Title: Evaluation of Vector and Chemoprevention-based Interventions to Reduce Malaria Burden in Urban Daaras of Touba, Senegal

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PARTICIPANT INFORMATION SHEET AND INFORMED CONSENT FORM

Study Title: Evaluation of a package of interventions to reduce the burden of malaria in the urban daaras of Touba, Senegal

Funder	PATH
Collaborating Institutions	Université Iba Der Thiam de Thiès (UIDT) University of California, San Francisco (UCSF) PATH
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The funding for this study is provided by PATH. PATH is a non-profit organization that supports health programs and health research. The University Iba Der Thiam de Thies will be leading this research study in daaras in Touba city, Senegal.

1. We are asking you/your child to be in a research study.

We invite you/your child to take part in a study on malaria in your daara. Malaria is one of the leading causes of death in Senegal. Studies in Senegal have shown that talibés living in daaras are highly vulnerable to malaria. Health authorities are looking for solutions to this problem. Iba Der Thiam University in Thiès, in collaboration with PATH and the University of California at San Francisco, is conducting this study.

This study will test whether a new health program can prevent malaria in children in daaras. The new health program will be implemented in some daaras and not others. The new health program has several parts. First, children in daaras with the new health program will be given a large insecticide-treated mosquito net that covers many children sleeping together. Second, all children in daaras with the new health program will be given a medicine to treat and prevent malaria during the time of year when malaria is the most intense. Finally, children in daaras with the new health program will participate in health education talks. These talks will help children understand how to prevent and treat malaria.

The new health program will be implemented in only half of the daaras included in the study. In half of the study daaras, children will participate in the standard health program implemented by the Ministry of Health. The standard health program includes standard insecticide-treated mosquito nets. The standard program also includes children taking a malaria medicine over three days each month for three months. However, the standard health program gives the malaria medicine to children aged 3 months to 10 years. The new health program will give the malaria medicine to all children who are 3 months or older. The standard health program uses the medicine SP/AQ. The new health program uses the medicine DHA/PQ.

We are asking you/your child to be in the study because your child studies in a daara in Touba City, Senegal. We plan to enroll about 70 daaras. There will be about 4200 talibés studying in these daaras.

This form explains what will happen in this study. We will tell you the risks and benefits of you /your child being in the study. Take your time to decide if joining the study is right for you/your child. If it helps, talk to people you trust. Ask questions about anything that is not clear. If you decide for you/ your child to join, you will sign or make your thumbprint on this form. We will give you a copy to keep.

2. Here are important points about this study:

- You/your child does not have to be in the study. You can say "yes" or "no" or you/your child may leave after joining. If you say "no" or you/your child drops out, we will treat you/your child the same.
- You/your child may or may not be in a daara that participates in the new health program. You/your child may be in a daara that says with the standard health program.
- If you agree to join/ for your child to join, you/your child will be in the study for 14 months. You/your child may be visited several times. The visits will last from 1-2 hours.
- If you/your child is in a daara that participates in the new health program, you/your child will be included in these activities:
    - Sleeping under a large insecticide-treated mosquito net that can cover many children who share the same sleeping area
    - Taking a malaria medicine (DHA/PQ) over three days each month for three months during the time when malaria is most intense
    - Health education talks
- The study will count the number of children who get sick from malaria in the daaras with the new health program. The study will also count the number of children who get sick from malaria in the daaras with the standard health program. We will then compare these numbers. Then we will know if the new health program is better or not.
- To compare the number of children who get sick from malaria, records from the community health workers in each daara will be collected. Additionally, records of sick children from daaras who are tested and treated for malaria at local health centers will be collected.
- At the beginning and end of the study, we will select some children to participate in a special survey. If you/your child is selected for the special survey, we will collect a small amount of blood to test your child for malaria. We will also ask you/your child questions.
- All research studies have risks. Children in the daaras with the new health program may feel minor side effects from the medicine (diarrhoea, vomiting or fever).
- What we learn from the study may help other children in daaras in the future.
- There are no costs or compensation for you/your child to be in the study.
- We will keep your/your child's information confidential to the extent allowed by law.

