STUDY TITLE: - IGHID 12334 - After the Flood: Optimal Strategies to Prevent Malaria Epidemics Caused by Severe Flooding
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INFORMED CONSENT FORM
ADULT PARTICIPANT including on behalf of your child if your child is being asked to participate in the study.

Version / Date:	Version 2.0, Dated March 10, 2025
Study Title:	After the flood: Optimal strategies to prevent malaria epidemics caused by severe flooding
Regulatory Approvals:	MUST Research Ethics Committee #2024-1474 UNC Institutional Review Board # 24-0233
Principal Investigators:	Edgar Mulogo, PhD, MPH Associate Professor Department of Community Health Mbarara University of Science and Technology Ross Boyce, MD, MSc Assistant Professor Division of Infectious Diseases University of North Carolina School of Medicine
Funding Source:	National Institute of Allergy and Infectious Diseases (R01AI173558)

Introduction

What you should know about this study:

1. You are being asked to join a research study.
2. This consent form explains the research study and your part in the study.
3. Please read it carefully and take as much time as you need.
4. You are a volunteer. You can choose not to take part and if you join, you may quit at any time. There will be no penalty if you decide to quit the study.

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Concise Summary

The purpose of this study is to test different ways to prevent malaria infections after flooding. To accomplish this, we will assign villages to different control strategies and measure the number of malaria infections in each of the villages. Residents of all villages will receive new bed nets, but in some villages, residents will be provided with a monthly medication Dihydroartemisinin-piperaquine (DP) (a drug that is approved by the WHO and regulatory authorities and widely used in Africa for Malaria treatment. This dug is not approved by Food and Drug Administration (FDA) because it is not used in the US,) to prevent malaria, while others will also receive a treatment that can be placed into pools of water around the home to prevent mosquitoes from breeding there. We will monitor you and your household members for mosquitoes and malaria over a period of 12 months after the flooding This study is important because, similar approaches could be used to prevent malaria after floods, which is occurring more frequently.

If you agree to participate, we will collect information about you and your household members. We will collect a small amount of blood from any children 2 to 12 years old to test for malaria. Lastly, we will also survey the area in and around your house to look for mosquitoes. Because flooding is unpredictable, we may repeat some of these activities every few months until a flood event occurs. After flooding, we will return to provide the interventions, depending on the strategy to which your village was assigned. We will then follow-up after the flood to assess how much malaria is present in the village and how it has impacted you.

The greatest risks of this study are mild discomfort from blood draws and the unintentional sharing of your personal information. Children taking the medication to prevent malaria may also experience side effects, the most common of which are nausea and vomiting. We will do everything possible to prevent these things from happening. You will receive incentives for your participation. If you are interested in learning more, please read below.

Brief background to the study

Malaria, which is transmitted by mosquitoes that breed in pools of standing water, is responsible for hundreds of thousands of deaths each year, mostly among young children in sub-Saharan Africa. Global climate change is causing more frequent and severe storms, resulting in more flooding, which then can increase the amount of malaria for many months after the event. Understanding how to best prevent malaria after flooding in therefore very important.

Purpose of the research project

The purpose of this study is to test different ways, including combinations of methods, to prevent malaria infections after severe flooding. The study, which is led by researchers at the Mbarara University of

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Science and Technology and the University of North Carolina at Chapel Hill in the United States, is being conducted at two sites in the Kasese District. We plan to enroll residents from upwards of 60 villages. In total, we expect this will represent approximately 4,000 households or 36,000 residents. Results of the study will be reported in international medical journals and will help us develop better protections against malaria after flooding.

Who is sponsoring this study?

This research is funded by the National Institutes of Health in the United States. This means that the research team is being paid by the sponsor for doing the study. The researchers do not, however, have a direct financial interest with the sponsor or in the final results of the study.

Why you are being asked to participate?

You are being asked to participate in this study because you:

- Are at least 18 years of age.
- You may have a child that is 7 year or younger that you will be consenting on their behalf.
- Are residents of a flood-prone village in the Kasese district.

Are there any reasons you should not be in this study?

You should not be in the study if:

- This is not your primary residence (i.e., where you live for ≥ 6 months per year)
- You plan on moving out of the area in the next 12 months.
- You will have difficulty completing study activities

How long will your part in this study last?

Flooding is unpredictable. After today's visit is complete, we will wait for a severe flood event to happen. It is possible that this could take place soon, but it might also be a year or more from now. Once a flood does occur, we will distribute the various tools to prevent malaria to each participant and conduct regular follow-up visits for up to a year.

What will happen if you take part in the study?

If you agree to participate, we will ask you to complete some questionnaires today regarding you and your household members, and your household's experiences with malaria as well as past flood events. We will also survey the area in and around your house for mosquitoes. Lastly, we will measure any children's vital signs (e.g., height, weight, arm-circumference) and collect a small amount (less than a teaspoon) of blood

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by finger prick from any children between the ages of 2 and 12 years to measure blood counts and test for malaria. If a flooding event does not happen in the next 6-12 months, we may need to repeat the mosquito survey and malaria testing so that we have up-to-date information prior to any flooding.

