national TB prevalence survey Cambodia (2023 – 2024)

Information for the participant

This informed consent form is for the household members who are invited to participate in the research study on the TB prevalence in Cambodia.

You and/or your child are being asked to participate in an epidemiological and clinical research study named "Third National TB Prevalence Survey of Cambodia (2023-2024)". The epidemiological study is the study to assess the situation of certain diseases and its change in the community. Clinical research is the study of human participants to improve the diagnosis and treatment of certain conditions. To decide whether you and/or your child agree to participate in this study, you should understand the risks and benefits of the study.

Therefore, please take your time in understanding the information in this form and do not hesitate to ask any questions if you have throughout the procedure. Once you understand the study, you will be asked to sign the informed consent form as a proof of your consent for you and/or your child to participate in the study.

Purpose of the study: Tuberculosis (TB) is an infection caused by bacteria that can affect the lungs and other parts of the body. Sometimes, you may not know you have TB disease and TB usually spread from person-to-person by coughing. TB remains as an important cause of illness in Cambodia. To better understand how well we are fighting this illness, it is important to know how many people have TB and how it changes in the community after the first survey in 2002 and the second survey in 2011.

National Center for Tuberculosis and Leprosy Control, Ministry of Health (CENAT) together with partners are doing a study on the Prevalence of Tuberculosis in Cambodia and the aim of this study is to determine the number of people aged 15 years and above with pulmonary TB in Cambodia during the study period of 2023-2024.

Participants selection: This study is being conducted in 84 sites all over the country and involves nearly 530 participants per site for a total of around 44,000 participants. Your village has been selected to participate in this study. Because you (or your child) are above 15 years of age and have lived in this place for at least 14 days, you are eligible to participate in this survey. The information that you will provide during this survey will help us to improve TB prevention and care activities in Cambodia and to provide better service for the community.

Your participation in this survey is entirely voluntary and you can choose to whether participate or not. Regardless of your choice, you will continue to receive the care that you are entitled to from your health care workers.

Survey procedures: If you agree to participate in this survey, you will be asked with some interview questions and your data will be collected. You will undergo a physical examination and principally undergo a chest Xray. On Day 1 of your visit, if your interview is possibly suggestive of TB and/or your chest Xray shows any abnormality in lung, sputum will be collected for the examination test at the district laboratory to detect the presence of TB. On day 2, another specimen of your sputum will be collected and send for testing with same test. In a few days, test results will be available. When it suggests presence of TB organism in your sputum or your CXR suggests presence of active TB disease, you will be asked to provide two additional sputum samples for culture examinations at Institute of Pasteur Cambodia. Specimens will be transported by the study team and no fee will be

charged to you and your family. National TB Prevalence Surveys have been widely conducted in Asia and African countries. In last decade neighboring countries such as Viet Nam, Lao PDR, Thailand, and Bangladesh completed the survey with methodologies similar to this survey.

Duration of the participation: Your interview, physical examination, and chest Xray should not take more than one hour. If your Xray or symptoms you feel are suggestive of TB, sputum will be collected after the Xray examination and the following day. Depending on the first result, additional sputum samples might be collected again. If you are randomly selected to participate in the additional interview, you might be asked to answer some additional interview questions during one-on-one interview or in a group discussion with your consent. And this might take another 45-60 minutes.

Possible risks of being in the study: There is no major risks for participating in this study. However, Xray uses radiation, which is associated with some health problems if high levels are used. Our radiographers have been trained to use the minimum amount of radiation necessary to obtain the essential results with minimal risks.

Especially if you are woman and happen to be pregnant, there is a concern that it might have effect on the unborn child if it is high radiation exposure. Attention will be paid to restrict the area of exposure to the chest only and avoid direct exposure to the abdomen and reproductive organs. If you are pregnant or think you may be pregnant and you are not reassured about safety, please share your concern with the study team and Chest X-ray will be exempted.

There is also a risk that others may find out that you have TB, although we have instituted measures to ensure the confidentiality of your records.

Possible benefits of participating in the study: This study may not benefit you directly, but the results of the survey will be used to support national TB program for the diagnosis, treatment, and prevention of TB. The data will benefit the national program which aims to control TB in the country. You will receive free tests for the diagnosis of TB and health information to help you prevent it. If during your participation, you are found to have TB, you will be quickly diagnosed and you will be referred to the local health facility for free of charge TB treatment. And if you discovered to have an illness other than TB during the study procedure, you will be referred to a health facility for proper treatment.

Compensation: You will not receive any compensation or payment for your participation in this survey. You will receive a token of appreciation for participation.

Rights to refuse and withdraw: You may refuse to participate in the survey or parts of this survey or withdraw your consent without any change in the care given to you. You may also choose not to undergo Xray examination for whatever reason but especially if you are female and suspect you are pregnant.

Privacy and Confidentiality of Records: Your personal information obtained from this study will be kept confidential. Information about you that will be collected during the survey will be stored in a secured room accessible only to the designated study persons. Any information about you will have a code number on it instead of your name. Information obtained from this study may be published or given to other people doing research, but neither your name nor your child's name will be mentioned. But if you are found to have abnormal results, health workers who are going to treat you may be given information that identified you.
Collected information and part of your sputum sample and/or TB isolates if any will be kept for further analysis if needed.

Results of the Survey: The results of this study will be submitted to the Ministry of Health through CENAT. If you wish to obtain a copy of the summary of results of the study, you are more than welcome to request through the following email: _____. There is also a possibility that the results will be used for publication in the academic journals.

Contacts and questions: If you have any questions, you may ask them now or later even after the study has started. For later, please contact any of the following:

Xxxxxxxxx
Xxxxxxxxx
Xxxxxxxxx

Consent Form

(Declaration part 1)

I have read the above document, or they has been explained to me by health staff. I have had the opportunity to ask questions about it and all the questions that I have asked were answered to my satisfaction. I have been informed that the risks by the survey are minimal. I know that I will be able to receive treatment at health centre or referral hospital if I have TB.

I have read/understand the above information. I agree to participate in this survey with understanding that I have the rights to refuse any interview/screening and withdraw from the participation without affecting my further medical care.

☐ I agree to participate in this study.

Name of participant . . . . . .

Signature or thumb print of participant . . . . . .

Date . . . . /. . . . ./. . . . . .

When the age of participant is under 18.

☐ I agree for my child to participate in this study.

Name of a parent or a guardian . . . . . .

Signature or thumb print . . . . . .

Date . . . . /. . . . ./. . . . . .

(Declaration part 2) <u>If a participant is unable to read</u>:
I have witnessed that the participant was fully explained about the accurate consent form and that the individual had the opportunity to ask any questions. I hereby confirm that the individual has been given informed consent to participate in the survey.
The witness must sign (if possible, this person should be selected by the participant out of the research team). The participant should leave his/her thumb print as well.

☐ I agree to participate in this study.

☐ I agree for my child to participate in this study.

Name of participant . . . . . .

Thumb print of participant

Name of witness . . . . . .

Signature of witness . . . . . .

Date . . . ./ . . . . . ./ . . . . .

Statement by the researcher/person taking consent

I have accurately read out and explained the information sheet the potential participant and to the best of my ability made sure that the participant understands the 1) Purpose of the study 2) Details of their participation 3) Confidentiality and anonymity and 4) Risks and benefits of the study.

I confirm that the participant was given an opportunity to ask questions about the study and all the questions asked by the participant have been answered correctly and to best of my ability. I confirm that the individual has not been coerced into giving consent and the consent has been given freely and voluntarily.

A copy of this informed consent form has been provided to the participant.

Informed consent obtained by:

Signature over printed name

Date signed: