

STI Knowledge and HPV Vaccine Acceptance in Bamako, Mali

March 18, 2011

Knowledge, Attitudes and Practices Study related to HPV and cervical cancer and Willingness to Participate in an HPV vaccine trial in the region of Bamako, Mali, West Africa



AMENDEMENT TO THE STUDY PROTOCOL # 11051 APPROVED BY IRC on March 18th 2011

In March-April 2011, the GAIA Vaccine Foundation did a pilot study in Sikoro, Mali West Africa. A team of interviewers, led by Dr. Tounkara Karamoko and Danielle Poole, completed 50 interviews to better understand the knowledge and views of participants on vaccination and the link between HPV, cervical cancer, and mortality.

This pilot study is currently in the analysis process and we found that gathering and analyzing data from four different questionnaires is very difficult. We want to compile all the questionnaires (Men - Women - Adolescent girls - Adolescent boys) in one single document using skip patterns. The content of the questionnaire remains the same.

We also want to add a site to this study and have interviewers submit this questionnaire in an additional village named Djikoro also located near Bamako. Adding this site will allow us to get a better sense of people's knowledge, attitude, and practice related to HPV and cervical cancer in the region of Bamako.

Below is the exact same protocol for the proposed study entitled "Knowledge, Attitudes and Practices Study related to HPV and cervical cancer and Willingness to participate in an HPV vaccine trial in the region of Bamako, Mali, West Africa". Two major modifications were made: (1) Djikoro is listed as an additional site and (2) one single questionnaire is attached.

I. OBJECTIVES OF THE PILOT STUDY AMENDMENT PROPOSED IN JULY 2010

In Mali, the estimated 1,336 women who are diagnosed with cervical cancer each year face a mortality rate of over 80%. Yet among Malian women ages 16 to 69, only 4.8% are tested for the disease. The high death rate and low percentage of women tested can be attributed to a lack of information about cervical cancer.

In July 2010, the Global Alliance to Immunize Against AIDS Vaccine Foundation (GAIA VF) carried out a study in the community of Sikoro-Mékin to determine the level of knowledge, attitudes, and practices (KAP study) related to HPV, cervical cancer, STIs, vaccines, and appropriate health services in these areas. A questionnaire was distributed to 318 members of the community (67 men, 142 women, 29 adolescent boys, 74 adolescent girls, and 6 people not specified) at the CSCOM in Sikoro. After filling out this first questionnaire, each person surveyed attended an information and education session about the topics in the table below. Participants then filled out the same questionnaire in order to measure the knowledge they had gained from the information-education session and to determine if their opinions had changed. The results are in the following table:

	<i>% before information session</i>	<i>% after information session</i>
Participants who knew of the existence of cervical cancer	46.1 %	84.7 %
Participants who knew that cervical cancer testing is free	30.9 %	60.9 %
Participants who could identify at least one symptom of cervical cancer	20.2 %	41.3 %
Participants who could identify at least one cause of cervical cancer	18.1 %	58.4 %

Furthermore, 97.5% of participants indicated after the information session that they would be in favor of an HPV vaccine trial. These results indicate that the residents of Sikoro were very receptive to the information sessions.

Yet this study revealed that in general there is a great deal of confusion between HPV and cervical cancer, and that the relationship between the two is not well established. The study

also showed us that certain questions in the questionnaire either were not appropriate or were not sufficiently clear.

Thus we would like to repeat this study in order to disseminate more information about HPV and cervical cancer in the community of Sikoro. We would like to modify our approach so as to better sensitize the residents to these subjects and to reinforce their knowledge. In order to do this, we propose an amendment to the pilot study conducted this summer. The main modifications concern:

- *The questionnaire*: Certain questions will be reformulated and clarified. We would also like to collect more information about willingness to participate in a vaccine trial.
- *Approaching the community and education sessions*: During the pilot study, the information sessions were done in groups of 20 to 40 people. We would like to improve both outreach and the quality of the information collected by:
 - (1) Reducing the size of the groups.
 - (2) Contacting and informing people individually by going door to door.
 - (3) Proposing information sessions in schools.
- *The duration of the study*: We would like to conduct this study over a period of 12 to 18 months (March 2011 – September 2012).

We believe that spreading information about HPV and cervical cancer will both increase the number of people being tested and increase acceptance of an HPV vaccine trial.

II. INTRODUCTION

Cervical cancer is the second most common cancer found in women globally. Though incidence and mortality rates have dropped appreciably in developed countries, cervical cancer is still the most common type of cancer among women in sub-Saharan Africa and is the main cause of cancer deaths among women in developing countries. Notably, 83% of all new cases of cervical cancer diagnosed each year and 85% of all deaths from the disease occur in developing countries.

