

# A Community Ebola Marklate Study in Sierra Leone



**MINISTRY OF HEALTH  
AND SANITATION**  
THE REPUBLIC OF SIERRA LEONE

Version 2016-07-19\_v02



**College of Medicine  
& Allied Health Sciences**  
University Of Sierra Leone

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## Presenter's Guide

This flipbook is for a facilitated discussion between study staff and participants who are potentially eligible to take part in the EBOVAC-Salone marklate study.

Sierra Leone College of Medicine and Allied Health Sciences (COMAHS)  
Sierra Leone Ministry of Health and Sanitation (MoHS)



# What is EBOVAC-Salone?





# What is EBOVAC-Salone?

GREET THE PERSON PLEASANTLY. SMILE.  
READ ALOUD THE FOLLOWING INFORMATION:

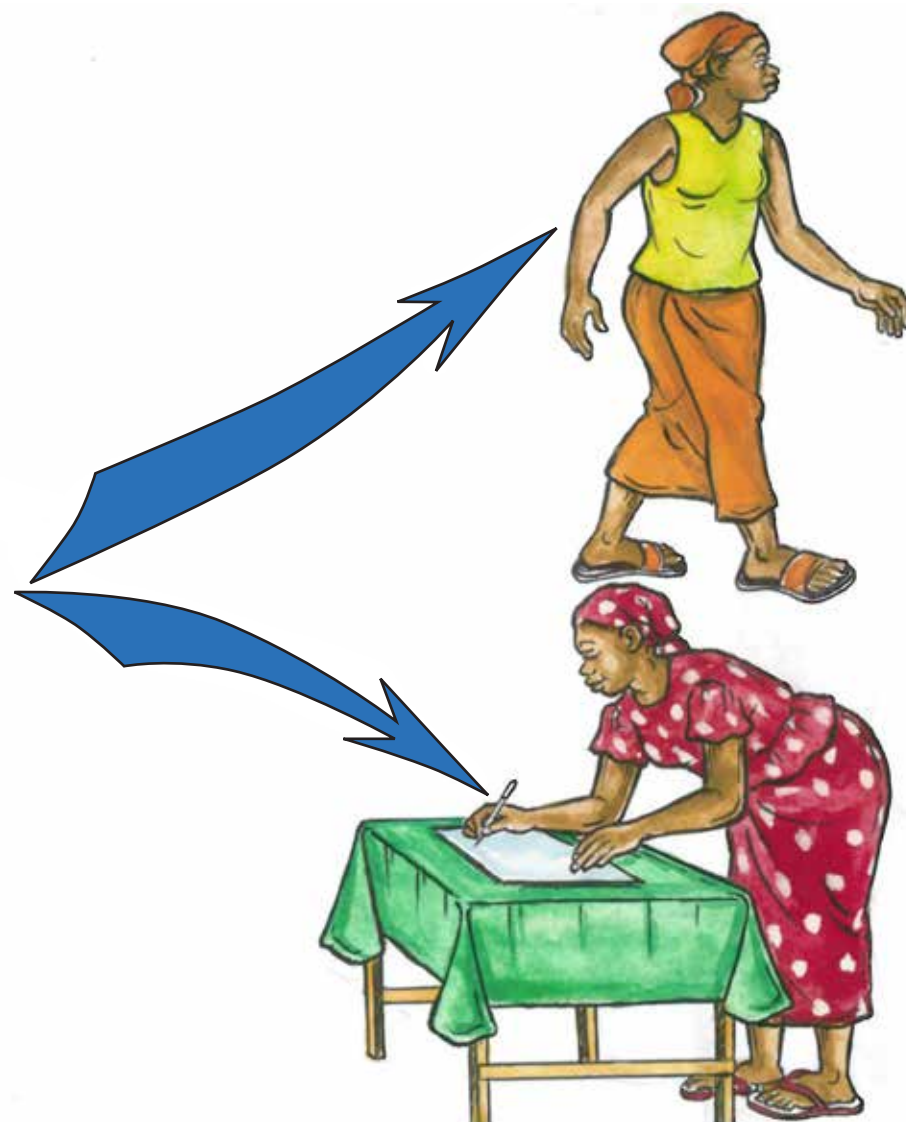


You are invited to take part in an Ebola prevention marklate study which is taking place in Sierra Leone. The aim of this study is to know whether a new marklate could protect people from Ebola.

