZZ ________ goes to another clinic outside the research centre because she is sick often. The doctor at the clinic advises her to have an HIV test. The results come back positive.

Then the administrator asks the volunteer:
What do you think she should have done?

<table>
<thead>
<tr>
<th>CONCEPT 2 – FALSE POSITIVE HIV TEST</th>
<th>SCORE: 1 = CORRECT 0 = WRONG</th>
</tr>
</thead>
<tbody>
<tr>
<td>1) If the volunteers get the study vaccine, they may test positive on standard HIV tests even if they are not HIV infected. If the volunteer does not mention the above, use the following question to get information. • If Mrs. ZZ tests outside the study clinic, what does she need to know about the HIV test result?</td>
<td></td>
</tr>
<tr>
<td>2) Only get tested at the research center and not outside. If the volunteer does not mention the above, use the following question to get information. • Where should Mrs ZZ go if she needs to get tested for HIV?</td>
<td></td>
</tr>
<tr>
<td>3) A positive HIV test from the study vaccine could last a short time or as long as several years. If the volunteer does not mention the above, use the following question to get information.</td>
<td></td>
</tr>
</tbody>
</table>
Handout # 2 – SCORING CARDS FOR CONCEPT 3 (Deck 3)

Scoring Card: Critical Concept 3 - Contraception

| Please read the following scenario out loud to the volunteer. |
| "While participating in this HIV vaccine trial and one month after Mrs. XX _______ received her first injection, she and her spouse want to have another child. She reports that she is thinking of stopping her contraception." |
| Then the administrator asks the volunteer: |
| What do you think about her decision to get pregnant and stop contraception at this time? |
| If Mrs. XX _______ told you this what would you say to him? |

<table>
<thead>
<tr>
<th>CONCEPT 3 – CONTRACEPTION</th>
<th>SCORE:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1) Volunteers must use contraception until four months after the last vaccination to prevent pregnancy.</td>
<td>1 = CORRECT</td>
</tr>
<tr>
<td>If the volunteer does not mention the above, use the following question to get information.</td>
<td>0 = WRONG</td>
</tr>
<tr>
<td>• What should the volunteer do to prevent pregnancy? And for how long?</td>
<td></td>
</tr>
<tr>
<td>2) This is to protect children from possible unknown effects of the study vaccine.</td>
<td></td>
</tr>
<tr>
<td>If the volunteer does not mention the above, use the following question to get information.</td>
<td></td>
</tr>
<tr>
<td>• Why should Mrs. XX not get pregnant during the vaccination period?</td>
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</tbody>
</table>
**Handout # 2 – SCORING CARDS FOR CONCEPT 4 (Deck 3)**

**Scoring Card: Critical Concept 4 - Enhanced Susceptibility to HIV**

<table>
<thead>
<tr>
<th>Please read the following scenario out loud to the volunteer.</th>
<th><strong>Score:</strong> 1 = Correct 0 = Wrong</th>
</tr>
</thead>
<tbody>
<tr>
<td>&quot;Mr. NN _______ tests HIV positive at the research center clinic. The laboratory test at the research center show that he is really infected with HIV. He is very angry and says to the counselor – 'I knew this vaccine would infect me with HIV' – Then he adds 'Even if the vaccine did not give me the HIV, it is part of the problem.&quot;</td>
<td></td>
</tr>
<tr>
<td><strong>Then the administrator asks the volunteer:</strong> What do you think about what Mr. NN _______ said?</td>
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</table>

**CONCEPT 4 - THE VACCINE DOES NOT CAUSE HIV BUT MAY ENHANCE SUSCEPTIBILITY TO INFECTION IF EXPOSED TO HIV THROUGH HIV RISK BEHAVIOUR**

1) The study vaccine cannot infect the volunteer with HIV.  
*If the volunteer does not mention the above, use the following question to get information.*  
- Can Mr. NN _______ get HIV from this vaccine? Why/why not?

2) It is not known whether the HIV vaccine could increase a volunteer's risk of getting HIV infected if the volunteer get the HIV vaccine during the study and engages in HIV risk behaviour.  
*If the volunteer does not mention the above, use the following question to get information.*  
- Can the study vaccine make it more likely that Mr. NN _______ might get HIV infection if he is exposed to HIV through risk personal behaviour? Why not?
False Sense of Protection
Sub-concept 1

- Some might not get the study vaccine.
- Some might get the placebo.
- Not everybody gets the vaccine.

Correct answer

Incorrect answer

If volunteer does not mention any correct answers - then administrator can give 3 prompts:

PROMPT
1) Do all volunteers in the study get the same injection?
2) What injections do they get?
3) What kind of protection do you think these vaccines for HIV provide?

Correct answer

RIGHT ANSWER
Score 1

WRONG ANSWER
Score 0

Continue until the end of AoU and re educate and depending on score you may retest
False Sense of Protection
Sub-concept 2

- The study vaccine may not protect volunteers against HIV Infection.
- The vaccine is being studied, the researchers will not know if it is effective against HIV until the study is finished.

Correct answer

Incorrect answer

- No answer
- Appears confused
- Unsure of what is being asked

If volunteer does not mention any correct answers - then administrator can give 1 prompt:

PROMPT
1) What kind of protection do you think this study vaccine gives?

Correct answer

RIGHT ANSWER
Score 1

WRONG ANSWER
Score 0
Continue until the end of AoU and re educate and depending on score you may retest
False Sense of Protection
Sub-concept 3

- Volunteers must not increase their risk behaviour.
- Volunteers must practice Safe Sex.
- One sexual partner
- Or use condoms

Correct answer

Incorrect answer

- No answer
- Appears confused
- Unsure of what is being asked

If volunteer does not mention any correct answers - then administrator can give 1 prompt:

PROMPT
1) What should volunteers be doing to help them not get HIV?

Correct answer

RIGHT ANSWER
Score 1

WRONG ANSWER
Score 0
Continue until the end of AoU and re educate and depending on score you may retest
False Positive HIV Test

Sub-concept 1

- If volunteers get the study vaccine they may test positive for HIV on a standard HIV test, even if they are not HIV infected.

Correct answer

Incorrect answer

- No answer
- Appears confused
- Unsure of what is being asked

If volunteer does not mention any correct answers - then administrator can give 1 prompt:

**PROMPT**

1) If the volunteer tests for HIV outside the study clinic, what does he or she need to know about the HIV test result.

Correct answer

RIGHT ANSWER
Score 1

WRONG ANSWER
Score 0

Continue until the end of AoU and re educate and depending on score you may retest
False Positive HIV Test
Sub-concept 2

- Volunteers must only get tested for HIV at the research center and not outside.
- Should always try to test at the research center.
- If chooses to test elsewhere must first inform research team.

Correct answer

Incorrect answer
- No answer
- Appears confused
- Unsure of what is being asked

If volunteer does not mention any correct answers - then administrator can give 1 prompt:

PROMPT
1) Where should the volunteer go if he or she needs to get tested for HIV.

Correct answer

RIGHT ANSWER
Score 1

WRONG ANSWER
Score 0
Continue until the end of AoU and re-educate and depending on score you may retest
False Positive HIV Test
Sub-concept 3

- A positive HIV test from the study vaccine could last a short time or as long as several years.
- It is not known how long the false positive test result will last.
- It may last a long time.

If volunteer does not mention any correct answers - then administrator can give 1 prompt:

**PROMPT**
1) How long could the volunteer test positive for HIV due to the study.

**RIGHT ANSWER**
Score 1
Continue until the end of AoU and re educate and depending on score you may retest

**WRONG ANSWER**
Score 0
Contraception
Sub-concept 1

• A female volunteer must commit to being on contraception until four months after the last trial vaccination to prevent pregnancy.
• Contraception must be used (even if no reference to time).
• The volunteer should not get pregnant (even if no reference to time).
• It is ok to stop using contraception 4 or more months after the last trial vaccination.

Correct answer

Incorrect answer

• No answer
• Appears confused
• Unsure of what is being asked

If volunteer does not mention any correct answers - then administrator can give 2 prompts:

PROMPT
1) What should the volunteer do to prevent pregnancy?
2) And for how long should the volunteer prevent pregnancy while in the trial?

Correct answer

RIGHT ANSWER
Score 1

WRONG ANSWER
Score 0
Continue until the end of AoU and re educate and depending on score you may retest
Contraception
Sub-concept 2

- This is to protect the child from possible unknown effects of the study vaccine.
- It is not known what the effect of the vaccine could be on the child.