Each year in Mali, an estimated 1,336 women are diagnosed with cervical cancer and 1,076 women succumb to the disease, resulting in an 80% mortality rate. Among the 16 countries of West Africa, Mali has the second highest rate of cervical cancer; in Mali alone, cervical cancer has the highest incidence rate of all cancers affecting women. Over half of these cancer cases are the result of an infection with HPV types 16 and 18. In Mali, the average age when people first begin a sexual relationship—and thus first risk contracting HPV—is 15 years old. Yet among women between the ages of 16 and 19, only 4.8% are tested for cervical cancer.

Just four years ago, the first human HPV vaccine was approved by American medical services. In the past four years, thousands of young women in Europe and the United States have been vaccinated against four strains of HPV. Two of these strains are responsible for 70% of cervical cancers, and the two others for 90% of genital warts.

In Mali, this disease is not well understood: the mortality rate remains very high, and methods to prevent and treat cervical cancer are still largely insufficient. Even the World Health Organization is currently debating how to collect necessary data for adopting vaccines in developing countries. It is urgent that an information and communication strategy be developed to confront this disease.

British studies¹ have shown that the individuals selected to receive the HPV vaccine are not interested in the scientific link between HPV and cervical cancer. The relationship between HPV or an abnormal Pap smear and cancer was too technical, and consequently was difficult to understand. This study thus concluded that the important message to emphasize was: “This vaccine prevents cervical cancer.” People were subsequently more inclined to accept the vaccine. In Great Britain, young girls were the target population for vaccination, even though adolescent boys and young men transmit the HPV virus to girls. Moreover, the vaccine protects against genital warts and cancers associated with HPV, both of which can affect men. It is for these reasons that it is also important to vaccinate boys. Thus in most countries, both boys and girls are now vaccinated against HPV.

In conducting this study, we hope to measure the level of knowledge in the population of Sikoro and Djikoro and to inform the community about HPV and cervical cancer. The data analysis and conclusions of this study will subsequently permit us to measure willingness to participate in a vaccine trial with Gardasil, which is already used in Europe and in the United States, in the hope that it would be distributed in Mali in the long run.

III. INTRODUCTION TO GAIA

The Global Alliance to Immunize Against AIDS Vaccine Foundation (GAIA VF) is a humanitarian organization based in Rhode Island that works in Bamako, Mali and in Providence, Rhode Island since 2002. Our mission is to promote HIV prevention while working for the development of a global vaccine that would be distributed on a not-for-profit basis in developing countries. The activities of GAIA VF are organized around four main themes: education, prevention, access to care, and vaccines. In collaborating with West African doctors and supporting clinical activities in the field of HIV, we strive to improve the health of children and their families while addressing the ethical aspects of a vaccine trial.

WHY IS GAIA PROPOSING TO CONDUCT THIS STUDY?

GAIA is focused on laying the groundwork for future vaccine trials in Mali. The GAIA vaccine against HIV is still in the development phase, but in the meantime, we hope to reinforce preparations currently in place, from the scientific approach to the aspects of prevention and education.

Dr. Tounkara Karamoko – Executive Director of GAIA VF – conducted a KAP study on HIV in 2008, which found that 78% of participants would be willing to participate in an HIV vaccine trial. This study allowed us to put our HIV prevention and education programs in place and to establish a relationship of trust between the medical personnel at the clinic and the population of Mekin-Sikoro.

The study that we are now proposing to conduct will allow us to measure the level of knowledge of the population of Sikoro and Djikoro, put in place an education program focusing on HPV and cervical cancer, and train our personnel. The data collected on willingness to participate in a vaccine trial will allow us to elaborate on an appropriate approach for establishing a vaccine trial.

Finally, we convey the data collected and analyzed to the MERCK laboratories – maker of Gardasil – in the hope that a vaccine will be introduced in the coming years.

¹ Bureau d'Immunisation de la Grande Bretagne (Bureau qui supervise les vaccins)

IV. GENERAL OBJECTIVES

- (1) Measure the level of knowledge of cervical cancer and HPV among the population of Mékin-Sikoro and Djikoro.
- (2) Measure the willingness to participate in an HPV vaccine trial.
- (3) Educate and inform the population of Sikoro and Djikoro.
- (4) Train GAIA VF personnel.

V. SPECIFIC OBJECTIVES

(1) Measure the level of knowledge of cervical cancer and HPV among the population of Mékin-Sikoro and Djikoro.

(2) Measure the willingness to participate in an HPV vaccine trial.

