

Solidarity Against Ebola/Tokomeza Ebola



Working together to find a vaccine against Ebola disease in Uganda

A flipbook for discussion between the study team and potential study participants

What will we cover in this session about Ebola disease and this vaccine study

Thank you for coming to this information session.

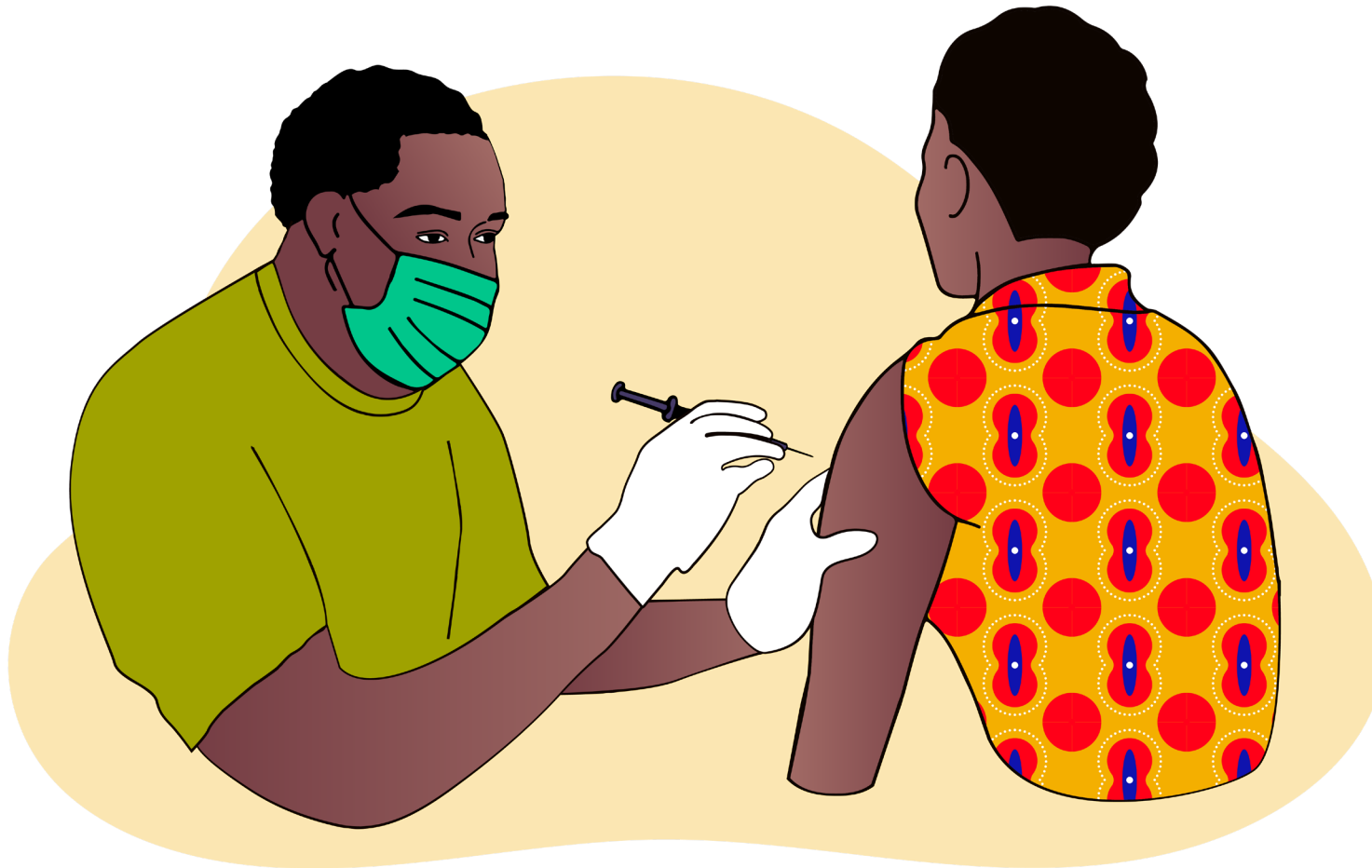
You have been invited to take part in a new research study because you have been in contact with someone who is sick with, or has died from, Ebola in Uganda.

The study aims to find vaccines that could protect you and others in your community from Ebola.

We will give you important information about the study and explain what will happen if you choose to take part. And we will answer any questions you have.

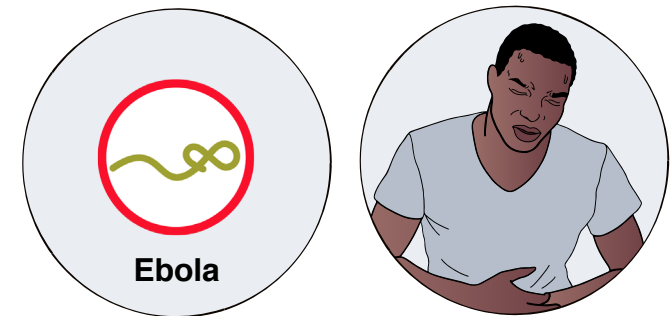
At the end of the session, you will have the information you need to decide whether or not you want to take part.





What is Ebola disease?

Facilitator note: The opening session gives people a chance to say what they already know about Ebola disease and ask what they would like to know about it. Use the frequently asked questions to provide clear information, building on what is already known in the community and addressing gaps or misunderstandings. Please see some key points to cover.



There is an outbreak of Ebola in Uganda.

Let's start this meeting talking a bit about that.

