MINISTRY OF HEALTH

AND PUBLIC HYGIENE

REPUBLIC OF COTE D'IVOIRE Union-Discipline-Labour



ASSESSEMENT OF THE IMPLEMENTATION, RECORDING, AND REPORTING OF INTENSIFIED TUBERCULOSIS CASE-FINDING IN THE HIV CARE AND TREATMENT SETTINGS IN COTE D'IVOIRE

STUDY REPORT

October 2016

Assessment of the implementation, recording, and reporting of intensified tuberculosis case-finding in the HIV care and treatment settings in Côte d'Ivoire

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2016

With the participation of:







and financial support of PEPFAR



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INVESTIGATORS AND INSTITUTIONAL AFFILIATIONS

FHI 360, FWA: 0000025, expiry date : 06/03/2018

- Dr. Traore-Toure Fatoumata, Project Director/ Director of Science;
- Dr. Ouffoue Ange Fulgence, Monitoring & Evaluation Senior Technical Officer, Co-investigator;
- Dr. Etheredge Gina, Strategic Information /Monitoring & Evaluation Senior Technical Advisor, Washington-USA, Co-investigator.

U.S. Centers for Disease Control and Prevention (CDC)

- Courtney Coleman Emerson, TB/HIV Team Focal Point, Côte d'Ivoire, CDC, Division of Global HIV/AIDS Atlanta (TB/HIV Team), Co-investigator;
- Dr. Anand A. Date, TB/HIV Team Leader, CDC, Division of Global HIV/AIDS Atlanta, Co-investigator;
- Dr. Nahoua Iremine, TB/HIV Technical Advisor at CDC Côte d'Ivoire, Co-investigator.

Ministry of Health and Public Hygiene

- Dr. Pongathie Adama Sanogo, Director of the Prospective, Planning, Evaluation, and Health Information (DPPEIS), Co-investigator;
- Dr. Abo Kouame, Director-Coordinator of the National AIDS Control Program (PNLS), Coinvestigator;
- Dr. Yapo Adja Beaudréa, TB-HIV Focal Point at the PNLS, Co-investigator.

National Institute of Statistics

- Bakayoko Massoma, Demographer, Co-investigator;
- Tuo Adama, Statistician, Co-investigator.

ABBREVIATIONS AND ACRONYMS

AARB	: Acid-Alcohol Resistant Bacilli
тс	: Tuberculosis Center
CDC	: U.S. Centers for Diseases Control and Prevention
DTC	: TB Diagnosis and Treatment Center
DPPEIS	: Direction de la Prospective, de la Planification, de l'Evaluation et de l'Information Sanitaire / Directorate of Prospective, Planning, Evaluation and Health Information
BMI	: Body Mass Index
INS	: National Institute of Statistics / Institut
01	: Opportunistic Infection
MSHP	: Ministèrre de la Santé et de l'Hygiène Publique / <i>Ministry of Health and Public</i> <i>Hygiene</i>
WHO	: World Health Organization
UNAIDS	: Joint United Nations Programme on HIV/AIDS
Care	: Care
MUAC	: Mid-Upper Arm Circumference
PEPFAR	: U. S. President's Emergency Plan for AIDS Relief
PNLS	: Programme National de Lutte contre la Tuberculose / National Tuberculosis Control Program
PNLT	: Programme National de Lutte contre le Sida / National AIDS Control Program
PLHIV	: People Living with HIV
ICF	: Intensified Tuberculosis Case Finding
RASS	: Annual Report on Health Situation
GPHC	: General Population and Housing Census
SOP	: Standard Operating Procedures
ART	: Antiretroviral Therapy
ТВ	: Tuberculosis
нсс	: HIV care and treatment center
HIV	: Human Immunodeficiency Virus

OPERATIONAL DEFINITIONS

Tuberculosis Intensified Case Finding (TB-ICF): Refers to the strategy to find TB symptoms during interviews with people living with HIV (PLHIV). TB-ICF is performed by the health care provider, at each follow-up visit after Pre-ART registration and every three months thereafter. According to the national guidelines in Côte d'Ivoire, the symptoms and risk factors to be identified are the followings:

- Cough that has been lasting for more than two weeks;
- Night sweats ;
- Weight loss (unintentional weight loss> 3 Kg in the last month);
- An evening fever that lasts for more than three weeks;
- Contact with a person with active tuberculosis.

Diagnostic evaluation: Refers to the process followed by the healthcare provider for TB diagnosis. It includes a diagnostic investigation (prescription of paraclinical tests) and the decision of the provider to initiate the patient's TB treatment in case of negative results.

Presumptive TB case: Any patient with the following symptoms:

- Cough that lasts for more than two weeks with or without other associated signs;
- All the following symptoms in the absence of cough:
 - ⊘ Night sweats;
 - Weight loss (unintentional weight loss> 3 kg in the last month);
 - Evening fever that lasts for more than three weeks;
 - Contact with a person with active TB.

Active file: Total number of people living with HIV (PLHIV) enrolled in care and having regular follow-up visits in the healthcare centers, regardless of whether or not they are receiving ART.

PLHIV on treatment: All PLHIV enrolled in care, receiving ART, and having regular follow-up visits in the healthcare centers.

Patient diagnosed with tuberculosis: Patient declared as having TB following a diagnostic evaluation.

ICF Cascade: Refers to the five successive steps from TB symptoms screening to treatment initiation. These steps are as follows:

- 1. TB symptoms screening;
- 2. Identification of presumptive TB patients;
- 3. Diagnostic evaluation of presumptive TB cases;

- 4. TB diagnosis among presumptive patients;
- 5. Initiation of TB treatment.

Cascade characterization: Calculation of the proportion of patients having received the service at each step of the cascade among those who had undergone the previous step.

EXECUTIVE SUMMARY

The study on the assessment of the implementation, recording, and reporting of tuberculosis (TB) intensified case finding (TB-ICF) among PLHIV in Côte d'Ivoire is a program evaluation conducted by the Ministry of Health and Public Hygiene (MSHP) in collaboration with CDC/PEPFAR and FHI 360. The study aimed at (i) measuring the performance of healthcare centers in the implementation and documentation of the steps involved in the TB-ICF cascade according to the national guidelines, (ii) describing TB-ICF routine practices in health facilities providing care for PLHIV, (iii) identifying barriers to the implementation, recording, and reporting of TB-ICF cascade variables, (iv) measuring the completeness of data related to TB-ICF cascade in the HIV care and treatment centers (HCC), (v) assessing the quality of data related to two TB/HIV indicators, and (vi) determining TB incidence among PLHIV aged 15 years old and older.

A total of 4,410 records were reviewed across 42 sites located in 39 HCC. The majority of the HCC (80%) were public facilities. More than half of those sites (21) had an integrated diagnostic and treatment center for TB. The majority of the PLHIV who had received care were women (73%) with a CD4 cell count below 500 cells / μ l. Men were on average older than women in this study (46 years versus 41 years, respectively).

Overall, the completeness of data related to the TB-ICF cascade indicators was 89%. The TB-ICF was performed for 79% of the patients in this study. However, only 1% of the patients who were screened for TB were found to be presumptive TB cases.

The results of the multivariate statistical analysis showed that age, number of PLHIV in the active file, number of PLHIV per health personnel providing care, site location, and CD4 count were all significantly associated with the implementation of TB-ICF among PLHIV. PLHIV not screened for TB were older than those screened (43.4 years on average versus 41.6 years, p<0.001). Similarly, patients with high CD4 count were the least likely to benefit from TB-ICF (p <0.001). HCC with a higher number of PLHIV in their active five and HCC with a ratio of number of PLHIV per healthcare provider above 50 were both the least likely to perform TB-ICF (p <0.001). The location of the HCC also played an important role in TB-ICF performance, with HCC located in Abidjan less likely to implement TB-ICF compared to those located outside of Abidjan (p <0.001). On the other hand, the existence of an integrated diagnostic and treatment center for TB (DTC) was not significantly associated with the implementation of TB-ICF.

TB incidence among PLHIV could not be determined in this study. During the six months observation period, no new TB cases were recorded among PLHIV meeting the inclusion criteria in the cohort, thus making it impossible to determine TB incidence among PLHIV in this study.

