

Protocol from "Prevalence of pulmonary tuberculosis among prison inmates: a cross-sectional survey at the Correctional and Detention Facility of Abidjan, Côte d'Ivoire"

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Abstract

Step 1: Enrolment of inmates eligible for study participation

Step 2: Study implementation

- 1st day of study: Inclusion of participants and questionnaire administration
- 2nd day of study: Preparing the list of participants for the 1st sputum sample collection and chest X-ray
- 3rd day of study: Collecting the 1st sputum sample and performing the chest X-ray
- 4th day of study: Transport of sputum samples to CeDRes and collection of chest X-ray and laboratory test results
- 5th day of study: Collecting the 2nd sputum sample, performing the HIV test and preparing the samples to be sent to CeDRes

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Protocol

Step 1.

Step 1: Enrolment of inmates eligible for study participation

- Hold collective information sessions on the study in each cell.
- At the end of each information session, enrol the inmates by collecting the following data: full name, warrant of committal, gender, date of birth or age, building and prison cell number, cell size.
- Carry out this activity with the support of the head of building, heads of prison cells and peer educators.
- This enrolment should lead to the establishment of inmates groups to participate in the study. Each cell will be divided into three groups maximum, as each group consists of 25 inmates maximum. Each group will have a 3-day participation in the study.

Step 2.

1st day of study: Inclusion of participants and questionnaire administration

The 1st day of each inmate group (group of 25 inmates per cell) should be structured in 2 steps: inclusion and identification of participants; questionnaire administration.

- After obtaining participants' signed consents, the physician should start recording their names in the "Participant register" by assigning them the first ID numbers available in the register.
- The physician should write the full name, warrant of committal, date of birth, building, cell and date of inclusion on the "Participant register" opposite the first ID number available. This register is the only document that ensures a correspondence between the name and study number of each participant. This register, which is under the control of the study physician, should be kept in the office of the TB ward physician. Only the study physician and coordinator have access to the "Participant register".
- The participant unique ID number consists of six characters. The first two characters (letters: BC for Building C, BF for Women's Building and BT CAT) identifies the inmate's building and the last four digits (in ascending order 0001, then 0002, etc.) help identify the inmate per building. For example: the first 3 participants of Building C will bear the numbers BC0001, BC0002, and BC0003.
- After assigning a unique ID number to each participant, the physician identifies the survey form by reporting the unique ID number on each page of the survey form and starts administering the questionnaire while following the completion instructions on the survey form.
- The physician should carefully complete the follow-up form of each participant: the ID number, warrant of committal, date of inclusion and date questionnaire administration.

This follow-up form should be given to the participant and help monitor his/her progress throughout the study. The participant should show it at every step in the study.

Step 3.

2nd day of study: Preparing the list of participants for the 1st sputum sample collection and chest X-ray

Since Day 2 is a visiting day for inmates' relatives, this day will be dedicated for preparing the list of participants who answered the questionnaire and are getting ready for the 1st sputum collection and chest X-ray.

- Along with the reporting schedule used for each group on Day 1, the study monitor should first determine the number of participants who will undergo the 1st sputum collection and chest X-ray. This number corresponds to the number of participants who signed the consent form for TB

testing and agreed to be administered the questionnaire.

- Then he/she should make two copies of this reporting schedule. A copy will be given to the lab technician for the 1st sputum collection, and the other copy to the X-ray technician for the chest X-ray.
- With the help of the lab technician, the study monitor should prepare the spittoons to be used for collecting sputum the following day (spittoon pre-labelling). Thus, he/she should write on the label: the unique ID number, date of sample collection, type of sample: tick the “1st sputum” box.

Step 4.

3rd day of study: Collecting the 1st sputum sample and performing the chest X-ray

The morning of Day 3 will be dedicated for two (2) activities: collecting the 1st sputum sample and performing the chest X-ray. The afternoon of this day will be dedicated for sorting out sputum samples of inmates presenting with a suspicion during the questionnaire and for preparing the list of participants who will undergo the 2nd sputum sample collection and HIV test.

1st sputum sample collection

- The 1st sputum sample collection should be done under the supervision of the lab technician, with the assistance of two (2) peer educators in the CAT yard.
- The lab technician should first check that the participant is actually at this stage of the study, using the copy of the reporting schedule received from the study monitor. He/she should check this on the reporting schedule as well as the individual follow-up form that the participant will show.
- The lab technician should provide clear instructions on how to collect sputum samples. The sputum should come from the distal airways: after deep breathing or exercise. This demonstration should be clear and explicit.
- After this verification, the participant should rinse his/her hands and mouth. The technician gives him/her the pre-identified spittoon for sputum collection.
- The lab technician and peer educators should make sure the person producing sputum is the right inmate and there was no exchange of prisoners.
- After the sputum collection, the lab technician should tick the “1st sputum collected” box on the copy of the reporting schedule and refer the participant to the vehicle for the chest X-ray.
- Each spittoon should be hermetically sealed and then wrapped in a plastic bag.