Correct answer

Incorrect answer

• No answer
• Appears confused
• Unsure of what is being asked

If volunteer does not mention any correct answers - then administrator can give 1 prompt:

PROMPT
1) Why should the volunteer not get pregnant during the vaccination period?

Correct answer

RIGHT ANSWER
Score 1

WRONG ANSWER
Score 0
Continue until the end of AoU and re educate and depending on score you may retest

No answer
• Appears confused
• Unsure of what is being asked

If volunteer does not mention any correct answers - then administrator can give 1 prompt:
Enhanced Susceptibility to HIV

Sub-concept 1

- The study vaccine cannot infect or cause HIV in a volunteer.

**Correct answer**

- No answer
- Appears confused
- Unsure of what is being asked

**Incorrect answer**

If volunteer does not mention any correct answers - then administrator can give 1 prompt:

**PROMPT**
1) Can the volunteer get HIV from the vaccine?
2) Why/why not?

**RIGHT ANSWER**
Score 1

**WRONG ANSWER**
Score 0

Continue until the end of AoU and re educate and depending on score you may retest.
Enhanced Susceptibility to HIV

Sub-concept 2

• It is not known whether the HIV vaccine could increase a volunteer’s risk of getting HIV infected if the volunteer gets the HIV vaccine during the study and engages in HIV high risk behavior.

Correct answer

Incorrect answer

• No answer
• Appears confused
• Unsure of what is being asked

If volunteer does not mention any correct answers - then administrator can give 1 prompt:

PROMPT
1) Can the study vaccine make it more likely that the volunteer might get HIV infection if he is exposed to HIV through risky personal behavior?

Correct answer

RIGHT ANSWER
Score 1

Wrong answer

Score 0

Continue until the end of AoU and re-educate and depending on score you may retest
**Scenario 1**

Please read the scripts below and answer questions in the boxes.

Mr. YY <agree on a context specific name and add here before finalizing> decides that he will enroll in this vaccine trial. So, he starts attending information sessions/discussion groups. On the way to attend one of his sessions at the vaccine trial site, he thinks to himself, "Once I am in the vaccine trial, I won’t need to worry about using protection during sex anymore".

If Mr.YY told you this what would you say to him?

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<thead>
<tr>
<th>What is this scenario referring to?</th>
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<table>
<thead>
<tr>
<th>Please list 3 points that are important for volunteer to understand this concept.</th>
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</table>
Scenario 2

While participating in this HIV vaccine trial, a volunteer, Mrs. ZZ <please agree on a context specific name and add here before finalizing – please choose a name that is not the same as in earlier scenario > goes to another clinic outside of the research centre because of being sick often. The doctor at the other clinic advises her to have an HIV test. The results come back positive.

What do you think she should have done?

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<tbody>
<tr>
<td>1.</td>
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<tr>
<td>2.</td>
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<tr>
<td>3.</td>
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</table>
Scenario 3

While participating in this HIV vaccine trial Mrs. XX and her spouse decide they want to have another child. She had received a study vaccine one month ago and she reports that she is thinking of stopping her contraception.

What do you think about her decision to stop her contraception at this time so she can get pregnant?

What is this scenario referring to?

Please list 2 points that are important for volunteer to understand this concept.

1. 

2. 
Scenario 4

After participating in the vaccine trial for one year, Mr. NN, <please use a context specific name indicating another volunteer in the same trial– do not use the same name as in earlier scenarios > tests HIV positive at the research centre clinic. The laboratory test at the research centre clinic shows that he is really infected with HIV. He is very angry and says to the counselor: “I knew this vaccine would infect me with HIV”. Then he adds: “Even if the vaccine didn’t give me the HIV, it is part of the problem.”

What do you think about what Mr. NN said?

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<table>
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</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
</tr>
<tr>
<td>2.</td>
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</tbody>
</table>
The Scenario:
Mr. YY ___________decides that he will enroll in this vaccine trial. So, he starts attending information sessions/discussion groups. On the way to attend one of his sessions at the vaccine trial site, he thinks to himself, "Once I am in the vaccine trial, I won’t need to worry about practicing this safe sex stuff anymore."

Question posed to the volunteer:
If Mr. YY ___________told you this what would you say to him?

Response from the volunteer:
"I would say to Mr YY ____________remember this is a research thing they are doing - you know it is not a hospital giving out real vaccinations that work, this vaccine it may not even work to protect us from HIV. It may do as much as taking a panadol to stop HIV – it may not even work. I would tell him safe sex stuff is important if you’re not getting the vaccine, but then it is always better to be safe than sorry. Also, it is hard to know if you’re on the vaccine - safe sex in this day and age is the only way and he is a man so that is easy for him, if he was a woman, like me, then safe sex is not always in her court – it is usually up to the man to decide how safe the sex is going to be, do you know what I mean!

So I’d say, ummm be careful, he must remember he may be unlucky and he’ll be getting the fake vaccine, the one that does nothing! They call that one the Play vaccine – playcbo, and if you get that one, then you’re just going to get HIV out there, unless you’re safe. But then maybe Mr YY should remember that he must not go crazy out there and get risky, thinking he’s on this magic thing that protects him and he can go and taste all the women out there! No! He must not do that without many condoms– otherwise that can make things worse and he can be unlucky and get HIV.

Key Sub-concept # 1
Some volunteers may not be getting the study vaccine; some may be getting the placebo.
Some might not get the study vaccine.
Some get placebo, others get the vaccine - Some might not get the vaccine - Some might get the placebo - Not everybody gets the vaccine.

Score:
1 = CORRECT
0 = WRONG

Key Sub-concept # 2
The study vaccine may not protect volunteers against HIV infection.
Vaccine may or may not protect - Vaccine is being studied so we don’t know – The researcher don’t know .

Score:
1 = CORRECT
0 = WRONG

Key Sub-concept # 3
Volunteers must not increase their risk behavior.
Practice safe sex - Use condoms - Have one partner.

Score:
1 = CORRECT
0 = WRONG
**Concept 2 - False Positive HIV Test**

**The Scenario:**
While participating in this HIV vaccine trial, a volunteer, Mrs. ZZ ____________ goes to another clinic outside of the research centre because of being sick often. The doctor at the other clinic advises her to have an HIV test. The results come back positive.

**Question posed to the volunteer:**
What do you think she should have done?

**Response from the volunteer:**
"Perhaps she went there because she was ashamed. I understand. She wanted to keep that she was feeling sick secret – maybe she had did not want the research people to know in case they would tell her to leave the study. It is ok. She is allowed to get care – it is a private matter. I would reassure her. Tell her it is ok."

Prompt 1 posed to the volunteer
If Mrs. ZZ ____________ tests outside the study clinic, what does she need to know about the HIV test result?

**Response from the volunteer**
"She needs to know that it will be positive or negative and if it is positive then she will be excluded from the research, that is why she went to the clinic outside, away from the researchers. Now she will need to go and tell them, that she has the disease and that will be difficult for her. I will tell her to have courage and go to the research clinic and to tell the truth. That she now has HIV. Yes – that will be the best for Mrs ZZ _____ "

**Prompt 2 posed to the volunteer**
How long could Mrs. ZZ test HIV positive due to the study vaccine?

**Response from the volunteer**
"Oh – she has HIV now and HIV will last her whole life – there is no cure, the test will be positive for life – but I believe there is treatment."

**Key Sub-concept # 1**
If volunteers get the study vaccine, they may test positive on standard HIV tests even if they are not HIV infected.

A standard test might show a false positive - A standard test might show volunteer is infected when s/he might not be.

**Score:**
\[1 = \text{CORRECT} \]
\[0 = \text{WRONG} \]

**Key Sub-concept # 2**
Only get tested at the research center and not outside the research center.

Should test at research center - Can test outside but need to inform study team first.

**Score:**
\[1 = \text{CORRECT} \]
\[0 = \text{WRONG} \]

**Key Sub-concept # 3**
A positive HIV test from the study vaccine could last a short time or as long as several years.

It is not known how long it will last OR no one knows how long it will last - don’t know - Long time only.
The Scenario:
While participating in this HIV vaccine trial and one month after Mrs. XX received her first injection, she and her spouse want to have another child. She reports that she is thinking of stopping her contraception.

Question posed to the volunteer:
What do you think about her decision to get pregnant and stop contraception at this time?