The evaluation of the quality of data related to the TB/HIV indicators routinely reported to CDC/PEPFAR was done by calculating the distortion rate between the values reported to CDC/PEPFAR by the implementing partners and the values calculated using the study data. The indicator for the number of PLHIV diagnosed with TB who have started TB treatment was generally overestimated (distortion rate of 89%) across all the visited sites. On the other hand,

the quality of reporting for the number of PLHIV having received at least one clinical service during the reporting period and the number of PLHIV screened for TB symptoms at their last follow-up visit was in general good, with distortion rates of 7% and 3%, respectively. Sites with an integrated DTC generally had a good reporting for the TB/HIV indicators compared to standalone HCC, with a zero distortion rate for the number of PLHIV having received at least one clinical service during the reporting period, and a distortion rate of -7% for the number of PLHIV screened for TB symptoms at the last follow-up visit. However, the number of PLHIV diagnosed with TB who have started TB treatment was not sufficiently reported by the integrated DTC.

Qualitative interviews were conducted with 42 health care providers, composed primarily of medical doctors (55%). According to them, the main obstacle to an optimal screening of TB symptoms among HIV positive patients were: i) visit not apparently related to TB ("*We consider the reason for each visit*")' 2) fear of contamination, especially among the medical doctors ("*The doctor refuses to screen for TB symptoms; s/he avoids contamination*"); lack of training on TB compared to HIV ("*There is more emphasis on HIV than TB*" "*Not enough training on TB*"). Moreover, the large number of patients, the fact that TB-ICF is an activity usually performed by doctors ("*It is the responsibility of the doctor*"), were among others, some reasons expressed by participants to explain the non- performance of TB-ICF.

Most HCC had TB-ICF reporting forms. In addition, across all the sites, an individual patient's file was available for recording the data related to TB-ICF. However, the notification of TB-ICF results was not always done, according to the majority of respondents.

Health care providers cited three main obstacles to the realization of a TB diagnostic evaluation. The first obstacle was financial: PLHIV did not always have resources to pay all the costs for the diagnostic evaluation for TB ("*Most patients generally have financial problems. It is difficult for them to come at each visit because they have no money*"). The second difficulty was due to the PLHV's negligence with respect to their diagnosis, which hindered the realization of the diagnostic evaluation, "*the negligence of diagnosis by patients; there is nothing more because radiography is free.*" The third difficulty was related to the accessibility of the DTC / TC from the HCC: "*The remoteness of the facility to which patients are referred to and patients' difficulty for paying their transportation.*" In spite of their usefulness for patient care, the results of the TB diagnostic evaluation from the TC/ DTC were not always notified in the patient's individual medical file, the absence of counter-referral, "*the TC provides treatment to patients without notifying us*" and lack of time due to "*the excessive number of patients*" are the main reasons cited by the health care personnel.

INTRODUCTION

Thirty years after the notification of the first cases, HIV has become more than a public health issue, a real problem of development. To date, the pandemic has killed more than 18 million persons worldwide.

To help countries from Africa, the Caribbean, and Asia that were heavily affected by HIV epidemic, President George W. Bush announced in 2003, the US President's Emergency Plan for AIDS Relief (PEPFAR). The objectives of this plan were to (1) provide treatment to two million patients using Highly Active Antiretroviral Therapy (HAART), (2) prevent seven million new HIV infections, and (3) provide care for 10 million people infected with or affected by HIV.

As one of the most affected countries by HIV in West Africa, Côte d'Ivoire has been receiving since 2004, the support of PEPFAR for providing care and treatment to PLHIVs as part of a multisectoral response. The infection prevalence accounting for 4.7% in 2005 [1], experienced a significant drop to 3.7% in 2012 [2]. It was lowered to 3.2% [3] according to UNAIDS latest estimates in 2015. The number of PLHIV in the active file has increased steadily since 2009, to reach 123,692 in 2013 [4].

This report is an evaluation of the "Care and treatment" Program for PLHIV, including TB intensified case-finding among them, and is based on the objectives, methodology, results, and recommendations submitted to the MSHP in order to contribute to the improvement of PLHIV care and treatment, and reduce TB-related morbidity and mortality in Côte d'Ivoire.

BACKGROUND AND JUSTIFICATION

According to an overall estimate from the Joint United Nations Programme on HIV/AIDS (UNAIDS), there were 35.3 million people living with HIV in 2012, with 2.3 million new infections and 1.6 million AIDS-related deaths [5]. In 2011, the World Health Organization (WHO) estimated that 8.7 million people were infected with TB and 1.4 million people died of the disease, including 430,000 PLHIV [6].

The immunodeficiency resulting from HIV infection makes infected people very vulnerable to TB [7]. Thus, for a non-HIV-infected subject, the lifetime risk of developing active TB ranges from 5% to 15% [8]. For HIV infected people, this risk increases to 5% to 15% per year, with that risk doubling during the first year of HIV infection [9]. TB is the most common cause of morbidity and mortality among PLHIV in countries with limited resources [10]. In 2009, 2.8 million new cases of TB were reported in Africa; the majority of cases were located in sub-Saharan Africa and 37% of cases were diagnosed among PLHIV [11].

To reduce the global burden of TB among PLHIV, WHO has recommended since 2004 as part of the "Three Is", three TB / HIV collaborative interventions as a key measure to reduce TB-related mortality and continuous TB transmission among PLHIV: (1) TB intensified case-finding (TB-ICF) among PLHIV, (2) isoniazid preventive therapy, and (3) TB infection control in health care settings and public places [3]. Implementation of this strategy through HIV care and treatment programs involves record screening, preventive and curative care, and follow-up with patients presenting TB symptoms. These strategies are elaborated in the WHO's Integrated Management of Adolescent and Adult Illness, including the guidelines on PLHIV's follow-up and antiretroviral treatment (ART) [12].

TB-ICF is a cascade process consisting of three main steps: (1) intensified screening for TB symptoms, (2) diagnostic assessment of presumptive TB cases, and (3) provision of TB treatment to patients diagnosed with TB. Patients enter the cascade upon their enrollment in the HIV care and treatment center (HCC) to seek care or receive ART. Patients exit the ICF cascade at different steps depending on the results of the TB screening or diagnostic tests, the quality and completeness of data recording, or because of the patient's own non-adherence (Figure 1).

A study conducted in Durban, South Africa, an area with high HIV prevalence, showed that up to 20% of PLHIV who initiated ART had not undergone the TB diagnostic procedures [13]. An effective TB-ICF is therefore critical to identify PLHIV with active TB and provide a timely treatment. However, for the intensified TB case-finding to be efficient, it is critical that: 1) PLHIV benefit from regular TB screenings using a standardized national screening tool, 2) presumptive TB patients be assessed clinically and biologically and receive the proper diagnosis, and 3) those diagnosed with TB receive treatment in a timely fashion. Health facilities delivering ART to PLHIV should implement the TB-ICF as a routine service and monitor the activity using the health information system that reports and records HIV data.

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Since 2010, Côte d'Ivoire has adopted and applied, among PLHIV aged 15 years and above, two of the three components of the "Three Is" strategy, namely (1) TB-ICF among PLHIV and (2) TB infection control in health care settings and public places. TB-ICF activities are implemented on sites by health care providers with the support of partners such as PEPFAR, and integrated into the global care for PLHIV. There 537 HCC in 2015 (Annex 1) that routinely implement ICF procedures for improved management of TB/HIV co-infected patients as per the national algorithm [14]. According to the national guidelines for PLHIV, patients diagnosed with TB/HIV co-infection should start ART two weeks after initiating TB treatment regardless of the type of TB or the CD4 count [15]. In 2008, an intensified TB case-finding form, called "screening form" (Annex 2) was introduced on all the HCC for the systematic recording of the information related to the screening of all HIV patients upon their enrollment, and every three months thereafter. In 2012, new patient individual files including TB ICF-related items were disseminated to all the HCC.

TB screening for all HIV-positive patients during their first clinic visit and at every follow-up visit, is therefore recommended at national level. The presumptive TB cases should be successively evaluated, diagnosed, and treated. HIV-positive patients, presumptive of TB, should also benefit from TB diagnostic evaluation, and if they are diagnosed with TB, they should be promptly treated for TB, i.e. on the day they receive their diagnosis. In practice, there are three scenarios:

(1) TB-ICF and diagnostic evaluation are performed in the HCC, and in the event of a TB diagnosis, the patient receives TB treatment at the HCC without any referral (usually the case in the integrated DTC);

(2) TB-ICF is performed in the HCC. The patient is referred for TB diagnosis (sputum examination) and come back in the HCC to initiate TB treatment (in the case the integrated DTC does not have a laboratory);

(3) TB-ICF is performed in the HCC. Presumptive TB patients are referred to the TB care and support center (CAT) or DTC for diagnostic assessment and TB treatment. The referral is done by giving the patient a check-up/consultation form or a referral/counter-referral form bearing his/her name.