Performing chest X-ray

The chest X-ray should be performed by the CNACI technicians in the vehicle especially in the infirmary yard under the protection of two prison guards.

- The study monitor should give a copy of the reporting schedule and the “chest X-ray reporting” forms to the X-ray technicians, before performing the test.
- Using the copy of the reporting schedule, the X-ray technician starts performing the X-ray after checking the “individual follow-up form” that the participant shows to him/her.
- After performing the chest X-ray, the X-ray technician should tick the “Chest X-ray performed” box on the copy of the reporting schedule and write the X-ray ID number on the copy of the reporting schedule. This will ensure conformity with the participant unique ID number.
- The X-ray technician should also write the X-ray ID number, participant unique ID number and date of X-ray (the X-ray reading is done at CNACI and not in the vehicle) on the “Chest X-ray reporting” form.
- At noon, the study monitor should collect all copies of the reporting schedule (copies of the lab and X-ray technicians) and report the data on the original copy of the reporting schedule.

Sorting sputum samples of participants suspected during the questionnaire

The sorting of the 1st sputum samples to be sent to CeDRes is done by the study monitor and lab technician: Sputum of participants suspected of TB (as per questionnaire).

- Prepare the “Sputum smear microscopy for AFB detection request forms” for each suspected sample by mentioning the unique ID number, date of sample collection, date of birth, gender, and have them signed by the physician.
- Complete the «Test register”.
- After this sorting, the sputum samples to be sent to CeDRes should be stored in the freezer. The other sputum samples should be destroyed as per MACA applicable procedure.
- Preparing the inmates list for the 2nd sputum sample collection and HIV test
- Along with the reporting schedule of the participants group that completed Day 1 and Day 2, the study monitor should determine the number of participants who will undergo the 2nd sputum sample collection and HIV test. This number corresponds to the number of participants who underwent the 1st sputum sample collection and chest X-ray.
- Then, the study monitor should make two copies of this reporting schedule. A copy will be given to the lab technician for the 2nd sputum sample collection and the other copy to the counsellor for the HIV test.

With the assistance of the lab technician, the study monitor should prepare the spittoons to be used for day 5 sputum collection (as previously described).

Step 5.

4th day of study: Transport of sputum samples to CeDRes and collection of chest X-ray and laboratory test results

Since the 4th day of the study is a visiting day for inmates' relatives, this day will be dedicated for the transport of sputum samples and collection of chest X-ray and laboratory test results.

The coordinator will also be in charge of digitizing all X-ray films while making the ID numbers visible. Then he/she should send these pictures to two other independent readers.

Step 6.

5th day of study: Collecting the 2nd sputum sample, performing the HIV test and preparing the samples to be sent to CeDRes

Day 5, morning: Collecting the 2nd sputum sample and performing the HIV rapid test

- The procedure for collecting the 2nd sputum sample is identical to that of the 1st sputum sample.
- After collecting the 2nd sputum sample, the laboratory technician should refer the participant to the Counsellor for the HIV rapid test.
- Along with a copy of the day's reporting schedule and after checking the individual follow-up form, the counsellor should sign, date and countersign the two copies of the HIV test consent form. She should tick the "consent obtained for HIV test" box on the copy of the reporting schedule, against the full name of the inmate.
- The counsellor should give a copy of the dated and signed consent form to the inmate. If he/she does not want any copy, the counsellor should write on the signed consent form that the inmate did not want to keep his/her consent form, and should file the two copies of the consent form in the dedicated "consent binder".
- After the rapid test, the counsellor should report the HIV test result: "Negative", "Positive" or "Indeterminate" on the "HIV test result form".
- The counsellor should tick the "HIV test performed" box on the reporting schedule.

Day 5, afternoon: Preparing the samples to be sent to CeDRes

The sorting of 2nd sputum samples to be sent to CeDRes should follow the same procedure as that described for the 1st sputum samples. Only sputum samples of inmates presenting with a suspicion during the questionnaire administration and/or abnormality on chest X-ray and/or "positive" or "indeterminate" HIV test result should be stored in the freezer. The other sputum samples should be destroyed as per MACA applicable procedure.