Response from the volunteer:
Perhaps it is the right time for her to have a child and she did not realize this when she started the trial – it is a shame. I think the timing is not good for her. She should reconsider. It depends maybe she is suddenly feeling pressure, that she did not feel before. I would tell her this is a difficult decision.”

Prompt posed to the volunteer
What should the volunteer do to prevent pregnancy? And for how long?

Response from the volunteer
“Oh my, I would tell this lady she must be careful – the counselor told me they don’t know if the vaccine may damage the baby, so if she got pregnant, she may have this problem. It is best now, if she wants to have a baby, that she stops being in the study and then she can get pregnant…..oh! but she must wait four months now, she must stay on the pill for 4 months before she can get pregnant. The vaccine they will give us, it can stay in the blood – 4 months she must wait. But perhaps it is better she stay in the research and then after the research she has her baby. But that is for her to decide.

Key Sub-concept #1
Volunteers must use contraception until four months after the last vaccination to prevent pregnancy.

Score:
1 = CORRECT
0 = WRONG

Key Sub-concept #2
This is to protect children from possible unknown effects of the study vaccine.

Score:
1 = CORRECT
0 = WRONG
Critical Concept 4 - Enhanced Susceptibility to HIV Infection with HIV High Risk Behaviour (for example, having sex without a condom)

The Scenario:
After participating in the vaccine trial for one year, Mr. NN, _________ tests HIV positive at the research center clinic. The laboratory test at the research center clinic shows that he is really infected with HIV. He is very angry and says to the counselor: "I knew this vaccine would infect me with HIV". Then he adds: "Even if the vaccine didn't give me the HIV, it is part of the problem."

Question posed to the volunteer:
What do you think about what Mr. NN said?

Response from the volunteer:
"I think this volunteer is very angry! I too would be very upset – even though there are medicines for this disease, it is not easy. He thinks the vaccine has infected him, maybe he thinks the vaccine is alive with the virus but then it seems that he sees that maybe it is not the vaccine that has infected him but that it has made his situation worse. I would say – yes, this is true the vaccine has not caused him to be infected, it cannot do this!

Prompt posed to the volunteer
Can the study vaccine make it more likely that Mr_______ might get HIV infection if he is exposed to HIV through risky personal behavior? Why/why not?

Response from the volunteer
"No – no it is sure the vaccine cannot cause infection – if he got HIV it is because he was sleeping with someone with HIV and he was not safe. It is sure that the vaccine cannot cause HIV! This is what he must know. His infection is of his doing."

<table>
<thead>
<tr>
<th>Key Sub-concept # 1</th>
<th>Score:</th>
</tr>
</thead>
<tbody>
<tr>
<td>The study vaccine cannot infect the volunteer with HIV.</td>
<td>1 = CORRECT</td>
</tr>
<tr>
<td>Volunteer says study vaccine cannot cause infection. - Study vaccine cannot infect volunteer.</td>
<td>0 = WRONG</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Key Sub-concept # 2</th>
<th>Score:</th>
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<tbody>
<tr>
<td>It is not known whether the HIV vaccine could increase a volunteer’s risk of getting HIV infected if the volunteer gets the HIV vaccine during the study and engages in HIV risk behavior.</td>
<td>1 = CORRECT</td>
</tr>
<tr>
<td>It could be more likely. - No one knows if it will increase, decrease or stay the same. - Don’t know OR it is not known.</td>
<td>0 = WRONG</td>
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</table>
HANDOUT # 6 – Adapting AoU: 9 Steps (Deck 5)

9 Step AoU Process

Step 1: Free List
Step 2: Group the similar issues/points together
Step 3: Prioritize most important concepts
Step 4: Identify core study concepts
Step 5: Identify sub-concepts
Step 6: Develop scenarios
Step 7: Develop prompts
Step 8: Assign scores and develop score card
Step 9: Develop true and false statements

Distribute - Handout #6 – Adapting AoU Steps

Explain - the steps in developing an AoU Mixed Method Tool

9 Step – Adapt AoU Process:

Step 1: Free List exercise
- Bring together a group of investigators, researchers, counselors, nurses and other relevant people.
- Each person should identify 5-6 aspects of the trial (product and trial procedure) that they think are important.
- Each person should write out the points - one issue per card.

Step 2: Group the similar issues/points together
- Group the similar issues/points together.
- Count the number of cards for each issue and rank them accordingly.
- The one with the most cards should be listed first.

Step 3: Prioritize most important concepts
- Work through the first 4 or 5 on the rank list of concepts and begin to prioritize them.
- Ask the group if the issues listed are what they feel are the critical issues that every trial volunteer needs to understand.

Step 4: Identify core concepts
- Some of these identified in Step 3 will now serve as the key "CONCEPTS" that will feature in the scenarios.
- The 4-6 core concepts should be similar across these groups. If not, identify the ones that are unique to the group and talk with your team about whether these should be included or not.
- Working with different stakeholders will ensure a more valid set of concepts.
Step 5: Identify sub-concepts
  • Once the main concepts have been identified, in the group, break down the concepts into key aspects for the volunteer to know.
  • List these sub-concepts for each of the concepts. Each concept should have at least 2 sub-issues or sub-concepts.

Step 6: Develop scenarios and identify correct and incorrect answers
  • That illustrate a misunderstanding or confusion around a key concept and match with the correct and incorrect answers.
  • In a group think through what are the 'correct' and 'incorrect' answers for each sub-concept.
  • These will serve as the guide for the answers and the probes for the scoring guide.

Step 7: Develop Prompts
  • Having develop the scenarios think through the prompts that can remind the respondent about the key concepts and sub-concepts without giving the answer.

Step 8: Assign scores and develop score card
  • Adapt the score sheet from previous modules by inserting the concept and sub-concepts and a place for the score.

Step 9: Develop true and false statements
  • In a group review what has been identified in the earlier steps (the concepts that were not short listed in the first stages).
  • Think about common misunderstandings. Use these to craft the ‘false’ statements and use some that can serve as ‘true’ statements.
  • Keep the true and false statements simple and very clear and make sure they are highlighting only ONE point.
IJKL Research Institute
Afya Hospital, 25 Drew Lane, MaTown, Country

Name of Principal Investigator – Dr PJ Peter
Name of Organization – IJKL Research Institute
Name of Sponsor – The Cereal Foundation

This Informed Consent Form has two parts:
• Information Sheet (to share information about the study with you)
• Certificate of Consent (for signatures if you agree that your child may participate)

You will be given a copy of the full Informed Consent Form

PART I: Information Sheet

Introduction
This informed consent form is for the parents of children between the ages of 1 and 4 years of age who attend clinic Afya, and who we are asking to participate in research called MalVac.

I am Anna Bwer, working for the IJKL Research Institute. We are doing research on the malaria disease, which is very common in this country.

I am going to give you information and invite you to have your child participate in this research. You do not have to decide today whether or not you agree that your child may participate in the research. Before you decide, you can talk to anyone you feel comfortable with.

There may be some words that you do not understand. Please ask me to stop as we go through the information and I will take time to explain. If you have questions later, you can ask them of me, the study doctor or the staff.

Purpose
Malaria is one of the most common and dangerous diseases in this region. The vaccine that is currently being used is not as good as we would like it to be but there is a new vaccine which may work better. The purpose of this research to test the new vaccine to see if it protects young children better than the current vaccine.

Type of Research Intervention
Your child will receive either an injection OR a series of three injections OR will take a vaccine by mouth.
Participant selection
The vaccine has been found to be effective with adults and older children. Because of how young children grow and develop, we can’t assume that the vaccine will be as effective on young children unless we test it on children.
We are inviting you to take part in this research because it is important that we test a new vaccine on children who do not have malaria but who live in an area where malaria is a serious problem. Because you and your child live in this area and your child does not have malaria, we are asking if you would allow your child to participate.
The malaria vaccine cannot infect your child with malaria. But your child may still get malaria while in the study. You must be alert to the symptoms of malaria – and report any fever to the clinic.