The National AIDS Control Program (PNLS) and the National Tuberculosis Control Program (PNLT) have to ensure that the monitoring and evaluation systems produce quality data to measure the success and challenges of these programs at reducing TB-related morbidity and mortality among PLHIV. Côte d'Ivoire, like other countries which implement PEPFAR-funded programs, used until 2015, two key indicators for monitoring TB/HIV co-infection interventions and providing guidance on funding priorities. These indicators are the following:

 Proportion of HIV-positive patients who benefitted from TB-ICF in the HCC at the last follow-up visit; Proportion of HIV-positive patients receiving HIV care or ART (pre-ART or ART) who initiated TB treatment.

Data are recorded by health facilities and transmitted to Health Districts and Regions, and finally to the Directorate of Prospective, Planning, Evaluation and Health Information (DPPEIS), which in turn transmits the data to the Ministry of Health and Public Hygiene (MSHP) and its partners. Furthermore, the public health monitoring and evaluation guidelines developed and used by CDC require periodic program evaluation to improve quality, efficiency and effectiveness [16]. A study conducted in 2011 by the International Center for AIDS Care and Treatment Programs (ICAP) in Côte d'Ivoire on 64 sites, revealed that 72% of HIV positive patients were screened for TB, 21% were declared presumptive TB cases, and 6% were diagnosed with TB and initiated TB treatment [17]. However, the incidence of TB among PLHIV remains unknown in the country.

Given the burden and the public health importance of TB and HIV infection, as well as the means deployed to control these infections in Côte d'Ivoire, the evaluation of the recording and transmission of monitoring and evaluation data collected as part of TB-ICF activities is essential for improving TB screening among PLHIV. The results of this evaluation will inform the MSHP on the current situation and will highlight policy and programmatic actions that are needed in order to improve the screening, diagnosis and treatment of TB among PLHIV, as well as improving the quality of TB data at the national level. Moreover, improving the quality of data on TB infection will allow the MSHP and key partners to make evidence-based decisions for better care and treatment of PLHIV.

DESCRIPTION OF THE PROGRAM

TB-ICF is a process cascade that begins with a screening for TB symptoms among PLHIV. ICF is performed by the health care provider through interviews with the PLHIV at every follow-up visit after Pre-ART registration and then every three months thereafter. According to the current national guidelines, the symptoms and risk factors to be identified are the following:

- Cough that has been lasting for more than two weeks;
- Night sweats ;
- Weight loss (unintentional weight loss> 3 kg in the last month);
- An evening fever that lasts for more than three weeks;
- Contact with a person with active tuberculosis.

TB-ICF cascade includes five main steps:

- TB symptoms screening;
- Identification of presumptive TB patients;
- Diagnostic evaluation of presumptive TB cases;
- TB diagnosis among presumptive patients;
- Initiation of TB treatment.

The patients exit the ICF cascade at different steps depending on the results of screening or other tests, the quality and exhaustiveness of clinical data, or because of the patient's own non-adherence. The patients exit the ICF cascade when:

- S/he does not receive a service related to the ICF cascade during the observation period;
- S/he receives negative results at a step of the cascade;
- Data are missing and do not help demonstrate the patient's evolution through the cascade;
- A patient diagnosed positive at step 5 fails to initiate TB treatment on the day s/he receives her/his diagnosis.

The ICF cascade for the cohort of PLHIV is presented in Figure 1.



Figure 1: ICF cascade flow chart of PLHIV registered in the HIV care and treatment centers

I. PURPOSE

To contribute to the improvement of the care and treatment of PLHIV in order to reduce the morbidity and mortality associated with TB in Côte d'Ivoire.

II. GENERAL OBJECTIVE

To assess the implementation, recording and reporting of TB ICF among PLHIV in Côte d'Ivoire.

III. SPECIFIC OBJECTIVES

- 1. To measure the performance of HCC in the implementation and documentation of the TB-ICF cascade steps in compliance with the national guidelines.
 - a) Identify, among patients enrolled in HIV care and treatment, the proportion of patients who were screened for TB at the last follow-up visit;
 - b) Identify, among HIV-positive patients screened for TB, the proportion of presumptive TB cases;
 - c) Identify, among presumptive TB cases, the proportion of patients who received a TB diagnostic evaluation;
 - *d) Identify, among HIV-positive patients who received a TB diagnostic evaluation of TB, the proportion of patients diagnosed with TB;*
 - *e) Identify, among patients diagnosed with TB, the proportion of patients who initiated TB treatment on the day of diagnosis.*
 - 2. To describe TB-ICF routine practices at the HCC.
 - 3. To identify the barriers to the implementation, recording, and reporting of TB-ICF cascade variables.
 - 4. To measure the completeness of data related to the TB-ICF cascade in the HCC.
 - 5. To evaluate the quality of data related to two TB/HIV indicators:
 - a) Proportion of HIV-positive patients screened for TB symptoms in the HCC at the last follow-up visit;
 - b) Proportion of HIV-positive patients under HIV care or treatment (pre-ART or ART) who have initiated TB treatment.
 - 6. To determine the incidence of TB among PLHIV aged 15 years and above in HCC.

METHODOLOGY

I. STUDY DESIGN

This was a mixed study, consisting of a quantitative and a qualitative component:

- 1. The quantitative component included three independent studies:
 - Two retrospective cohort studies from a sample of the medical records of adult patients who attended the HCC during the study period for:
 - TB-ICF cascade characterization and the assessment of the completeness of the cascade related data;
 - Estimation of TB incidence among adult PLHIV.
 - A retrospective study using the medical records from all the patients (adults and children) who visited the HCC during the study period, for assessing the quality of data related to the TB/HIV indicators.
- 2. The qualitative component focused on TB-ICF practices and consisted of individual semi-structured interviews with the health care personnel from the HCC.

II. STUDY SITE

This study was conducted in the HCC supported by CDC / PEPFAR in Côte d'Ivoire, but also in the TB treatment centers where presumptive TB cases were referred for the diagnostic evaluation.

III. STUDY POPULATION

3.1. Characterization of TB-ICF cascade and evaluation of the quality of the cascade related data

Inclusion criteria

The inclusion criteria for patients whose records were included in the study were as follows:

- HIV-positive patient aged 15 years or older ;
- Have a medical record and be enrolled in the pre-ART register in the selected HCC;
- Have attended at least one visit in the selected HCC during the semester ending six months before the beginning of data collection.

Exclusion criteria

The exclusion criteria for patient records were the following:

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- Patient not maintained in care or under treatment during the quarter following immediately the date of enrollment in the cohort;
- Patient diagnosed with active TB at the date of enrollment in the cohort.

3.2. Determination of TB incidence among PLHIV

Patients selected for TB incidence determination were the same as those selected for the TB-ICF cascade characterization (as described above) with two additional exclusion criteria: 1) patients must be free of TB during the six months period preceding the date of enrollment; and 2) patients must not have been screened for TB symptoms at the date of enrollment in the cohort.

3.3. Assessment of the quality of the TB/HIV indicators

Inclusion criteria

Eligible patients for this component were HIV positive patients: 1) of any age, 2) registered in the pre-ART registers; 3) with an individual medical record; and 4) had completed at least one follow-up visit in the HCC during the quarter ending six months before the beginning of data collection.

3.4. Qualitative evaluation of TB-ICF practices

Inclusion criteria

The participants in the qualitative component should have: 1) been employed in the selected HCC for at least one year; 2) been involved in the TB-ICF activities; 3) been present at the time of the interview; and 4) given his/her informed consent to participate in the study.

IV. SAMPLING FRAME AND SAMPLE DESIGN

The HCC were selected with a probability proportional to the size of their active file. The sampling frame consisted of a list of 431 HCC supported by CDC / PEPFAR in Côte d'Ivoire.

4.1. TB-ICF cascade characterization and evaluation of the quality of cascade-related data

The sampling frame consisted of a list of eligible patients' individual medical record numbers for the study period during which a fixed number of records (110) was selected successively starting from a random date.

4.2. Determination of TB incidence among PLHIV

The sampling frame was made of the list of 110 patients initially selected in the previous step (i.e. the TB-ICF cascade characterization).

