

MODULE 7

Community involvement and participation

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Outcomes of this module

By the end of this module, you should be able to:

1. Explain what we mean by 'community' and what makes you part of a community.
2. Explain what we mean by 'involvement and participation'.
3. Discuss why it is important to have community involvement and participation.
4. Discuss what community involvement and participation mean for HIV vaccine research and development.
5. What steps are involved in participating in an HIV vaccine clinical trial?





Section 1: Background information on community involvement and participation in HIV vaccine research and development

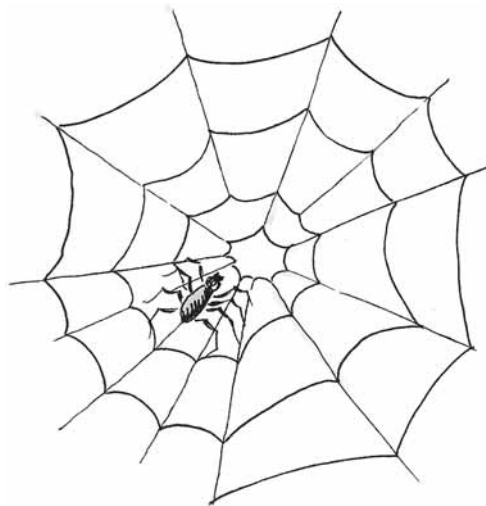
1. WHAT IS A COMMUNITY?

Before we can look at how to facilitate community involvement and participation, we first need to understand what we mean by 'community'.

Take 5 minutes ...

- *How would you describe the community to which you belong?*
- *Who is part of your community (who is inside the community)?*
- *Who is not part of your community (who is outside the community)?*
- *What do you understand by the term 'the community'?*

We talk about 'the community of Soweto', or 'the community of Mitchells Plain' or 'the community of Pinetown' as if they were one group of people, who are all the same. But in fact, a 'community' is more like a spider's web. It is made up of many different people, of different ages, who may look, feel and believe differently from one another. So it is very difficult to talk simply about 'the community'.



A community is like a spider's web with different groups or 'threads' joined together.

KEY WORD

Community:

Any group of people who are linked to one another because they share something in common.

We suggest that a **community** is a complex web of people, groups and relationships. It involves different groups of people who are linked to one another because they share something in common. For example, they are from the same family; they share the same land or area; they share resources (like water); they do the same activities (like work); they belong to the same organisation (e.g. burial society); they share the same risks; or, they share the same beliefs and practices (like religion).



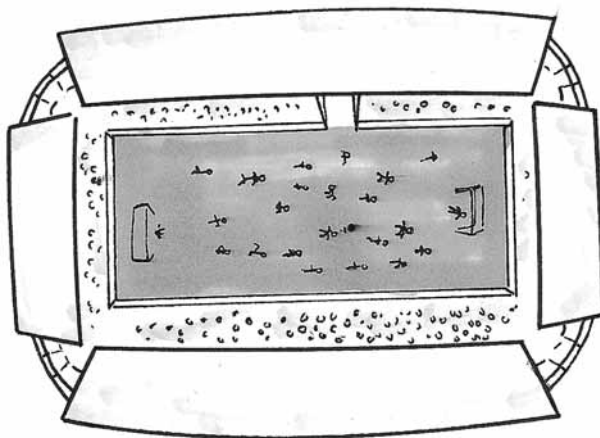
Within these communities there are different groupings of people who may have different positions or status, based on factors like age, race, class, gender, employment or unemployment, language, religion, education level, marital status, and sexual orientation. For example, in some communities older males have more power than women, youth and children.

Rural communities are also different to urban and peri-urban communities. For example, in rural areas in South Africa, there are more elderly black women, who live in poverty and tend to look after the younger children, the aged and the sick. However in many of these areas traditional leaders, who are usually men, are the main decision – makers. In urban communities the divide between rich and poor is more obvious than in rural communities. Also access or lack of access to social services and other facilities is more obvious, e.g. access to transport systems, schools, hospitals, clinics, police stations, homes for the elderly, shops, sports fields, sanitation, running water, electricity, telephones and roads.

Most of us also belong to different **subgroups** within our broader community, for example, we might belong to a particular religious group who all share the same belief or culture – we are all Christians, or Muslims or Hindus. Or we may belong to a subgroup who are of the same age, gender or race. Or we may belong to a subgroup that shares a common condition, e.g. we are all living with HIV and/or AIDS. Within these different subgroups we also play different roles, e.g. in some we are the leaders, decision-makers, or counsellors, in others we are the ordinary members, and in yet others we are educators or learners.

KEY WORD

*Subgroups:
Groups within
a community.*



Most of us belong to many different subgroups. For example, someone may belong to a soccer club and to the 'soccer community'. And within this community, she/he might be part of the supporter subgroup.



Sometimes we feel proud to be part of a subgroup, for example, we may be proud supporters of a particular soccer team. Other times we feel anxious or fearful that we are part of a subgroup and don't want others to know. We also often define our community by saying who is part of it and who is NOT – who is an 'insider' and who is an 'outsider'.

Take 5 minutes ...

- *Turn to page 40 in this module, to Handout 1. Make a photocopy of the handout for yourself, or use a pencil in this exercise, so that you can rub it out.*
- *Circle the words in the handout that you would use to describe yourself and the communities you belong to. Add in other words that you would use.*
- *Is there only one community that you belong to? Or are there many different communities or subgroups?*
- *Are there any words on the list that describe people who are not part of the communities you belong to?*
- *What links or binds the communities that you belong to together? What do the people have in common?*

So far we have said that a community contains many different groups of people who are linked to one another because they share something in common. And we have said that most of us belong to more than one community or subgroup. How does this understanding of 'community' link with the ideas of involvement and participation?

2. WHAT DO INVOLVEMENT AND PARTICIPATION MEAN?

Take 5 minutes ...

- *What is involvement?*
- *What is participation?*
- *What are the differences between involvement and participation?*
- *How do involvement and participation link with the concept of community?*

This is what other workshop participants have said about involvement and participation. How does it compare with what you said?



When you are involved in something you are part of making decisions about things that affect you.



Community participation is when community members come together to share and discuss their problems and needs. They then choose the most important ones to work on.



Involvement and participation don't just happen once. You must carry on being involved and participating.

The **literature** as well as different people and organisations have different definitions and views about involvement and participation and may use different ideas and theories when implementing their community involvement and participation activities. The definitions and descriptions used in this module largely come from the view and practice of *Masikhulisane*, SAAVI's Community Involvement Programme. For more information about this model, please contact the Programme.

So we use the word, 'involvement' to mean:

- being involved more fully in the HIV vaccine research and development process *as a means to an end*. In other words, to make sure that through our involvement we contribute to finding a successful HIV vaccine.
- being involved in the process as an end in itself. In other words, to make sure that through our involvement we help grow and develop as individuals and as communities;
- helping communities and different subgroups within communities become more involved as early as possible in the research and development process; and
- facilitating the ongoing, long-term and sustained involvement of different groups of people. This could include involving children and youth in sharing decision-making, where appropriate.

KEY WORD

Literature:
Research papers,
books, articles and
other publications.



People need to become involved in a meaningful way – they should take part in and influence decisions and activities relating to HIV vaccine research and development, and at the same time take part in building a human rights culture. We can say that involvement is the beginning of point of participation. It leads to participation. Involvement includes raising awareness about an issue (e.g. HIV vaccine research and development), and could include getting ‘buy in’ and support from different subgroups.

Through becoming involved, people then begin to participate and contribute to the process in different ways. Some people may just want more information about the vaccines. Other people will form their own opinions and ideas about the process or about the vaccines. Still others will take part in activities and projects to do with and/or to promote the research and development process.

Both involvement and participation in the research and development process can help to build and develop a community. People’s independence, confidence, knowledge and skills are developed. Their pride and dignity is built up or restored. And the community develops more effective structures and organisation.

3. WHY IS *COMMUNITY INVOLVEMENT AND PARTICIPATION* IMPORTANT?

As you read through the case study below, think about why you think the projects failed and what could have been done differently.

CASE STUDY

In KwaZulu-Natal there is a community with a population of about 2 500 people. The people have many problems – their soil is poor, their farming methods are poor, and there is not much rainfall. Recently there was an outbreak of diarrhoea, followed by measles and many people lost their lives.

The tribal authority in the area approached a funding agency for help. They said that the major problems were ignorance, poverty, lack of schools and health services. The funding agency agreed to help.

The funding agency visited the area and chose a site on which to drill a well. The well was drilled and a pump installed, and two months later the agency handed over the well to the tribal authority during an elaborate ceremony.

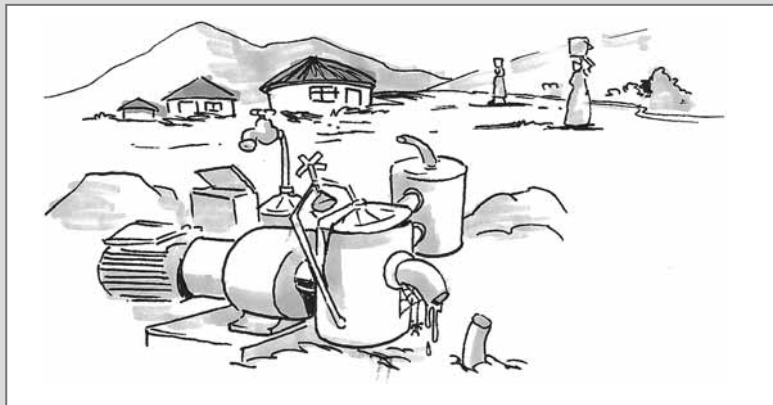




At the same time the funding agency also started a project to improve child nutrition in the area. They trained the mothers how to make groundnut cakes so that they could feed their children. They explained that the mothers could also sell their cakes to earn some extra money. The funding agency went away satisfied.

One year later the funding agency visited the area and found the following:

The people had used the well for one month and then the pump broke down. They had sent a message to the tribal authority telling him of this and in the meantime they went back to drawing water from the open, unprotected river that flows through the area. To this day, the pump has still not been repaired and, in fact, parts of it have now been stolen. Also, since the funding agency left, hardly any mothers had made the groundnut cakes.



(Adapted from Ibundela - Stories from the Transkei (The Adult Literacy and Advice Centre))

A project will fail if there is no community 'buy in' – where for various reasons, people do not feel that the project is theirs, they do not support it, or they feel that it is of no benefit to them. Many times there is no 'buy in' because of the approach that was used to introduce and implement the project. In the above case study, the tribal authority and funding agency used what is called a 'top-down approach' – they entered the community as the 'experts' and made all the decisions about what should be done:

- They did not consult the people in the community about their needs or involve them in discussions on how to solve these needs.



- They did not involve the community in making decisions that led to the projects.
- They did not invite the community to participate in running or maintaining the projects.
- They did not empower the community or share information, knowledge and skills.
- They did not draw on the community's existing knowledge, skills, experience, resources or structures.

Generally, the projects did not belong to the community – they belonged to the funding agency. There was no real partnership between the community and the funding agency. Without this partnership, support and participation, it is very difficult to keep a project going.