Voluntary Participation
Your decision to have your child participate in this study is entirely voluntary. It is your choice whether to have your child participate or not. If you choose not to consent, all the services you and your child receive at this clinic will continue and nothing will change.
You may also choose to change your mind later and stop participating, even if you agreed earlier, and the services you and/or your child receives at the clinic will continue.
The MALVAC vaccine has been tested twice before but only with older children and adults. In both studies, the vaccine worked better than the vaccine that currently exists. While the current vaccine protects only 60% of people who take the vaccine the new one protected more than 80% of the people. The new vaccine also protected the people taking it for a longer time period. We want to compare the two vaccines - the current one and the new one - in a younger age group, and that is why we are doing this research.
The drug is made by Company AB. It’s called a _______ type of drug because it helps part of the blood to______. The new vaccine that we are studying has no known side effects. The current vaccine that is being used in the study also has no known side effects.

Procedures and Protocol
Because we do not know if the new vaccine is better than the currently available vaccine for treating this disease, we need to make comparisons. Children taking part in this research will be put into groups which are selected by chance, as if by tossing a coin.
One group of participants will get the vaccine we are testing, and the other group will get the malaria vaccine which is currently used in this region. It is important that neither you nor we know which of the two vaccines your child was given. This information will be in our files, but we will not look at these files until after the research is finished. This is the best way we have for testing vaccines without being influenced by what we think or hope might happen. We will then compare which of the two has the best results.
The healthcare workers will be looking after you and the other participants very carefully during the study. If we are concerned about what the medicines or treatment is doing, we will find out which vaccine your child is getting and make changes.
A placebo or inactive medicine looks like real medicine but it is not. It is a dummy or pretend medicine. It has no effect on a person because it has no real medicine in it. Sometimes when we want to know whether a new medicine is good, we give some people the new medicine and some people the pretend or dummy medicine. For the research to be good, it is important that you and your child do not know whether the real medicine or the pretend or dummy medicine was given. This is one of the best ways we have for knowing what the medicine we are testing really does.

If we find that the medicine that is being used does not have the desired effect, or the side effects are too great, we will use an antidote that will reverse the effect of the vaccine.

**Part 2: Description of the Process**

You may stay with your child during each of the visits and during the procedures. In the first visit, a small amount of blood, equal to about a teaspoon will be taken from your child’s arm.

This will be tested for the presence of substances that help your child’s body to fight infections. Your child will feel some discomfort when the needle stick goes into her/his arm but this will go away very quickly. There may be slight bruising where the injection was given but this will disappear in a few days. If bruising is seen anywhere else on the body after the injection – come to the clinic.

We will ask your child’s physician to give us the details of your child’s health and illness related information. If you do not wish us to do that, please let us know. However, because your child’s health records are very important for the study, if we cannot look at the health records, we will not be able to include your child in the study.

At the end of the study, we will contact you by letter to tell you which of the two vaccines your child was given.

Your child will receive the treatment for his/her condition according to national guidelines. The sample will be taken using a local anesthesia which means that only the part of your child that we are taking the sample from, and a small surrounding area, will lose feeling for a short time. Your child shouldn’t feel pain.

**Duration**

The research takes place over 12 months in total. During that time, it will be necessary for you to come to the clinic/hospital/health facility 1 day every 3 months, for 4 hours each day. We would like to meet with you six months after your last visit for a final check-up. Altogether, we will see you and your child 4 times over a year.

**Side Effects**

These vaccines can have some unwanted effects or some effects that we are not currently aware of. However, we will follow your child closely and keep track of these unwanted effects or any problems. We will give you a telephone number to call if you notice anything out of the ordinary, or if you have concerns or questions. You can also bring your child to this health facility at any time and ask to see the Research Nurse, Research Doctor or the Principal Researcher.
We may use some other medicines to decrease the symptoms of the side effects or reactions. Or we may stop the use of one or more drugs. If this is necessary we will discuss it together with you and you will always be consulted before we move to the next step.

**Risks**

The new vaccine may not protect your child from malaria. Your child may still get malaria. We will give your child a mosquito net to use throughout the trial. If your child shows signs of malaria bring him or her to the research clinic and not to any other clinic.

The new vaccine that we are studying has no known side effects. The current vaccine that is being used in the study also has no known side effects. However, there is a possibility that vaccine may cause unreported signs or symptoms in your child. While the possibility of this happening is very low, you should still be aware of the possibility and aware of any unusual signs. You must come to the hospital immediately if you see any signs of sickness in your child. If you cannot get to the clinic for some reason, you must call our hotline and we will arrange to collect you and your child.

This vaccine may cause your child to test positive for malaria, even if she does not have malaria. It is very important that if your child gets sick that you come to or contact the research clinic and that you do not get tested anywhere else. If you go to another clinic, they will use a different malaria test and your child may be told she or he has malaria even if she does not. For the next year you should come to us for all medical care for your child to avoid this problem.

**Discomforts**

If something unexpected happens and harm does occur, we will provide your child with the highest quality of care offered by our resident consultant pediatric physician at no cost to you.

By participating in this research it is possible that your child may experience some discomfort such as the discomfort of the injections. There may be a slight hardening and/or swelling where the needle stick goes into the skin. This should disappear in one day. Your child may also be fussier than usual or more tired. These behaviors usually stop within one day but if you are concerned, please call me or come to the clinic.

**Benefits**

If your child participates in this research, he/she will have the following benefits: any interim illnesses will be treated at no charge to you. If your child falls sick during this period he/she will be treated free of charge. There may not be any other benefit for your child but his/her participation is likely to help us find the answer to the research question. There may not be any benefit to the society at this stage of the research, but future generations are likely to benefit.

**Reimbursements**

You will not be provided any incentive to take part in this research. However, you will be reimbursed with ($/ZAR/KES etc) for your lost time and travel expense and offered food for your child and caregiver during the 4 hours at the clinic.
Confidentiality
The information that we collect from this research project will be kept confidential. Information about your child that will be collected from the research will be put away and no-one but the researchers will be able to see it. Any information about your child will have a number on it instead of his/her name. Only the researchers will know what his/her number is and we will lock that information up with a lock and key. It will not be shared with or given to anyone except [name who will have access to the information, such as research sponsors, DSMB board, your clinician].

Sharing of the results
The knowledge that we get from this study will be shared with you before it is made widely available to the public. Confidential information will not be shared. There will be small meetings in the community and these will be announced. Afterwards, we will publish the results in order that other interested people may learn from our research.

Right to Refuse or Withdraw
You do not have to agree to your child taking part in this research if you do not wish to do so and refusing to allow your child to participate will not affect your treatment or your child’s treatment at this Centre in any way. You and your child will still have all the benefits that you would otherwise have at this Centre. You may stop your child from participating in the research at any time that you wish without either you or your child losing any of your rights as a patient here. Neither your treatment nor your child’s treatment at this Centre will be affected in any way.

Alternatives to participating
If you do not wish your child to take part in the research, your child will be provided with the established standard treatment available at the centre/institute/hospital. People who have malaria are given.

Who to Contact
If you have any questions you may ask them now or later, even after the study has started. If you wish to ask questions later, you may contact any of the following: [name, address/telephone number/e-mail given].

This proposal has been reviewed and approved by [name of the IRB], which is a committee whose task it is to make sure that research participants are protected from harm. If you wish to find about more about the IRB, contact [name, address, telephone number given].

Part 3: Certificate of Consent
This section should be written in the first person and have a statement similar to the one in bold below. If the participant is illiterate but gives oral consent, a witness must sign. A researcher or the person going over the informed consent must sign each consent. The certificate of consent should avoid statements that have “I understand....” phrases. The understanding should perhaps be better tested through targeted questions during the reading of the information sheet (some examples of questions are given above), or through the questions being asked at the end of the reading of the information sheet, if the potential participant is reading the information sheet him/herself.
I have been invited to have my child participate in research of a new malaria vaccine.

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily for my child to participate as a participant in this study.

Print Name of Participant: ________________________________________________

Print Name of Parent or Guardian: _________________________________________

Signature of Parent or Guardian: __________________________________________

Date: ___________________________________________________________________

Day/month/year

If illiterate
A literate witness must sign (if possible, this person should be selected by the participant and should have no connection to the research team). Participants who are illiterate should include their thumb print as well.

I have witnessed the accurate reading of the consent form to the parent of the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness: ____________________________________________________ AND

Signature of witness: _____________________________________________________

Date: ___________________________________________________________________

Day/month/year Thumb print of parent

Statement by the researcher/person taking consent
I have accurately read out the information sheet to the parent of the potential participant, and to the best of my ability made sure that the person understands that the following will be done:

1. ________________________________________________________________

2. ________________________________________________________________

3. ________________________________________________________________

I confirm that the parent was given an opportunity to ask questions about the study, and all the questions asked by the parent have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this ICF has been provided to the participant.