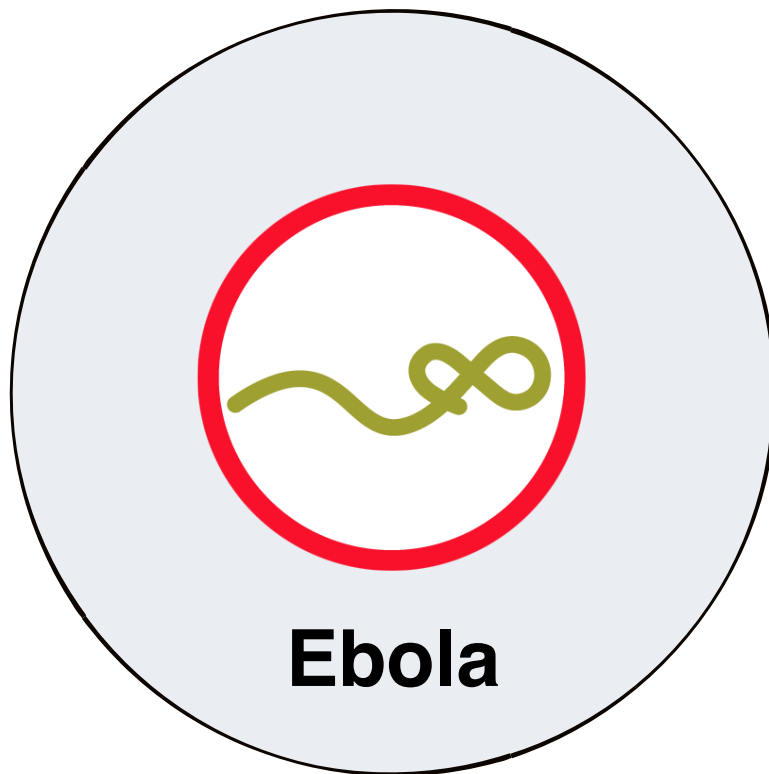
What do you know about Ebola disease?

What would you like to know about Ebola disease?

Facilitator note: Cover the following points:

- Ebola disease is caused by a virus.
- People get very sick with Ebola disease and at least 4 out of every 10 people who get it die.
- A person can pass on the virus as soon as they start having symptoms.
- Early symptoms of Ebola disease are: fever, headache, weakness, vomiting, bloody diarrhoea or urine, bleeding from body openings. These symptoms can look a lot like other kinds of diseases such as malaria.

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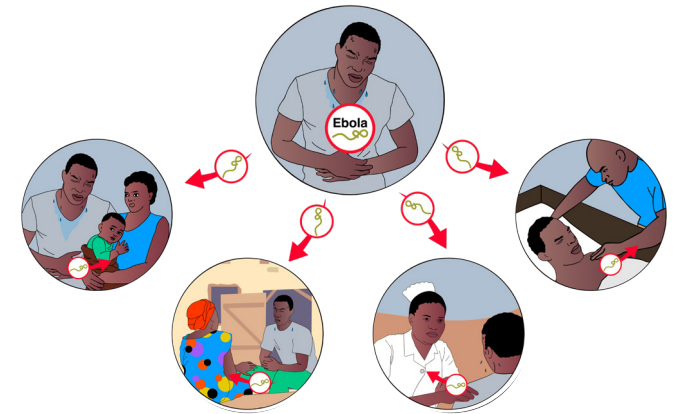
Who is at greater risk of Ebola disease?

A person is at greater risk of becoming infected with Ebola if they have had close contact with a person who is sick with the disease or someone who has recently died of it.

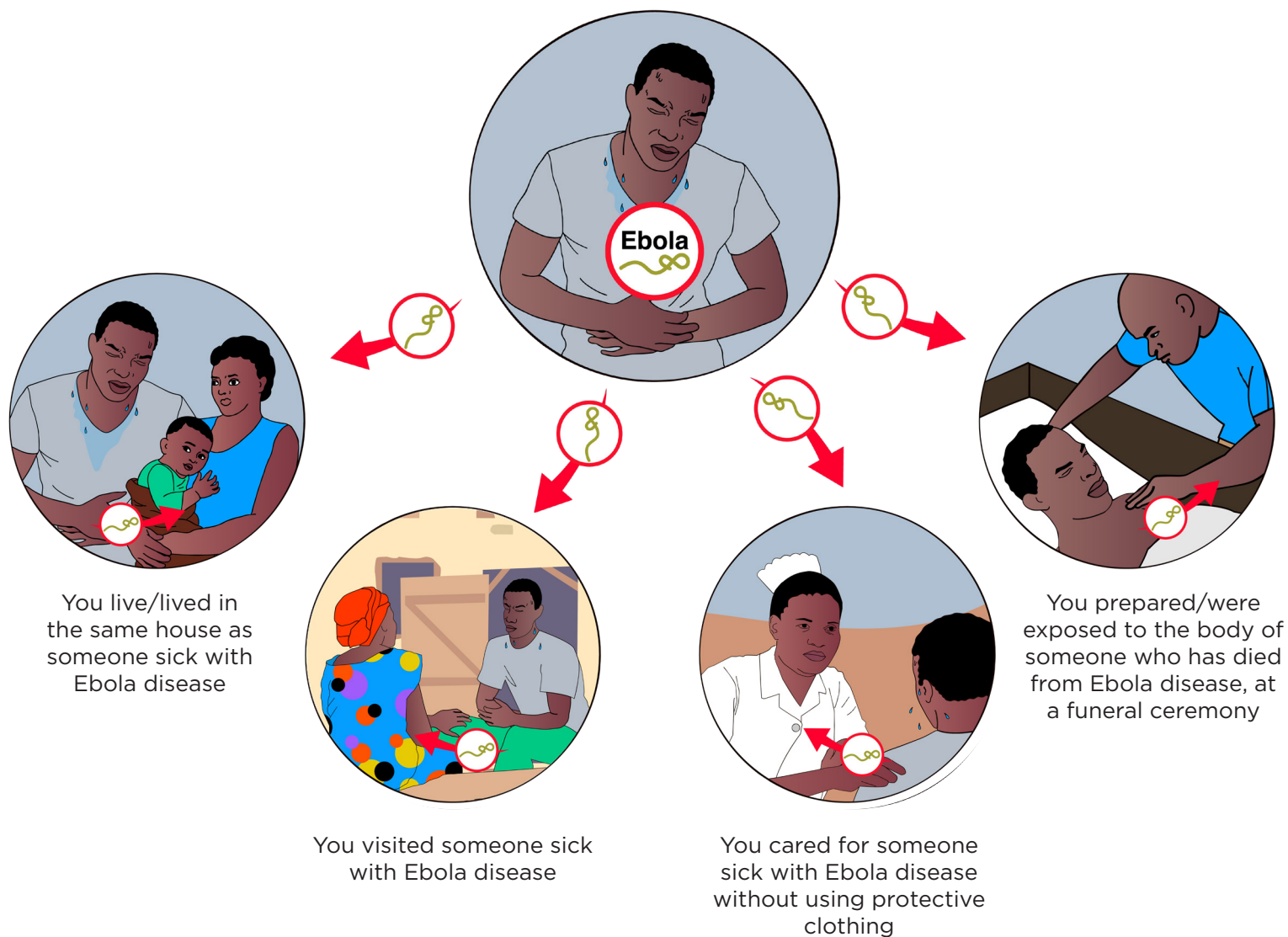
This is because the virus that causes Ebola disease can be spread by touching their body or bodily fluids, such as blood, vomit, saliva, urine and faeces.