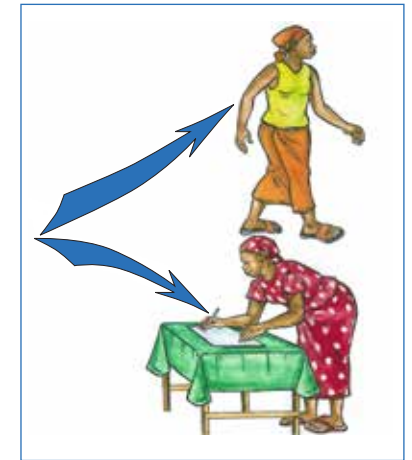
We would like to discuss this study with you so that you can decide whether or not you would like to take part.

Please take your time to think about this and ask as many questions as you would like before you decide.

You have a choice



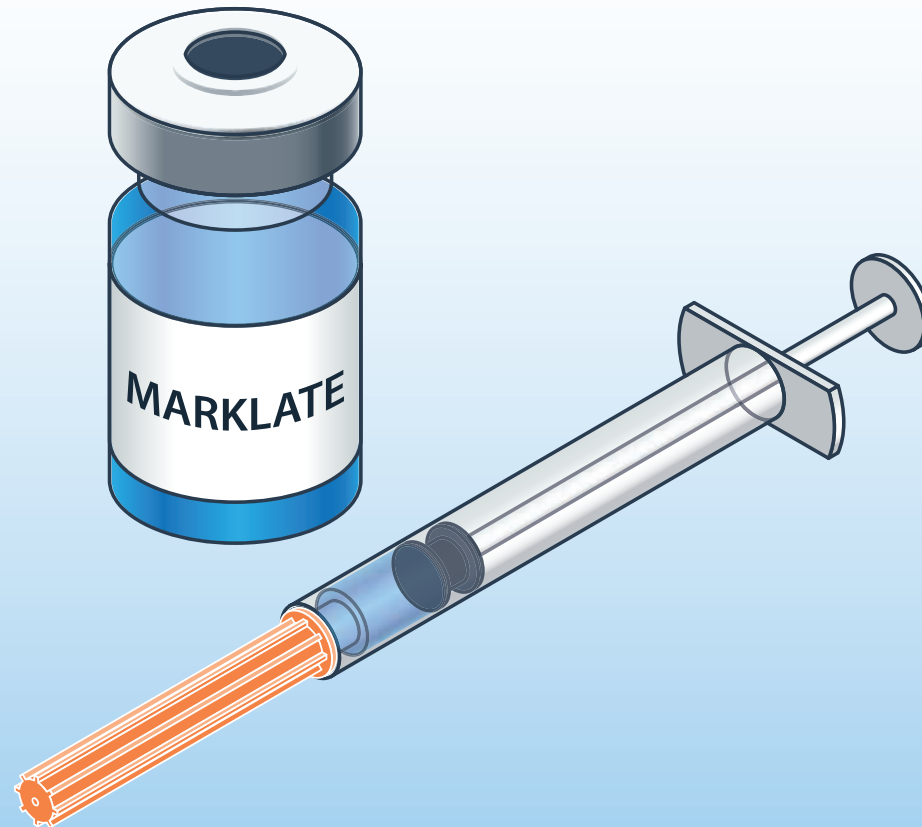
# You have a choice



This study is voluntary, which means you can decide yourself whether you would like to take part in the study. You do not have to take part if you don't want to. You can decide to stop being a part of this study at any time.

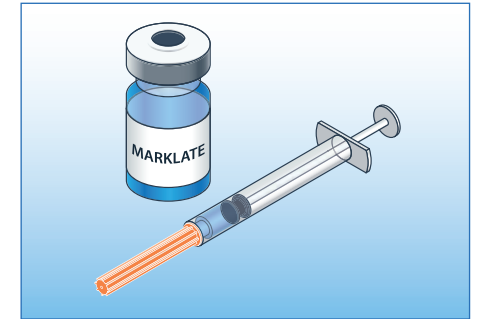
If you decide to take part in the study, we will first explain the study to you, and then you will be asked to answer some questions about the study to check that you have understood everything that we have talked through today. Finally you will be asked to sign or thumbprint a consent form.