Presumptive TB cases were looked for in Pre-ART registers or the individual patients' files during the observation period.

Patients diagnosed with TB were looked for in the case notification registers available at centers offering TB-related services (TC/DTC).

4.3. Evaluation of the quality of the TB/HIV indicators

The investigators selected all eligible patient records who attended the selected HCC during the study period.

4.4. Qualitative evaluation of TB-ICF practices

The sampling frame consisted of a list of eligible staff at each selected HCC; two health care providers from each site were selected by simple random sampling.

V. SAMPLE SIZE

5.1. TB-ICF cascade characterization and evaluation of the quality of cascade-related data

The sample size was calculated to estimate the proportion of patients who started TB treatment on the day of diagnosis (step 5). The expected proportion of PLHIV who started TB treatment on the day of diagnosis was estimated at 80%. The design effect was set at 2 to take into account the cluster sampling design. The sample size was increased by 10% to take into account missing records. The statistical margin of error was set at 5%. A total of 328 patient records were required at step 5 of the cascade.

For each step of the ICF cascade, the sample size was extrapolated using the one calculated at the previous step, by dividing it by the expected proportion of patients who reached the next step. Thus, the sample size at step 4 corresponded to the size calculated at step 5 divided by the proportion of patients expected to move from step 3 to step 4.

The proportion expected at step 1 of the cascade, corresponding to PLHIV screened for TB symptoms at the last visit was 72%, according to the study conducted by ICAP in 64 health care facilities [5]. The same study showed that 21% of the PLHIV who were screened for TB symptoms were suspected with TB (step 2). Step 3 indicates the proportion of presumptive TB cases who received a TB diagnostic evaluation. Sputum sample collection and/or chest radiography were systematically and immediately done at the time of clinical diagnosis. Therefore, to take into account human errors, we assumed in this study that the expected

proportion of presumptive TB cases received a diagnostic evaluation was 95%. The proportion expected at step 4, corresponding to the proportion of PLHIV diagnosed with TB among presumptive TB cases evaluated for TB was estimated at 50%, in the absence of data. Table 1 shows the calculation of the total sample size.

	Step 5 (Proportion of patients at step 4 who initiated TB treatment 4)	Step 4 (Proportion of step 3 patients diagnosed with TB)	Step 3 (Proportion of step 2 patients who received a TB diagnostic evaluation)	Step 2 (Proportion of step 1 pre- sumptive TB cases)	Step 1 (Proportion of eligible patients screened for TB symptoms)
Expected proportion	0.80	0.50	0.95	0.21	0.72
Sample size	328 ÷ 0.5 =	656 ÷ 0.95 = 6	91 <i>÷ 0.21</i> = 3291 <i>÷</i>	- 0.72 = 4,571	

Table 1 : Calculation of th	e cohort sample si	ze for the study
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To evaluate the cascade, a sample of 4,571 patients' records was required, and data should be collected from 42 HCC. To obtain the proper sample size from these 42 sites, 110 individual patients' records originating from each HCC was selected for the study, i.e. a total of **4,620** patients' records.

5.2. Determination of TB incidence among PLHIV

The incidence of TB among PLHIV is the proportion of PLHIV diagnosed with TB during their follow-up period. The observation period necessary to determine TB incidence corresponded to six months from the date of enrollment for each patient (date of the first observation of the cascade). The date of TB contagion was estimated to be halfway between the date the patient is suspected of having TB and the date of the previous ICF.

For this study, the incidence was estimated using the following formula:

 $TB Incidence = \frac{Number of new TB cases observed during the period}{Total number of PLWH * Time of exposure during the period}$

VI. DATA COLLECTION

6.1. Training of the data collection teams

The 12 interviewers making up the six data collection teams were trained, during a three-day workshop, on ethics in research involving human subjects, study protocol, data collection tools, and study procedures.

6.2. Pretesting of tools

Before the beginning of the study, all the data collection tools were pre-tested for two days in two HCC located in Abidjan and not selected for the study. The pre-test was helpful in assessing the quality of the data collection tools, and provided guidance for the proper administration and filling of the various tools.

6.3. Data collection procedures

The six data collection teams were simultaneously assigned to the different HCC. Data collection took place over a seven weeks, starting by the 23 sites in Abidjan, and before going to the 19 sites outside of Abidjan.

6.4. Data collection tools and type of data collected

6.4.1. Site characteristics

Information related to the site was collected from the manager of the HCC and included the following items:

- 1. Type of structure: public, private, confessional;
- 2. The integrated or non-integrated nature of the health facility;
- 3. The source of financial/technical support: government, NGOs, religious affiliation;
- 4. The number of staff;
- 5. The number of HIV positive patients currently enrolled in care.

6.4.2. TB-ICF cascade characterization and evaluation of the quality of the cascade-related data

Data were collected from the pre-ART registers and included basic administrative information (Site name, Patient registration number, Date of registration, Date of last visit during the study period), biological data (CD4 count at the date of enrollment in the cohort), basic demographic data (Sex, Age), and TB-ICF cascade variables. These variables were the following:

- 1. TB symptoms screening performed at the last visit during the study period;
- 2. Results of the TB symptoms screening at the last visit during the study period;
- 3. Referral to a TC or DTC for a TB diagnostic evaluation;
- 4. TB diagnostic evaluation and the date of the evaluation.
- 5. Results of the TB diagnosis evaluation and date of results.
- 6. Initiation of TB treatment and date of initiation.

VII. STUDY PERIODS

Data collection took place from September 7th to October 23rd, 2015, and medical records of eligible PLHIV were processed from September 7th, 2014 to March 7th, 2015. Enrollment periods for the TB-ICF cascade characterization and evaluation of the quality of cascade-related data for the selected TB/HIV indicators were identical on all sites. Figure 2 illustrates the enrollment periods for the retrospective studies.

Beginning 09/07/2015

Study periods	M1	M2	М3	M4	M5	M6	M7	M8	M9	M10	M11	M12	Data collection
TB-ICF cascade characterization	From September 7 th , 2014 to March 7 th , 2015												
TB incidenceFrom September 7th, 2014 to March 7th,determination2015			ch 7 th ,	Obs	ervatio	on perio detern	od for T ninatior	B incide	ence	From September 7 th to October 23 rd ,			
Validation of		From	Octob	er 1 st									2015
TB/VIH		to De	cembe	r 31 st ,									
indicators			2014										

Figure 2: Data collection periods for the retrospective studies

VIII. STUDY MONITORING

A study monitoring committee, led by the DPPEIS, was composed of five representatives from the following organizations: PNLS, PNLT, INS, CDC/PEPFAR, and FHI 360.

The committee helped in finalizing the protocol, the data collection tools, and the study final report. The committee also monitored the implementation of activities on sites.

The internal supervision was done by the team leaders through debriefing sessions organized at the end of each day, to anticipate any challenges. A report on the study progress and difficulties encountered was then presented, on a daily basis, to the supervisor.

The external supervision was carried out by FHI 360, in collaboration with two other members of the monitoring committee.

IX. DATA MANAGEMENT

The semi-structured interview notes were converted into MS Word files on a daily basis and all the data collection forms were collected by the team leaders and stored in archive boxes on a daily basis. Patients' record identification codes were destroyed prior to leaving the data collection sites. At the end of the study, all the study forms were transported by the team leaders to the FHI 360 office in Abidjan.

A double entry of the quantitative data was performed using CSPro (Census and Survey Processing System) version 6.2. Data were compared and all differences were corrected; all inconsistent values were identified and corrected. The majority of the qualitative data (collected using a semi-structured questionnaire) was coded and entered using an input mask developed using CSPRO version 6.2.

X. DATA ANALYSIS

Data were analyzed using STATA 13. The analysis of the quantitative data consisted of a description of patient and site characteristics, and a logistic regression to identify the key factors associated to TB-ICF implementation in the HCC.

The TB-ICF cascade characterization was done by calculating, at each step of the cascade, the proportion of patients who received the appropriate service overall and by type of sites. The quality of the TB / HIV indicators was assessed by comparing the values from pre-ART registers to values reported to CDC by the implementing partners. The distortion rates between the two values were computed using the formula below:

Distortion rate =
$$\frac{\text{Reported result} - \text{Calculated result}}{\text{Reported result}} \times 100$$

Qualitative data were also analyzed using STATA 13 after being coded. A content-driven by theme approach was used for the open-ended responses to highlight similarities and differences between the various interviews with respect to the barriers to the optimal implementation, recording, and reporting of TB-ICF, and participants' suggestions for improving TB-ICF in the HCC.