KEY WORD

Sustainable:

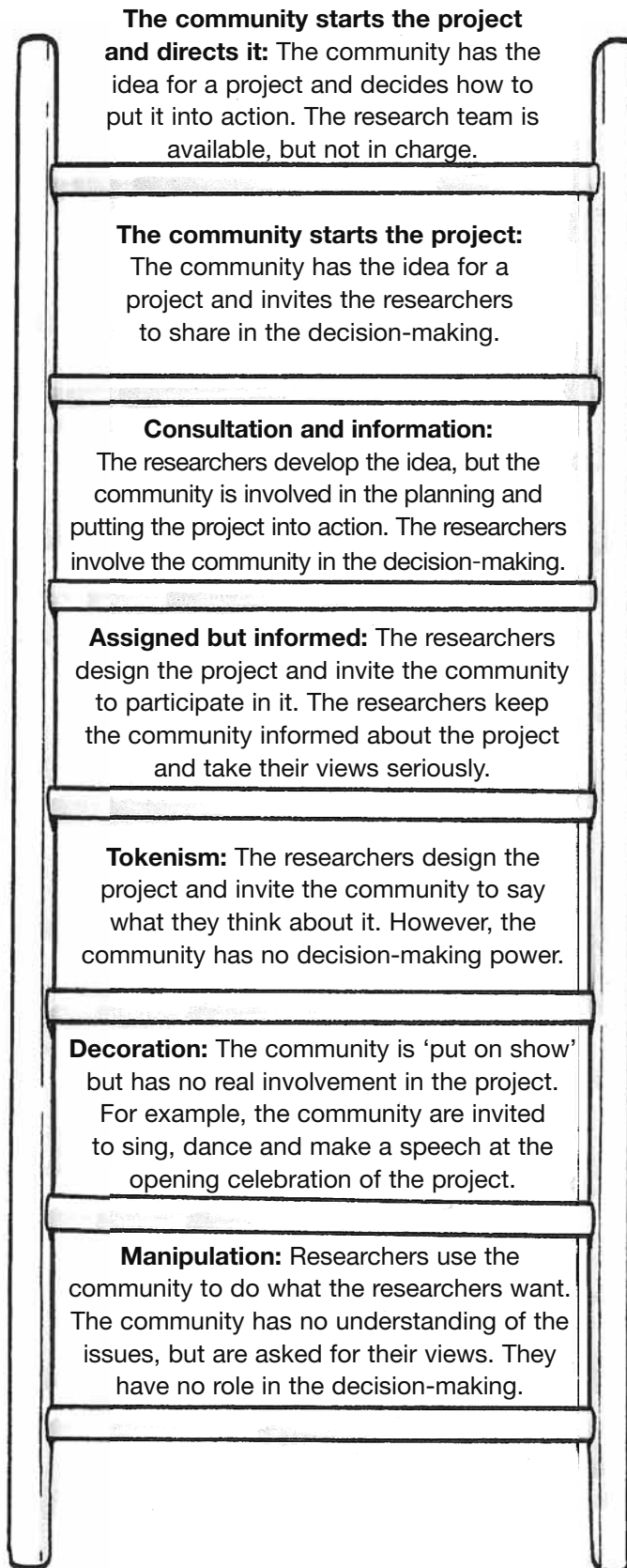
Long lasting; it can keep going.

A more *participatory approach* can promote community participation and involvement, and make sure that a project is **sustainable**. This is what other workshop participants have said would assist with community involvement and participation:

- There should be consultation with a broad range of people in the community.
- There should be ongoing dialogue and consultation – talking and discussing issues.
- The community should be involved in making decisions that affect them, e.g. via an elected representative committee.
- The structures, committees, decision-making processes, resources, experience and knowledge that already exist in the community should be recognised and drawn into the process.
- People's knowledge and skills must be developed so that they can participate effectively.
- Communities must be helped to organise and take action around an issue or need.
- There should be networking with others, both inside and outside the community around specific issues or for particular assistance.
- *What other ideas would you add to this list...*

Ladder of participation

The 'Ladder of participation' on page 9 is adapted from *Childrens' participation from tokenism to citizenship* by Roger Hart, UNICEF, 1992. We could all strive to move from the bottom of the ladder to somewhere at the top. As you read through the different steps on the ladder, think about projects that you have been involved in and where the type of community involvement and participation the projects had would fit on the ladder. Also think about what is ideal, and what is practical and realistic.



The ladder of participation – adapted from 'Children's participation from tokenism to citizenship' by Roger Hart, UNICEF, 1992.



4. WHAT DOES COMMUNITY INVOLVEMENT AND PARTICIPATION MEAN FOR HIV VACCINE RESEARCH AND DEVELOPMENT?

Take 5 minutes ...

- *Why should researchers ensure community involvement and participation in the HIV vaccine research and development process?*
- *Why should communities become involved and participate in this process?*
- *What would happen if the community were not invited to be an active partner and participant in the process?*
- *What information do communities need to know so that they can make a decision about becoming involved?*

Why is it important to the researchers that the community gets involved and participates in the HIV vaccine research and development process?

Researchers know that it is in the interests of research to inform and educate *all* communities so that there is a widespread and general understanding about HIV vaccine research and development. If people understand something and are involved in it from early on, then they are in a better position to decide how to support it.

Researchers have an added responsibility to the communities where they plan to start an HIV vaccine trial. They must make sure that their research is ethical – that it is based on respect for people's right to choose and act; respect for justice; and, that it is to the benefit of all those involved. During the research process, researchers also need to ensure that the legal and human rights of trial participants and their communities are respected, protected, promoted and fulfilled. To fulfil these responsibilities researchers need to help communities to become involved in the process through:

- being honest and transparent with communities;
- *consulting* with trial and potential *trial communities* where they would like a vaccine trial to start;
- ensuring opportunities for ongoing discussions or *dialogue* about the *research*;
- giving the community access to as much *information* as possible to make informed decisions about whether they will become involved and how;
- providing opportunities for the development of the communities and community members involved; and
- helping to establish a formal mechanism to represent the interests of the community and to ensure community involvement

You can read more about ethics in Module 5; and about legal and human rights in Module 6.



in their research. For example, researchers can help the community form a *core group, representative of the community*, usually called a Community Advisory Group or CAG. This group should engage with the researchers as an equal partner, and meaningfully contributes to relevant decision-making about issues that affect the community. Researchers should also work with *existing community structures* to ensure community involvement and participation. We will discuss this later in more detail.

Why should the community become involved in HIV vaccine research and development?

Why do we participate in something? Usually because we think we will get something out of it – some benefit. Perhaps we participate because it helps us learn, grow or develop in some way. We may want the opportunity to give back something to our community. We also participate so that we can have a say in, and can influence, decisions and actions that affect our lives. If we participate in something that affects us, there is more chance that we will be committed to it and be able to influence it.

Take 5 minutes ...

Think about a community that needs to decide whether to become involved in the HIV vaccine research and development process or some part of it, e.g. clinical trials:

- *What information does this community need to know?*
- *What do you think they would see as a benefit of involvement and participation?*
- *What would they worry about and see as being a risk of involvement and participation?*

What information does the community need to know so that they can make a decision to become involved?

In order to make a decision about becoming involved in the research and development process, ideally, communities should have access to and a good understanding of the following:

- They need scientific and technical information, e.g. what vaccines are and how they work; the different types of HIV vaccines; and stages in developing an HIV vaccine; what is involved in each phase of a clinical trial, etc.
- They need to understand ethical, legal and human rights issues and how to ensure that these are applied in the research process.
- Communities need to know about trial processes and standards, e.g. that trials must be approved by the South African Medicines Control Council (MCC); that researchers must follow Good Clinical Practice (GCP) and ethical guidelines, and where to find more information on them.



- Communities need practical information on the HIV vaccine development process, e.g. how a volunteer enrolls in the trial, what process the volunteer will go through, what they are likely to experience, the kind of support to expect, etc.
- The community needs to know the benefits and risks of the HIV vaccine research and development process, including the clinical trials.
- They also need to know in what ways they can participate in the research and development process. (See page 20–24 for more information on ways to participate.)

What are the benefits to developing countries, and communities becoming involved in the HIV vaccine research and development process, and what are the risks to them becoming involved?

The table below includes some of the main arguments that communities, researchers, organisations and governments have made when trying to answer the above questions:

Benefits to becoming involved	Risks to becoming involved
<p>Developing countries ensure faster access to a successful HIV vaccine:</p> <ul style="list-style-type: none"> • Some vaccines that are in public use today have taken up to 20 years to become available in developing countries, once they were licensed. So, developing countries may want to get involved in the HIV vaccine research and development process as early as possible, to ensure that manufacturing capacity, funding and supply agreements are built up early to ensure faster access to a successful HIV vaccine once it is found. <p>Developing countries increase the chances of finding an HIV vaccine that works against the most common subtype of HIV in their region:</p> <ul style="list-style-type: none"> • We do not know yet if an HIV vaccine designed for use against one subtype of HIV will work against another subtype. By lobbying for and developing vaccines that work against the subtype of HIV that is most common in their region, developing countries can, however, increase their chances of finding an HIV vaccine that works in their communities. <p>Developing countries build research capacity and infrastructure:</p> <ul style="list-style-type: none"> • By developing and testing vaccines in their countries, and by collaborating with research institutions and vaccine manufacturers in developed countries, 	<p>Potential exploitation:</p> <ul style="list-style-type: none"> • Poor communities may be unintentionally exploited, e.g. a poor community that lacks adequate health care may decide to participate in a trial because they think that it will lead to better health care, food and money. They may not completely understand the consequences of participation. • Communities who participate in the research and who need the HIV vaccine the most, might not have access to it when it becomes available because of the costs. However, according to the UNAIDS document, <i>Ethical considerations in HIV preventive vaccine research</i>, “making a safe and effective vaccine reasonably available to the population where it was tested is a basic ethical requirement” (page 13). According to this document, any preventative HIV vaccine that is safe and effective, as well as other knowledge and benefits resulting from the HIV vaccine research, should be



developing countries can build their research capacity, expertise and infrastructure. Infrastructure includes laboratories and storage facilities and is important to ensure that the vaccine can be distributed once it is available.

Communities help find a solution to HIV and AIDS:

- Being involved and participating in the HIV vaccine research and development, including clinical trials, gives community members the chance to give something back to the community. It also gives the community a chance to help find a solution to the spread of HIV and possibly to reduce the rate of HIV infection in the future.
- If the vaccine is effective, then the community might have helped to prevent others from becoming infected with HIV. Or if people do still get infected, they might only get AIDS much later because the vaccine may slow down the progression of the disease.

Community and people development:

- Research, including clinical trials, that encourages meaningful community involvement and participation helps to develop the knowledge, confidence, independence and skills of community members.
- The information and experience gained could lead to a better-informed community, empowered to make decisions about issues affecting them.
- Trials could lead to the development of a better infrastructure in the community, e.g. better health services and support.
- Research, including clinical trials, could provide an opportunity to build relationships between researchers and communities, and between different groups and individuals within a community. This could lead to increased trust and interaction in the community.
- Current research and development including clinical trials, may lead to better future scientific research which, in turn, may benefit the community.

made available as soon as possible to all trial participants and populations at high risk of infection. Efforts are being made to establish a funding mechanism if an effective HIV vaccine becomes available to ensure access to the vaccine.

Community conflict and stigmatisation:

- There might be conflict if some members of the community do not support HIV vaccine research and development or if members of a community do not support holding a trial there. This shows us the importance of ensuring community involvement and participation as early as possible in the research process, and with a broad range of community stakeholders.
- A community where trials take place may be stigmatised because they are seen to be at high risk of HIV infection because of, e.g., how the stories are reported in the **media**.

KEY WORD

Media:

TV, radio, newspapers, magazines.

DID YOU KNOW?

Many of the concerns or risks raised in the table above can be addressed by ensuring research that follows a scientifically and ethically sound protocol, and that meets with GCP and other relevant guidelines and legislation. This is to ensure research that is relevant and necessary, and which is properly done to give reliable and valid results. See Module 4 for more information on the approval process, the clinical and ethical guidelines, as well as the legal framework which have been put in place to address many of the above issues.