# What is a marklate?





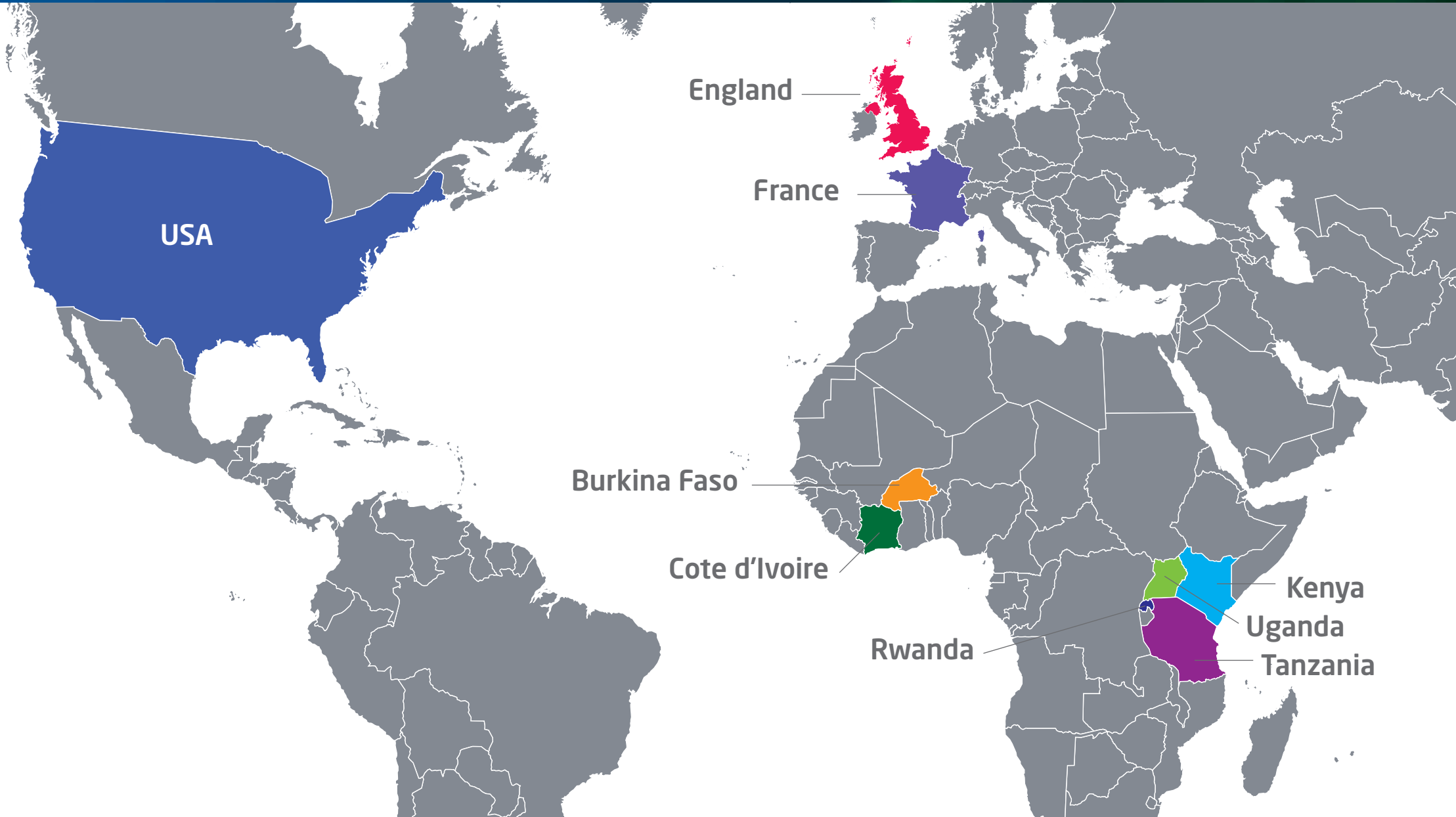
# What is a marklate?