ETHICAL CONSIDERATIONS

Before the beginning of the study, the protocol was submitted for approval to the National Ethics Committee for Research in Côte d'Ivoire, the FHI 360 Protection of Human Subjects Committee, and the technical review in CDC Atlanta.

As quantitative studies were retrospective and did not involve any interaction with the patients or biological sample collection, this component did not require any informed consent administration.

Informed consented was administrated to each participant of the qualitative study. Participants were briefed on the purpose of the study, their role in the study, how information would be collected, the voluntary nature of their participation, and measures taken to protect the confidentiality of data collected during the study. Participants were then asked to sign the informed consent form.

I. QUANTITATIVE STUDIES

The 42 study sites that were visited were located in 39 HCC. Overall, 4,410 records were reviewed by the data collectors. One medical record with lots of missing data was excluded, leaving 4,409 medical records for all subsequent data analysis. TB-ICF was considered as not implemented when it was not documented.

1.1. Description of the study sites and study population

1.1.1. Characteristics of the study sites

• Type of study sites

The study was conducted across 42 sites, including 23 sites in Abidjan. The majority of the sites (80%) was public facilities, private not-for-profit sites and confessional sites representing 10% each of all the selected sites (Figure 1).



Figure 3: Distribution of the 42 study sites

More than half of the study sites (54%) were sites with an integrated TB diagnosis and treatment center (DTC), i.e. 21 out of the 39 HCC.

• Number of PLHIV receiving care on the study sites

The number of PLHIV receiving care on the study sites showed high variability (Table 2). For half of the study sites, the number of PLHIV receiving care was below 1,189 PLHIV. The smallest site had a number of 95 patients, while the largest site had 6,471 HIV positive patients.

The private not-for-profit sites had a number between 1,089 and 4,822 PLHIV. Overall, 50% of the confessional sites had less than 949 patients.

Type of facility	Number of facil- ities	Median Number of PLHIV receiv- ing care	Minimum Number of PLHIV receiv- ing care	Maximum Number of PLHIV receiv- ing care
Public	31	1,185	95	6,471
Private, not-for-profit	4	2,346	1,089	4,822
Confessional	4	949	477	6,031
Total	39	1,189	95	6,471

• Number of staff providing care and treatment to PLHIV

On all the study sites, an average of 33 health care providers was in patient care and treatment (Table 3). Public health care facilities showed great variability in the size of the number of their staff members. Overall, private not-for-profit facilities had a higher number of staff compared to other types of facilities, with an average of 41 health care personnel involved in patient care and treatment.

Type of facility	Number of facil- ities	Average Number of HCP	Minimum number of HCP	Maximum number of HCP
Public	31	34	3	129
Private, not-for-profit	4	41	15	55
Confessional	4	23	13	43
Total	39	33	3	129

Table 3 : Description of the healthcare personnel (HCP) of the 42 study sites by type of facility

1.1.2. Characteristics of the PLHIV selected for the study

• Socio-demographic characteristics

About two thirds of the HIV patients in this study (73%) were women.

HIV positive patients had a mean age of 42 years (range: 15 to 84 years). Men had a mean age of 46 years compared to 41 years for women.

There was no significant age difference with respect to geographic location (Table 4).

Table 4: Age of the PLHIV selected for the study by sex and site location

		Number of	Average	Median	Minimum	Maximum
		PLHIV	age (years)	age (years)	age (years)	age (years)
Sex	Male	1,208	46	46	16	84
	Female	3,201	41	40	15	80
	Total	4,409	42	41	15	84
Sites	Sites outside Abidjan	2,065	42	41	15	75
	Sites in Abidjan	2,344	42	41	16	84
	Total	4,409	42	41	15	84

• Description of PLHIV CD4 count

CD4 is an important marker of the immune system. HIV infection has a negative effect on CD4 cell count, making HIV positive patients more vulnerable to opportunistic infections. The normal values for CD4 count vary between 500 and 1200 cells / μ l.

Overall, PLHIV had an average CD4 count of 426 cells / μ l (median value = 382 cells / μ l; range: 2 - 3,012 cells / μ l). The average CD4 count was 366 cells / μ l for men and 449 cells / μ l for women. There was no difference in the average CD4 count by geographic location (Table 5).

		Number of PLHIV	Average CD4 count	Median CD4 count	Minimum CD4 count	Maximum CD4 count
	Male	1,208	366	329	2	1,625
Sex	Female	3,201	449	402	2	3,012
	Total	4,409	426	382	2	3,012
Sites	Sites outside Abidjan	2,065	426	382	2	3,012
	Sites in Abidjan	2,344	426	384	2	1,939
	Total	4,409	426	382	2	3,012

Table 5: CD4 count of the 4,409 PLHIV who participated in the study by sex and site location

• Ratio of number of PLHIV per number of health care personnel

The number of PLHIV per health personnel involved in the care and treatment of PLHIV and involved in the TB-ICF activities (or ratio of number of PLHIV per health personnel involved in care and treatment) was 68. More than half (58%) of the sites that performed TB-ICF had less than 50 PLHIV per health personnel.

1.2. Completeness of data and TB-ICF cascade characterization

1.2.1 Completeness of TB-ICF cascade data

The completeness of data is an aspect of data quality and reflects whether data are missing or not. Missing data negatively influence the level of completeness of a variable. Table 6 shows

the completeness of TB-ICF cascade variables computed as the ratio of existing values per the number of expected values for a given variable.

Variables	Completeness
Variables	(%)
TB symptoms screening at last follow-up visit	91
Results of the TB symptoms screening	100
Referral for a TB diagnostic evaluation	80
Date of referral	100
TB diagnostic evaluation	57
Date of the TB diagnostic evaluation	100
Date of TB diagnosis	100
Results of the TB diagnostic evaluation	59
Initiation of the TB treatment	100
Date of the TB treatment initiation	100

Table 6 : Completeness of the TB-ICF cascade variables

Overall, TB-ICF variables were complete in 89% of the cases. Information about the performance of TB symptoms screening at last visit existed in almost all the medical records that were reviewed (91%). Information about the "Results of the TB symptoms screening" (i.e. whether or not the patient is a presumptive TB case) was present in all the medical records (100%). This is also the case for information about the "Date of referral", "Date of TB diagnostic evaluation" and "Date of TB diagnosis". However, information related to the "TB diagnostic evaluation" and the "Results of the TB diagnostic evaluation" were only present in less than 60% of the medical records.

1.2.2 TB-ICF cascade characterization

• TB-ICF cascade characterization for the visited sites

For all the sites, 79% of the PLHIV benefited from TB-ICF during the study period. Following this ICF, 1% of the PLHIV were reported as being presumptive TB cases. Slightly less than 50% (49%) of presumptive TB cases received a TB diagnostic evaluation. Among them, one third (35%) were diagnosed with TB. The very low number of presumptive TB cases identified following TB-ICF among the PMHIV (35 presumptive TB cases out of 3,485 patients screened for TB symptoms) influenced the remaining steps of the TB-ICF cascade. At the end of the cascade, only six PLHIV were diagnosed with TB, with one patient initiating TB treatment on the day of their diagnosis. Figure 2 shows the TB-ICF cascade characterization for all the 42 study sites.

% of PLHIV who benefited from TB-ICF at the last follow-up visit, among the PLHIV who received HIV care and treatment during the study period: **79%** (n=3,485)

% of presumptive TB cases among patients who benefited from TB-ICF at the last follow-up visit: **1%** (n=35)

% of PLHIV who received a diagnostic evaluation for TB, among patients with suspected TB: **49%** (n=17)

% of PLHIV diagnosed with TB, among presumptive TB patients who received a TB diagnostic evaluation: **35%** (n=6)

% of PLHIV who initiated TB treatment on the day of their diagnosis, among patients diagnosed with TB: **17%** (n=1)

Figure 4 : Results of the TB-ICF cascade for the study sites

• TB-ICF cascade characterization according to site location

Out of the 42 sites covered by the study, 23 were located in Abidjan and 19 outside of Abidjan. Figure 3 shows the TB-ICF cascade characterization by site geographic location.

HIV patients from sites located outside of Abidjan were more likely to benefit from TB-ICF than patients from sites located in Abidjan (86% against 73%, p <0.001; Figure 3).