Close contact means that in the past 21 days:

- you have been living in the same household as a person who is sick with Ebola disease
- you visited a person who is sick with Ebola disease
- you provided care to a person who was sick with Ebola disease and may have had contact with their body, bodily fluids or clothes without using special equipment to prevent infection
- you prepared the body of a person who was sick with Ebola disease and who died, or were exposed to their body at a funeral ceremony without using special equipment to prevent infection



Who is at greater risk of Ebola disease?



We need to test promising vaccines against Ebola disease

People can survive Ebola.

There is no vaccine that can protect us from the kind of Ebola disease that is in Uganda now. However there are promising vaccines we think might work to protect you and your community against Ebola disease in Uganda.

These vaccines are being given as part of a new study so we can learn if they work and are safe.

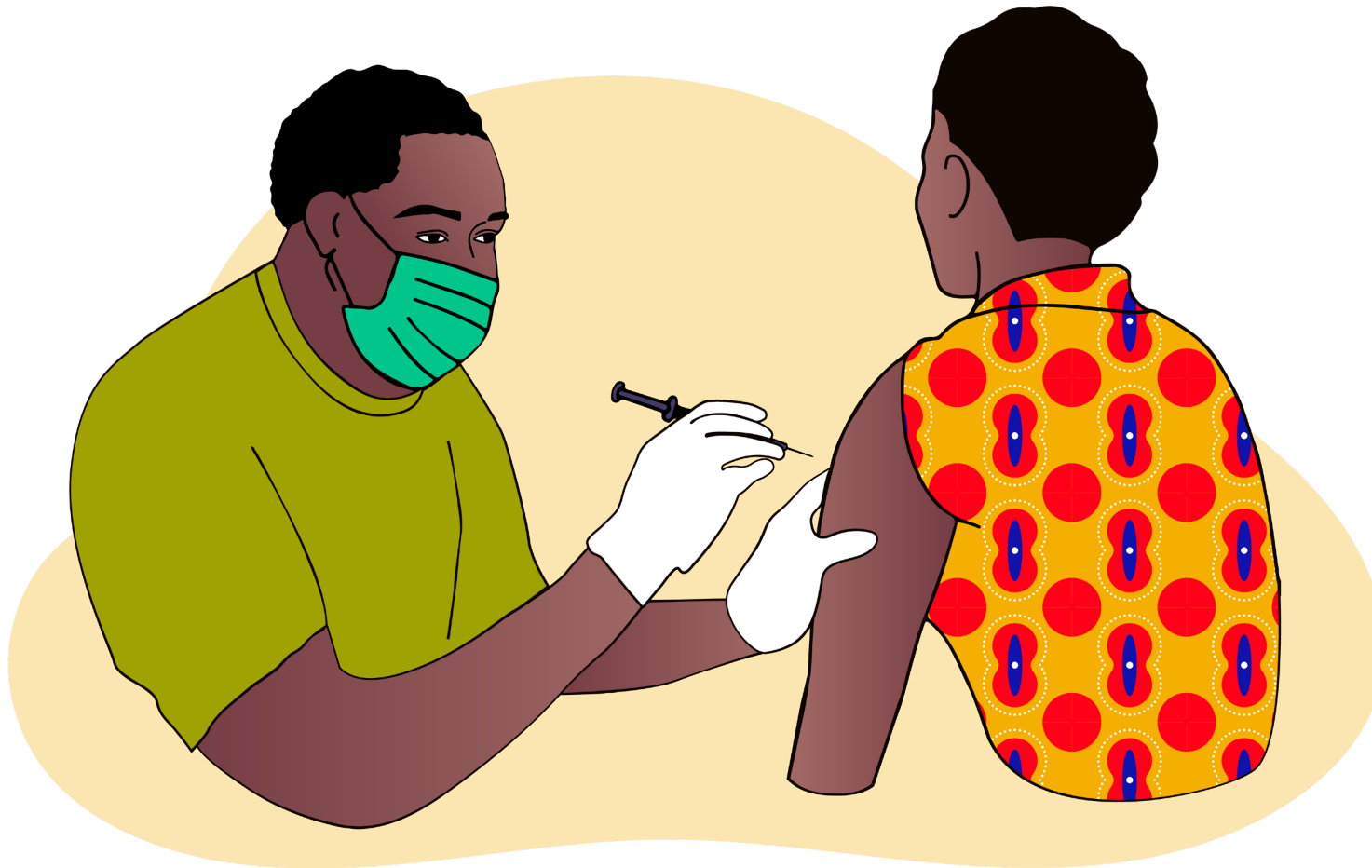
You can take part in the study because you have been in close contact with someone who is sick or has died with Ebola.

It is your choice whether or not to take part.

We will now give you all the information you need to decide if you wish to take part or not.