5. WHAT STEPS ARE INVOLVED IN PARTICIPATING IN AN HIV VACCINE CLINICAL TRIAL?

Take 5 minutes ...

- How can community involvement and participation be promoted in HIV vaccine research and development including clinical trials?
- Who in the community should be involved?

Refer to Module 5 for information on ethics.

In HIV vaccine research and development we use a participatory approach to encourage community involvement and participation. This approach is in line with our biomedical ethical principles of: treating people with dignity and respect; protecting their rights and welfare; and, promoting and improving their well-being and safety. As we can see on pages 10–13, through meaningful involvement and participation, communities can be involved in making decisions that affect them and they can ensure that their rights, welfare and well-being are protected. They can also share in the benefits of the research including community development, as well as the risks, failures and responsibilities.

My job is to be the site co-ordinator of this trial. My team knows something about science, but you are the experts in the needs of your community. Together we can design a vaccine trial with a brain and a heart.



I like that - 'a vaccine trial with a brain and a heart'.

On the following pages we discuss the participatory approach that should be used in the HIV vaccine research and development process including clinical trials.

The participatory approach we use is an ongoing process that involves the community in each of the following steps:

- Step 1:** Consultation, choosing the trial site and establishing a CAG.
- Step 2:** Trial site staff recruit and pre-screen potential trial participants.
- Step 3:** Researchers screen volunteers again for eligibility.
- Step 4:** Enrolment (part 1): Informed consent and allocation to a trial group.



- Step 5:** Enrolment (part 2) and administration of the first dose of the vaccine or placebo.
- Step 6:** Monitoring for immediate adverse events.
- Step 7:** Follow-up visits and doses.
- Step 8:** Data is analysed by researchers.
- Step 9:** Feedback and unblinding interviews.
- Step 10:** Long-term follow up of participants with breakthrough infections and/or pregnancy.
- Step 11:** Decisions about whether to take the vaccine candidates to the next phase.

We will firstly discuss Step 1 in more detail. Then we will continue with Steps 2–11.

Step 1: Consultation, choosing the trial site and establishing a CAG

In Module 4 we spoke about:

- clinical trials as the final stage of HIV vaccine research and development;
- factors involved in choosing a trial site; and
- the need to consult with and get 'buy in' and the agreement of stakeholders in those communities affected by the research that will take place at those sites. Community stakeholders may include different levels of government (national, provincial and particularly local government) and other relevant leaders and community structures.

Once researchers consult with the relevant stakeholders and have their agreement for the research to take place, a new level of community involvement begins. This is done to inform the wider community about the HIV vaccine research that is likely to take place in their area, and to encourage meaningful community involvement and participation in this process.



Step 1 Researchers consult with community stakeholders

Refer to Modules 3 and 4 for more information about the approval process for a clinical trial.



Step 1

Consultation with the community

From the very beginning of preparing for the trials, researchers and community outreach staff must try to consult and work with existing structures and organisations in a community. They may also find it useful to understand how these committees tie in with district, provincial and national structures. (see opposite)

They can arrange consultation workshops and meetings with the various community leaders and other stakeholders, e.g. non-governmental organisations (NGOs), community or civic groups and AIDS service organisations. The purpose of these consultations is to get 'buy in' and support for the upcoming trial and to encourage ongoing and meaningful community involvement.

Groups such as *Masikhulisane*, SAAVI's Community Involvement Programme, may be involved in similar activities in different sectors of the community, while still in collaboration with the trial site community outreach staff. *Masikhulisane* may also have worked in the trial site area before the site was established. This means that some organisations that are part of the sectors in which *Masikhulisane* works may already be aware of the HIV vaccine research and development process.

To aid consultation, the researchers and community outreach staff also need to do background research into the community, in which they may do trials, to understand the following:

- the culture, norms, beliefs and attitudes that exist in the community;
- the local government and community structures and committees that already exist and which they must work with or through, e.g. the clinic and/or community health centre committees and street committees;
- other community organisations that need to be consulted, including NGOs, AIDS Service Organisations (ASOs), health organisations, faith based organisations (FBOs), schools, welfare organisations;
- who the different leaders are and their leadership styles, e.g. traditional leaders, educational leaders, political leaders, religious leaders;
- what decision-making processes are used in the community;
- what the different sub-groups are in the community, e.g. are there women's groups, men's groups; church groups, youth groups, political groups, sports groups?;
- who are the most **marginalised** groups and how can they be given a 'voice';
- what power relationships exist between various subgroups in the community, e.g. is there gender segregation, are all leaders men or are women also involved in the initiatives?;
- what resources and assets there are; and
- what the most urgent needs and problems are in the community.

KEY WORD

Marginalised:

Those people who usually do not have a 'voice' because they are the poorest or most uneducated or most disempowered. This may include people living with HIV and/or AIDS, disabled people, elderly people, gay people, the unemployed and the homeless.

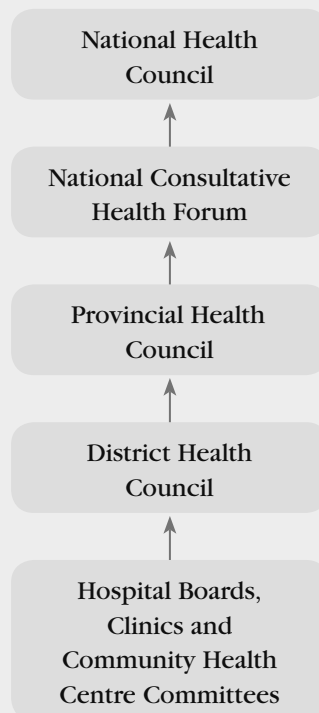


DID YOU KNOW?

In South Africa, the government encourages community involvement at various levels. It encourages partnerships and agreements between various stakeholders, including government bodies, business and community. Here are some examples of how our Constitution and legislation encourages community involvement:

- Chapter 4 of the Constitution, Clause 59 says: The National Assembly must (a) facilitate public involvement in the legislative and other processes of the Assembly and its committees.
- Section 42 [1] (a, b, c) of the *National Health Act*, 2003, says that provincial legislation must provide for the establishment in the province of a committee for: a clinic or a group of clinics; a community health centre; or a clinic and a community health centre or a group of clinics or community health centres.
- Section 42 [2] (a, b) of the same Act ensures community participation by stating that any of the above committees must include at least one or more local councillors; and one or more members of the community served by the health facility.

The diagram below is an example of a governance structure in a District Health System and shows how this links into the provincial and national health structures. Hospital boards and community health centre committees feed into the District Health system (see arrows), which is responsible for district health matters. They are committed to and actively encourage community involvement in health matters. Each hospital board or clinical and community health centre committee has representatives from the community that they serve. This is one of the structures that researchers and community outreach staff should consult, and with whom they should work to ensure ongoing community involvement and participation.





Take 5 minutes ...

- *Imagine that you have a box of oranges in front of you. Pick an orange from the box and briefly describe it to yourself or to a group. Imagine putting the orange back in the box. Now, again imagine picking the same orange out of the box. Again describe the orange to yourself or to the group. You will probably see that the second description is much more detailed than the first. Why is this so?*

What does the above exercise tell us about consultation in a community?

We already know that a community is a complex being – what we see at first glance is usually quite superficial. We only discover more about a community when we get to know the people better. And the more we get to know people, the more we discover.

On initial contact, the community may be reluctant to expose information about themselves or to show their true nature. So if you only visit or consult with the community once, you would miss many things. Researchers and community outreach staff need to spend time in a community and to repeat their visits. Only then can they start building up relationships with people, and only through repeated visits will they begin to understand more and more about the community.

During these repeated visits, researchers and other outreach staff need to meet and consult with the different types of leaders, stakeholders, as well as ordinary community members, including the most marginalised groups, as it is important that they have a voice in decisions that could affect them. These consultations must be done in a highly sensitive way and should be about giving people access to information about the research and development process, for example:

- what the HIV vaccine research and development is about;
- what the benefits and risks of the research are to the community;
- why this community has been identified for participation in the research;
- what processes the trials should follow; and
- how they want the leaders and community members to be involved and to develop.

This information should be given in plain, easy-to-understand language so that it makes sense to everyone.

As you read through the case study on the next page think about what you like about what the researchers did, what you do not like, and what else they could do.



Researchers and community outreach staff need to consult with a broad range of community members.



CASE STUDY

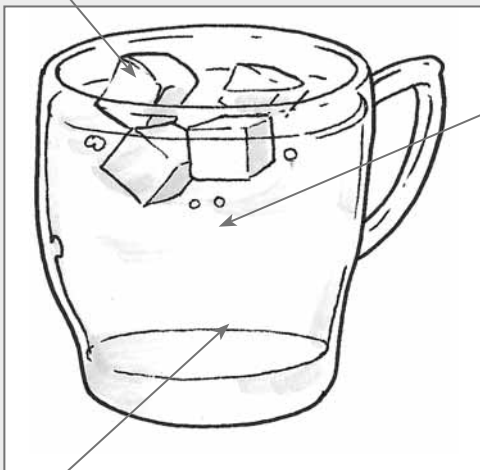
Researchers have decided to set up an HIV vaccine trial in a village surrounding a rural clinic. They want to encourage the villagers to become active in the trial processes and the researchers take the following steps to begin the process of consultation:

- They introduce themselves to the village head and explain the HIV vaccine trial.
- With the village head, they contact community leaders and together they gather information about the village. They look at current resources, committees, structures, etc.
- With community leaders they look for more concrete information about the village by asking government services and organisations who work in the area.
- They attend a meeting with the village head, which is also attended by community leaders and the community in general. At this meeting the researchers give practical information about the intended trial and answer questions.

DID YOU KNOW?

The picture below is called Penina's cup. It represents the different layers of people in a community. It is important to consult with each layer, especially the top layer in order to reach the bottom. It is also particularly important to consult with third layer as it include the most marginalised community members who need to have a 'voice'.

The ice at the top is light and hard. It is like the top layer of a community who often pretend to speak for the community. Often they prevent people from actually reaching the community.



The second layer of the cup is made up of cold, icy water which is semi-hard. This layer represents the more advantaged community members. Some of them are the natural leaders who know the community better than the top layer.

The third layer is usually warmer than the rest and represents the silent majority who are usually the last to be seen and consulted.



Take 5 minutes ...

- *Who are the leaders in your area or community?*
- *Who would you turn to in the community if you had a problem or needed advice?*
- *Are women involved in projects in your community?*
- *Who do women turn to for leadership?*
- *Who are the other stakeholders in your community?*
- *Who are the silent voices or the marginalised people in your community?*
- *How would you explain to people in the community why they should become involved in HIV vaccine research and development?*

Consultation does not end here, but is ongoing and involves dialogue and discussions throughout the research and development process including clinical trials.

Establishing a group that represents the community interests

Usually researchers are responsible for setting up a formal structure or group which will represent the interests of the community and will encourage the community to get involved in the research process. For example, they can involve an existing community health structure as an equal partner in the research and development process or they can help the community to form a *core, representative group* that can engage with the researchers as an equal partner. This core group is called a Community Advisory Group or a CAG. On the other hand, the community also has a responsibility once they have decided to become involved in the research process. They too need to make sure that there is a formal group that they can join, such as a CAG, so that they can continue to actively and meaningfully participate, and have an ongoing role in all parts of the research process including the trials. The CAG should be a group of volunteers elected to represent the **diverse** interests and views of the community.

A CAG can be formed in the following ways:

- The trial site staff can invite community leaders, public health officials and individuals who have shown an interest in the research and/or the trial to join the group.
- They can invite representatives of relevant organisations and bodies in the community to join the group. These people may come from NGOs, CBOs, ASOs, FBOs and other existing community structures.
- They can issue an open invitation to all interested people and, in this way, any community members to come forward to join the group.
- They can actively encourage representatives of the more marginalised groups in the community to join the CAG.