No patient had been diagnosed with TB in Abidjan following the TB diagnostic evaluation. All the six PLHIV diagnosed with TB came from outside of Abidjan.



Figure 5 : TB-ICF cascade indicators by site geographic location

• TB-ICF cascade characterization per type of sites

Two types of sites were taken into account: integrated sites (i.e. sites with a DTC) and nonintegrated sites. The majority of the PLHIV benefited from TB-ICF, irrespective of the type of sites (Figure 4). Among the PLHIV who benefited from TB-ICF on the integrated sites, less than 1% was reported as presumptive TB cases. The six patients diagnosed with TB attended integrated sites and the PLHIV diagnosed with TB and who initiated TB treatment on the day of their diagnosis attended an integrated site located outside of Abidjan.



Figure 6 : TB-ICF cascade indicators by type of site

The proportion of PLHIV benefiting from TB-ICF in the public health care facilities was higher compared to those in the private and confessional sites (85% against 54% and 63%, respectively, p<0.001; Figure 5).



Figure 7 : TB-ICF cascade indicators by type of health care facilities

• TB-ICF cascade characterization by source of financial/technical support

HCC were supported by the government, NGOs, or religious institutions. A site could be supported by one or more of these organizations. The proportion of PLHIV benefiting from TB-ICF in the HCC supported by the government represented 95%, against 100% for the facilities supported by religious institutions, and 63% for sites supported by NGOs (Figure 6). Sites receiving a joint support also had a better completeness of TB-ICF data.



Figure 8 : TB-ICF cascade indicators by type sites' source of financial/technical support

• TB-ICF cascade characterization according to the number of PLHIV receiving care and the number of health care personnel

The study sites performing TB-ICF had an average of 1,668 PLHIV, which was substantially lower than the average number of PLHIV receiving care on sites where ICF was not performed (3,485; p< 0.001; Table 7).

		Number of PLHIV	Average	Std. Err.	Confidence Interval (95%)
	Yes	3,485	1,668	25	[1,619 – 1,717]
TB-ICF performed	No	924	2,155	53	[2,051 – 2,260]
	Total	4,409	1,770	23	[1,726 – 1,815]

Table	7:	TB-ICF	according	to th	ne number	of PLHIV	' in tl	he acti	ve file
						•, • • • • •			

In contrast, TB-ICF implementation in the HCC did not depend on the number of health care personnel involved in patients' care and treatment (Table 8).

Table 8: TB-ICF according to the number of health care personnel involved in patients' care and treatment

		Number of PLHIVs	Average Care	Std. Err.	Confidence Interval (95%)
	Yes	3,388	35	1	[34 - 35]
TB-ICF performed	No	911	35	1	[34 - 37]
	Total	4,299	35	1	[34 - 35]

• TB-ICF cascade characterization according to the ratio of number of PLHIV per number of health care personnel providing HIV care and treatment

The ratio of number of PLHIV per number of health care personnel providing HIV care and treatment was 68 for sites where PLHIV were benefiting from TB-ICF, compared to 86 for sites where PLHIV were not benefiting from TB-ICF (p < 0.001).

Sites recording more than 50 PLHIV per health care personnel performed less TB symptoms screening than sites where each staff was providing care and treatment to less than 50 PLHIV (70% against 87%, p<0.001).

• TB-ICF cascade characterization by patients' age

HIV patients benefiting from TB-ICF were on average younger than those who were not benefiting (p < 0.001; Table 9).

Table 9: TB-ICF in relation to the patients' age

		Number of PLHIV	Average Age	Std. Err.	Confidence Interval (95%)
	Yes	3,482	42	10	[41 - 42]
TB-ICF performed	No	924	43	10	[43 - 44]
	Total	4,406	42	10	[41.7 – 42.3]

• TB-ICF cascade characterization in relation to CD4 count

PLHIV who benefited from the TB-ICF had, on average, a lower CD4 count compared to patients who did not benefit TB-ICF (418 cells / μ l against 457 cells / μ l, p <0.001; Table 10).

Table 10 : TB-ICF in relation to patients' CD4 count	
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		Number of PLHIV	Average CD4	Std. Err.	Confidence Interval (95%)
	Yes	3,453	418	5	[409 – 427]
TB-ICF?	No	915	457	9	[439 - 475]
	Total	4,368	426	4	[418 – 434]

1.2.3 Key factors related to TB-ICF implementation

To identify TB-ICF key factors, a multivariate logistic regression was used to examine the effect of variables that were significantly associated with TB-ICF in the previous (univariate) analyzes: age, number of PLHIV receiving HIV care, number of PLHIV per number of health care personnel, site location, and CD4 count.

The results of the logistic regression are presented in Table 11 below. The older the patients, they less likely they were to benefit from TB-ICF (p <0.001). Similarly, patients with higher CD4 count were less likely than those with lower CD4 count, to benefit from TB-ICF (p <0.001). Health care facilities with a high number of PLHIV in care were less likely to implement TB-ICF (p <0.001). Finally, sites with a ratio of number of PLHIV per number of health care personnel higher than 50 (compared to sites with a ratio below or equal to 50 PLHIV) and sites located in Abidjan (compared to sites outside of Abidjan) were both less likely to implement TB-ICF (p <0.001).

Table 11 : Key factors related to TB-ICF impl	ementation
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Factor	Odds Ratio	р	Confidence Interval 95%
Age	0.9824	<0.001	[0.9755 – 0.9895]
CD4 count	0.9995	<0.001	[0.9992 – 0.9997]
Number of PLHIV in care	0.9998	<0.001	[0.9998 – 0.9999]
More than 50 PLHIV per staff	0.3583	<0.001	[0.3075 – 0.4173]
Site located in Abidjan	0.4353	<0.001	[0.3730 – 0.5078]

1.3. Quality of the TB/HIV indicators

The quality of the TB / HIV indicators was measured using data collected in the pre-ART registers. Data compiled from the registers or the sites' electronic information system (when available) was compared with results submitted to CDC/PEPFAR by these sites in order to calculate the distortion rate using the following formula:



1.3.1. Global Distortion

Data on the two TB / HIV indicators were not 100% complete. The number of HIV-positive patients who benefited from TB-ICF at last visit was known for 36 sites out of 39, corresponding to a completeness of 92%. The completeness of data related to the number of HIV-positive patients diagnosed with TB who started TB treatment was 67% (i.e. 26 sites out of 39).

The distortion rate was calculated by comparing, for each indicator, the absolute number of patients reported to CDC to the absolute number of patients calculated from the sites with complete data. A distortion rate above zero meant that the reported value was higher than the calculated value, whereas a negative distortion rate meant that the calculated value was higher

than the reported value. The distortion rate was categorized for ease of interpretation. The distortion rate was considered low if its absolute value was below or equal to 10%, average if it was between 10% and 20%, and high if it was higher or equal to 20% in terms of absolute value.

From the 36 sites with complete data, the number of PLHIV who received at least one clinical service in the HCC and the number of PLHIV who benefited TB-ICF during the reporting period showed a low distortion rate (7% and 3%, respectively).

On the other hand, the number of PLHIV diagnosed with TB who initiated TB treatment was overestimated, with a distortion rate of 89% (Table 12).

Indicators	Calculated	Reported	Distortion%
Number of HIV-positive patients who received at least one clinical service during the reporting peri- od (36 sites)	41,578	44,892	7
Number of HIV-positive patients who benefited from TB-ICF at the last visit (36 sites)	30,552	31,611	3
Number of HIV-positive patients diagnosed with TB who initiated TB treatment (26 sites)	163	1,427	89

Table 12: Global distortion rate for the TB/HIV indicators

1.3.2. Distortion according to sites' location

Concerning sites located in Abidjan, the reporting quality was poor for the number of HIV positive patients diagnosed with TB who initiated TB treatment (distortion rate of 80%). The reporting quality was average for the number of PLHIV who benefited from TB-ICF at the last visit (distortion rate of 13%) and the number of PLHIV who received at least one clinical service during the reporting period (distortion rate of 12%).

Sites located outside of Abidjan had generally good quality data about the number of PLHIV who received at least one clinical service during the reporting period. However, the reporting quality was average for the number of PLHIV who benefited from TB-ICF at the last visit, and poor for the number of PLHIV diagnosed with TB who initiated TB treatment (Table 13).