Please ask all the questions you might have and we will make sure we answer them.





How the trial works – Overview

This picture shows how the study works.

We will go through it step by step.

As we have said, only people who have been in direct contact with someone who is sick with or died from Ebola disease are invited to join the study. This is important.

We do not know for certain that the vaccines being evaluated in the study work.

This is why we are doing the study.



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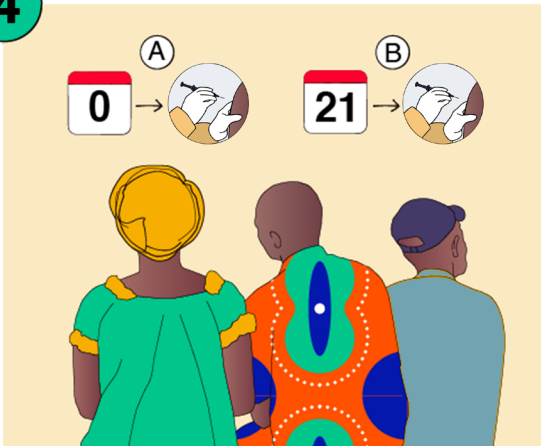


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If **Yes** ...

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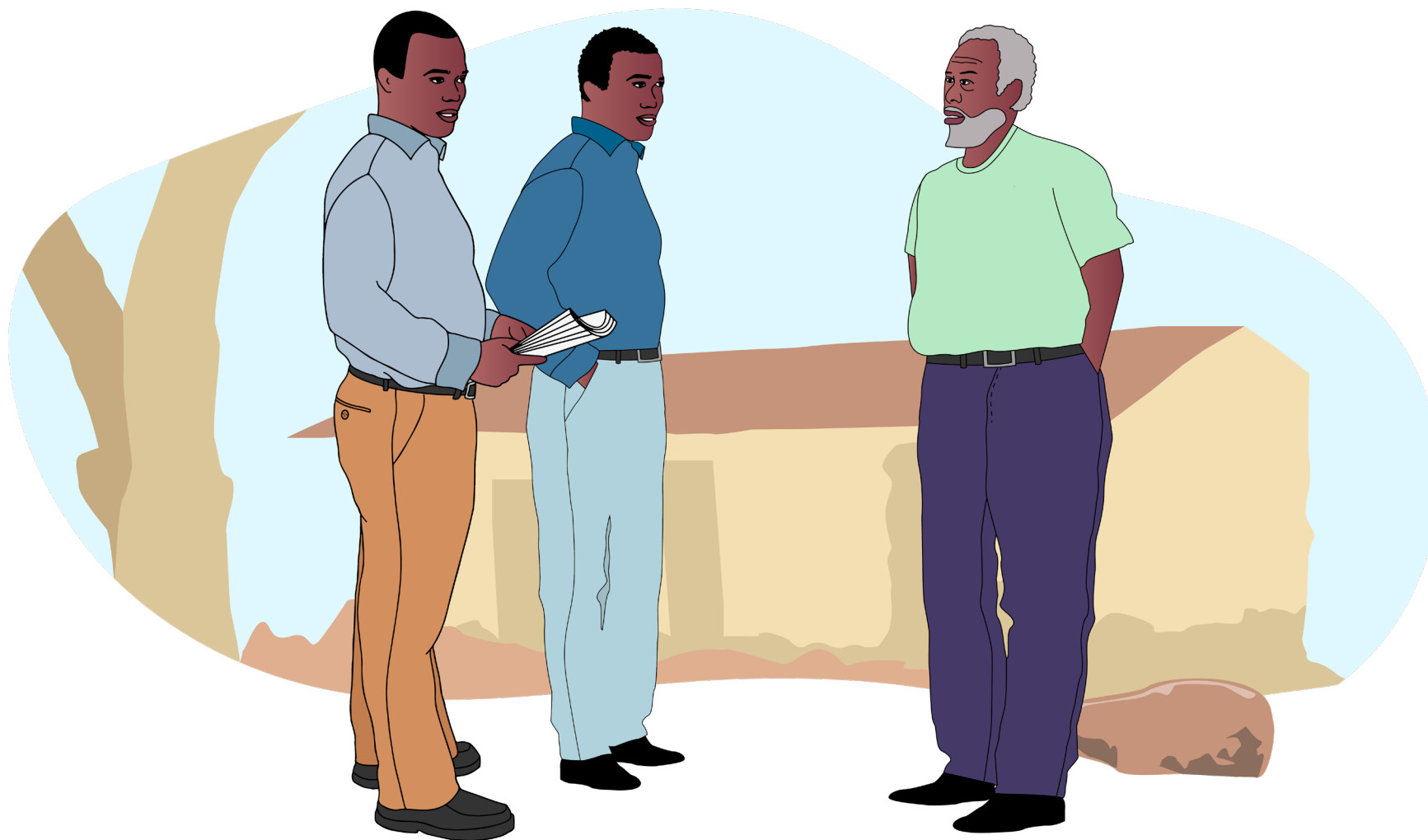
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How the trial works – Step 1

In Step 1 of the trial, the study team speaks to leaders of the community where the person who was sick with Ebola disease comes from to ask their permission to do the study.

We have already done this - so, we have permission to begin the study.





How the trial works – Step 2

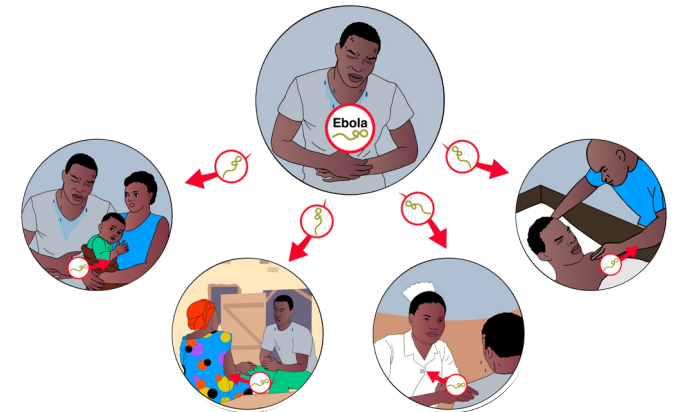
In Step 2 of the trial, the study team identifies all the people known to have been in contact with someone who is infected with or has died from Ebola disease.