KEY WORD

Diverse:
Different, varied.

Refer to Module 5 for information about the ethical requirements of developing meaningful participation.



People can volunteer to sit on the CAG or they can be formally elected by their organisation, group or community to represent them on the CAG.

DID YOU KNOW?

In other parts of the world, a CAG may be called a 'Community Advisory Board' or CAB. We prefer the term Community Advisory Group as in South Africa the word 'Board' could imply legal responsibilities, which go beyond what is expected from volunteers. At present in South Africa, CAGs do not have legal authority to insist on changes in research, but they can provide input and guidance on all aspects of research that affect the community.



How does a CAG operate?

Each CAG may operate in a slightly different way, but here is one process that some CAGs may go through:

1. The trial site staff may help the CAG with the following: information; organisational support; finding office space; administration; budgeting; technical support, e.g. telephones, message system, computers, Internet access, photocopying; capacity development and training programmes for new and existing CAG members.
2. The CAG meets to start working together. They may put together a Mission or Vision statement and/or a Constitution. Members of the CAG are appointed into positions on the steering or executive committee, e.g. chairperson, treasurer, secretary.
3. Together, the trial site staff and the CAG discuss how to carry out relevant trial activities and together they negotiate strategies and solutions.
4. The CAG keeps accurate records, including minutes of their meetings, and records all their activities.
5. The CAG may decide to become a more formal organisation and may decide to raise funds for specific projects linked to the trial. Many CAGs do not only look at HIV vaccine research and development, but are involved more broadly in other research areas affecting their community.

The major responsibilities of the CAG

The major responsibility of the CAG is to represent the community. The CAG engages with researchers as an equal partner, and meaningfully contributes to decision-making around trial-related issues affecting the community. We can group and summarise the responsibilities of the CAG as follows:



CAGs do not recruit trial participants, but give information PLUS they have many other roles and responsibilities.



The CAG's responsibilities to the community and trial participants ...

The CAG:

- serves the community and helps the trial site in their task of serving the community;
- represents the interests of the community and the rights of individuals in the community;
- is accountable or answerable to the community;
- gives information and educates the community about HIV vaccine research and development, including the vaccine trials, encourages broader community involvement and participation in the processes, and answers queries from community members;
- helps resolve conflicts that could arise between different groups – trial participants, trial site staff and the community;
- participates in all levels of decision-making to do with the trials that affect their community. For example, they need to be included in, and consulted about, decisions such as how to reimburse trial participants for costs related to their participation, their access to medical treatment should they need it, and so on.
- ensures that any human rights and ethical issues, and personal concerns raised by the community and or the trial participants are addressed; and
- creates a supportive environment in the community for those participating in the trial and for their families.



Vaccine trials take a lot of work. The whole community can help in some way or another so that we can all benefit from the research.

The CAG's responsibilities to the trial site staff ...

The CAG:

- is a channel of communication between the community and the trial site;
- gives input into the information and communication aimed at the community; and
- advises the researchers on all matters affecting the community, e.g. community expectations and concerns, local community health beliefs, how to best give the community information, and how to recruit participants.

The CAG's responsibilities to others ...

The CAG:

- negotiates with others on behalf of the community;
- forms networks and partnerships with other committees and organisations that work in the community; and
- continues to consult with formal community structures, other relevant stakeholders, and committees or forums that are part of programmes established by national, provincial or local government. Examples of these programmes are the Integrated Development Programmes required by the *Municipal Systems Act* (No. 32 of 2000) in order to work in the community in a co-ordinated way. (You can download this document by following links from: <http://www.info.gov.za/documents/index.htm>)



DID YOU KNOW?

According to the Good Clinical Practices (GCP) requirements, communities should be represented on committees that are responsible for the review and approval of research, e.g. Medicines Control Council (MCC) and the Research Ethics Committees (RECs). For more information about the MCC and RECs, see Modules 3 and 4.



Networking helps with the following:

- it prevents duplication of work;
- it allows different organisations and parties to support each other;
- resources can be shared more equally between partners;
- knowledge, experiences and problems can be shared;
- it avoids unnecessary competition and confusion;
- people become more committed and involved;
- it can bring together people from different backgrounds;
- it encourages a holistic approach to a problem or issue;
- information can be given to the relevant structures;
- joint discussions can be planned with other local structures; and
- it allows for better communication between organisations and bodies.



Although we have said that a CAG is one way of encouraging community involvement and participation, there are many other ways that communities can participate in clinical trials and in all other parts of the research and development process. On page 24 we include some ideas to think about and to discuss. Also try to brainstorm other ways that you can think of.



Community members can attend meetings on HIV vaccines

Other ways that community members can be involved and participate in HIV vaccine research and development:

- Attend meetings and workshops on HIV vaccines, e.g. HIV vaccine discussion groups.
- Become part of, or volunteer to help, existing community organisations to spread the message about HIV vaccines.
- Become vaccine education trainers.
- Do peer education by going door-to-door to explain to others what the research is about.
- Volunteer to participate in an HIV vaccine clinical trial.
- Join or form an HIV vaccine interest group to debate issues around, or advocate for, HIV vaccine research and development.
- Facilitate HIV vaccine awareness events.
- Volunteer to help the CAG or other community groups at various times.
- Support the CAG or other community groups through offering a street theatre show, drama or music.
- Keep up-to-date on the trials and HIV vaccine development by reading newspapers and listening to the radio.
- Encourage the media to write stories and spread the news about HIV vaccines. Or, become a journalist who specialises in reporting on these issues.
- Now add some of your own ideas.

So far we have only discussed the main activities of Step 1 of the participatory approach that we use in HIV vaccine research and development. Now we turn to the rest of the steps involved in a clinical trial.

6. VOLUNTEERING AS A TRIAL PARTICIPANT IN AN HIV VACCINE CLINICAL TRIAL

We have already said that one of the many ways that people can participate in HIV vaccine research and development is by volunteering as trial participants. In Module 4, we looked at some of the places in South Africa and around the world where trials are currently taking place. We will now look at some of the steps involved in running a clinical trial and how they apply to volunteers and trial participants.

Take 5 minutes ...

- *Why would someone want to volunteer as a trial participant?*
- *What kind of sacrifices would a volunteer have to make?*
- *What are some of the fears and concerns volunteers might have?*
- *How would you feel if you had participated in a clinical trial that helped to find a successful HIV vaccine?*
- *How long would volunteers need to be involved in a trial?*



Step 2: Trial site staff recruit and pre-screen potential trial participants

- The trial site community outreach team recruits potential trial participants.
- Volunteers may also hear about the trial through the radio, newspaper, TV, posters, their local voluntary counseling and testing (VCT) centre or through meetings in the community, including workshops held by *Masikhulisane*.
- People who want to volunteer or know more about the trials can tell the community outreach team or *Masikhulisane* that they are interested. They can also contact the SAAVI Info-Line on 080 8222 463 (080 VACCINE).
- Volunteers will be referred to their nearest trial site/s for further education and information sessions on the trial. If there is no trial site near where they live, they will be encouraged to participate in other ways (see list of suggestions, page 24).



Step 2

DID YOU KNOW?

There are several organizations in the general South African community who are raising awareness and educating others about HIV vaccines. These organisations include NGOs, ASOs, FBOs, as well as *Masikhulisane*, the South African AIDS Vaccine Initiative (SAAVI) Community Involvement Programme. These organisations do not recruit trial participants but can refer interested people to the relevant trial sites, or to the SAAVI Info-Line.

Pre-screening: One of the trial site staff e.g. a nurse counsellor, will pre-screen volunteers. He or she will ask the volunteer questions that they can answer, such as their age or knowledge about their HIV status, to see if they meet the criteria for a specific trial. For example, the criteria of a specific trial may be e.g. that trial participants must be 18–40 years of age, healthy, HIV-negative and not pregnant, breastfeeding or intending to become pregnant while on the trial.

Sometimes volunteers who call in or attend information sessions at the site, ask questions that make them realise that they cannot participate e.g. 'Must I be HIV-positive to participate?'. If they are told that the particular trial requires people who are HIV-negative, and they know that they have HIV, they will 'screen' themselves out as volunteers i.e. they will realise that they do not meet the trial criteria and will withdraw from volunteering for the trial.



Step 3



Step 4

For more details on informed consent see Module 5 on Ethics, and Module 6 on Legal and human rights.

Step 3: Researchers screen volunteers again for eligibility

Volunteers who meet the pre-screening criteria and want to continue will go on for further screening against stricter criteria. For example, volunteers for a preventative HIV vaccine trial undergo an HIV test and, if necessary, a pregnancy test. They receive thorough *counselling* about what tests and procedures to expect, and must give consent to proceed before the tests are done. Volunteers also undergo a complete *medical check-up* to see whether they are healthy.

During the screening process of a preventative HIV vaccine trial, researchers or counsellors might ask potential volunteers trial-related questions about their sexual risk behaviour. This is to establish whether they are at the appropriate level of risk for HIV infection for the particular phase of the trial. Refer to Module 4 for more information about HIV risk criteria for different phases of clinical trials.

Step 4: Enrolment (part 1): Informed consent and allocation to trial group

Those volunteers who meet the trial criteria and want to continue now go through the *informed consent* process. This is a process during which a trained counsellor explains, and answers questions from the volunteer, about how the trial will work, the nature of the test HIV vaccine, the risks and benefits involved in participating, their rights as a trial participants and so on (see page 20, Module 5). Once the counsellor is sure the volunteer understands the information and is willing to continue, the counsellor will ask the volunteer to sign a full-study consent form.

Volunteers will get time to study the information on the form and to ask questions. They may also take it away for a few days to read and to think about their decision. Volunteers should only decide whether or not to participate if they are free of all pressure, and they have all the information they need to make an informed choice.

All consent forms should be written in a language that the volunteer understands and should contain accurate information as explained by the counsellor. The form must also include the names and numbers of key people involved in the trial. This helps volunteers to know who is responsible, e.g. the PI, and who they can speak to if anything goes wrong, or if they have questions or are unhappy with any aspect of the trial.

The volunteer needs to sign and date the consent form if he or she decides to participate. The person who conducted the informed consent discussion must also sign and date it. If the volunteer



cannot read or sign the form, then a neutral witness or the person's legally acceptable representative must be with them throughout the informed consent discussion and should sign the form on their behalf. By signing the form, the volunteer shows and records that he or she clearly agrees to participate in the trial, after having been through a thorough information process. Volunteers will receive a signed copy of the consent form to keep.

Once a volunteer gives informed consent, then s/he is enrolled onto the trial and becomes a trial participant. This participant is then *randomly assigned to a trial group* to receive either the vaccine or the placebo. As the trial is a double-blind study, neither the researchers nor the trial participants know to which group they are assigned. They also do not know if they are getting the vaccine or the placebo.

In addition to the initial informed consent process, there is ongoing informed consent throughout the trial (see page 28).

Step 5: Enrolment (part 2) and administration of the first dose of the vaccine or placebo

Baseline information: Once a volunteer becomes a trial participant, the trial site team collects 'baseline' information about the status of the participant's body, their immune system and their health. Researchers gather this information by doing a thorough medical check-up, which may include tests, before any dose of the vaccine or the placebo is given. Information collected at follow up visits is then compared to the baseline information to see if there are any changes. If there are any changes that are adverse events, then trial site staff will need to take appropriate action. Researchers track and record these changes to see, by doing data analysis, if the vaccine is safe, and depending on the aims of the trial, if it is having an effect.