- We want to gather KAP data that will allow us to measure:

(A) Knowledge related to cervical cancer:

- (a) Places where one can be tested and receive care in Mali
- (b) Causes of cervical cancer
- (c) Symptoms of cervical cancer
- (d) How the disease is contracted
- (e) The link between HPV and cervical cancer

(B) Knowledge related to HPV:

- (a) How the virus is contracted
- (b) Symptoms of HPV
- (c) Prevention methods
- (d) Places where one can be tested and receive care in Mali
- (e) The link between HPV and cervical cancer

(C) The willingness to participate in an HPV vaccine trial:

- (a) Know the reasons of those in favor of participating in a vaccine trial
- (b) Know the reasons of those not in favor of participating in a vaccine trial
- (c) Evaluate the best way of contacting the public
- (d) Know who will give consent for receiving the vaccine

(D) The framework needed in place for a vaccine trial :

- (a) Know where people would prefer to be vaccinated (schools, clinics, other)
- (b) Know the cost people would be willing to pay to receive the vaccine

(3) Educate and inform the population of Sikoro and Djikoro.

The study that we are proposing to do will be conducted over a period of 12 to 18 months. This extended period of time will allow us to put in place a cervical cancer education program. As indicated before, the June 2010 pilot study revealed that the link between HPV and cancer was not evident among our study population. Therefore we will strive to clarify this point.

Other than the modes of transmission and the symptoms, we will emphasize methods of prevention and places where one can be tested in the Bamako region.

(4) Train GAIA VF personnel.

The GAIA personnel will be trained so they will be capable of disseminating information about cervical cancer and HPV.

VI. KEY PERSONNEL

(1) Principal Investigators in Mali:

Ousmane Koita, PhD: Head of the Laboratory of Applied Molecular Biology, Department of Biology, Faculty of Sciences and Techniques, University of Bamako, Bamako, MALI

Karamoko Tounkara, MD: Director of GAIA in Mali

(2) Principal Investigator in the United States:

Anne De Groot, MD: Lecturer at the Brown University Medical School and at the University of Rhode Island; researcher and scientific director of GAIA VF.

(3) Co-Investigators :

Danielle Poole: Brown University, United States

(4) Consultants:

Kate Tracy : Professor – University of Maryland

Dr Samba Sow: Centre pour le Developpement du Vaccin Bamako Mali

Flabou Bougoudogo, PhD: INRSP, Bamako, Mali

Yssouf Kone, MD: Head doctor of the CSCOM in Sikoro

Tembely Fanta, MD: CSCOM de Sikoro

Rokia: Vice president of the l'ASSACO

Badialo: Person in charge of the CAFO

(5) Other participants:

Peer Educators

Community leaders of Sikoro-Mékin and Djikoro

Translators (if necessary)

Mali Rochas: Management and finance (United States)

Lauren Levitz: Translation – Literature review (United States)

PERCENTAGE OF PARTICIPANTS' INVOLVEMENT

Principal Investigator:

Karamoko Tounkara, MD

50%

GAIA Mali director

Ousmane Koita, MD

25%

Co-investigators:

- Anne de Groot, MD

20%

Student Investigators:

Danielle Poole

80%

Study and training

Mamadou Daou

30%

Translator

Consultants:

- Fanta Siby

20%

- Dr Moussa Hama Sankare

25%

- Flabou Bougoudogo, PhD, INRSP, Bamako, Mali

25%

- Kate Tracy

25%

- Samba Sow

25%

CSCOM Personnel Involved:

Kone Yssouf, MD	15%	Head doctor
Tembely Fanta, MD	15%	Doctor
Peer Educators (12)	50%	Peer Educators

VII. METHODOLOGIE

(1) Recruitment and getting in contact with the population

We plan to contact the inhabitants of Sikoro and Djikoro with the help of community leaders and peer educators.

(2) Sample size

We want to interview around 300 people total, from ages 12 to 50. These 300 people (150 per study site) will be interviewed twice: with a first questionnaire, and then again with an identical questionnaire following the information and education session. This study population must be representative of the following categories: men, women, adolescent boys, and adolescent girls.

- Questionnaire(s)

Two questionnaires will be given. The participant will be given the first questionnaire, which will be followed by an information and education session. This will be followed by a second, identical questionnaire that will permit us to measure information retention and comprehension from the information session.

- Education

The information and education sessions will take place after the first questionnaire, and will be followed by a second questionnaire to measure what was learned.

As indicated before, the information sessions will be conducted either in small groups or individually in order to improve the quality of information provided, as well as the contact and communication with the person being surveyed.

Study period: The study will take place from March 2011 to march 2012. Data analysis is planned to take place from March 2012 to September 2012.