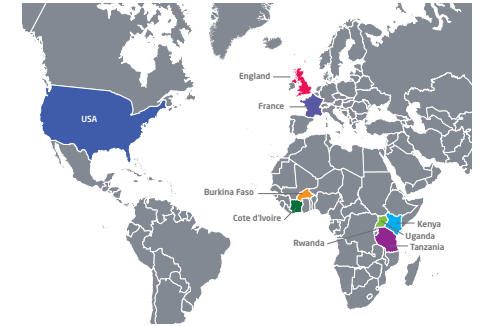
Marklates are available for other serious diseases, like polio and measles. They protect your body from germs that cause these diseases.

- Ebola is a serious disease which can be deadly.
- We need to test a marklate in a country which has been affected by Ebola, like Sierra Leone, to be able to know whether this marklate can protect people from getting Ebola.

# Is this marklate safe for you?



# Is this marklate safe for you?



- People in Sierra Leone will not be the first people to receive this Ebola marklate. This Ebola marklate has already been studied in various countries, including England, America, Kenya, Tanzania and Uganda.
- This Ebola marklate cannot give you Ebola.

# Eligibility criteria



# Eligibility criteria

PLEASE EXPLAIN TO THE PERSON THAT DETAILED QUESTIONS ABOUT THEIR HEALTH WILL BE ASKED AT A LATER STAGE



## YOU MAY TAKE PART IN THIS STUDY IF YOU:

- Are aged 1 years or older (if you are aged between 1-17 years, the parent/legal guardian will have to consent on your behalf) AND
- Are willing to continue living in the study area throughout the study period AND
- Are able to provide correct information about your health now and in the past AND
- Agree to come to all study visits AND
- Agree to take body temperature and record any problems in the symptom diary for 7 days after each marklate AND
- Agree not to receive any marklates for other infections within 15 days before and after each study marklate AND
- Are willing to receive the study marklate soon (within the next few weeks) AND
- Are willing to follow recommendations for prevention against Ebola infection.

## YOU CANNOT TAKE PART IN THIS STUDY IF YOU:

- Have had Ebola
- Have received another marklate against Ebola in a previous study
- Have been told that you have a disease that makes it hard for your body to fight infections
- Have had a serious allergic reaction or became very sick soon after you received a marklate in the past
- Are pregnant or planning to become pregnant during the first 3 months of the study (or until 28 days after the second marklate), or are breastfeeding
- All women who are of an age where they might be pregnant will be asked to give a urine sample to check if they are pregnant.
- If you are pregnant or think there is a chance you might be pregnant be sure to inform the doctor



# Are you eligible to take part?

Yes	No
<input checked="" type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>



# Are you eligible to take part?



- You will be asked some questions by the study nurse or doctor about your health.
- It is important to answer the questions with as much information as possible because some people, such as pregnant women, are not able to take part in this study.