3. What do we want to learn in this study?

We want to know whether a new health program can reduce the amount of malaria in daaras. The new health program includes a large insecticide-treated mosquito net ("meganet) that covers many children sleeping together. The new health program also includes taking a malaria medicine (DHA/PQ) over three days each month for three months during the time of year when malaria is most intense. The new health program also includes health talks.

We will select 70 daaras in Touba City. The new health program will be carried out in half of the daaras. We will select 35 daaras for the new health program by flipping a coin. In the other daaras, the national malaria control program in Senegal will continue their standard health program.

At the end of the project, we want to know if the new health program is easy to implement. We want to know if the new health program is acceptable to the community. We want to know if the new health program can prevent malaria. We also want to know how much this new health program costs compared to the standard health program.

4. Will this study help your child?

Being in this study may or may not help you/your child. Your/your child's participation will be beneficial for the whole community. The results of this study will help the Senegal Ministry of Health decide how to prevent malaria in daaras in Senegal.

5. How will you find out if your child can be in the study?

All talibés who wish to take part in the study are welcome to do so. Children who have an allergy to the medicines used may not take medicines for malaria when they are given during the malaria season. If your child is aged between 12 and 17, your child must also sign a paper saying they agree to join the study. If you/your child does not wish to join the study, your child will continue to receive the standard health program. If you/your child does not wish to join the study, you/your child's health care will not be affected.

6. If my child is in a daara selected for the new health program what will happen during the study?

We will record the names of all the daara's residents. We will also record their sleeping arrangements. We will consult with the daara community to determine how many "meganets" are needed. We will hold communication sessions with all the members of the daara. We will try and identify ways of fighting malaria more effectively. If you agree, the discussion will be recorded on a dictaphone so as not to modify or misinterpret your words. To protect your identity, this will be done without mentioning any information that could identify you or your child (last name, first name, etc.)

During the months of July, August and September, you/your child will join a group of participants of around 10 individuals who will be asked questions. Eligible individuals will receive malaria medicines. This medicine is called dihydroartemisin-piperaquine (DHA-PQ). DHA-PQ has no serious side effects. It is already used in Senegal to treat malaria. The malaria medicines will be given during the winter period. We will give the medicine over three months in a row. In each month, one treatment cycle will be given. Each cycle takes place over 3 days in a row. At the time we give medicine, we will ask for your consent again to make sure it hasn't changed in the meantime.

At two times at the beginning and end of the study, we will choose 2,450 individuals from 70 daaras to see how well the new health program is working. This evaluation will include a questionnaire and a malaria diagnostic test. One to four drops of blood will be taken from the fingertip to see if you have malaria. We will tell you the results of these tests. If your results show that you/your child may have malaria, we will refer you/your child for proper treatment. At the time of collection, we will ask for your consent again to make sure it hasn't changed.

7. Will you learn the results of the study?

We will share the overall results of the study with your community. You/your child will be told if you/your child has malaria.

8. What are the risks of this study?

Blood sampling by finger prick may cause slight pain and bruising. It is very unlikely, but sometimes taking blood can cause an infection.

Taking the DHAPQ drug may cause minor side effects such as diarrhoea, vomiting or fever, which disappear very quickly.

There are no other risks associated with your/your child's participation in this study. If we learn new information during the study that might affect your decision to stay in the study, we will tell you about it.

9. What will happen if you are hurt?

In the case of an adverse event linked to the use of the drug, the project, in conjunction with the PNLP, will cover all expenses related to the adverse event.

10. Confidentiality and handling of personal information

All the information you provide will be confidential. Your name or your child's name will not appear on any survey document. This data will be identified by a unique number. Your/your child's data will not be used outside of this study and by anyone outside the research team. The data we collect in this study will be shared with the funder. It may be made open to the public so that others can learn from it. If data are shared publicly, they will not be linked to you personally. You can ask for your/your child's information to be removed from the database at any time.