Study location: The study will take place in Mékin-Sikoro and Djikoro, two peri-urban communities located in the neighborhood of Bamako.

Benefits:

For the NGO: Measure the level of knowledge among the population of cervical cancer and evaluate the degree to which an HPV vaccine trial would be accepted.

For the patients: Inform and sensitize the inhabitants of Mékin-Sikoro and Djikoro about cervical cancer and the possibility of a vaccine.

Risks: The study population will be comprised of adolescents. This will require either the presence of parents or parental agreement to allow minors to respond to the questionnaire.

Ethical considerations: The current study protocol will be submitted to the FMPOS committee in order to detect any human rights anomalies in form or content.

We will conduct a study (see the attached questionnaires). Before participating in this study, participants will complete a one-page consent form in French or in Bambara, which will define the objectives of this study. Participants will be informed of the fact that the study is anonymous and that they do not have to give their name other than their signature on the consent form, which is separate from the study. The consent form will be read out loud to participants, and careful attention will be paid while reading the consent form to illiterate participants. A literate companion can verify the document if a participant wishes. For all participants, a good understanding of consent will be established by checking off answers to questions at the end of the form.

Confidentiality: The confidentiality of participants will be respected. We plan to collect and link information using a coding system.

Compensation:

Compensation for participating in the questionnaire: 2,000 CFA

Data collection and analysis: Data collected from the questionnaires will be assembled into tables and analyzed. All the information will be kept at GAIA headquarters and will remain confidential.

VIII. CONCLUSION

HPV has been identified as a cause of cervical cancer, of pre-cancer, of benign cervical lesions, and of genital warts.

Setting up a simple test in certain European countries and in the United States resulted in an 80% reduction in the incidence and mortality of cervical, much more than the vaccine and for a much lower cost.

This study underlines the importance of adopting an information and communication strategy in order to give children of developing countries a chance against this disease.

Finally, we hope that the collection and analysis of KAP data from this study will be used for the goal of promoting the introduction of the Gardasil vaccine in Mali.

Bibliographic References:

1. Steben M, Louchini R and Duarte-Franco E. High risk of anal cancer in individuals treated for anal condyloma in a population-based transversal study in Quebec (Canada), 1990-1999. In: Program and abstracts of the *18th International Society for Sexually Transmitted Disease Research*, June 28– July 1, 2009. London, UK.
2. Palefsky J, for the male quadrivalent HPV vaccine efficacy trial team. Efficacy of Gardasil in men aged 16-26 years naïve to vaccine HPV types at baseline: the latest data. In: Program and abstracts of the *European Research Organization on Genital Infection and Neoplasia*, 17-20 February 2010, Monte Carlo, Monaco. Abstract TC 4-2.
3. Palefsky J, for the male quadrivalent HPV vaccine efficacy trial team. Quadrivalent HPV vaccine efficacy against anal intraepithelial neoplasia in men having sex with men. In: Program and abstracts of the *European Research Organization on Genital Infection and Neoplasia*, 17-20 February 2010, Monte Carlo, Monaco. Abstract SS 19-2.
4. Wilkin T, Lee J, Goldstone S, et al. Safety and immunogenicity of the quadrivalent HPV vaccine in HIV-infected men: primary results of the AIDS Malignancy Consortium Trial 052. In: Program and abstracts of the *17th Conference on Retroviruses and Opportunistic Infections*, 16-19 February 2010, San Francisco, U.S. Abstract 1015.
5. Smith JS, Moses S, Hudgens MG, et al. Increased risk of HIV acquisition among Kenyan men with human papillomavirus infection. *Journal of Infectious Diseases*. 2010 Jun 1;201(11):1677-85.

CONSENT FORM

Adult

Study title: Knowledge, Attitudes and Practices Study related to HPV and cervical cancer and Willingness to Participate in an HPV vaccine trial in the region of Bamako, Mali, West Africa

Institution name: GAIA Foundation, Hippodrome, Rue 224 Porte 1803 Bamako Mali

Principal Investigator: Dr. Karamoko Tounkara
Tel: 76495886
Email: tounkara.karamoko@gmail.com

What are the implications of participating in this study?

Your participation in this study is voluntary and anonymous. No one other than the principal investigators will have access to your information. You are not obligated to participate in this study.

In signing your consent, you give us permission to use your responses for the collection, analysis, and processing of data in writing and publishing medical articles.

Risks of your participation: The risks linked to your participation in this questionnaire are minor. You are not obliged to respond to every question.