Your household along with other households in the village will then be randomly assigned (like the flip of a coin) to receive one of three malaria control strategies after a flood. All households in a village will receive the same strategy. You nor the researchers will not be able to choose. You will have an equal chance to be in all groups. These are:

1. Distribution of new bed nets to ensure that there is at least one net for every two people.
2. Bed nets plus a long-acting malaria medication given to all children 2- 12 years of age each month for three months after the flood. This medication, called dihydroartemisinin piperaquine or DP, treats any infection and prevents future infections for up to a month. It is approved for this use.
3. Bed nets plus malaria medication plus a supply of granules that are placed into any standing water around your household. This larvicide, which is to be re-applied every few weeks, kills any young mosquitoes that are growing in the water. We will teach you how to apply it. You will sprinkle it in standing water around your house where mosquitos may live. You should not put it in any water that is used for drinking or bathing. It is safe for humans and animals.

We would deliver these after the water has receded and it is safe to travel, likely few weeks after the flooding. During that visit, we will ask you some questions about how your household was affected by flooding. We will also survey for mosquitoes and take a small amount of blood for malaria testing again.

We will repeat similar visits 2- and 3-months after the flood. The 3-month visit will be the last time that we provide medication and larvicide. We will, however, return again at 6- and 12-months after flooding to assess how the flooding has impacted your household and survey for mosquitoes and test for malaria. After the 12-month visit, your participation will be complete.

If we are unable to conduct the visits after the flood or if there is another flood, the medicine should prevent your child from getting ill for a month, but then after that, the medicine will not work, and your child may be able to get malaria. You should keep using the bed nets. We will try to conduct the visit as soon as possible. There is no harm to your child if they do not take the malaria medicine the three times.

If at any time during the study you or a member of your household develops symptoms concerning malaria such as fever or poor feeding, we will ask you to take an identification card showing that you are part of the study with you to the health facility. This will help us keep track of the number of malaria cases in your village during the study period. This will not affect the care you receive at the clinic or hospital.

We may ask to collect mosquitoes in and around your house. This involves putting a mosquito trap in your bedroom and another outside the house. We will collect the mosquitoes in the morning. For the best results, we ask to do this every few weeks while you are enrolled in the study. We only need to trap

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mosquitoes in a few households from each village, so you may not be asked to participate in this part of the study.

We will store any blood collected for a period of 10 years for future studies of malaria and other diseases that are made worse by flooding. There is a separate form that describes this process. We will review that form in a few minutes.

What will happen if you are injured by this research?

All research involves a chance that something bad might happen to you. If you are hurt, become sick, or develop a reaction from something that was done as part of this study, the researcher will help you get medical care, but the University of North Carolina at Chapel Hill and Mbarara University of Science and Technology has not set aside funds to pay you for any such injuries, illnesses or reactions, or for the related medical care. Any costs for medical expenses will be billed to you or your insurance company. You may be responsible for any co-payments and your insurance may not cover the costs of study-related injuries.

If you think you have been injured from taking part in this study, call the Principal Investigator at the phone number provided on this consent form. They will let you know what you should do.

What is the general schedule of study activities?

Each participant will be asked to participate in the following activities:

	Long Questionnaire	**Brief Questionnaire**	**Mosquito Survey**	**Vital Signs & Finger Prick***	**Distribute Interventions**	**Exit Questionnaire**
Before Flooding						
Initial Visit	X		X	X		
Update Visit(s)		X	X	X		
After Flooding						
1 Month Visit		X	X	X	X	
2 Month Visit		X	X	X	X	
3 Month Visit		X	X	X	X	
6 Month Visit		X	X	X		
12 Month Visit			X	X		X

**Only for children 2 to 12 years of age.*

How long will it all take?

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Because we want to learn more about you and your household members, the initial visit includes a detailed questionnaire that will likely take about 60 minutes of your time. The other elements, including the household and mosquito surveys and malaria testing will probably take another 30 minutes. Most of the future visits will be much shorter, generally around 30 minutes. We will do our best to be efficient and respectful of your time.

Risks or discomforts

There is a risk that this information collected about you could be shared with people outside of the study. However, we will do everything possible to prevent this, including keeping your name separate from the study information.

Some people may develop itching or a rash from your skin touching the larvicide.This is uncommon, but if your village is assigned to receive this, we will provide you with a pair of gloves to wear and you should wear these when touching the larvicide. You should also make sure children do not touch or eat it or drink the water where the larvicide was placed. If your skin or eyes become irritated, rinse with water for 20 minutes. If this does not help, you should go to your health facility.

If your village is assigned to receive the Dihydroartemisinin-piperaquine (DP) treatment drug you may experience nausea and vomiting after taking the initial dose. Your child should not take this medication if they have problems with their heart or it could cause the heart problems to get worse. If you have other side effects, you should go to your health facility.