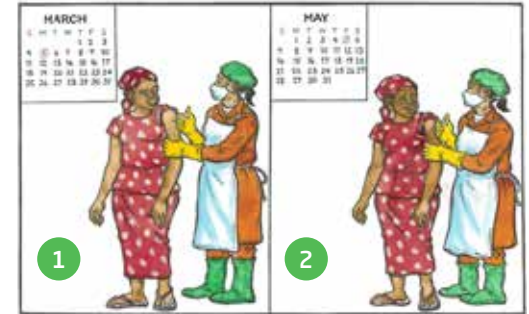
# You will receive two marklates

MARCH						
S	M	T	W	T	F	S
				1	2	3
4	5	6	7	8	9	10
11	12	13	14	15	16	17
18	19	20	21	22	23	24
25	26	27	28	29	30	31



1

## 7. You will receive two marklates

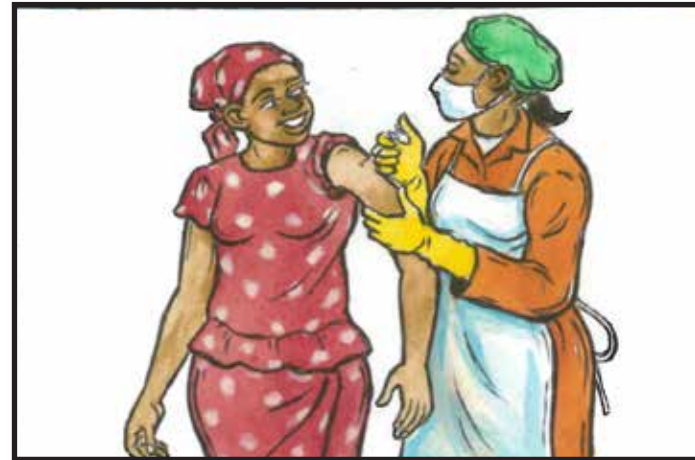


- If you choose to take part in this study, you will receive 2 marklates.
- The second marklate will be given 2 months after the first marklate.
- We give 2 marklates because other studies have shown that this might protect people from Ebola for a longer time.

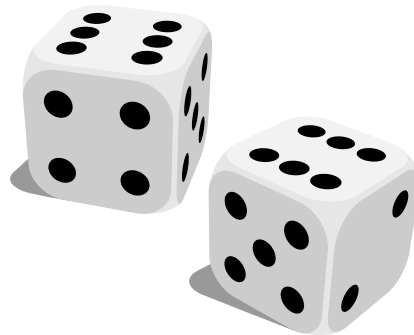
Not everybody will receive the same marklates.



OPTION 1



OPTION 2





# Not everybody will receive the same marklates.



OPTION 1

OPTION 2



- You will be randomly chosen (like a lottery) to receive either the study marklates or a marklate which we know protects people from meningitis. Meningitis is a serious illness that can cause infections of the brain and blood.
- Neither you or the study team will know which marklate you have received until the study has finished
- This is how we usually test new marklates as it is very important to compare people who have received the study marklates with people who have not.

We will ask you for a blood sample

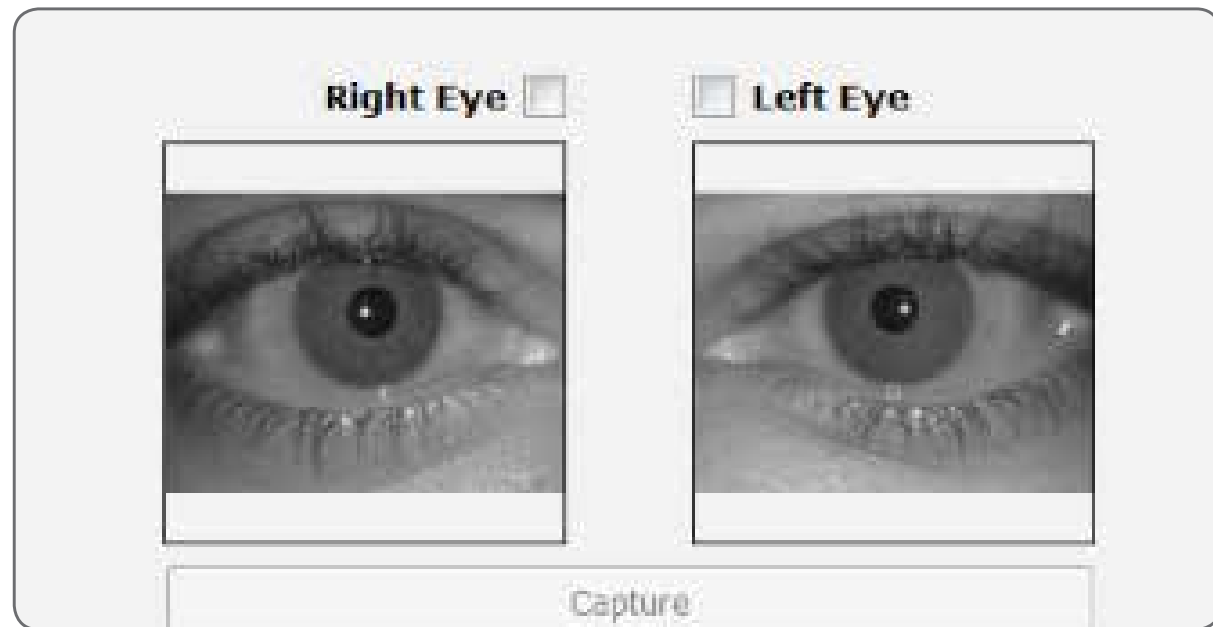


# We will ask you for a blood sample



- If you choose to take part in the study, we will need to take a small amount of blood from you.
- This will be done through placing a small needle into your arm.
- We need to do this to check that your liver and kidneys (two organs inside your body) are working normally.