The benefits of your participation are the following:

Your responses and opinions will allow us to evaluate Knowledge, Attitudes, and Practices on the subject of cervical cancer, as well as willingness to participate in an HPV vaccine trial in the region of Bamako.

For all questions or complaints, please contact the principal investigator, Dr. Tounkara Karamoko (Tel: 76495886). You may also contact the president of the FMPOS Ethical Committee at Point G, Bamako (Tel: 20225277).

Declaration of consent

I the undersigned Mr/Mrs _____, resident of _____, confirm that the objectives and methods of the Knowledge, Attitudes, and Practices study on cervical cancer and perspectives on an HPV vaccine trial in the region of Bamako were explained to me and that I was given the chance to ask questions about the study.

I have confidence that the investigator will guarantee that all sensitive information collected will remain confidential. I was informed of the risks and benefits linked to my participation. I have considered the time constraints that I may incur with participation. I was informed that my participation does not involve payment either to me or to another member of my family. I understand that participation is voluntary and that I have the right to remove myself from the study at any time.

I voluntarily agree to participate in this study: /___/ Yes /___/ No.

Signature/fingerprint: _____ **Date :** _____

Full name of the investigator: _____

Anne De Groot, MD
Fondatrice et Directrice Scientifique

Dr Tounkara Karamoko
Directeur Executif

CONSENT FORM

Guardian

Study title: Knowledge, Attitudes and Practices Study related to HPV and cervical cancer and Willingness to Participate in an HPV vaccine trial in the region of Bamako, Mali, West Africa

Institution name: GAIA Foundation, Hippodrome, Rue 224 Porte 1803 Bamako Mali

Principal Investigator: Dr. Karamoko Tounkara
Tel: 76495886
Email: tounkara.karamoko@gmail.com

What are the implications of participating in this study?

Participation in this study is voluntary and anonymous. No one other than the principal investigators will have access to this information. The adolescent you are accompanying is not obligated to participate in this study.

In signing your consent, you give us permission to use the adolescent's responses for the collection, analysis, and processing of data in writing and publishing medical articles.

Risks of your participation: The risks linked to participation in this questionnaire are minor. The adolescent is not obliged to respond to every question.

The benefits of your participation are the following:

The adolescent's responses and opinions will allow us to evaluate Knowledge, Attitudes, and Practices on the subject of cervical cancer, as well as willingness to participate in an HPV vaccine trial in the region of Bamako.

For all questions or complaints, please contact the principal investigator, Dr. Tounkara Karamoko (Tel: 76495886). You may also contact the president of the FMPOS Ethical Committee at Point G, Bamako (Tel: 20225277).

Declaration of consent

I the undersigned Mr/Mrs _____, resident of _____, confirm that the objectives and methods of the Knowledge, Attitudes, and Practices study on cervical cancer and perspectives on an HPV vaccine trial in the region of Bamako were explained to me and that I was given the chance to ask questions about the study.

I have confidence that the investigator will guarantee that all sensitive information collected will remain confidential. I was informed of the risks and benefits linked to participation for the adolescent I am accompanying. I have considered the time constraints that he/she may incur with participation. I was informed that his/her participation does not involve payment either to him/her or to me. I understand that participation is voluntary and that he/she has the right to remove him/herself from the study at any time.

I voluntarily agree to the adolescent's participation in this study: /___/ Yes /___/ No.

Signature/fingerprint: _____ **Date:** _____

Full name of the investigator: _____

Anne De Groot, MD
Fondatrice et Directrice Scientifique

Dr Tounkara Karamoko
Directeur Executif

CONSENT FORM

Adolescent

Study title: Knowledge, Attitudes and Practices Study related to HPV and cervical cancer and Willingness to Participate in an HPV vaccine trial in the region of Bamako, Mali, West Africa

Institution name: GAIA Foundation, Hippodrome, Rue 224 Porte 1803 Bamako Mali

Principal Investigator: Dr. Karamoko Tounkara
Tel: 76495886
Email: tounkara.karamoko@gmail.com

What are the implications of participating in this study?

Your participation in this study is voluntary and anonymous. No one other than the principal investigators will have access to your information. You are not obligated to participate in this study.

In signing your consent, you give us permission to use your responses for the collection, analysis, and processing of data in writing and publishing medical articles.

Risks of your participation: The risks linked to your participation in this questionnaire are minor. You are not obliged to respond to every question.

The benefits of your participation are the following:

Your responses and opinions will allow us to evaluate Knowledge, Attitudes, and Practices on the subject of cervical cancer, as well as willingness to participate in an HPV vaccine trial in the region of Bamako.