Risk-reduction counselling: Trial participants also receive risk-reduction counselling, and there is pregnancy-prevention counselling for women. A trained counsellor reminds participants that they may receive the placebo and that even if they receive the vaccine, that it is still being tested and that it is not guaranteed to prevent or treat (in the case of a therapeutic trial) HIV infection. In a preventative HIV vaccine trial, the counsellor will also explore various ways for participants to prevent HIV infection. Throughout the trial, participants have access to free condoms and femidoms.

First dose: Trial participants who are in the intervention group receive their first dose of the vaccine, while those in the control group receive the placebo. Researchers remind trial participants that they may receive a placebo and not the vaccine and that even if they get the test HIV vaccine, that it is not yet shown to work and that it is still in testing.

For more information about randomisation and placebos, see Module 3.



Step 5



Step 6

Observation: Each participant remains under observation for a few hours, so that trial site staff can see if there are any immediate adverse events (AEs).

Step 6: Monitoring for immediate adverse events

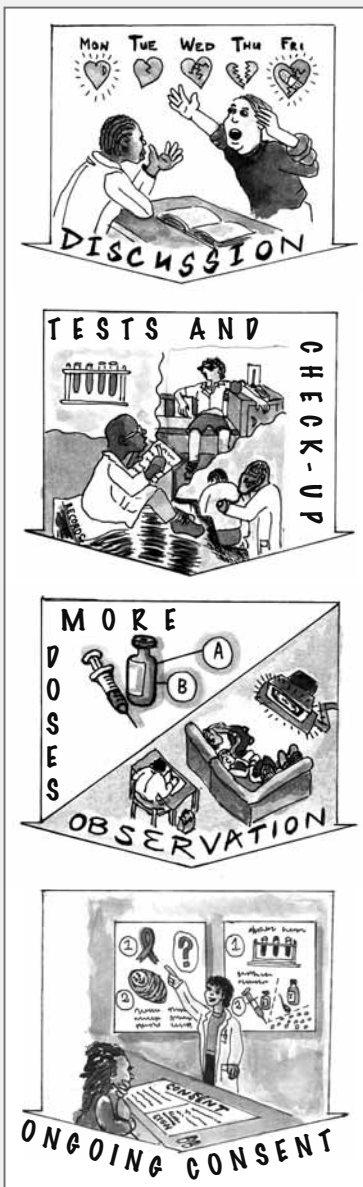
In the first few weeks of the trial, participants are asked to *keep a diary* to record how they feel physically and emotionally, and to keep a record of their sexual behaviour if they are in a preventative HIV vaccine trial. If they experience changes such as nausea, these may be caused by the vaccine, others may be psychological (e.g. anxiety), or for other reasons. The trial site staff must analyse the changes and symptoms that the trial participant records to ensure that they are carefully noted and that the necessary action is taken. Trial participants will have access to counsellors for ongoing support and counselling.

Steps 5 and 6 are usually repeated, i.e. several doses of the vaccine or placebo are given.

Step 7: Follow-up visits and doses

Trial participants will have several follow-up visits to check that the vaccine is safe and to see what effect it is having in their body. Generally follow-up visits include a session with one of the trained counsellors to *discuss* the participant's trial diary and to note any important signs for the trial. HIV, pregnancy and other tests (e.g. CD4 and viral load tests in the event of HIV infection or in a therapeutic trial) may be done, as well as a physical check-up. *A dose of the vaccine or placebo may be given.* The exact number of doses given during the trial depends on the trial design. There are some visits where no vaccine or placebo is given, but blood or other samples are taken. The length of time between visits will vary according to the trial. There may be telephone interviews to check for adverse events.

Ongoing informed consent: There is ongoing informed consent throughout the trials. In preventative HIV vaccine trials, there is also ongoing risk-reduction and pregnancy-prevention counselling. During this process the information that was initially given to the trial participant is given again and their understanding is checked. This ensures that they understand all the trial procedures and processes, as well as their rights regarding trial participation, e.g. their right to withdraw from the trial at any time. Any changes to the information given during informed consent and the related forms must be approved by the relevant REC before they are implemented. Researchers and staff must tell trial participants about these changes and trial participants will need to give written consent on the updated informed consent documents.



Step 7



Step 8: Data is analysed by researchers

- At certain points in the trial, and once all the data from the trial is collected, researchers analyse data for results. They submit the results to the relevant parties discussed in Module 4.
- The results may be published for peer review.
- If results from phase I/II trials show that the vaccine is safe and promising, then researchers can submit protocols for approval of the next phase.
- There may be a phase IIb trial, which is smaller than a phase III trial but is big enough to show, e.g. whether a large-scale phase III efficacy trial should be done.
- If data from phase III shows that the vaccine is safe and effective, researchers can apply for registration/licensure of the vaccine. If approved, the vaccine is licensed, manufactured, marketed and distributed to the public. Remember it takes time to manufacture the vaccine in large quantities for widespread distribution. So it is important for developing countries to be involved throughout the research process to ensure that manufacturing capacity is built up to secure early access to the vaccine.

For more information on issues about access to a successful HIV vaccine, see the *IAVI AIDS Vaccine Literacy Toolkit*. Contact IAVI through their website for a copy at: www.iavi.org.



Step 8

KEY WORD

Breakthrough infection:
An infection caused by the germ that the substance is designed to protect against (in this case HIV).

Refer to Module 4 for more information about preventative and therapeutic HIV vaccines.

Step 9: Feedback and unblinding interviews

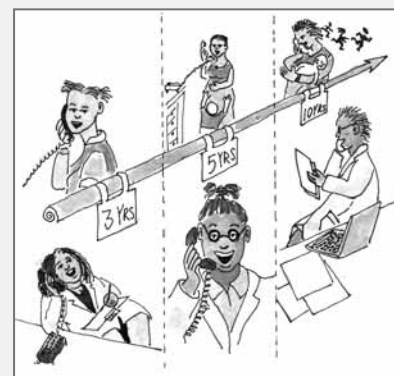
Once trial results are available, then trial participants are asked to a final interview so trial staff can explain the results, and so that trial participants can get feedback and find out whether they received the vaccine or the placebo – this is called ‘unblinding’. If it was a successful phase III trial, then participants who got the placebo should be offered the HIV vaccine. Researchers will also discuss arrangements for long-term follow up with the trial participants.



Step 9

Step 10: Long-term follow up of participants with breakthrough infections and/or pregnancy

The trial site team follows up all trial participants. If a trial participant has a **breakthrough infection** during a preventative HIV vaccine trial, then he or she is likely not to get further doses of the vaccine or placebo and will be followed up for several years to monitor treatment and disease progression.



Step 10

Step 11: Decisions about whether to take the vaccine candidates to the next phase

Only the most promising vaccine candidates will go through to the next phase of clinical trials or to application for licensure of the vaccine.



FREQUENTLY ASKED QUESTIONS



Participant: When are HIV-positive people not included in the trials?

Answer: Currently most of the HIV vaccines that we are testing are to prevent HIV infection and so only HIV-negative people can be included in these trials. But researchers are also testing therapeutic (treatment) HIV vaccines. South Africa is busy taking part in testing this kind of vaccine.



NOTE

Apart from HIV status there are a number of other criteria that are used to select trial participants for HIV vaccine trials. Refer to Module 4 for details. We need to explain all the criteria to communities so that they understand why someone qualifies for a trial, or not.



Participant: What will happen if people test HIV positive during the screening process or during a preventative HIV vaccine trial?

Answer: The person will be referred to a local clinic or hospital, and other organisations that offer appropriate ongoing treatment, care and support. Unfortunately, those who test HIV-positive during screening cannot participate in a preventative HIV vaccine trial. If a trial participant becomes HIV-infected during the trial, he or she will stop receiving doses and will be followed up, where appropriate, to monitor how long their disease progression takes. Remember that the vaccine cannot infect you with HIV. But despite HIV risk-reduction counselling, some trial participants may still have unsafe sex which could lead to them becoming infected with HIV.





Participant: What if a trial participant becomes pregnant while participating in the trial?

Answer: The person will not receive any further doses during the trial. But they will still be followed up to keep track of their health.



Participant: What adverse events can we expect as a result of the test HIV vaccines?

Answer: We do not expect the vaccine to cause serious adverse events. Some trial participants may experience effects which do not last long, such as: swelling, pain, itchiness, or redness on their arm where the vaccination was given; or they may experience general symptoms similar to flu, e.g. headaches, fever, tiredness, swollen glands and so on.



Participant: If I test HIV antibody-positive because of the preventative HIV vaccine, then how can I prove that I do not have HIV?

Answer: The trial site should give trial participants a trial identification number to show that they are in an HIV vaccine trial. Then if you need an HIV test at another clinic or lab, you need to inform them that you are part of an HIV vaccine trial and give them your identification number. If the standard HIV antibody test comes back showing that you are antibody-positive, then the clinic must do a second test to check for the presence of the HI virus itself.





Participant: Who is responsible for the trial participant's routine medical care during the trial?

Answer: The trial participant must give permission for the trial site staff to contact his or her doctor. Before the trial starts, ideally the site staff must agree with the doctor about who will manage the participant's day-to-day medical care. The doctor must also agree to report any adverse events and medicines given to treat these. This helps the trial team accurately record and analyse all the data.



It is best if the participant's doctor is aware of their patient's participation in the trial – especially in the case of a medical emergency. Trial participants will get a contact number for any medical emergencies. Their healthcare providers should also have this number.

Refer to Modules 5 and 6 for more information about social harms, stigma and discrimination and how these may apply to HIV vaccines.



Participant: What are the most stressful aspects of a trial for a participant and what kind of support can they expect?

Answer: Some participants are worried about the HIV testing, or about how long they must be involved in the trial, or about the personal issues they need to discuss. Other participants in a preventative HIV vaccine trial may be worried about having to ask their partners to use a condom because their partners do not understand that there is no guarantee that the test HIV vaccine will protect them against HIV infection. Also, fearful community members may expect the vaccine to cause HIV infection and they may assume that participants are HIV-positive. The counsellor must help participants to deal with these issues.





Participant: Will children be included in HIV vaccine trials?

Answer: For a successful preventative vaccine to make an impact on the HIV epidemic, it should ideally be given to people before the age that they first start to have sex. But there are specific ethical and human rights issues around children under 18 years old and special measures that must be taken if they are to be involved in HIV vaccine trials. SAAVI is currently investigating at which phase in the HIV vaccine clinical trials children should or could be involved as trial participants.



Refer to Modules 5 and 6 for more information about children and HIV vaccine clinical trials.

Take 5 minutes ...