Print Name of Researcher/person taking the consent: _________________________

Signature of Researcher /person taking the consent: _________________________

Date: __________________________________________________________________

Day/month/year
False Sense of Protection
Sub-concept 1

- Correct answer
- Incorrect answer
  - No answer
  - Appears confused
  - Unsure of what is being asked

If volunteer does not mention any correct answers - then administrator can give prompts:

- PROMPT
  - Correct answer

RIGHT ANSWER
Score 1

WRONG ANSWER
Score 0
Continue until the end of AoU and re-educate and depending on score you may retest
Developing a Scenario

Here is an opportunity during practice and consolidation sessions to write a few scenarios. The first line of the scenario is there for you – now work with your complex concepts that you highlighted as well as the critical points. Choose one concept per scenario. Complete a minimum of 2 scenarios.

Scenarios

Please read the scripts below and answer questions in the boxes.

Mama Elizabeth decides that she will enroll her child in the malaria vaccine trial. So, she starts attending information sessions/discussion groups. On the way to attend one of her sessions at the vaccine trial site with her daughter on her back, she thinks to herself,

If Mama Elizabeth told you this what would you say to her?

What is this scenario referring to?

Please list 2 points that are important for volunteer to understand this concept.

Sub-concept # 1:

Sub-concept # 2:
Scenario 2
While her daughter is participating in this malaria vaccine trial, Mama Judy takes down the mosquito net and

If you saw her do this what would you tell her?

What is this scenario referring to?

Please list 2 points that are important for volunteer to understand this concept.

Sub-concept # 1:

Sub-concept # 2:
Scenario 3
While participating in this MalVac vaccine trial Baby Ruth becomes sick with fever, Mama Ruth, lives next door to you and your baby is also in the malaria vaccine trial. You see Mama Ruth doing

What would you tell her when you hear and see what she has decided to do?

What is this scenario referring to?

Please list 2 points that are important for volunteer to understand this concept.

Sub-concept # 1:

Sub-concept # 2:
**True/False Checklist for Malaria Trial**

Please complete the less complex concepts from the Malaria Trial Information Sheet as true (T) or false (F).

<table>
<thead>
<tr>
<th></th>
<th>True</th>
<th>False</th>
</tr>
</thead>
<tbody>
<tr>
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</table>
Example Information Sheet

Institution: WXYZ Institute
Participant Information and Consent Form
For an Efficacy Study of ABCDEFG Vaccination against Plasmodium falciparum infection.

INVESTIGATORS AND INSTITUTIONS

xxxxxx

LAY TITLE: A study to find out if a new malaria vaccine regimen can protect against malaria in African adults.

What is the WXYZ Institute

It is a government organization under the Ministry of Health, which carries out medical research. Research is different from normal treatment because research aims to find better ways of preventing and treating illness in the future for everybody’s benefit. One of the projects of the WXYZ Institute is to contribute in development of a malaria vaccine and we are asking you to participate in this malaria vaccine study.

What is this research about?

Malaria is a common and serious disease in young children that results in many childhood deaths. Although malaria is becoming less frequent in some parts of Africa as bed nets and anti-malarial drugs become more available, vaccines are still needed to prevent malaria as it is still a major problem.

Everywhere in the world, when new drugs or vaccines are being developed for children, research is first done in a few healthy adults, then in bigger numbers of healthy adults before children can finally be included. This malaria vaccine study is the same. Some studies involving small groups of adults in xxx, xxx and xx and in older children in the xxx have already been done and showed that the vaccine helps people to develop protection against malaria and had no serious side effects. We are now trying to conduct research on the vaccine with larger numbers of healthy adults.

We do not know whether the new malaria vaccine will protect you against infection, so you should take the usual measures to prevent malaria infection from mosquito bites during, and following the trial. These measures include the use of bed nets and seeking treatment for any illness including malaria.

In research to find out how well a vaccine is working, researchers usually have to compare two groups of similar people where only one group has been given the vaccine being developed. Both groups of people are followed up over time to see which group develops best protection against malaria. This allows us to understand how well the new vaccine is working.
In this study, we shall divide the participants into two groups. The new malaria vaccine will be given to one group and another vaccine that we know does not protect against malaria will be given to the other group. The vaccine we will use in the comparison group is the XYZ vaccine, which is a very useful vaccine that is already in use worldwide to protect people against the illness called NMOP. People will be divided into the groups using a system based on chance without any preference, such that everyone has the same chance of being in either group. We hope to include 180 healthy adult men in this study, with 90 in each group.

**What will it involve for me?**

If you agree to take part in this study, the following will happen:

1. **Health check:** A clinician will check your general health by asking questions, examining you and taking blood samples for testing. 5mls (1 teaspoon) of blood will be taken from your arm for this purpose. If we find you have any health problems or abnormal blood tests, we will explain this to you and refer you for any further tests or treatment you need at the most appropriate government health facility. We will not ask you to continue to participating in this study.

   One of these blood tests will be an HIV test. A trained counsellor will explain the HIV test to you before it is done, and discuss the results with you afterwards. All results will be kept confidential. You will be given your results in private. If you are HIV positive, you will be referred to a local government health facility where you will receive standard medical care according to the ministry of health guidelines.

If you are found to be fit to receive the vaccinations and agree to take part, the study will involve the following activities:

2. **Vaccination and home visit:** Participants will be given either the new malaria or the NMOP vaccine, depending on which group they are allocated to. Both vaccines will be given in two doses; the first in week 1 (day 0) and the second in week 9 (day 56). You will be asked to remain at the clinic for half an hour after each vaccination to check for any side effects. A field worker will visit you at home on the first day after each vaccination check on your progress. If necessary they will continue to visit you at home daily until any symptom(s) have resolved. At this visit, the field worker will also ask questions about your use of bed nets in the home and will also ask for permission to check your bed net.

3. **Malaria treatment:** You will be asked to take anti-malarial drugs starting from week 10 (day 63), in order to clear any malaria parasites that may be in your blood. It is possible to have malaria without you having any symptoms. The anti-malarial drugs will be administered in the clinic over 3 days. You will also be required to come to the clinic should you be unwell and in need of anti-malarials, at any other time during the study period.
4. Follow up and blood samples:

- Blood sampling will be done several times as part of the research in order to check on how well the vaccine is working and how your body is reacting to the vaccine. Some blood samples will be taken from the arm and some from a finger prick.

- During these scheduled clinic visits, the clinician will also check your health in general. There will be a total of 24 scheduled clinic visits.

- 40 participants from both vaccine groups will have a slightly different plan for sample taking to others because more research tests will be done with these 40 participants that are not being done for everyone at a few (4) clinic visits. This means that participants will follow one of two plans for sampling, but we will not be able to tell you now which plan you will follow. This decision will be made later in the study, based on the same system of chance used to decide which vaccine participants will receive. Before any samples are taken, we will give you exact details about which sampling plan you should expect. The two sampling plans are:

**Blood sampling plan A (xx participants):**

<table>
<thead>
<tr>
<th>Time Period</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>In weeks 1 (day 0), 3 (day 14) and 10 (day 63) and In week 24 (day 161):</td>
<td>40mls of blood (8 teaspoons) will be taken from the arm</td>
</tr>
<tr>
<td>In week 9 (day 56):</td>
<td>5 ml blood will be taken from the arm</td>
</tr>
<tr>
<td>In weeks 11, 12, 13 &amp; 14:</td>
<td>0.5 ml (few drops of blood) will be taken from finger prick 3 times per week</td>
</tr>
<tr>
<td>In weeks 15, 16, 17 &amp; 18</td>
<td>0.5 ml (few drops of blood) will be taken from finger prick once per week</td>
</tr>
</tbody>
</table>

**Blood sampling plan B (xx participants):**

<table>
<thead>
<tr>
<th>Time Period</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>In week 1 (day 0), 3 (day 14), 9 (day 56) and 24 (day 161):</td>
<td>40mls of blood (8 teaspoons) will be taken from the arm</td>
</tr>
<tr>
<td>In week 9 (day 56):</td>
<td>5 ml blood will be taken from the arm</td>
</tr>
<tr>
<td>In weeks 11, 12, 13 &amp; 14:</td>
<td>0.5 ml (few drops of blood) will be taken from finger prick 3 times per week</td>
</tr>
<tr>
<td>In weeks 15, 16, 17 &amp; 18:</td>
<td>0.5 ml (few drops of blood) will be taken from finger prick once per week</td>
</tr>
</tbody>
</table>
Are there any risks or disadvantages to me for taking part in the study?