These are the people who are invited to take part in the study.

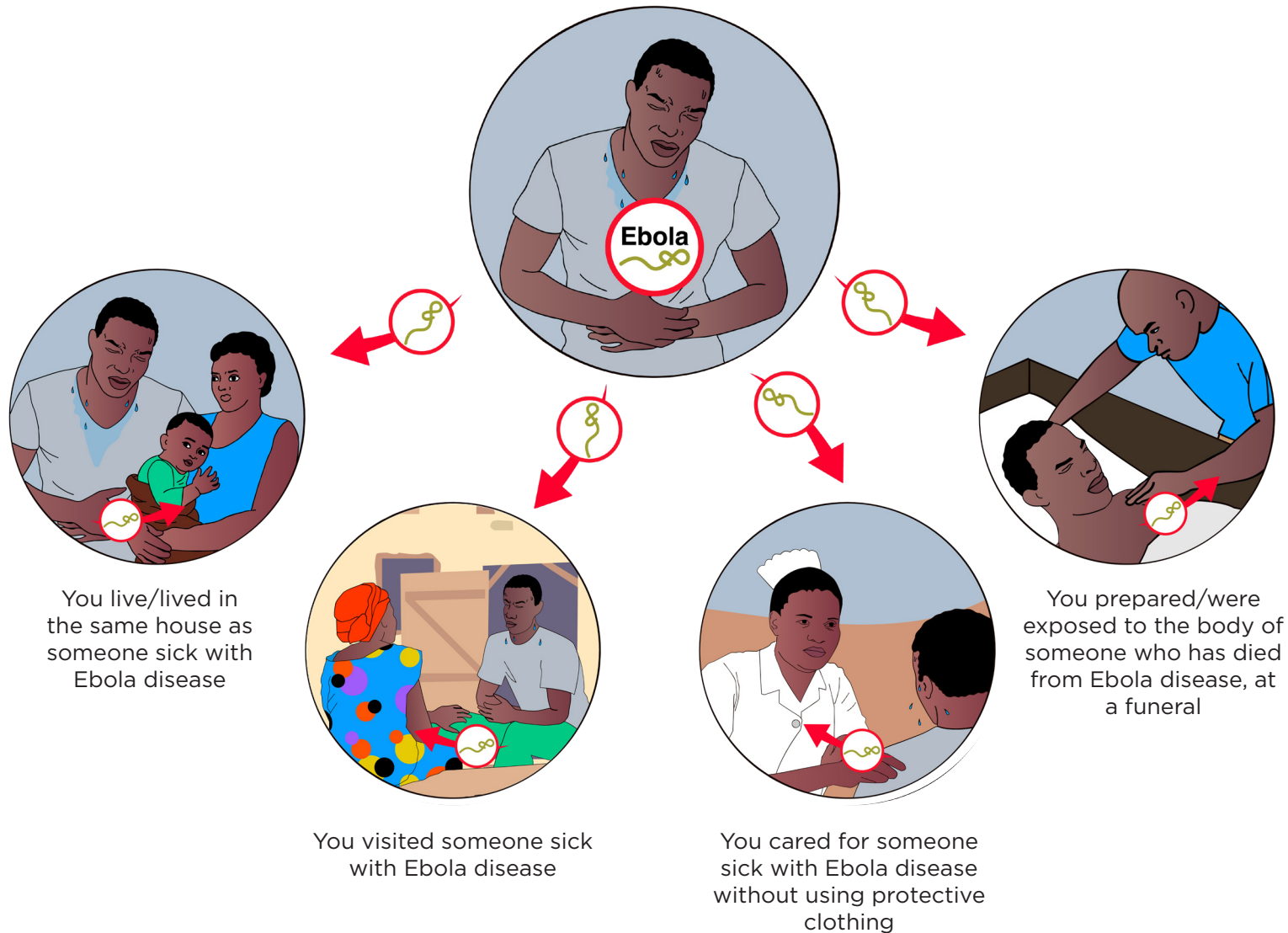
Everyone who has been in close contact with a person who was ill, or has died from, Ebola become a group.

And everyone in the group can join the study.

This step has also already happened. You are part of this group.

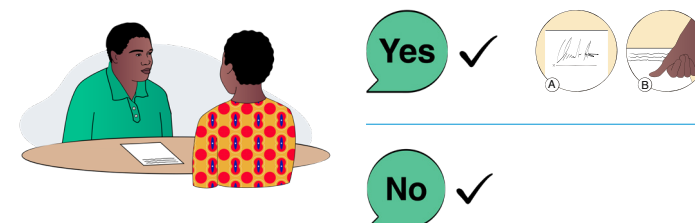


Everyone who has had close contact with someone who is sick with, or has died of, Ebola can take part in this study



How the trial works – Step 3

During this step, the research team speaks with each person to see if they wish to join the study. The team will provide information and answer all the questions you have so you can reach a decision. This is what we are doing right now. We will also assess whether you are eligible to take part.



You can take part in the study if you have been in close contact with someone confirmed to have Ebola disease and:

- you are 6 years old and above.
- you are able to give signed informed consent. If you are 6-7 years old you will need a parent or legal guardian to consent to you taking part. If you are aged 8-17 then both your assent and the consent of a parent/legal guardian will be needed.

If you are pregnant or breastfeeding, you are still able to take part if you wish to do so. There is limited information about the safety of this vaccine among women who are pregnant or breastfeeding. It is your decision whether or not you wish to join the study.