For all questions or complaints, please contact the principal investigator, Dr. Tounkara Karamoko (Tel: 76495886). You may also contact the president of the FMPOS Ethical Committee at Point G, Bamako (Tel: 20225277).

Declaration of consent

I the undersigned _____, resident of _____, confirm that I was accompanied by a guardian who gave his/her agreement for my participation in this study. I also confirm that the objectives and methods of the Knowledge, Attitudes, and Practices study on cervical cancer and perspectives on an HPV vaccine trial in the region of Bamako were explained to me and that I was given the chance to ask questions about the study.

I have confidence that the investigator will guarantee that all sensitive information collected will remain confidential. I was informed of the risks and benefits linked to my participation. I have considered the time constraints that I may incur with participation. I was informed that my participation does not involve payment either to me or to another member of my family. I understand that participation is voluntary and that I have the right to remove myself from the study at any time.

I voluntarily agree to participate in this study: /___/ Yes /___/ No.

Signature/fingerprint: _____ **Date :** _____

Full name of the investigator: _____

Anne De Groot, MD
Fondatrice et Directrice Scientifique

Dr Tounkara Karamoko
Directeur Executif

Knowledge, Attitudes and Practices Study related to HPV and cervical cancer and Willingness to Participate in an HPV vaccine trial in the region of Bamako, Mali, West Africa

Date : _____
ID Code : _____

Part I : Background information about the participant

1. How old are you?:
_____ years
 - o Prefer not to answer
2. Marital status: Are you:
 - o Married
 - o Married in a polygamous family If yes: How many wives are there? _____
 - o Cohabiting
 - o Single
 - o Prefer not to answer
3. (a) Did you go to school? :
 - o Yes
 - o No (Go directly to Part II)
3. (b) If yes, until what age? : _____
3. (c) or what grade?: _____

Part II: Sexual history

4. Are you circumcised?
 - o Yes
 - o No
 - o Prefer not to answer
 - o Don't know
5. (a) Have you ever had a sexual relationship?
 - o Yes
 - o No *(For men and adolescent boys go directly to Part IV)*
(For women and adolescent girls go directly to Part III)
 - o Prefer not to answer
 - o Don't know
5. (b) How old were you when you had your first sexual relationship? : _____
 - o _____ Years old
 - o Prefer not to answer
 - o Don't know
6. How many sexual partners have you had? :

- o _____ Partners
 - o Prefer not to answer
 - o Don't know
7. Have you ever been forced to have sexual relations?
- o Yes
 - o No
 - o Prefer not to answer
8. Have you had sexual relations in exchange for something?
- o Yes for money
 - o Yes for food
 - o Yes for shelter
 - o Yes for other reasons,(please elaborate): _____
 - o No
 - o Prefer not to answer

If the person is married:

9. How many sexual partners did you have before getting married? :
- o _____ Partners
 - o Prefer not to answer
 - o Don't know
10. Do you have – or did you have - any sexual partners other than your husband?
- o Yes
 - o No
 - o Prefer not to answer

FOR MEN AND TEENAGE BOYS GO DIRECTLY TO PART 4

Part III - Gynecological information

FOR WOMEN AND TEENAGE GIRLS ONLY

11. (a) Are you menstruated?
- o Yes
 - o No (*Go directly to Q14*)
 - o Prefer not to answer
 - o Don't know (*Go directly to Q12*)
11. (b) How old were you when you began menstruating? _____
- o Prefer not to answer
 - o Don't know
12. (a) Do you have children? :
- o Yes
 - o No (*Go directly to Q13*)
 - o Prefer not to answer (*Go directly to Q13*)
 - o Don't know (*Go directly to Q13*)
12. (b) How many children do you have?
- o _____ children
 - o Prefer not to answer
 - o Don't know
13. (a) How many pregnancies have you had?

- o ____pregnancies (if none, Go directly to Q14)
- o Prefer not to answer
- o Don't know

13. (b) How old were you when you had your first pregnancy?

- o ____years
- o Prefer not to answer
- o Don't know

14. (a) Have you ever gone to a gynecologist? for reasons other than pregnancy care?

- o Yes
- o No (Go directly to Q15)
- o Prefer not to answer (Go directly to Q15)
- o Don't know (Go directly to Q15)

14. (b) How many times have you gone to a gynecologist?

- o ____Times
- o Prefer not to answer
- o Don't know

14. (c) For what reasons?

- o Pain
- o Itching
- o Abnormal bleeding
- o Vaginal discharge
- o Loss of menstrual periods
- o Others: _____
- o Prefer not to answer
- o Don't know

15. Do you know what a Pap smear is?

- o Yes
- o No
- o Prefer not to answer

If no, explain what a Pap smear is: *A gynecological Pap smear is a procedure that uses an instrument (a spatula) to collect and examine cervical cells for health reasons.*

16. (a) Have you ever gotten a Pap smear?