Our priority for every participant is their well-being. There may be some pain and bruising associated with blood drawing which will resolve after a few days. There is a small risk of infection. This risk is minimized by use of pre packaged sterile equipment and trained staff.

Very rare serious side effects can be seen with any vaccination. These include skin swelling, shortness of breath and light-headedness or fainting. Medical equipment necessary to treat serious reactions will be available. As with any injection you may feel pain at the injection site. Other common side effects are swelling and reddening (discolouration) at the site a few days after the vaccination. Occasionally there is some itching and warmth at the injection site. You will be closely monitored by a study clinician who will deal with any vaccine related illness should they occur.

Some volunteers may have fever during the evening after the vaccine is given. Other symptoms that one may experience are headache, joint pains, muscle pains and nausea or vomiting. These should disappear after a few days. Some medication that you might receive during the trial (such as medicine to treat malaria or other infections) may cause side effects in rare occasions.

This study will involve taking your time and you may have travel costs. However we will compensate for your time and travel expenses with a payment of xxx for each day that you have to attend the clinic for the scheduled clinic visits.

Are there any benefits for taking part?

If you participate in this study, you will receive medical care for any acute ailments from the day of the first dose of vaccine until the completion of the study free of charge. Treatment of chronic illnesses or long term injuries unrelated to the study procedures will not be paid for by the study. If you are found to have such illnesses/injuries, you will be treated under the existing government programs.

NMOP vaccine will be given to all participants after the study ends. Participants however will not be compensated for these clinic visits that will happen after the end of the study.

By participating in this study, you will be helping to develop a malaria vaccine that will bring health benefits to future generations of children.

What will happen if I refuse to participate?

All participation in research is voluntary. You are free to decide if you want to take part or not. You will still receive the recommended standard of care at the study clinic even if you do not take part. If you do agree to participate, we would like you to understand that you are free to change your mind at any time and withdraw from the research. This will not affect your health care now or in the future.

In the event that you leave the study before its completion, we still encourage you to have the examinations and take only blood tests to assess safety for those who received the malaria vaccine. This will involve clinic visits at weeks 3(day 14), 10(day 63) and 24(day 161).
**What happens to the samples?**

The blood samples will be coded with your study identification number and no personal information such as your name or date of birth will be included. This is to ensure that samples can only be linked to the participants by people closely concerned with the research.

Samples will be processed in WXYZ Institute, and some samples may be sent to the UK. Because adults often have low levels of malaria parasites in the blood and we need to detect these, we are using specialized tests (more accurate than the usual malaria tests available in hospitals) and we may need to double-check some of our results by sending samples to another country. Any remaining samples will be stored at our research laboratories at the WXYZ Institute. In the future, new research may be done on these stored samples. Any future research must first be approved by a national independent expert committee to ensure that participants’ safety and wellbeing are protected.

**Who will have access to information about me in this research?**

All our research records are stored securely in locked cabinets and password protected computers. Only the people who are closely concerned with the research will be able to view information from participants just to be sure that the study is being run correctly and the health of every participant is protected and they will keep the information confidential.

**Who has allowed this research to take place?**

This study had been approved by local and international committees including expert committees in the capital city and a committee in the Institute to make sure the research is conducted properly and that participants’ safety and rights are respected. They have looked carefully at this work and agreed that the research is important, relevant to the wellbeing of people living here and follows nationally and internationally agreed guidelines.

The local and international committees will be informed about any serious side effects that are noticed, and if we receive new information about the vaccine during the course of the trial, we will inform you.

**What if I have any questions?**

You may ask any of our staff questions at any time. You can also contact those who are responsible for this research:

1. Dr XXX: WXYZ Institute Trust, P.O Box vvv, Research Town, Telephone: 898887664
2. Dr. XXX: WXYZ Institute Trust, P.O Box vvv, Research Town Tel. 898887667

**If you want to ask someone independent anything about this research please contact:**

The Community Liaison Manager, Mobile: 0889 356789

This research is supported by HHH Foundation, who will pay for any treatment or compensation in the unlikely event of any injury resulting from this trial.
Preamble

What follows are scenarios and a scoring guide that illustrates how the Mixed Method AoU works.

Please take note of the colour coding.

- **Green** represents the concepts you are looking for to assign a CORRECT = 1 score

- **Red** represents answers that are assigned a WRONG = 2 score where the research volunteer has incorrectly understood the informed consent.

- **Purple** represents instructions to you, the administrator of the tool.

Scenario 1

Please read the following scenario highlighted in purple out loud to research volunteer or the person role playing as a research volunteer.

Mr. YY <agree on a context specific name and add here before finalizing> decides that he will enroll in this vaccine trial. So, he starts attending information sessions/discussion groups. On the way to attend one of his sessions at the vaccine trial site, he thinks to himself, "Once I am in the vaccine trial, I won't need to worry about practicing this safe sex stuff anymore".

If Mr._________ told you this what would you say to him?

<table>
<thead>
<tr>
<th>Concept 1 - FALSE SENSE OF PROTECTION</th>
<th>Score:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Some volunteers <strong>may not be getting</strong> the study vaccine; some may be getting the placebo.</td>
<td>1 = Correct</td>
</tr>
<tr>
<td>If volunteer does not mention the above, use the following question to get more information</td>
<td>0 = Wrong</td>
</tr>
<tr>
<td>Do all volunteers in the study get the same injection?</td>
<td></td>
</tr>
</tbody>
</table>

**Key Concept to look for:**

Some might not get the study vaccine.

**CORRECT (score = 1)**

If the volunteer states any of the following:

- Some get placebo, others get the vaccine
- Some might not get the vaccine
- Some might get the placebo
- Not everybody gets the vaccine

| | |
| | |
### Concept 1 - FALSE SENSE OF PROTECTION

<table>
<thead>
<tr>
<th>The study vaccine may not protect volunteers against HIV infection. <em>If volunteer does not mention the above, use the following question to get more information.</em></th>
<th>Key Concept to look for: Vaccine may or may not protect – the research study does not know.</th>
</tr>
</thead>
</table>
| What kind of protection do you think this study vaccine gives? | **CORRECT** (score = 1) *IF the volunteer states any of the following:*  
  • vaccine may or may not protect  
  • vaccine is being studied so we don’t know  
  • don’t know  
  Make sure the volunteer is saying that the scientists or public in general don’t know if the vaccine will protect from HIV and NOT that s/he does not know the answer. |
| Volunteers must not increase their risk behavior. *If volunteer does not mention the above, use the following question to get more information.* | **WRONG** (score = 0) *IF volunteer states:*  
  • study vaccine does protect *(Score =0)*  
  • Practice safe sex  
  • Use condoms  
  • Have one partner |

**Score:**  
1 = Correct  
0 = Wrong
Scenario 2

Please read the following scenario highlighted in purple out loud to research volunteer or the person role playing as a research volunteer.

While participating in this HIV vaccine trial, a volunteer, Mrs. ZZ goes to another clinic outside of the research centre because of being sick often. The doctor at the other clinic advises her to have an HIV test. The results come back positive.

What do you think she should have done?