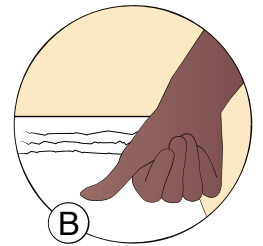
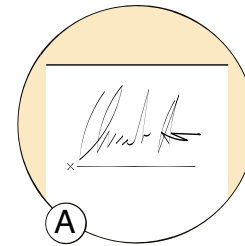
The following people cannot take part in the study. Those who:

- have been ill with Ebola disease
- have had other experimental treatments in the last 28 days
- have had a bad reaction to vaccines in the past
- have a serious illness needing hospital treatment at the time of vaccination

If you do decide to take part in the study, the study team will need some specific information from you. You will also be asked to put a signature or thumbprint on a form. This provides written confirmation of your consent to join the study after being given all the information you need.



Yes ✓



No ✓

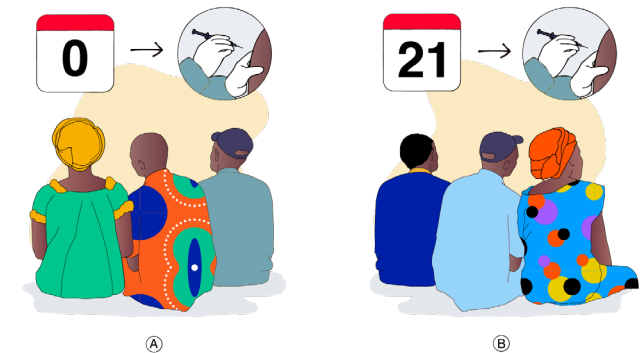
How the trial works – Step 4

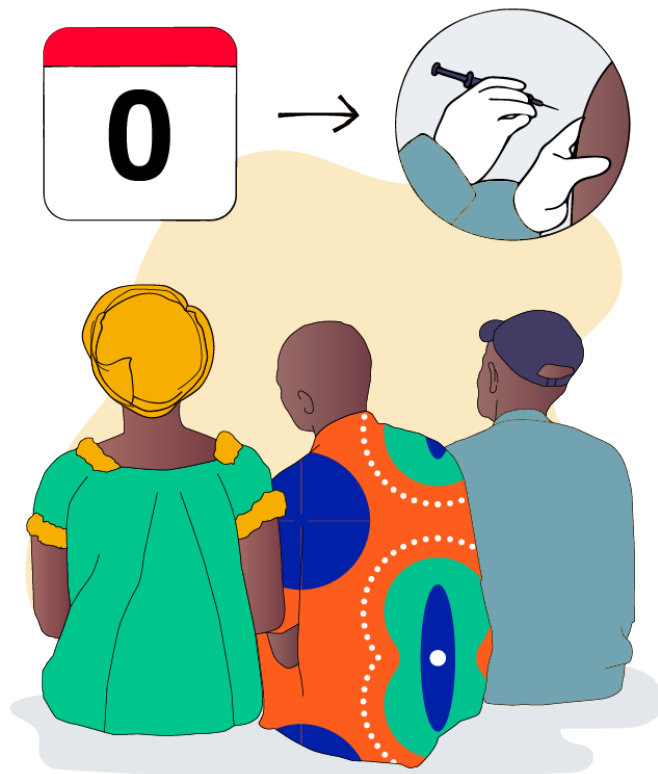
Once everyone in the group has made a decision about whether or not they wish to take part, then the group is closed.

Everyone in the group who has agreed to be in the study will then receive the study vaccine: either straight away or 21 days later.

The decision about when the group will receive the study vaccine will be made at random.

Having different groups allows researchers to check how effective the study vaccine has been in protecting people from Ebola.





(A)



(B)

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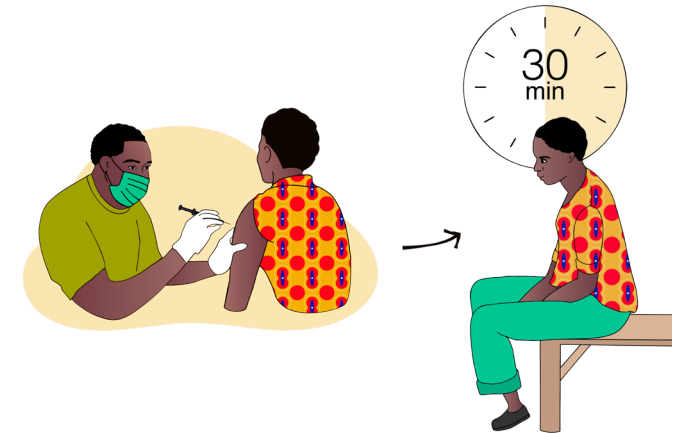
How the trial works – Step 5