	Sites l	ocated in A	d outside of Abidjan			
Indicators	Calculated	Reported	Distorsion %	Calculated	Reported	Distorsion %
Number of HIV-positive patients who received at least one clinical service during the reporting period	26,852	30,555	12	14,726	14,337	-3
Number of HIV-positive patients who benefited from TB-ICF at the last visit	18,493	21,341	13	12,059	10,270	-17
Number of HIV-positive patients diagnosed with TB who initiated TB treatment	112	562	80	51	865	94

Table 13: Distortion rate for the TB/HIV indicators in relation to the sites' location

1.3.3. Distortion in relation to the type of site

Sites with an integrated DTC which had complete data on the number of HIV patients who received at least one clinical service during the reporting period accounted for 18 (i.e. 50% of sites with complete data for this indicator). They showed a good level of reliability (zero distortion rate) concerning the number of PLHIV who received at least one clinical service during the reporting period and number of HIV-positive patients who benefited TB-ICF at the last follow-up visit (distortion rate of -7%). In contrast, the number of HIV-positive patients diagnosed with TB who initiated TB treatment was insufficiently reported by these sites.

Concerning sites without any integrated DTC, the distortion rate for the number of HIV-positive patients who benefited from TB-ICF at the last visit (12%) and for the number of PLHIV who received at least one clinical service during the reporting period (13%) was average. The number of HIV-positive patients diagnosed with TB was, on the other hand, insufficiently reported, with a distortion rate of 92% (Table 14).

	S	Site with an DT	.C	Site without an integrated DTC			
Indicators	Calculated	Reported	Distorsion %	Calculated Reported		Distorsion %	
Number of HIV-positive patients who received at least one clinical service during the reporting period	20,437	20,498	0	21,141	24,394	13	
Number of HIV-positive patients who benefited from TB-ICF at the last visit	15,111	14,157	-7	15,441	17,454	12	

Table 14: Distortion rate for the TB/HIV indicators in relation to the type of site

Number of HIV-positive						
patients diagnosed with TB who	55	94	42	108	1,333	92
initiated TB treatment						

1.4. Calculation of TB incidence among PLHIV

Presumptive TB cases among patients preselected for the TB cascade characterization, who did not have TB at the date of enrollment in the cohort and six months before their selection, were followed for six months (in the period from September 2014 to August 2015). During this observation period, only seven PLHIV were suspected of having TB, and among those, no new TB cases were diagnosed, thus limiting any calculation of TB incidence using data collected from this study.

II. QUALITATIVE STUDY

The semi-structured individual interviews were conducted on the 42 study sites. On each site, the interview with the health care personnel was conducted by a sociologist from the data collection team. Participants in interviews were mainly doctors (23 persons out of 42) and had an average of six years in HIV care and treatment. Interviews focused on the following topics:

- TB-ICF among PLHIV;
- Patients referral to TB control services;
- Suggestions for improving TB-ICF among PLHIV.

2.1. TB-ICF among PLHIV

The majority of the respondents stated that TB-ICF was systematically performed among PLHIV. ICF was usually performed by screening patients for TB symptoms through a series of interview questions. The symptoms that were most frequently looked were: cough, fever, night sweats, weight loss, and contact with a person coughing or with active TB. However, some participants indicated that TB-ICF was not routinely performed for various reasons:

- A visit not apparently related to TB ("We consider the reason for each visit");
- For fear of contamination, especially among the medical doctors ("*The doctor refuses to perform ICF; he avoids contamination*");
- Lack of training on TB compared to HIV ("There is more emphasis on HIV "; "Not enough training on TB").

Moreover, the large number of patients, the fact that TB-ICF is an activity usually performed by doctors ("*It is the responsibility of the doctor*"), were other reasons given by participants to explain the non-performance of TB-ICF.

Interviews showed that TB diagnosis among PLHIV was made through two different approaches. The first approach consisted in analyzing sputum from presumptive TB cases and referring them to a DTC / TC for treatment in case of a sputum smear-positive. The second approach consisted in immediately referring presumptive TB cases to a DTC / TC for a TB diagnostic evaluation and possibly a TB treatment.

Most the sites had a TB case reporting form, according to the respondents. Moreover, there was an individual patient's file at all the visited HCC. When TB-ICF was performed, information was usually noted in the individual patient's record. However, the notification of TB-ICF results was not always done according to the large majority of respondents.

2.2. Referral to TB control services

Interviews revealed that when a patient was reported as a presumptive TB case, a referral was issued to the patient for a sputum examination and/or X-ray. Patients were mainly referred to the TC / DTC and sometimes to the laboratory. Advice were also given to the patient to avoid contaminating others.

According to respondents, patients faced three main challenges for completing the TB evaluation. The first obstacle was financial as PLHIV did not always have financial resources to cover the costs related to the TB diagnostic evaluation at the TC / DTC:

"The only major problem is patients' lack money "

"Most patients we receive here generally have financial problems. It is difficult for them to come at each visit because they do not have money "

"The lack of financial means. We often provide financial means to help needy patients because we have some funds for this purpose. "

Comments of health care providers

The second difficulty concerned the PLHIV's negligence in relation to the diagnosis made by the health care provider. This may hinder the completion of the diagnostic evaluation, as evidenced by the remarks below.

"The negligence of the diagnosis by patients"

"The negligence of the diagnosis by patients; just that and nothing else because chest X-ray is free of charge."

Finally, the third difficulty was related to the accessibility of the TB services. Indeed, the distance between the DTC/TC and the HCC was a significant obstacle to the completion of the diagnostic evaluation according to the respondents:

"The distance that the patient must travel back and forth, hospital-district-hospital"

"The remoteness of the facility where they were referred and lack of financial means for patients' transportation"

"The distance between the DTC and the General Hospital."

Besides these three major challenges, the poor reception in the TC / DTC, lack of laboratory supplies, stigmatization by the society, and absence of an effective referral system were mentioned as other obstacles to the implementation of the TB diagnostic evaluation.

Following referral of presumptive TB cases to a TC/DTC for the TB diagnostic evaluation, the respondents' comments with regards to how the diagnostic evaluation results are notified to the referring HCC could be summarized as follows:

- No notification from the TC/DTC, in most cases;
- Very often, results notified by the patient himself/herself;
- Sometimes, results notified to the referring health care facilities by the TC itself (usually in writing by registered mail, or verbally).

According to the health care personnel, the results of the TB diagnostic evaluation of TB were useful for readjusting the patient's HIV treatment and educate them with respect to the treatment's adherence. This information was also noted in the patient's medical file.

Although very useful for patients' follow-up, information obtained from the TB diagnostic evaluation was not always notified. The absence of counter-referral and lack of time were the reasons stated by the respondents, as well as the non-notification of the TB diagnostic evaluation results: "the patients who were referred did not return with their results", "the characters in the reporting form are too small and difficult to read and complete" and "TC/DTC put patients on treatment without notifying us". Another respondent stated that "the high volume of patients" is an obstacle to the notification of information related to the diagnostic evaluation.

2.3. Suggestions of health care providers for improving TB-ICF among PLHIV

To improve TB-ICF practices, health care providers were asked to make some suggestions on the following three key practices:

- TB-ICF among PLHIV;
- Referral and counter-referral between the HCC and the TC / DTC;

- Reporting of TB-ICF data among PLHIV.

2.3.1. For a better implementation of TB-ICF

The health care personnel involved in this activity made some suggestions to alleviate the obstacles to the implementation of TB-ICF among PLHIV. These suggestions could be summarized as follows (by order of frequency):

- Train health staff on TB-ICF;
- Sensitize health staff on the usefulness of TB-ICF;
- Integrate TB diagnosis and treatment into the HCC;
- Provide the TB diagnostic exams (sputum examination and pulmonary radiography) free of charge for PLHIV in the TC /DTC;
- Improve the quality of the individual patient's file;
- Give financial incentive to the agents responsible for reporting.

It has also been suggested to "*create an integrated TB diagnostic and treatment center across all the sites providing care and treatment to PLHIV*". The introduction of free examination in the TC / DTC for HIV positive patients could begin by a "*subsidy to cover the cost of pulmonary radiography*" according to a respondent.

In addition, a better reception in the TC / DTC, increasing the number of health care personnel involved in TB-ICF would alleviate some of the obstacles identified for implementing TB-ICF among PLHIV in the HCC.