<table>
<thead>
<tr>
<th>Concept 1 - FALSE POSITIVE HIV TEST RESULT DUE TO RECEIPT OF STUDY VACCINE</th>
<th>Score: 1 = Correct 0 = Wrong</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>If volunteers get the study vaccine, they may test positive on standard HIV tests even if they are not HIV infected.</strong>&lt;br&gt;<strong>If volunteer does not mention the above, use the following question to get more information</strong>&lt;br&gt;<strong>If Mrs. ZZ tests outside the study clinic, what does she need to know about the HIV test result?</strong></td>
<td><strong>Key Concept to look for:</strong>&lt;br&gt;Vaccine may or may not protect – the research study does not know.&lt;br&gt;CORRECT (score = 1)&lt;br&gt;<strong>If the volunteer states</strong> any of the following:&lt;br&gt;• A standard test might show a false positive.&lt;br&gt;• A standard test might show volunteer is infected when s/he might not be.&lt;br&gt;<strong>WRONG (score = 0)</strong>&lt;br&gt;<strong>IF volunteer states:</strong>&lt;br&gt;• Anything else&lt;br&gt;&lt;br&gt;<strong>Only get tested at the research center and not outside the research center.</strong>&lt;br&gt;<strong>If volunteer does not mention the above, use the following question to get more information</strong>&lt;br&gt;<strong>Where should Mrs. ZZ go if she needs to get tested for HIV?</strong></td>
</tr>
<tr>
<td>Concept 2 - FALSE POSITIVE HIV TEST RESULT DUE TO RECEIPT OF STUDY VACCINE</td>
<td>Score: 1 = Correct 0 = Wrong</td>
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</table>
| **A positive HIV test from the study vaccine could last a short time or as long as several years.**  
*If volunteer does not mention the above, use the following question to get more information*  
How long could Mrs. ZZ test HIV positive due to the study vaccine? | **Key Concept to look for:**  
Take a long or short time – don’t know how long.  
**CORRECT (score = 1)**  
*If the volunteer states* any of the following:  
- It is not known how long it will last  
- OR no one knows how long it will last - don’t know.  
- Long time only.  
However make a note and ensure that counselor goes over this again with volunteer before the end of visit.  
**WRONG (score = 0)**  
*IF volunteer states:*  
- Short time only.  
- No positive HIV test at all.  
If volunteer says that a false positive test will not happen at research center (as research center can distinguish true infection from false one) then ask what about at routine test center? |
Scenario 3

Please read the following scenario highlighted in purple out loud to research volunteer or the person role playing as a research volunteer.

While participating in this HIV vaccine trial and one month after Mrs. XX <please use a context specific female name indicating another volunteer in the same trial– do not use the same name as in earlier scenarios > received her first injection, she and her spouse want to have another child. She reports that she is thinking of stopping her contraception.

What do you think about her decision to get pregnant and stop contraception at this time?

<table>
<thead>
<tr>
<th>Concept 3 - CONTRACEPTION</th>
<th>Score:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Volunteers must use contraception until four months after the last vaccination to prevent pregnancy. If volunteer does not mention the above, use the following question to get more information</td>
<td>1 = Correct 0 = Wrong</td>
</tr>
<tr>
<td>What should the volunteer do to prevent pregnancy? And for how long?</td>
<td>Key Concept to look for: Use of contraception at least until 4 months post last injection. CORRECT (score = 1) If the volunteer states any of the following: • Volunteers must use contraception until four months after last vaccination. • Contraception must be used – no reference to time. • Should/would not get pregnant – no reference to time. • It is okay to stop 4 or more months after last vaccination. WRONG (score = 0) IF volunteer states: • Okay to stop in less than four months</td>
</tr>
</tbody>
</table>
### Concept 3 - CONTRACEPTION

| This is to **protect children** from possible **unknown effects** of the study vaccine.  

*If volunteer does not mention the above, use the following question to get more information*  

**Why should Mrs.XX not get pregnant during vaccination period?** | Key Concept to look for:  

Effect on child not known.  

**CORRECT (score = 1)**  

*If the volunteer states* any of the following:  

- It is not known what the effect could be on the child.  

**WRONG (score = 0)**  

*IF volunteer states:*  

- The vaccine is safe for unborn children.  

- The vaccine will definitely/probably harm unborn children. | Score:  

1 = Correct  

0 = Wrong |
Scenario 4

Please read the following scenario highlighted in purple out loud to research volunteer or the person role playing as a research volunteer.

After participating in the vaccine trial for one year, Mr. NN, <please use a context specific name indicating another volunteer in the same trial– do not use the same name as in earlier scenarios> tests HIV positive at the research center clinic. The laboratory test at the research center clinic shows that he is really infected with HIV. He is very angry and says to the counselor: “I knew this vaccine would infect me with HIV”. Then he adds: “Even if the vaccine didn’t give me the HIV, it is part of the problem.”

What do you think about what Mr. NN said?

| Concept 4 - POSSIBLE ENHANCED SUSCEPTIBILITY TO HIV INFECTION AFTER RECEIPT OF STUDY VACCINE IF EXPOSED TO HIV THROUGH HIGH-RISK BEHAVIOR | Score:  
1 = Correct  
0 = Wrong |
|---|---|
| The study vaccine cannot infect the volunteer with HIV. If volunteer does not mention the above, use the following question to get more information | Key Concept to look for: Study vaccine cannot cause infection; study vaccine cannot infect a volunteer.  
CORRECT (score = 1)  
If the volunteer states any of the following:  
• Volunteer says study vaccine cannot cause infection.  
• Study vaccine cannot infect volunteer.  
WRONG (score = 0)  
IF volunteer states:  
• Anything else |
| Can Mr _______ get HIV from this vaccine? Why/ why not? |  |
### Critical Concept 4 - POSSIBLE ENHANCED SUSCEPTIBILITY TO HIV INFECTION AFTER RECEIPT OF STUDY VACCINE IF EXPOSED TO HIV THROUGH HIGH-RISK BEHAVIOR

<table>
<thead>
<tr>
<th>Score:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 = Correct</td>
</tr>
<tr>
<td>0 = Wrong</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Key Concept to look for:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not known if the study vaccine could increase a volunteer's risk of infection if volunteer gets study vaccine AND engages in high risk behavior.</td>
</tr>
</tbody>
</table>

**CORRECT (score = 1)**

If the volunteer states any of the following:
- It could be more likely.
- No one knows if it will increase, decrease or stay the same.
- Don't know OR it is not known.
- No one knows.

Make sure the volunteer is saying that the scientists or public in general don't know and NOT that s/he does not know the answer).

However make a note and ensure that counselor goes over this again with volunteer before the end of visit.

**WRONG (score = 0)**

If volunteer states:
- No (the study cannot make it more likely).
- 'Because there is live HIV in the vaccine', that is wrong.
- No other reason provided other than change in behavior.

**If increase in risky behavior is mentioned, ask if any other reason.**
Handout # 13 – Brief Informed Consent Assessment Questionnaire

Instructions:
• Please complete this one page assessment by filling in the circles next to the correct answers. ☑
• Please ignore the far right column.
• You have 10 minutes available.
• Please complete your name here: [ ]

<table>
<thead>
<tr>
<th>Questions</th>
<th>Choose answers here</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 A competent individual can freely and voluntarily consent or refuse consent to participation in a trial if they have access to key pieces of information and fully understand the information. Please select the 3 key categories of information that a research volunteer needs in order to make an informed decision to consent or refuse consent.</td>
<td>Benefits, Timeframe, Costs, Location, Burdens, Reimbursement, Risks.</td>
<td>☑</td>
</tr>
<tr>
<td>2 There are four key aspects of informed consent discussed in the Belmont Report which is one of the three most important documents in the history of the ethics of medical research. Please select the 4 requirements that must be met for someone to be able to make an informed decision to consent or not to consent to participation in a research study.</td>
<td>Disclosure of information, Level of Education, Freedom of choice, Availability to participate, Comprehension of information, Capacity to make a decision, Appropriate age.</td>
<td>☑ ☑ ☑ ☑</td>
</tr>
<tr>
<td>3 There are 3 necessary conditions that must be satisfied when seeking informed consent. Please select the 3 conditions that must be satisfied once someone has consented to participate in a research study.</td>
<td>The decision was voluntary, The decision was timely, The decision was made with an appropriate understanding of the circumstances, The decision was made in consultation with a family member, The decision or choice was deliberate insofar as the patient has carefully considered all of the expected benefits, burdens and risks.</td>
<td>☑ ☑ ☑ ☑</td>
</tr>
</tbody>
</table>
| 4 The requirement to obtain informed consent from individuals before involving them in research is based on the principle of respect for persons. Respect for persons in the context of informed consent in research means which of the following? Please select one. | The person is treated as completely autonomous, The person is made comfortable, The person is addressed respectfully. | ☑ ☑ ☑  
| 5 Informed consent is an on-going exchange of information between subject and investigator. Informed consent may be documented with a form that provides the key information about the research. Providing a consent form is enough to ensure consent – is this true or false? | True, False | ☑ ☑  
| 6 Comprehension is a key aspect of informed consent. Assessing the level of understanding of the informed consent information sheet is an essential ethical requirement. Assessing level of understanding can be done as follows – please select the most appropriate method. | Checklist with multiple choice answers, Open ended narratives & vignettes, Mixed methods including checklists & narratives. | ☑ ☑ ☑  


Activities
GAME # 3 - Linking Game (Deck 3)

Instructions to Trainer:
Please prepare yourself for the Linking Game before the session.