11. Using your samples for future research

We are asking to store blood samples for use in future malaria research. If you agree, your/your child's samples may be stored and used for 10 years.

You can say "yes" now and change your mind later, and we will destroy any extra samples and in our storage. We cannot destroy samples that are already used or that have your code number removed.

If you say yes, we will store the samples in a secure place at the University of Thies. The samples and information will be labeled with a study number, not with your name. When we share your sample for future research, we will do this in a way that other researchers will not be able to identify you/your child.

12. Will you be paid for being in this study?

You will not be paid for participating in the study. We will reimburse you for any costs incurred because of adverse drug reactions.

13. Are there any costs to you if you join the study?

There are no costs if you/your child joins the study.

14. What to do if you want to leave the study?

You/your child may stop participating at any time, without giving a reason, simply by telling the study team.

15. Your rights

You have rights in this study:

- Take time to think before deciding whether to participate in this study.
- You/your child does not have to be in this study. You can say yes or no to joining. You can leave the study at any time. If you do not join or you leave early, there will not be any penalties. You should not feel pressure to join or stay in the study.
- You may stop participating at any time, without giving a reason.
- By signing this consent form, you do not lose any rights you normally have.
- If we learn new information about the study, we will tell you.
- We will inform you of the overall study results.
- You may oppose the transmission of your/your child's personal data, and check or correct the data.

16. Who to contact if you have questions.

If you would like further information about the study, please contact:

Prof. Jean L Abdourahim Ndiaye, Université Iba Der Thiam de Thiès
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or Dr Samba Cor Sarr (CNERS) tel: 77361 42 13

This study has been reviewed and approved by Senegal's National Ethics Committee for Health Research Comité (CNERS), which ensures that participants in the study are protected from unnecessary harm.

CONSENT FORM FOR PARENTS OR GUARDIANS (OF CHILDREN)

Participant identity	
Participant name	

By signing below, I voluntarily agree to the following:

- To my/my child's participation in this study.
- I confirm that I have received the informed consent form version xx of 10/2/2023. The information was presented to me in a language I understand.
- I have had the opportunity to ask all the questions I wished about the nature, objectives, and constraints of my/my child's participation in this study.
- I have had sufficient time for reflection between information and consent.
- **I understand** the constraints involved in taking part in this study**.**
- **I understand** that I am free to interrupt my/my child's participation in this study at any time without having to explain why, simply by informing the interviewer.
- **I agree** that the data collected during this study may be processed and computerized, analyzed and used within the framework of this research.
- **I agree** that the researchers involved in this study and persons mandated by health researchers in Senegal and abroad may have access to the information in the strictest respect of confidentiality.
- My consent in no way relieves the study organizers of their responsibilities. I retain all rights guaranteed by law.
- At the end of the study, **I will be informed** of the overall results by the research correspondent.

I further indicate that (tick as applicable):

I/my child can provide a blood sample for malaria testing. I/my child may also be asked questions.	Yes	No
Blood samples provided by me/my child can be stored for up to 10 years and used for future malaria research not described in this form.	Yes	No
I/my child may receive the DHAPQ drug during the peak malaria season, which will include three cycles lasting three days each, one month apart. I/my child may sleep under an insecticide treated net and participate in health education talks.	Yes	No
I/my child may take part in a focus group or an in-depth individual interview if the research team invites me/my child to do so.	Yes	No

_____
Name of participant **OR** guardian if under 18

_____
Signature (or other mark if unable to sign)

_____
Date

Witness

As a witness, I confirm that all information regarding the study has been accurately given and that the parent/guardian has given consent for his/her child/ward to participate in the study.

_____ _____
Name of witness Date

_____
Signature

For study team members

I, _____confirm that I have explained the nature of this study to _____. He/she understood what I was explaining, was able to ask me questions and freely consented to his/her child/pupil taking part in the study.

_____
Printed name

_____ _____
Signature of study team member Date