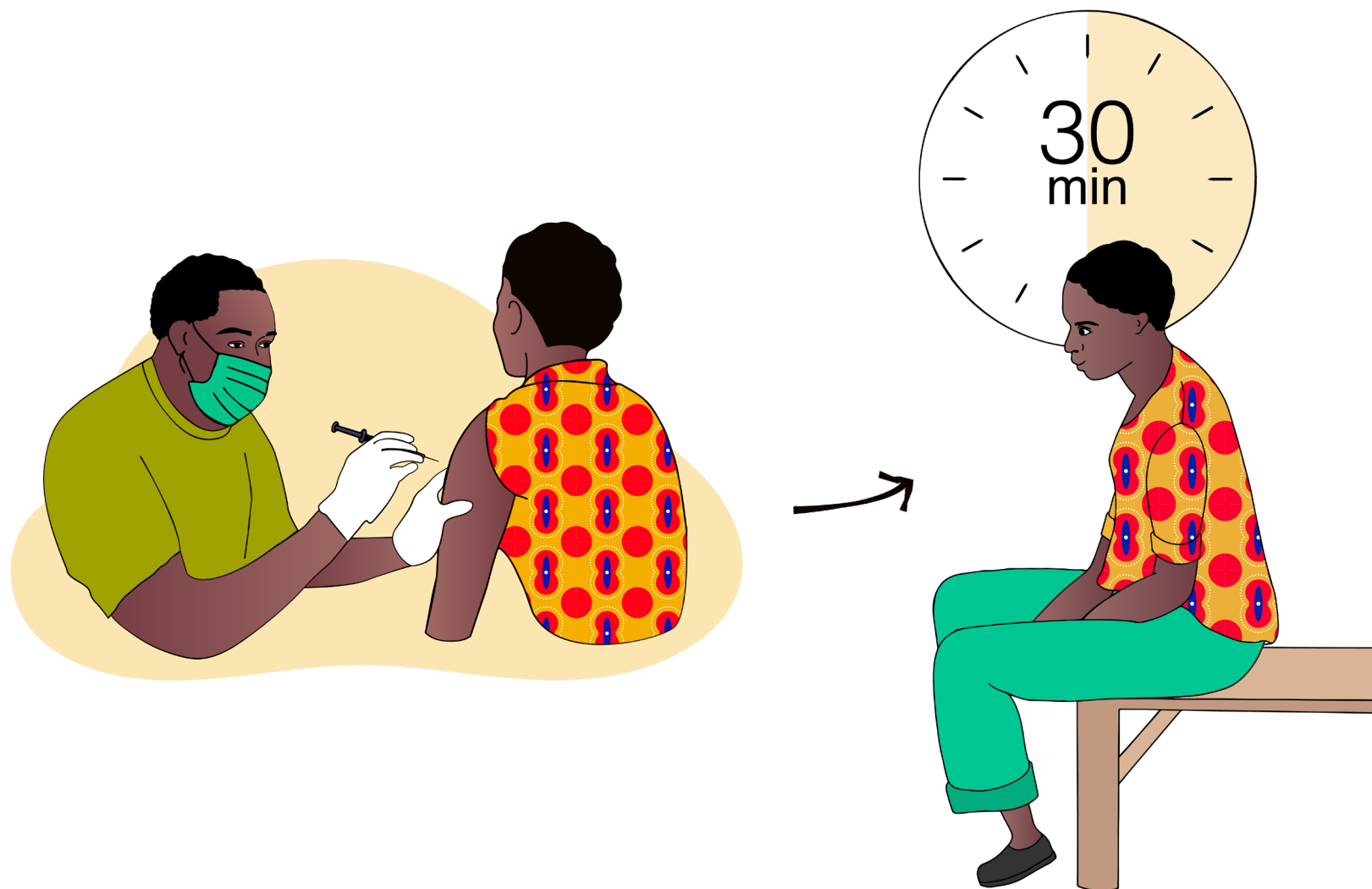
A team will come to give you the study vaccine.

It will be injected into your upper arm using a clean needle and syringe.

You will be asked to wait for 30 minutes after receiving the vaccine.

Then you can go.



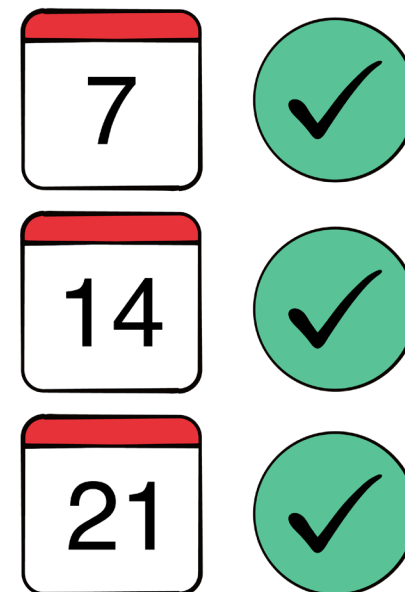


How the trial works – Step 6

The study team will visit you once a week for 3 weeks at home after you have received the vaccine.

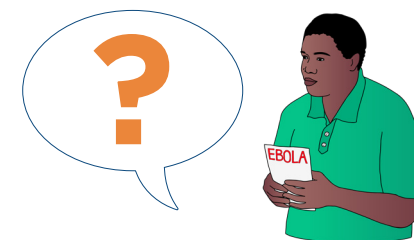
The team will ask you how you are, if you have any signs of being unwell, have had any side-effects, or have any questions or concerns.





Question break

Let's pause at this point. What questions do you have about the different steps in the study?



Facilitator note: Use the study-specific frequently asked questions to answer any questions that people may have.

If you do not know the answer to a question, say the following: "I don't know the answer to that. I will ask the person in charge of the study and come back to you later today or tomorrow with the answer."

Be sure to cover the following points:

What are the risks and benefits of taking part in the study?

By taking part in this study, you can help to find out if a number of vaccines that have shown promising early results work to protect you and your community against Ebola disease.

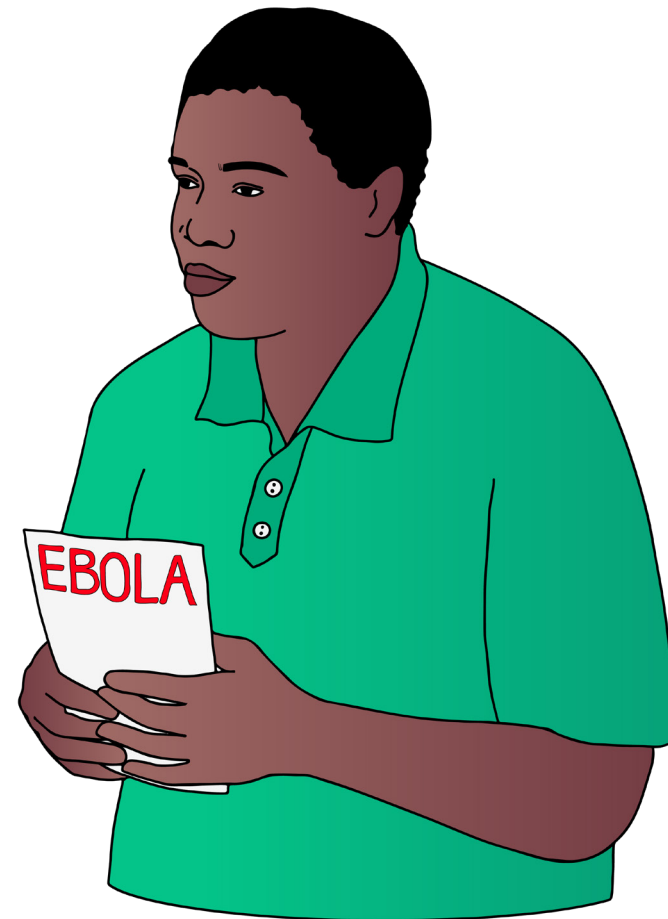
The main risk in taking part is that you could experience some side-effects from the vaccine. The study team will give you more information about these.