Materials required:
• Tape
• Cards prepared and cut out before training
• Box for holding cards

Training methods used:
• Lecture
• Group Discussion
• Games

Delivery:
• Prepare participants to play a game – that involves moving around
• Clear a space

After you have given the explanations, you can give out the cards and tape or safety pins for the participants to attach to their chests. Do not give the cards out until you have explained the instructions. Set a clock or timer so that the group that finishes first and links up in the correct order is given a total time to complete and the same for the runner up teams.

When the linking game is complete review the links and make sure that all the pieces are in the right place.

• Explain the Game:
  - Each training participant in the training to take one card from a box full of concepts, scenarios and the key points and stick it to his/her shirt with tape.
  - Each person will try to find all the other people 3 - 4 or 5 people who have the other cards that fit together with the piece of the concept they have.
  - When all the pieces of the team have found each other, they should line up with a Concept – Scenario and each sub-concept in the correct order and SHOUT AoU.
  - The team that does this first and has all the pieces in the right place is the Winner!

• Remind Participants:
  - Concept 1: False sense of protection, it has 1 scenario and 2 sub-concepts that the trial volunteer will need to grasp.
  - Concept 2: False positive HIV test result due to receipt of study vaccine, has 1 scenario and 3 sub-concepts.
  - Concept 3: Contraception has 1 scenario and 2 sub-concepts.
  - Concept 4: Possible enhanced susceptibility to HIV infection after receipt of study vaccine if exposed to HIV through high-risk behavior. This concept has 1 scenario and 2 sub-concepts.

• Set the timer, hand out the cards, ask everyone to attach them to their shirts/dresses and then launch the game.
Mr. YY decides that he will enroll in this vaccine trial. So, he starts attending information sessions/discussion groups. On the way to attend one of his sessions at the vaccine trial site, he thinks to himself, “Once I am in the vaccine trial, I won’t need to worry about using protection during sex anymore”. If Mr. YY told you this what would you say to him?

Some volunteers may not be getting the study vaccine - they may be getting the placebo.

The study vaccine may not protect volunteers against HIV Infection.

Volunteers must not increase their risk behavior.
ACTIVITIES - GAME # 3 - LINKING GAME (DECK 3)
False Positive HIV test

Mrs. ZZ goes to another clinic outside of the research center because of being sick often. The doctor at the other clinic advises her to have an HIV test. The results come back positive.

If the volunteer gets the study vaccine, he may test positive on standard HIV tests even if not infected.

Volunteers must only get tested for HIV at the research center and not outside.

A positive HIV test from the study vaccine could last a short time or as long as several years.
Contraception for female volunteers

While participating in this HIV vaccine trial and one month after Mrs.XX received her first injection, she and her spouse want to have another child. She reports that she is thinking of stopping her contraception.

Female volunteers must commit to being on contraception for the time specified by the trial after the last trial vaccination to prevent pregnancy.

Staying on contraception for a specified time after the last trial vaccination is to protect children from the possible unknown effects of the study vaccine.
**Possible enhanced susceptibility to HIV infection after receipt of study vaccine if exposed to HIV through high-risk behavior**

After participating in the vaccine trial for one year, Mr. NN tests HIV positive at the research center clinic. The laboratory test at the research center clinic shows that he is really infected with HIV. He is very angry and says to the counselor: “I knew this vaccine would infect me with HIV”. Then he adds: “Even if the vaccine didn’t give me the HIV, it is part of the problem.”

The study vaccine cannot infect or cause HIV in a volunteer.

It is not known whether the HIV vaccine could increase a volunteers risk of getting HIV infected if the volunteer gets the HIV vaccine during the study and engages in HIV high risk behavior.
GAME # 4: Jigsaw Puzzle Game 1

Instructions: Please cut out these jigsaw puzzle pieces carefully and insert in an envelope, mixed with the pieces from the other jigsaw puzzles. Each participant should receive an envelope with mixed up jigsaw pieces.
GAME # 4: Jigsaw Puzzle Game 2

Instructions: Please cut out these jigsaw puzzle pieces carefully and insert in an envelope, mixed with the pieces from the other jigsaw puzzles. Each participant should receive an envelope with mixed up jigsaw pieces.
GAME # 4: Jigsaw Puzzle Game 3

Instructions: Please cut out these jigsaw puzzle pieces carefully and insert in an envelope, mixed with the pieces from the other jigsaw puzzles. Each participant should receive an envelope with mixed up jigsaw pieces.

- Contraception
- It is okay if the volunteer gets pregnant while receiving injections in the trial.
- Protect children from possible unknown effects of the vaccine
- She reports that she is thinking of stopping her contraception
- What should the volunteer do to prevent pregnancy?
- Volunteers use contraception for a period specified by trial
- She reports that she is thinking of stopping her contraception
**GAME # 4: Jigsaw Puzzle Game 4**

**Instructions:** Please cut out these jigsaw puzzle pieces carefully and insert in an envelope, mixed with the pieces from the other jigsaw puzzles. Each participant should receive an envelope with mixed up jigsaw pieces.

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The vaccine does not cause HIV

I knew this vaccine would infect me with HIV. Even if the vaccine didn’t give me HIV, it’s part of the problem

No one knows if the risk will increase, decrease or stay the same

The vaccine suppresses your immune system and you can get HIV

Vaccine will increase risk of infection if the volunteer has unprotected sex

The laboratory test at the research centre clinic shows that he is really infected with HIV. He is very angry.
GAME # 4: Jigsaw Puzzle Game 5

Instructions: Please cut out these jigsaw puzzle pieces carefully and insert in an envelope, mixed with the pieces from the other jigsaw puzzles. Each participant should receive an envelope with mixed up jigsaw pieces.

- The vaccine suppresses your immune system and you can get HIV.
- It is okay if the volunteer gets pregnant while receiving injections in the trial.
- Volunteers taking the vaccine are safer than those on the placebo.
- A positive standard HIV test means that the trial volunteer has HIV.
GAME # 4: Jigsaw Puzzle Blank x 6

**Instructions:** Please cut out these jigsaw puzzle pieces carefully and insert in an envelope, mixed with the pieces from the other jigsaw puzzles. Each participant should receive an envelope with mixed up jigsaw pieces.
ACTIVITIES - GAME # 4: PUZZLE BLANK X 6
GAME # 4: Jigsaw Puzzle Blank x 6

Instructions: Please cut out these jigsaw puzzle pieces carefully and insert in an envelope, mixed with the pieces from the other jigsaw puzzles. Each participant should receive an envelope with mixed up jigsaw pieces.
GAME # 4: Jigsaw Puzzle Blank x 6

Instructions: Please cut out these jigsaw puzzle pieces carefully and insert in an envelope, mixed with the pieces from the other jigsaw puzzles. Each participant should receive an envelope with mixed up jigsaw pieces.
GAME # 4: Jigsaw Puzzle Blank x 6

Instructions: Please cut out these jigsaw puzzle pieces carefully and insert in an envelope, mixed with the pieces from the other jigsaw puzzles. Each participant should receive an envelope with mixed up jigsaw pieces.
GAME # 4: Jigsaw Puzzle Blank x 4

Instructions: Please cut out these jigsaw puzzle pieces carefully and insert in an envelope, mixed with the pieces from the other jigsaw puzzles. Each participant should receive an envelope with mixed up jigsaw pieces.
GAME # 4: Jigsaw Puzzle Blank x 4

Instructions: Please cut out these jigsaw puzzle pieces carefully and insert in an envelope, mixed with the pieces from the other jigsaw puzzles. Each participant should receive an envelope with mixed up jigsaw pieces.
GAME # 4: Jigsaw Puzzle Blank x 4

Instructions: Please cut out these jigsaw puzzle pieces carefully and insert in an envelope, mixed with the pieces from the other jigsaw puzzles. Each participant should receive an envelope with mixed up jigsaw pieces.
GAME # 4: Jigsaw Puzzle Blank x 4

Instructions: Please cut out these jigsaw puzzle pieces carefully and insert in an envelope, mixed with the pieces from the other jigsaw puzzles. Each participant should receive an envelope with mixed up jigsaw pieces.
ACTIVITIES - GAME # 4: PUZZLE BLANK X 4