Blood collection through a finger prick may cause mild discomfort and bleeding.

While we hope that this research study will reduce the risks of your child getting malaria, it may be upsetting and scary if your child is diagnosed with malaria.

Benefits

Research is designed to benefit society by gaining new knowledge. The benefits to you from being in this study may be a reduced risk of malaria infection from the items we will be providing to participants.

Will I receive any of the test results?

The results of any test that is performed on site will be communicated with you, including tests for malaria and anemia (i.e., blood counts). Some malaria tests require special equipment and will not be performed until after the study is complete. You will not receive these results.

Incentives or rewards for participating

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You will be eligible to receive incentives for your participation in the study. These include items that will benefit your household such as soap, sugar, or cooking oil. The type and amount of these items will vary based on local availability, but the value will generally be:

Event	Eligibility	Amount (UGX)
Initial Visit (today)	Visit Completed	20,000
Follow-up Visit (4)	Visit Completed	5,000
Final Visit	Visit Completed	10,000
POTENTIAL TOTAL		**50,000**

In addition, if we ask to perform overnight mosquito collections in your house, we will provide additional in-kind incentives valued at approximately 5,000 UGX for each night of collection.

Participating children undergoing any examination, blood draw, or medication administration will also receive an in-kind incentive such as a juice, biscuit, or similar item.

Protecting data confidentiality

All study interactions are private and information about you cannot be disclosed to anyone outside of the study team. Your name will only be listed on this consent form and the enrollment form. For all other documents and samples, we will use a unique number to identify you. Only study team members will have access to the link between your name and the number. Absolute confidentiality cannot be guaranteed because of the need to give information that identifies you to these regulatory agencies. Your information may be given to the following groups for the purpose of studying the results and/or to see if the study was done right:

- Sponsor or the sponsor's representatives
- The United States Food and Drug Administration (FDA)
- Governmental agencies in other countries, and
- MUST Research Ethics Committee and UNC Institution Review Board

We will keep your records secure using a password-protected electronic database. Approximately five years after the study is complete, all information linking your name to the responses will be destroyed. Participants will not be identified in any report or publication about this study. We may use de-identified data and/or specimens from this study in future research without additional consent.

Protecting subject privacy during data collection

All study activities will take place in the privacy of your home, unless you prefer another nearby location.

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Your coded data will be used only for as long as it is needed for the study. It may be kept for longer, where required by law. The researcher does not have plans to use your data for profit.

A description of this clinical trial will be available on www.clinicaltrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

What is a Certificate of Confidentiality?

Most people outside the research team will not see your name on your research information. This includes people who try to get your information using a court order in the United States. One exception is if you agree that we can give out research information with your name on it or for research projects that have been approved under applicable rules. Other exceptions are for information that is required to be reported under law, such as information about child or disabled abuse or neglect or certain harmful diseases that can be spread from one person to another. Personnel of a government agency sponsoring the study may also be provided with information about your involvement in the research study.

How will the study team communicate with me?

The study team will schedule visits ahead of time. We will communicate the dates of study visits to your Village Health Team but would like to be able to send you reminders and notifications by text message. However, you may say "no" to receiving these messages and still participate in this study. If you say "yes", messages may contain personal information about you and may be sent or received by the study team's personal electronic devices or in a method that is not able to be protected and there is the risk your information could be shared beyond you and the study team.

If you wish to stop receiving text communication from the study team or have lost access to your device, please notify the study team using the study contact information on the last page of this consent form. After the study is complete and all research activities finished, or you withdraw from the study or request to stop receiving unprotected communication, you will no longer receive messages.

Yes, I consent to the study team utilizing the following mobile phone number(s) to send communications:

- Phone 1:
- Phone 2:

No, I do not consent to receive un-protected communication from the study team.

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Right to refuse or withdraw

You can withdraw from this study at any time, without penalty. The investigators also have the right to stop your participation at any time. This could be because you have had an unexpected reaction, or have failed to follow instructions, or because the entire study has been stopped.

What happens if you leave the study?

If you withdraw or are withdrawn from this study all data collected up until the point of withdrawal will be retained, however no additional information will be collected unless you provide additional written permission for further data collection at the time of your withdrawal.

Who do I ask/call if I have questions or a problem?

Assoc. Prof. Paul Alele
Chairman, MUST-REC
P.O. Box 1410 Mbarara
Tel: 0485433795/0773573372

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What does your signature or thumbprint on this consent form mean?

Your signature on this form means

- You have been informed about this study's purpose, procedures, possible benefits and risks
- You have been given the chance to ask questions before you sign
- You have voluntarily agreed to be in this study

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Name of adult participant	Signature/Thumbprint of participant/ Parent/Guardian/Next of Kin	Date
_ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _	_ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _	_ _ _ _ _ _ _ _ _ _ _ _
Name of person obtaining consent	Signature	Date
_ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _	_ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _	_ _ _ _ _ _ _ _ _ _ _ _
Print Name of witness	Signature or thumbprint or mark	Date

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