- *What is meant by 'community'?*
- *What is meant by 'community involvement and participation'?*
- *Why is it important to involve a community in HIV vaccine research and development?*
- *Who from the community should be involved in the HIV vaccine research and development process?*
- *Why would a community want to become involved in the process?*
- *What steps are involved in facilitating community involvement and participation?*
- *What is a CAG? What tasks does it perform, and who is involved in running it?*
- *Aside from joining a CAG, how else can members of a community become involved and participate in the HIV vaccine research and development process?*
- *How can volunteers join a trial?*
- *What happens during the different steps in a clinical trial?*
- *What is informed consent and what kind of information is given to trial participants throughout the trial?*



TO SUM UP

- HIV vaccine research and development is about developing and testing either a preventative or a therapeutic HIV vaccine. But it is also about developing people and their communities, building capacity and skills, improving facilities, services and resources, and ultimately finding a successful vaccine to reduce the rate of HIV infection.
- Communities need to be actively involved and participate in all aspects of the research and development process, including clinical trials, to make informed decisions and to ensure that their legal, ethical and human rights are respected, promoted, protected and fulfilled.
- Communities should understand the benefits and risks of the research and development process, so as to increase the benefits and reduce the risks by being involved in the planning and implementation of the research and clinical trials.
- Community involvement is an ongoing process that involves various steps.
- Communities can participate and become involved in the HIV vaccine research and development process in many ways including joining or forming a CAG to represent the community's interests, becoming trial participants, doing peer education or facilitating HIV vaccine awareness events.
- In a clinical trial we use the participatory approach at various steps or stages in the research and development process.
- The steps used include:
 - Step 1:** Consultation, choosing the trial site, and establishing a CAG.
 - Step 2:** Trial site staff recruit and pre-screen potential trial participants.
 - Step 3:** Researchers screen volunteers again for eligibility.
 - Step 4:** Enrolment (part 1): Informed consent and allocation to trial group.
 - Step 5:** Enrolment (part 2) and administration of the first dose of the vaccine or placebo.
 - Step 6:** Monitoring for immediate adverse events.
 - Step 7:** Follow-up visits and doses.
 - Step 8:** Data is analysed by researchers.
 - Step 9:** Feedback and unblinding interviews.
 - Step 10:** Long-term follow up of participants with breakthrough infections and/or pregnancy.
 - Step 11:** Decisions about whether to take the vaccine candidates to the next phase.



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MODULE 7: COMMUNITY INVOLVEMENT AND PARTICIPATION



Section 2: Activities to help you present information on community involvement and participation to others

OVERALL OUTCOMES

By the end of these activities, workshop participants should be able to:

1. Explain what we mean by 'community' and what makes us part of a community.
2. Explain what we mean by 'involvement' and 'participation'.
3. Discuss why it is important to have community involvement and participation.
4. Discuss what community involvement and participation mean for HIV vaccine research and development.
5. Explain what steps are involved in participating in an HIV vaccine clinical trial.

NOTE

For copies of the *HIV Vaccines Learner's Handbook* or overheads for the Activities, please contact *Masikhulisane* who will send you an electronic copy of the document. You can use the document to print the pages that you need as this may be easier and less costly than photocopying notes from Section 1 of the Manual.

NOTE

Always let participants express all their ideas before you add ideas of your own or from the module. Remember that you can use the activities in this section as they are or you can adapt or change them to suit the needs of your audience as long as you cover the learning outcomes.

ACTIVITY 1: WHAT IS A 'COMMUNITY'?

OUTCOMES OF THIS ACTIVITY

By the end of this activity, workshop participants should be able to:

- Identify the diverse people who make up a 'community'.
- Identify the many different groups that they belong to.

MATERIALS NEEDED

- See the checklist of resources needed on page 7 of Module 1.
- Try to ensure that each workshop participant has an *HIV Vaccines Learner's Handbook* to work through.
- Use overheads on 'What is a community?' for this activity.

TIME: 1 hour

PREPARATION

- Read through Section 1, pages 2–4 and make your own notes.
- Photocopy Handout 1 on page 40 for each participant.
- Make photocopies of any handouts needed (see process notes).



You could use a mind-map to record key ideas – refer to Module 1 for information about mind-maps.

PROCESS

1. Start the discussion by asking participants questions like: How would you describe yourself? Where do you live? What work or other activities do you do? What sports do you play? Or ask any other questions that might help people see what different communities they belong to. When you ask questions, be sensitive to issues which may affect workshop participants, e.g. unemployment.
2. Write key words from the discussion on a flipchart for everyone to see, e.g. mother, father, Mamelodi soccer, choir, church, builder. Point out that all of these words describe particular communities that we belong to.
3. Ask what they understand by the word ‘community’ and what binds a community together. Allow them time to come up with their own definition. Once the discussion has run its course, you can suggest that a community is: A group of people who are linked to one another because they share something in common. (see page 2).
4. Share the points below that are relevant to your discussion.
5. Sum up and give input from pages 2–4 in Section 1.
6. Refer participants to the *HIV Vaccines Learner’s Handbook*, or give them copies of pages 2–4 from Section 1.

Some points that relate to the discussion:

- Explain that some people feel anxiety, guilt or conflict about belonging to one subgroup, e.g. perhaps that group takes up too much of the person’s time and energy.
- Certain words describe people who are often marginalised, such as mentally ill, etc. People may be reluctant to admit to these labels. Explore the implications of this with workshop participants.
- This is an opportunity to discuss the notion of ‘insiders’ and ‘outsiders’. It may reveal some of the participants’ prejudices. It is also an opportunity for you to see how people describe their own sense of belonging by describing people who do not ‘belong’.

ANOTHER WAY OF DOING THIS ACTIVITY

1. Give each person a copy of Handout 1 (page 40) or make your own list of words that you think reflect the interests, language and slang expressions used in the communities of workshop participants.
2. Read through a few of the words and explain that people use some of these words to describe themselves. Explain any words that are unfamiliar to participants. Also explain that a word can be used to mean different things, e.g. a person may use the word

Remember to be sensitive to different literacy levels in your groups. If there are more illiterate participants, then use more oral work, or always make sure that a literate person is nearby to help.



'Sepedi' because they can speak the language, and not because they are part of the Pedi nation.

3. Ask participants to circle the words that they would use to describe themselves. When they are finished, ask the questions below. Go through each question, allowing enough time for discussion before you move onto the next one – this is the foundation for everything else that follows in this module.

QUESTIONS FOR DISCUSSION:

1. How many items did you circle?
2. To which subgroups do you see yourself belonging?
3. Together, do these words describe one or many different communities or different subgroups within one community?
4. Do you ever experience problems in belonging to more than one subgroup? What problems?
5. What items on this list do you think people will not share with the group? Why?
6. Are there any words on this list that describe people who are not part of the community, or communities, you belong to?
7. What is a community?
8. What binds a community together?



HANDOUT 1

Words people may use to describe themselves:

- Foreigner • Young • Zulu • Gay • Tennis player • Child
- Landowner • Hindu • PAC supporter • Afrikaans • Parent
- Socialist • Teacher • Heterosexual • Soccer lover
- Radio listener • IFP supporter • White • Disabled
- Revolutionary • Employer • Pensioner • Sotho • Christian
- Female • Condom user • Writer • Burial society member
- Leader • Actor • Married • Philosopher • Coloured
- Male • Dependant • Computer user • Greek
- Television owner • Alcoholic • ANC member
- Professional • DVD owner • Creditor • Home owner
- Believer • Sex worker • Indian • Traditional leader
- NGO worker • Artist • Patient • Tswana • Activist
- Insurance salesman • Employee • Environmentalist
- Counsellor • HIV positive • Husband • Transvestite
- Kwaito lover • Drug user • Italian • Musician
- Squatter • Cell phone owner • Researcher • Outsider
- Woman • Pedi • African • Lesbian • Deaf
- Traditional healer • Student • HIV negative • Internet surfer
- Gangster • Degree holder • English • Son • Artist
- Muslim • Bisexual • R&B lover • Tsonga
- Victim of violence • Depressed • Black • Trader
- Rugby player • Entrepreneur • Client • Wife • Atheist
- Interior designer • Researcher • Raver • Xhosa
- Communist • Jazz enthusiast • Democratic Alliance supporter

Photocopy this handout for workshop participants.



ACTIVITY 2: WHAT DO WE MEAN BY INVOLVEMENT AND PARTICIPATION?

OUTCOMES OF THIS ACTIVITY

By the end of this activity, workshop participants should be able to:

- Explain that involvement is the first step towards participation and that involvement should be an ongoing process.
- Explain the difference between involvement and participation.

MATERIALS NEEDED

- See the checklist of resources needed on page 7 of Module 1.
- Try to ensure that each workshop participant has an *HIV Vaccines Learner's Handbook* to work through.
- Use overheads on community involvement and participation.

TIME: 10 minutes

PREPARATION

- Read through Section 1, pages 4–6 and make your own notes.
- Prepare a flipchart with the following questions on it for discussion:
 - *What kind of things are you involved in, in the community where you live or work? For example, are you involved in a church fundraising committee or a soccer club, etc.?*
 - *How did you become involved and drawn into this and why?*
 - *How do you invite and draw new people in to this organisation, club, etc.?*
- Make photocopies of any handouts needed (see process notes).

PROCESS

1. Ask workshop participants to work in pairs to discuss the questions on the flipchart paper.
2. Give people five minutes to answer the questions, then have a round of feedback in plenary. Write up the answers on flipchart paper.
3. End the activity by pointing out that involvement is the first step towards participation and that involvement should be an ongoing process. Use your notes as back up if necessary. Look at page 24 of Section 1 for ideas on different ways people could participate in the research and development process.
4. Sum up and give input from pages 4–6 in Section 1.
5. Refer participants to the *HIV Vaccines Learner's Handbook*, or give them copies of pages 4–6 from Section 1.



ACTIVITY 3: WHY IS *COMMUNITY INVOLVEMENT AND PARTICIPATION* IMPORTANT?

OUTCOMES OF THIS ACTIVITY

By the end of this activity, workshop participants should be able to:

- Discuss some obstacles to community involvement and participation.
- Identify what will assist with community involvement and participation.

MATERIALS NEEDED

- See the checklist of resources needed on page 7 of Module 1.
- Photocopies of pages 6–8 in Section 1, or copies of the *HIV Vaccines Learner's Handbook* for participants to work through.
- Use overheads on community involvement and participation.

TIME: 1 hour

PREPARATION

- Read through Section 1, pages 6–8 of this module and make your own notes.
- Photocopy pages in 6–7 for participants or refer them to the relevant pages in the *HIV Vaccines Learner Handbook*.
- Prepare the following discussion questions on flipchart paper:
 - *Why do you think it is important for the researchers to get the community to actively participate in the research?*
 - *How do you think they should go about doing this?*
 - *Who in the community should be involved?*
 - *What role should the community play in the research?*
- Make photocopies of any handouts needed (see process notes).

PROCESS

1. Begin with a broad discussion about why it is important to involve a community in research and development. Use the questions that you prepared on the flipchart.
2. If participants have a copy of the *Learner Handbook*, then refer them to their copy of the case study in the handbook. Or hand out photocopies of the case study to them.
3. Read through the case study with the group
4. Divide workshop participants into two groups to discuss why they think the project failed and what could have been done differently.
5. Now give one group time to prepare to role-play the case study as it is. Ask the other group to discuss what went wrong and to prepare to role-play how the situation should have been handled.
6. After the role-plays, have a group discussion filling in responses on a flipchart under the headings in the table to follow:

You can read more about doing role-plays in Module 1.



What prevents community involvement and participation?	What assists community involvement and participation?

7. Give input from pages 7–8 of Section 1 and add to the lists those points not already mentioned.

As an alternative to the role-play, ask workshop participants to read the case study, to discuss why the project failed and what should have been done differently. Then ask for their answers using the ‘But why?’ game. This game works by asking ‘but why?’ every time participants give an answer or input. This helps to get people thinking more broadly than they normally would.

8. Sum up this section on community involvement and participation by asking questions like: What are the differences between involvement and participation? What do we mean by *community* involvement and participation?
9. Give input using the overheads if necessary.
10. Sum up and give input from pages 6–8 in Section 1.
11. Refer participants to the *HIV Vaccines Learner’s Handbook*, or give them copies of pages 6–8 from Section 1.

ACTIVITY 4: HOW CAN WE ENCOURAGE PARTICIPATION AND INVOLVEMENT?

OUTCOMES OF THIS ACTIVITY

By the end of this activity, workshop participants should be able to:

- List the levels of possible community participation.
- Explain each level on the ‘Ladder of participation’.
- Identify which level they participate at in their workplace, organisation, etc.