- o Yes
- o No (Go directly to Q17)
- o Prefer not to answer (Go directly to Q17)
- o Don't know (Go directly to Q17)

16. (b) How old were you when you got your first Pap smear?

- o ____years
- o Prefer not to answer
- o Don't know

16. (c) If yes Where did you have the Pap smear done?

- o At the hospital
- o At the CSCOM
- o At a free testing center
- o At home
- o Prefer not to answer

- Don't know
16. (d) Who performed this Pap smear?
- A gynecologist
 - A midwife
 - Other: Explain: _____
 - Prefer not to answer
 - Don't know
17. Do you know what contraception means?
- Yes
 - No (*Go directly to Q19*)
 - Prefer not to answer (*Go directly to Q19*)
18. Do you use a method of contraception?
- Yes Which one(s)? : _____
 - No
 - Prefer not to answer
 - Don't know
19. How frequently do you wash your genitals?
- Never (*Go directly to Part IV*)
 - Once a day
 - Less than once a day
 - More than once a day
 - Prefer not to answer (*Go directly to Part IV*)
 - Don't know (*Go directly to Part IV*)
20. (a) Do you use any feminine hygiene products?
- Yes
 - No
 - Prefer not to answer
 - Don't know
20. (b) If yes to question: Which product(s) do you use?
- Soap
 - Other (Explain: _____)
 - Prefer not to answer
 - Don't know
- If no to question : What do you use?
- Water
 - Other (Explain: _____)
 - Prefer not to answer
 - Don't know

Part IV – STIs and HPV

21. Do you know what an STI is?
- Yes
 - No (*Go directly to Q26*)
 - Prefer not to answer
22. Do you know how to protect yourself against STIs?
- Yes (Explain: _____)

- o No
 - o Prefer not to answer
23. Do you know where to go to get tested for STIs?
- o Yes (Where : _____)
 - o No
24. Have you ever had an STI?
- o Yes: Which one (s)?:
 - o No (*Go directly to Q26*)
 - o Prefer not to answer (*Go directly to Q26*)
 - o Don't know (*Go directly to Q26*)
25. How many times have you had an STI?:
- o _____times
 - o Prefer not to answer
 - o Don't know
26. Do you know what HPV is?
- o Yes: Please elaborate: _____
 - o No (*Go directly to part V*)
 - o Prefer not to answer

HPV is the human papilloma virus. It is an STI that is common among sexually active people.

27. Do you know one or more of the symptoms of HPV?
- o Yes : Which ones : _____
 - o No
28. HPV affects:
- o Women?
 - o Men?
 - o Adolescent girls?
 - o Adolescent boys?
 - o Prefer not to answer
 - o Don't know
29. Is HPV related to cervical cancer?
- o Yes
 - o No
 - o Prefer not to answer
 - o Don't know
30. Is HPV one of the main causes of cervical cancer?
- o Yes
 - o No
 - o Prefer not to answer
 - o Don't know
31. (a) Can cervical cancer be avoided if one is vaccinated against HPV?
- o Yes
 - o No
 - o Prefer not to answer
 - o Don't know

- (b) Among women, is HPV one of the main causes of cervical cancer?
- ☐ Yes
 - ☐ No
 - ☐ Prefer not to answer
 - ☐ Don't know

FOR MEN AND ADOLESCENT BOYS GO TO PART VI

PART V – Cervical cancer

FOR WOMEN AND ADOLESCENT GIRLS ONLY

32. Have you heard of cervical cancer?
- ☐ Yes
 - ☐ No
 - ☐ Prefer not to answer
 - ☐ Don't know
33. Do you know one or more of the symptoms or signs of cervical cancer?
- ☐ Yes: Which ones?
 - ☐ No
 - ☐ Prefer not to answer
 - ☐ Don't know
34. Have you heard that there is free testing for cervical cancer in Mali?
- ☐ Yes
 - ☐ No
 - ☐ Prefer not to answer
35. Do you know where to go to get tested (i.e. get a cervical exam)?
- ☐ Yes : Where ?;
 - ☐ No
 - ☐ Prefer not to answer
36. Have you ever been tested (i.e. gotten a cervical exam)?
- ☐ Yes: Where? _____ How many times? _____
 - ☐ No (*Go directly to Q37*)
 - ☐ Prefer not to answer
37. Do you know what happens during a cervical exam?
- ☐ Yes
 - ☐ No
 - ☐ Prefer not to answer
38. True/False: A screening test tells you if you have cervical cancer?
- ☐ True
 - ☐ False
 - ☐ Don't know
 - ☐ Prefer not to answer
39. True or False: Cervical cancer is a cause of death among women?
- ☐ True
 - ☐ False
 - ☐ Don't know
 - ☐ Prefer not to answer