We will ask for your finger prints  
and snapshot of your eyes



# We will ask for your finger prints and snapshot of your eyes



- If you choose to take part in the study, we will ask you for your fingerprints and we will take a picture of your eyes using a special machine. This is so that we know who you are when you come back for the second marklate. It is important to receive both doses of the marklate for the best chance of the marklate protecting you.
- Any of the information that we collect from you as part of the study will be made anonymous – this means that nobody outside the study team can see your name or personal details. This information will not be shared with anybody without asking you first. You are able to tell people that you are taking part in this study if you would like to.

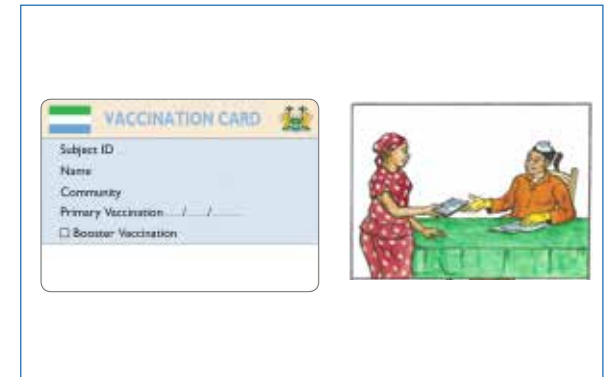


# End of screening visit



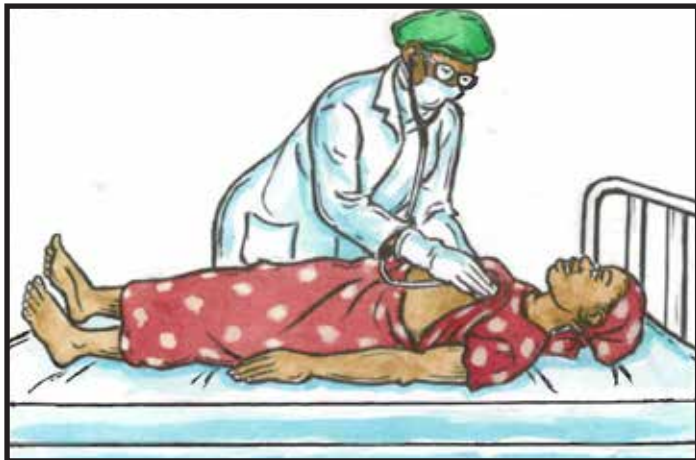
VACCINATION CARD	
Subject ID	
Name	
Community	
Primary Vaccination	...../...../.....
<input type="checkbox"/> Booster Vaccination	

# End of screening visit



- Once you have done all of these things, you will be able to go home. The study nurse or doctor will arrange for you to come back another day to get your results from screening and see if you are eligible to receive the first marklate.

# You will receive the first marklate



## You will receive the first marklate



- When you return for your next visit, the study nurse or doctor will give you your results from screening. If you are eligible, we will need to take another small blood sample from you. The study nurse or doctor will then give you the marklate in your arm.
- You will be looked after closely by study staff for up to 30 minutes after you receive the marklate to check that you are feeling OK.
- Once we know that you are feeling fine, a member of study staff will give you a symptom diary.