MATERIALS NEEDED

- See the checklist of resources needed on page 7 of Module 1.
- Copies of the an *HIV Vaccines Learner’s Handbook* or photocopies of pages 8–9 of Section 1.
- For each group, make a set of seven cards – one card for each level on the ‘Ladder of participation’.
- Use overheads on the ‘Ladder of participation’.

TIME: 45 minutes

PREPARATION

- Read pages 8–9 of Section 1 and make your own notes.



- Make a set of seven cards for each small group. Each set should have one card for each of the seven levels on the ladder as described on page 9. Use the overhead on 'Ladder of participation' or copy it onto a flipchart.
- Make photocopies of any handouts (see process notes).

PROCESS

1. Work in small groups and give each group a set of cards. Explain that each card in their set shows a different level of community participation.
2. Ask groups to arrange the cards in a ladder from top to bottom. The top is the most appropriate form of community participation and the bottom is the least appropriate. They must decide in which order to place the cards on the ladder.
3. Once the ladder is done, ask each person to remain in their group and to say how and at which level/s they participate in their own organisation, workplace, social club, etc. For example, as chairperson or as ordinary member, etc. They should also say at which level they want to participate and why. This should take about 15 minutes.
4. Ask each group to present their 'Ladder of participation' to the plenary.
5. Discuss the various outcomes, then summarise and correct any misunderstandings.
6. Sum up and give input from the pages in Section 1. Present the 'Ladder of participation' on flipchart or on an overhead to the group. Remind participants that we should aim for community participation and involvement to move towards the top rungs of the ladder.
7. Refer participants to the *HIV Vaccines Learner's Handbook*, or give them copies of pages 8–9 from Section 1.

ACTIVITY 5: WHY SHOULD RESEARCHERS ENSURE COMMUNITY INVOLVEMENT AND PARTICIPATION IN THE HIV VACCINE RESEARCH AND DEVELOPMENT PROCESS?

OUTCOME OF THIS ACTIVITY

By the end of this activity, workshop participants should be able to:

- Explain why it is important for researchers to involve the community in the HIV vaccine research and development process.



MATERIALS NEEDED

- See the checklist of resources needed on page 7 of Module 1
- Copies of the *HIV Vaccines Learner's Handbook* or photocopies of pages 10-11 of Section 1.
- Use overheads on why researchers should ensure community involvement and participation in HIV research and development.

TIME: 30 minutes

PREPARATION

- Read through Section 1, pages 10–11 and make your own notes.
- Prepare the following discussion questions on flipchart paper:
 - *Why should researchers ensure community involvement and participation in the HIV vaccine research and development process?*
 - *What would happen if the community were not invited to be an active partner and participant in the process?*
 - *What information would the community need to know so that they can make a decision to become involved?*
- Make photocopies of any handouts needed (see process notes).

PROCESS

1. Explain that researchers have identified a community in which to set up an HIV vaccine clinical trial. Ask workshop participants to work in pairs or small groups and to discuss the above questions.
2. Ask participants to write their responses on flipchart paper or ask a volunteer to write these up as people give their feedback. You could suggest the use of a mind-map to brainstorm ideas.
3. Sum up and fill in any gaps by giving input from pages 10–11 of the module.
4. Refer participants to the *HIV Vaccines Learner's Handbook*, or give them copies of pages 10–11 from Section 1.

ACTIVITY 6: WHY SHOULD DEVELOPING COUNTRIES, AND COMMUNITIES BECOME INVOLVED IN THE HIV VACCINE RESEARCH AND DEVELOPMENT?

OUTCOMES OF THE ACTIVITY

By the end of this activity, workshop participants should be able to:

- Discuss the possible benefits and risks of developing countries, and communities becoming involved and participating in the HIV vaccine research and development process.



MATERIALS NEEDED

- See the checklist of resources needed on page 7 of Module 1.
- Copies of the *HIV Vaccines Learner's Handbook* or photocopies of pages 12–13 of Section 1.
- Use overheads on the benefits and risks to communities and developing countries of becoming involved and participating in the HIV vaccine research and development process.

TIME: 45 minutes

PREPARATION

- Read through pages 12–13 of Section 1 and make your own notes.
- Make photocopies of any handouts needed (see process notes)

PROCESS

1. Recap in a five-minute discussion why participants are involved in their own 'communities' i.e. organisations, committees, clubs etc. Refer to the relevant flipchart paper where this information was captured (for Activity 2).
2. Use the relevant overheads from Modules 3 and 4 to briefly recap the information about the stages in the vaccine development process.
3. Then ask workshop participants to work in pairs or small groups to discuss why they think there should be community involvement and participation in the HIV vaccine research and development process, or why not – what are the benefits and risks to communities, and developing countries. Give groups about 10 minutes to discuss.
4. Summarise participant's inputs on the flipchart under the following headings:

Benefits to involvement and participation	Risks to involvement and participation

5. If there is enough time, divide the workshop participants into two groups for a debate around: 'HIV vaccine research and development will have a positive impact on our country and communities'. The purpose of the debate is for workshop participants to present the benefits and risks of having HIV vaccine research in a community.
6. Each group prepares one side of a debate, i.e. either 'for' or 'against' the issue. Give groups about 20 minutes to prepare



their arguments. They can use the information in the tables in the *Learner Handbook* or on pages 12–13 of Section 1.

7. The two groups then spend 15 minutes debating. A team member from the first team presents an argument/point, followed by a team member from the second team, and so on until all the arguments/points have been covered. Participants should be allowed to express all their ideas before you add ideas from pages 12–13.
8. Refer participants to the *HIV Vaccines Learner's Handbook*, or give them copies of pages 12–13 from Section 1.

ACTIVITY 7a: WHAT ACTIONS CAN WE TAKE TO INVOLVE THE COMMUNITY AND ENCOURAGE PARTICIPATION?

OUTCOMES OF THIS ACTIVITY

By the end of this activity, workshop participants should be able to:

- Explain the importance of community preparation.
- Discuss why it is important for all parties to be involved in a research programme from the very beginning.
- Explain the actions to be taken to involve a community or community group.

MATERIALS NEEDED

- See the checklist of resources needed on page 7 of Module 1.
- Copies of the *HIV Vaccines Learner's Handbook* or photocopies of pages 14–24 of Section 1.
- You also need a set of cards using the list of actions on pages 50 and 51 for each group (see below), and photocopies of the case studies on page 49.

TIME: 1 hour

PREPARATION

- Read through pages 14–24 of Section 1 and make your own notes.
- For each small group, photocopy the case studies on page 49 and make a set of cards using the list of actions on pages 50 and 51. Each set should be marked A or B and each set should have a number of different cards – one for each of the actions. Do not use the numbers in the lists, on the cards. The numbers in the lists are so you know what order the steps should go in.
- Make photocopies of any handouts needed (see process notes).

PROCESS

1. Ask workshop participants to work in small groups of about six people.



2. Hand out the case studies and a set of cards to each group.
3. Ask the groups to discuss the case study that matches their set of cards, i.e. if their set is marked A they should discuss Case Study A.
4. Tell the groups that once they have finished they must choose from their set of cards, the five most appropriate actions to facilitate community involvement for their case study. Ask them to arrange the five cards in order of importance, with card 1 being the most important or the first step that they would take, etc. Give the groups about 30 minutes to discuss the cases and to make their choices.
5. When each group is finished, then ask them to present and explain the reasons for their choices. Then give other groups a chance to ask about or to comment on anything that is still unclear.
6. Identify and explore the differences in the group findings.
7. You will find the list of actions in order of importance on pages 50–51. Use this to refer to when giving your feedback in point 6.
8. Sum up and give relevant input from pages 14–24 in Section 1.
9. Refer participants to the *HIV Vaccines Learner's Handbook*, or give them copies of pages 14–24 from Section 1.



CASE STUDY A

A rural clinic has decided to set up a community health programme aimed at improving the health of children in several of the surrounding villages. The objective is to encourage the villagers to become active in preventative programmes so that they can improve their own and their families' health, and so that the clinic can reduce the number of patients needing treatment.

CASE STUDY B

HIV vaccine researchers want to set up an HIV vaccine clinical trial site in the Northern Cape. They have a few ideas about different communities that could be places in which to establish trial sites and have done some initial research. They are committed to ensuring that there is ongoing community involvement and participation and have been talking to different government and community structures involved in these areas about how to achieve this. They believe that awareness raising and education about HIV vaccine research and development, including clinical trials, is very important to ensure community 'buy in'.



ANSWERS TO CASE STUDY A:

Actions to take to facilitate community involvement in Case Study A

These are the actions in order of importance:

1. Introduce yourselves to the village head or community leader/s.
2. With the village head and community leaders gather information on existing problems in the community including finding out the concerns/problems from community members. Also gather information about existing assets, e.g. services and facilities.
3. Discuss and analyse the problems to determine which can be handled first.
4. With community leaders, look for more concrete information about existing problems and assets from other government services and organisations.
5. Attend a meeting with the village head, community leaders and the community in general, at which you provide practical information about the proposed project.
6. Give mothers a list of tasks, which they must carry out to keep their children healthy.
7. Ask the people, through the village head, to bring all sick children to the clinic for treatment.
8. Ask an appropriate agency to provide 'Road to Health' charts for all mothers with children under five so that mothers can be made aware of the connection between weight loss and poor health.
9. Ask the village to begin a programme to train mothers to weigh their babies and to take those babies who fail to grow to the clinic.
10. Ask the people, through the village head, to bring all children to a central place to assess their disease problems.

This exercise was adapted from Johnston and Rifkin's book *Health Care Together, Training Exercise for Health Workers in Community Based Programmes*.

You can easily use an example that is more appropriate to local situations or adapt these to your own conditions.

**ANSWERS TO CASE STUDY B:****Actions to take to facilitate community involvement in Case Study B**

These are the actions in order or importance:

1. Consult with and obtain 'buy in' and agreement from stakeholders in the communities affected by the research. Stakeholders may include different levels of government (national, provincial and particularly local government) and other relevant leaders and community structures.
2. Researchers and community outreach staff do background research into the community to find out their beliefs and attitudes; what community structures and organisations exist; decision-making processes; groups and subgroups; relationships; resources and assets; and needs and problems.
3. Researchers and community outreach staff consult with and work with existing structures and organisations within the community.
4. Together with the community leaders and/or the existing structures and organisations, researchers repeatedly visit the community to present practical information about the project or to study other members of the community.
5. Help the community establish a core group or a Community Advisory Group (CAG) to represent the interests of the community on the project or study.
6. Help the core group or CAG action plan, i.e. decide which tasks need to be carried out, in which order, and who will do what.
7. With the CAG or core group, discuss ways of ensuring ongoing community participation in the project/study, e.g. through community and peer education, workshops, etc.
8. With the CAG or core group, take action, e.g. run information and education workshops about the project or study.



ACTIVITY 7b: HOW DO WE FACILITATE COMMUNITY INVOLVEMENT?

The following activity will build on the knowledge from Activity 7a.

OUTCOMES OF THIS ACTIVITY

By the end of this activity, workshop participants should be able to:

- Discuss the steps involved in facilitating community involvement in the research process.
- Explain how to do background research into the trial community.
- Talk about who to consult with, in the community and how to do this.

MATERIALS NEEDED

- See the checklist of resources needed on page 7 of Module 1.
- Copies of the *HIV Vaccines Learner's Handbook* or photocopies of pages 14–24 in Section 1.
- You also need a box or bag of oranges; and photocopies of the case studies on page 49 for participants.
- Use overheads on the steps involved in an HIV vaccine clinical trial; the community entry process; and Penina's Cup.