40. Do you know one or more of the causes of cervical cancer?

- ☐ Yes: Which ones?: _____
- ☐ No
- ☐ Don't know
- ☐ Prefer not to answer

Part VI – Vaccines and vaccine trials

41. Have you ever been vaccinated?

- ☐ Yes: list the names of the vaccines you received:
- ☐ No
- ☐ Prefer not to answer
- ☐ Don't know

41. If the HPV vaccine were available in Mali, to whom should it be given? (Mark your response for each of the following groups.)

(a) To young adolescent girls before their first sexual relationships?

- ☐ Yes
- ☐ No
- ☐ Prefer not to answer
- ☐ Don't know

(b) To young adolescent boys before their first sexual relationships?

- ☐ Yes
- ☐ No
- ☐ Prefer not to answer
- ☐ Don't know

(c) To women?

- ☐ Yes
- ☐ No
- ☐ Prefer not to answer
- ☐ Don't know

(d) To men?

- ☐ Yes
- ☐ No
- ☐ Prefer not to answer
- ☐ Don't know

42. If you were going to be vaccinated, who would make this decision or give their permission?

- | | | | |
|-----------------|---------------------------|--------------------------|--|
| - Your husband: | <input type="radio"/> Yes | <input type="radio"/> No | <input type="radio"/> Prefer not to answer |
| - You: | <input type="radio"/> Yes | <input type="radio"/> No | <input type="radio"/> Prefer not to answer |
| - Your father: | <input type="radio"/> Yes | <input type="radio"/> No | <input type="radio"/> Prefer not to answer |
| - Your mother: | <input type="radio"/> Yes | <input type="radio"/> No | <input type="radio"/> Prefer not to answer |

43. If you were going to vaccinate your child(ren), who would make this decision or give their permission?

- | | | | |
|-----------------|---------------------------|--------------------------|--|
| - Your husband: | <input type="radio"/> Yes | <input type="radio"/> No | <input type="radio"/> Prefer not to answer |
| - You: | <input type="radio"/> Yes | <input type="radio"/> No | <input type="radio"/> Prefer not to answer |
| - Your father: | <input type="radio"/> Yes | <input type="radio"/> No | <input type="radio"/> Prefer not to answer |
| - Your mother | <input type="radio"/> Yes | <input type="radio"/> No | <input type="radio"/> Prefer not to answer |

44. The vaccine against HPV (to prevent cervical cancer) is given by:
- ☐ An injection into the cervix
 - ☐ An injection into the arm
 - ☐ Prefer not to answer
 - ☐ Don't know
45. You can protect yourself against HPV by:
- ☐ Using condoms
 - ☐ Being vaccinated
 - ☐ Both
 - ☐ Prefer not to answer
 - ☐ Don't know
46. The vaccine against HPV (to prevent cervical cancer) is already available in Europe and in the United States. Would you want it to be available in Mali, as well?
- ☐ Yes
 - ☐ No
 - ☐ Prefer not to answer
 - ☐ Don't know
47. Would you want to participate in a vaccine trial to get the vaccine approved for use in Mali?
- ☐ Yes: For what reason?: _____
 - ☐ No: For what reason?: _____
 - ☐ Prefer not to answer
 - ☐ Don't know
48. Would you want your child(ren) to participate in a vaccine trial?
- ☐ Yes: For what reason?: _____
 - ☐ No: For what reason?: _____
 - ☐ Prefer not to answer
 - ☐ Don't know
- (a) If the vaccine is approved in Mali, would you want to get vaccinated?
- ☐ Yes
 - ☐ No (*Directly go to Q 50*)
 - ☐ Prefer not to answer
- (b) Where would you want to be vaccinated? (Keep in mind that there are three shots, given at three separate appointments.)
- ☐ At the hospital
 - ☐ At the CSCOM
 - ☐ At school
 - ☐ At home
 - ☐ Other: _____
49. How would you like to be contacted for these three appointments?
- ☐ By phone call
 - ☐ By text message
 - ☐ By a visit to my house
 - ☐ Other
 - ☐ Prefer not to answer
 - ☐ Don't know
50. I would get vaccinated/I would vaccinate my child(ren) against cervical cancer:

- o If the vaccine were free.
- o If the vaccine were less expensive than ____.
- o I would not get vaccinated or vaccinate my children against cervical cancer.