You will then go home



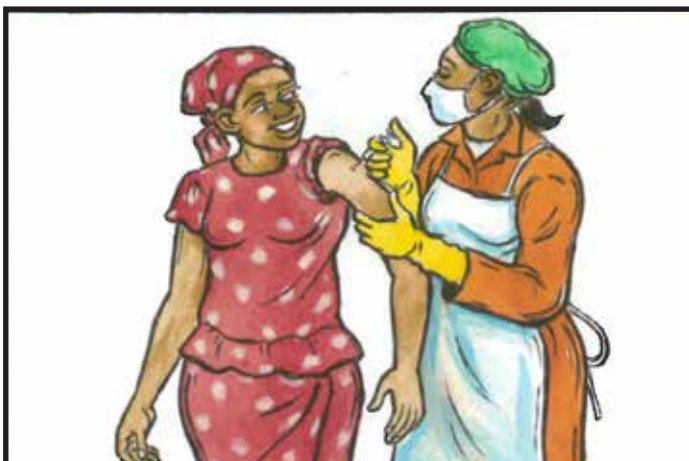
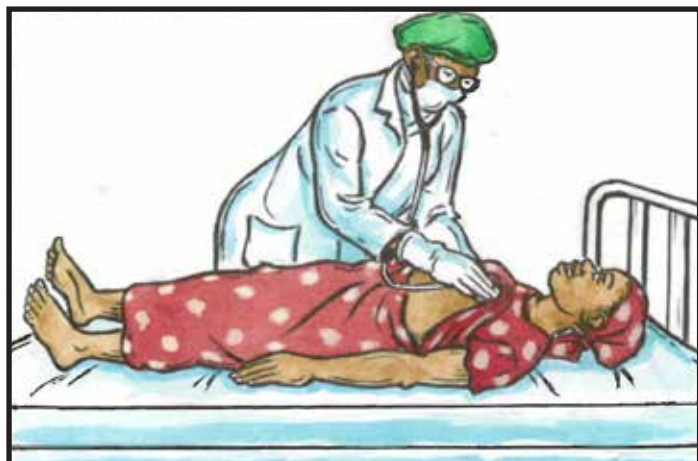
## You will then go home



- Somebody from the study team will come to your home every day for a week after having the marklate to help you fill out the symptom diary.
- This is to check how you feel each day and to make sure that everything is OK.
- If you have a mobile phone, you may also choose to receive voice messages or SMS reminding you to return for the second vaccination.



# You will receive the second marklate



## You will receive the second marklate

- 2 months after your first marklate, we will ask you to come back to the clinic for the second marklate. This will be exactly like your visit for the first marklate.

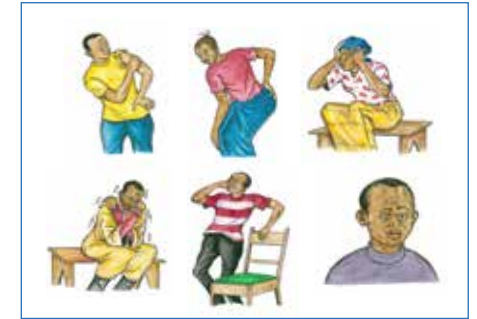


- When you come back for the second marklate, we will need to take a small amount of blood from you, the same as in your first visit.
- The study nurse or doctor will then give you the marklate in your arm. You will be looked after closely by study staff for up to 30 minutes after you receive the marklate to check that you are feeling OK.
- Once we know that you are feeling fine, a member of study staff will give you a symptom diary. Like with the first marklate, a field worker will come and visit you in your home for 7 days after you have received the marklate to make sure you are feeling well.

# What could be the side effects?



# What could be the side effects?



These study marklates could cause some common side-effects, just like you might have experienced after receiving other marklates for diseases like polio or measles. The study doctor will discuss the possible side-effects with you in more detail during individual consent, but they could include:

1. Sore arm
2. Muscle or joint pain
3. Feeling tired
4. Headache
5. Feeling sick
6. Fever



What do you do if you feel ill?



# What do you do if you feel ill?



- The marklates may cause other problems that we do not yet know about. If you feel unwell at all, you must call the number provided in the emergency card that will be provided to you.
- A study nurse or doctor will be available at any time of the day or the night to give you advice if you feel ill.



**You still need to protect yourself from Ebola**



# You still need to protect yourself from Ebola



## REMEMBER:

Until we complete the study

**WE DO NOT KNOW** if this marklate will protect you from Ebola.

Therefore, it is very important you continue to protect yourself and your family from Ebola by following the national Ebola prevention guidelines.

**Any questions?**



# Any Questions?



## ASK THE PARTICIPANT:

- Is there anything which is not clear to you?
- Do you have any questions or doubts that I can help you with today?

## THANK THE PARTICIPANT:

- Thank you for taking the time to talk with us about this marklate study. By taking part in this study, you are helping the study team know if this marklate could protect people from Ebola.



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