TIME: 1 hour

PREPARATION

- Read through the notes on Activity 7a and use Case Study B on page 49. Also read pages 14–24 of Section 1.
- Photocopy the case study for workshop participants.
- Prepare these questions for discussion on flipchart paper:
 - *Who are the leaders in your area or community?*
 - *Who would you turn to in the community if you had a problem or needed advice?*
 - *Who are the other stakeholders in your community?*
 - *Who are the silent voices or the marginalised people in your community?*
 - *How would you explain to people in the community why they should become involved in the HIV vaccine research and development process?*
- Make photocopies of any handouts needed (see process notes).

PROCESS

1. Explain that there are a number of steps that are usually followed in the participatory process that we use in HIV vaccine research and development, including clinical trials. Use your overheads to show each step.



2. Give input on choosing the trial site (from Module 4) and how consultation with the community is part of this process. Have a general discussion on government's commitment to community involvement using information on page 17. Draw out examples that participants can think of in their own community.
3. Introduce consultation with the community. Ask participants to imagine that there is a box of oranges in front of them (or, better still, use a real box of oranges). For this activity, follow the steps in *Take 5 minutes* on page 18 of Section 1 of this module. Discuss what the exercise tells us about consultations in a community (also see page 18).
4. Give input about consultation, using Penina's cup (refer to page 19 of Section 1).
5. Ask workshop participants what different groups should be contacted in the community and why. Try to get them to think of and talk about the different subgroups and stakeholders in their own communities.
6. Ask participants to work in small groups to answer the discussion questions on the flipchart paper. They can then report back to plenary.
7. Briefly introduce *Establishing a group that represents the community interests*, but explain that you will look at this in more detail in another activity.
8. Sum up and give relevant input from pages 14–24 of Section 1.
9. Refer participants to the *HIV Vaccines Learner's Handbook*, or give them copies of pages 14–24 of Section 1.

ACTIVITY 8: HOW IS A CAG FORMED AND HOW DOES IT OPERATE? WHAT IS THE ROLE OF A CAG?

OUTCOMES OF THIS ACTIVITY

By the end of this activity, workshop participants should be able to:

- Understand that a body like a CAG is a way to encourage ongoing community involvement and participation.
- Understand how a CAG is formed.
- Discuss how a CAG operates.
- Discuss the role a CAG can play in HIV vaccine trials.

Part 1 of the activity: The responsibilities of a CAG

MATERIALS NEEDED

- See the checklist of resources needed on page 7 of Module 1.
- Copies of the *HIV Vaccines Learner's Handbook* or pages 20–23 of Section 1.
- Use an overhead on the CAG responsibilities.

TIME: 15 minutes



PREPARATION

- Read through Section 1, pages 20–23 of this module and make your own notes.
- Write up the following words on flipchart paper:

CAG, represent, educate, supportive environment, information resource, network, recruit, monitor, decision-making.

- Make photocopies of any handouts needed (see process notes).

PROCESS

1. Give input on a CAG – use the information on pages 20–23 of this module.
2. Work in pairs. (Ensure that at least one in the pair is literate.) Give each pair two key words or phrases to use from the words in the box. They should use these words or phrases to create or write two meaningful sentences to explain the responsibilities of a CAG.
3. Allow them five minutes to complete this. They can write them up on flipchart paper for everyone to see.
4. Discuss the sentences in the plenary session.
5. Sum up the responsibilities and role of a CAG.
6. Refer participants to the *HIV Vaccines Learner's Handbook*, or give them copies of pages 20–23 from Section 1.

Part 2 of the activity: Role-plays

If there is time, try the following role-play exercise.

TIME: 1 hour

PREPARATION: Photocopy the case studies on page 56.

PROCESS

1. Work in two groups. Ask each group to choose one person from their group to play the leading role (protagonist) in a short role-play.
2. Give each protagonist one of the case studies on page 56 to read and to 'get into' the character described.
3. The remaining members of each group play the members of a CAG. Encourage workshop participants to imagine exactly who they are on that CAG. Suggest that they think back to the list of words used in Activity 1, Handout 1 (page 40) to help build up characteristics of an imaginary character to play.
4. Now ask the protagonist to approach their group as a member of the community coming to the CAG for help and advice. Give the groups 10–15 minutes to do the role-play in their own



groups. You can walk around listening and taking note of what is happening.

5. At the end of the interaction between each protagonist and their CAG, ask the protagonists how they felt, and then ask the CAG members how they felt.
6. Then open up a discussion. Try to link the feedback to specific insights about the people coming to the CAG for advice and the role of the CAGs.
7. Sum up and give input from pages 20–23 in Section 1.
8. Refer participants to the *HIV Vaccines Learner's Handbook*, or give them copies of pages 20–23 from Section 1.



CASE STUDY A

Pravitha works as the chairperson of the Society for People Living with HIV and/or AIDS (PLWHA) in her town. She has heard about the preventative HIV vaccine trials to be conducted in the main hospital which serves her community. She has also heard about the CAG that has been formed. She is concerned because PLWHAs are not represented on this CAG. She has heard that some CAG members are not aware of the role that HIV-positive people can play in HIV vaccine development. She has been told that the CAG members feel that PLWHA participation may cause a conflict of interest between vaccines and treatment. She decides to approach the CAG.

CASE STUDY B

Vanessa is very enthusiastic about her planned participation in the preventative HIV vaccine trial. She gave informed consent for the site to give her an HIV test for screening purposes. She was asked to return to the trial site for post-test counselling and was informed that as she is HIV positive so she cannot participate in the vaccine trials. She is experiencing very difficult emotions, including rejection when told by the HIV counsellor that she could not participate. The counsellor informed her that she unfortunately has no role to play. Vanessa approaches the CAG for advice.



ACTIVITY 9: WHAT ARE THE WAYS IN WHICH COMMUNITIES CAN PARTICIPATE IN THE HIV VACCINE RESEARCH AND DEVELOPMENT PROCESS?

OUTCOMES OF THIS ACTIVITY

By the end of this activity, workshop participants should be able to:

- Discuss the different ways that people can participate in the HIV vaccine research and development process.
- Explain that membership of a CAG and trial participation are only two ways that people can participate.

MATERIALS NEEDED

- See the checklist of resources needed on page 7 of Module 1.
- Copies of the *HIV Vaccines Learner's Handbook* or photocopies of page 24 of Section 1.
- Use overheads on ways that communities can participate in the HIV vaccine research and development process.

TIME: 25 minutes

PREPARATION

- Read Section 1, page 24 of the module and make notes.
- Use overheads on ways that communities can participate in the HIV vaccine research and development process.
- Make photocopies of any handouts needed (see process notes).

PROCESS

1. Explain that the CAG is one way to encourage community participation but that there are also many other ways in which community members can participate.
2. Ask workshop participants to think about the different ways they participate in their workplace or organisation, e.g. by doing fundraising, advocating for better services, etc.
3. Then ask them to brainstorm as many ways that they can think of for people in the community to participate in the HIV vaccine research and development process. Write up their ideas on a mind-map.
4. Summarise and add any gaps in information from your notes.
5. Refer participants to the *HIV Vaccines Learner's Handbook*, or give them copies of page 24 from Section 1.



ACTIVITY 10: HOW DOES TRIAL PARTICIPATION WORK?

OUTCOME OF THIS ACTIVITY

By the end of this activity, workshop participants should be able to:

- Explain how to join a trial and the steps involved in trial participation.

MATERIALS NEEDED

- See the checklist of resources needed on page 7 of Module 1.
- Copies of the *HIV Vaccines Learner's Handbook* or photocopies of pages 24–33 of Section 1.
- Use overheads on the steps involved in participating in an HIV vaccine clinical trial.

TIME: 1 hour

PREPARATION

- Read through Section 1, pages 24–33 of this module and make your own notes.
- Make photocopies of any handouts needed (see process notes).

PROCESS

1. Using the overheads, give a short input on Steps 2 to 11 described on pages 24–33 of Section 1.
2. Ask workshop participants to work in pairs to prepare for a role-play. One person should take the part of a volunteer interested in joining a trial. The other person will pretend to be an HIV vaccine educator.
3. Ask them to read through a description of Steps 2 to 11 in the *Learner Handbook*, or give them photocopies of pages 24–33 to use. Give them 25 minutes to do this.
4. Then ask pairs to role-play by doing the following:
 - The volunteer says that s/he has heard about the trial and asks how to join up. The volunteer asks the educator what steps will be involved in participating in the trial.
 - The vaccine educator's role is to answer the volunteer's questions. The educator must also check to see if the volunteer understands the information that he or she is given. One way to do this is to ask the volunteer to explain what she or he has understood from the information.
5. Tell the workshop participants to refer to their notes if they get stuck or can't remember all the information. Give them 20 minutes to do the role-play in their pairs. Make sure to walk around so that you offer help or answer questions that pairs might have.

NOTE TO THE FACILITATOR

This role-play aims to give workshop participants a fair idea of the kind of process that takes place during informed consent, i.e. a counsellor giving information about the trial and checking for questions and to see whether the volunteer has understood before asking if they want to proceed.



6. While participants are still in their pairs, round off the activity by asking each pair what they learnt from this experience. Ask the 'volunteers' if they are still interested in joining the trial, or if not, why. Ask the 'educators' what they found difficult or challenging in this process. Write up any new points on the flipchart for the group to discuss.
7. Summarise the discussion and the steps involved in participating in a trial. Fill in any gaps by using the overheads to help you.
8. Refer participants to the *HIV Vaccines Learner's Handbook*, or give them copies of pages 24–33 from Section 1.

ACTIVITY 11: APPLYING YOUR UNDERSTANDING OF A CAG TO A REAL-LIFE SCENARIO

OUTCOME OF THIS ACTIVITY

By the end of this activity, workshop participants should be able to:

- Apply their understanding of a CAG to a real-life situation.

MATERIALS NEEDED

- See the checklist of resources needed on page 7 of Module 1.
- Copies of the *HIV Vaccines Learner's Handbook* or photocopies of pages 20–23 of Section 1.

TIME: 45 minutes

PREPARATION

Make photocopies of any handouts needed (see process notes).

PROCESS

1. Recap the information on the responsibilities of CAGs from pages 20–23 of Section 1.
2. Give copies of the case study on page 60 to the group and read through the case study with them.
3. Ask and discuss the following questions:
 - *What are the problems in the case study?*
 - *How can these problems be addressed by the CAG?*
 - *What information does the CAG or community need to address the problem/s?*
 - *Can you think of other real-life situations where there may be problems that the CAG needs to address?*
4. Highlight any important points.
5. Sum up and give input from your notes on the CAGs.
6. Refer participants to the *HIV Vaccines Learner's Handbook*, or to pages 20–23 from Section 1.

If you have enough time, then do this final activity on applying knowledge about the CAGs to real life.



CASE STUDY A

There has been a good working relationship between the trial site staff and the CAG of a particular town. CAG members are therefore very puzzled when they read an interview with the trial site director in a newspaper. In the interview, the director says that the trials might be moving to a nearby town with better resources to cope with the scientific demands of clinical trials. CAG members are disappointed, as they have worked hard to prepare the community for the trials. They are also concerned that they have not been informed about the trial site staff's concerns and have therefore not participated in the decision-making. They feel that there are serious implications for their community.

SUM UP

Ask workshop participants:

1. What do we mean by 'community' and what makes someone part of a community?
2. What do we mean by 'involvement' and 'participation'?
3. Why is it important to have community involvement and participation in HIV vaccine research and development?
4. How do we involve the community and encourage participation?
5. What steps are involved in participating in an HIV vaccine clinical trial?

Use your overheads and points under, *To sum up*, on page 34 of Section 1 to sum up the whole workshop. If you do not have copies of the *HIV Vaccines Learner Handbook*, you can give copies of page 34 to your workshop participants.