Side-effects include; tenderness, hardness of the skin, muscle and/or joint pain, fatigue, vomiting, diarrhoea and headache.

What do I do if I experience some side-effects of the vaccine?

If you are unwell, please do contact the study team.

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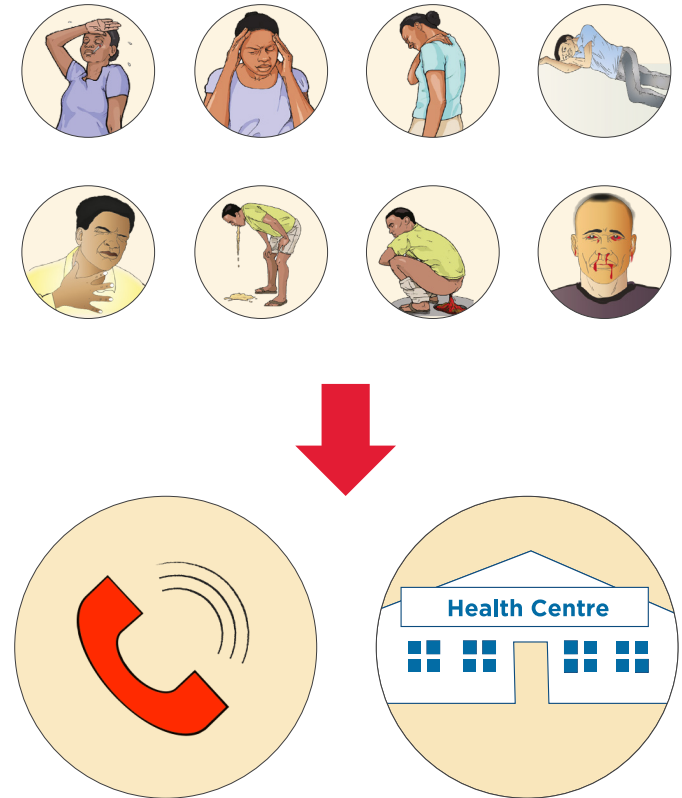
What should I do if I suspect I have Ebola?

The signs and symptoms of Ebola are: headache, having red eyes, weakness, vomiting, bloody diarrhoea or urine and bleeding from body openings.

If you have any of these symptoms contact the study team or the local health emergency number immediately. Or you can go straight to a health facility.

The study vaccine cannot cause Ebola.

We know that people who get help early have a greater chance of surviving Ebola than those who come later.



Facilitator note: For more information on Ebola disease please use the 'Frequently Asked Questions About Ebola' leaflet (Republic of Uganda Ministry of Health/WHO/UNICEF)



Sudden onset of fever



Headache



Muscle pain



Intense body weakness



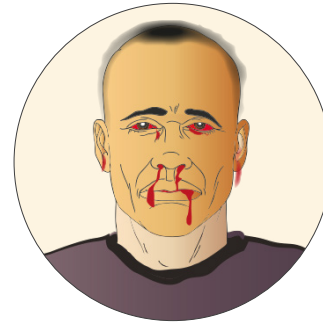
Sore throat



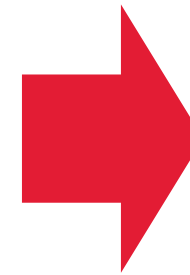
Vomiting



Bloody diarrhoea or
urine



Bleeding from body
openings

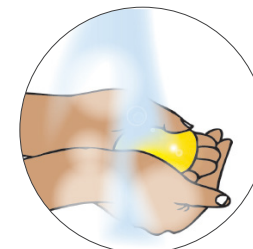


Protect yourself and others from Ebola disease

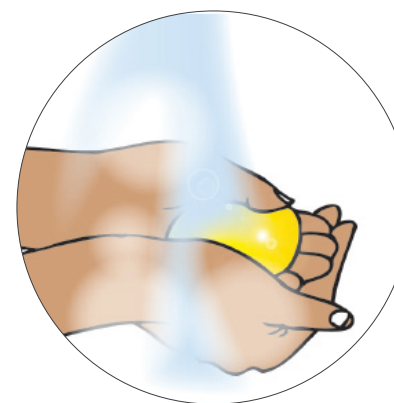
Whether or not you take part in the study it is important to keep doing all the things that we know protect people from becoming infected with the virus that causes Ebola disease.

Taking the following actions could save your life and the lives of others:

- Avoid direct contact with the bodily fluids of people who are suspected of, or are confirmed to have, Ebola disease.
- If you must have contact with people who are suspected of, or are confirmed to have, Ebola disease, wear protective equipment – such as gloves and a mask - and wash your hands regularly.
- Do not handle or prepare the bodies of people who are suspected of, or confirmed to have, died from Ebola disease. Their bodies will need to be buried by a trained burial team.



Protect yourself and others from Ebola disease



Images taken from Ebola information poster (Republic of Uganda Ministry of Health/WHO/UKAID/USAID/UNICEF)

What happens now?

You need to decide whether or not you want to take part in the study. It's entirely your choice whether or not to take part.

To help you make the decision, we will now answer any questions you have. Then you will need to make the decision today.

Now, do you have any final questions that can help you to make your decision?





Yes ✓

No ✓