2.3.2. For an effective referral of presumptive TB cases in the TC/DTC

The study participants were asked to make some suggestions for the proper functioning of the referral and counter-referral system between the HCC and the TC/DTC. These suggestions are listed below by order of occurrence:

- Establish an effective communication system between the HCC and the TC / DTC;
- Make referral and counter-referral forms available at all levels;
- Require documented referrals and counter-referrals between the different services;
- Ensure that the exams for the TB diagnostic evaluation are free of charge at the TC / DTC for PLHIVs;
- Open a DTC at all the HCC.

Other suggestions included "the appointment of an agent to accompany the presumptive TB cases to the health care facilities" and "taking into account patients' home address prior to

referring him/her to a given facility." In addition, respondents suggested to "*sensitize patients and review the cost related to the medical exams*».

2.3.3. For a better reporting of TB-ICF data

Overall, the reporting of TB-ICF data is an activity that needs to be improved at the HCC. The analysis of the interviewed health staff answers highlighted the following proposals to improve the reporting of TB-ICF data:

- Reinforce the capacity of the agents involved in reporting;
- Sensitize the agents in charge of reporting;
- Give financial incentives to the agents;
- Provide staff dedicated to data reporting at all levels;
- Increase the number of staff involved in data reporting;
- Reduce the number of data collection tools to be filled;
- Adapt the patient's medical record for the reporting of TB-ICF data;
- Develop new individual patient's files.

CONCLUSION

The MSHP of Côte d'Ivoire has benefited from the financial support of PEPFAR for more than a decade (2004-2016), through the implementation of the "Care and treatment" program for PLHIV.

The evaluation of TB-ICF implementation, recording, and reporting among PLHIV in Côte d'Ivoire has highlighted a number of issues with respect to the effective implementation of this strategy. TB-ICF was only performed for 79% of PLHIV and only 1% of those were identified as presumptive TB cases. Despite the availability of tools for notifying and recording the diagnosed cases (TB reporting forms and individual patient files) across most of the health facilities that were visited, the notification of TB-ICF results was not always done by the majority of health care providers.

Overall, data related to the cascade indicators showed a completeness level of 89%. This study also showed that patients' age, the number of PLHIV receiving HIV care, the number of PLHIV per number of personnel providing care, site location, and CD4 count were factors that significantly influenced TB-ICF performance. On the other hand, the existence of a DTC within the HCC was not significantly associated with the performance of TB-ICF.

The main reasons cited to explain the non-performance of TB-ICF were related to the program, the health care provider or the patient. As for the program, reasons were related to the high number of patients and the fact that the performance of TB-ICF is the responsibility of doctors. Those concerning the health care provider were, among others, visit not apparently related to TB, the fear of contamination, and a lack of training on TB compared to HIV. Finally, patient-related reasons concerned the lack of financial means to cover the costs for carrying out the TB diagnostic evaluation at the TC / DTC, the negligence by PLHIV of their diagnosis, and access to TB services.

The evaluation of the quality of data related to the TB/HIV indicators also showed relatively important differences between the values transmitted to CDC by the implementing partners and the values calculated using the study data.

To improve TB-ICF practices in the HCC, interviewed health care providers made some suggestions for improving the TB-ICF, referral and counter-referral between the HCC and the TC/ DTC, and the reporting of TB-ICF data.

RECOMMENDATIONS

In order to consolidate the achievements of the HIV "Care and treatment" program and contribute to improving the systematic implementation of TB-ICF among PLHIV, the following recommendations are proposed to the MSHP:

- Train the health care providers on TB-ICF, especially paramedics and community health workers;
- Sensitize the health care personnel on the need for TB-ICF;
- Reinforce the capacities of the agents involved in reporting;
- Ensure the coaching of the health care providers regarding the correct filling of the primary data collection tools;
- Make staff available for data reporting;
- Promote the integration of TB services into the HCC by opening a laboratory where needed;
- Strengthen the referral and counter-referral system between the HCC and the TC / DTC;
- Enhance communication among health workers;
- Ensure that pulmonary radiography at the TC / DTC are free of charge for PLHIV not yet diagnosed with TB;
- Delegate TB-ICF tasks to paramedics including nurses and midwives, and community health workers.

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ANNEXES





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Annex 2 : Data recording slip of TB-ICFamong HIV infected adults/teenagers



 4. Have you had an evening fever that has lasted for more than 3 weeks? 5. Have you recently been in contact with a person with TB disease? 	Ves No	Ves No	Yes No	Yes No				
INSTRUCTIONS								
Think about TB and do a diagnostic investigation for the following situations: - Cough that lasts for more than 3 weeks with or without other associated signs (see question # 1); - All other signs (see questions 2 to 5) in the absence of cough; - Difficult breathing, edema and ascites syndrome, lymph node swelling, neck stiffness, bone pain; CONCLUSION								
tuberculosis	Yes No	Yes No	Yes No	Yes No				
RECOMMENDATIONS								
If the patient is suspected of Tuberculosis, select an option below depending on the status of your institution :								
The patient is supported in your organization for Tuberculosis diagnosis and treatment	Yes No	Yes No	Yes No	Yes No				

The patient is referred for diagnosis and supported in your organization for Tuberculosis treatment	Yes No	Yes No	Yes No	Yes No
The patient is referred to a Tuberculosis diagnosis and treatment center	Yes No	Yes No	Yes No	Yes No

Annex 3 : "Form A" for site data collection

Site Name:	Investigator:
District:	Position of interviewee:
Region:	Data collection date ://

	Center Status			HIV ated æ	Source of Financial/Technical Support			Number of staff involved in	Active File (at the end of the 02 TB/HIV	Number of PLWHA attended on the reporting quarter corresponding to	
Public	Private	Religious	Yes	No	State (BGE)	NGO	Religious	PLWHA* care	indicators reporting period)	the recruitment period	

*Physician, druggist, pharmacy manager, IDE, SFDE, assistant nurse, bio technologist, community advisor, social worker

Annex 4 : Data collection "Form B" for determining TB-ICF cascade and incidence of TB

Site name: _____

Interviewer : _____

District: _____

Data collection date : _____/____/_____

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Region: _____

Recruitment date : ______

	Data source	Patient N°	Inclusion of date in the cohort	Numb follow- mor	per of up nths	Sex	Age (year)	CD4 count at entry	TB Screening performed	TB Intensive Finding result	Referred for TB diagnostic	Referral	TB diagnostic investigation (yes/no)	TB diagnostic investigation date	TB diagnostic investigation result	TB Diagnosis Date	TB treatment initiated (ves/no)	TB Treatment start-up date	1 st visit date of the	following the i inclusion in e cohort	2 nd vis the dat in t	it following e of inclusion he cohort	3 rd visit date of th	following the f inclusion in e cohort	Patient Name
				ART	Pre ART			in the cohort		TB (S or NS)	evaluation	Date					(10)	uute	Date	Suspect (yes/no)	Date	Suspect (yes/no)	Date	Suspect (yes/no)	
1	VIH File																							ſ	
	TB File																								
2	VIH File																								
	TB File																							ľ	
3	VIH File																								
	TB File																							1	
4	VIH File																								
	TB File																								1
5	VIH File																							ľ	j
	TB File																								
6	VIH File																							· ·	l
	TB File																								1
7	VIH File																								1
	TB File																							ľ	J
8	VIH File																								
	TB File																							1	l
9	VIH File																						1		1
	TB File																								1
10	VIH File																								

Annex 5 : "Form C" data collection for PEPFAR's TB/HIV indicators quality assessment

Site name:	Interviewer :
District:	Data collection date//
Region:	Study period :

Record page	Number of recorded patients	Number of patients who received at least one clinical service during the reporting period	Number of HIV positive patients screened for TB symptoms during last visit	Number of HIV patients diagnosed positive for TB who have inititated TB treatment

Annex 6 : Semi-structured interview guide for qualitative evaluation of onsite TBICF practices

Site name:	Interviewer:					
District:	Data collection date ://					
Region:	Study period :					
Person interviewed (position):						
Number of years working at this facility in this position :						
Sex : 🔄 Male 📃 Female						

A: TB Intensive Finding among PLWHA

1. How do patients benefit from TB Intensive Case Finding?

- Do you have the records of active research of TB in PLHIV?
- Do you have the individual patient records?
- Are you actively looking for TB in PLHIV?
- When do you suspect tuberculosis in a PLWHAA?
- Can you tell me about the process of actively searching for TB?
- When do you make an active search for TB in PLHIV?
- What specific questions would you ask the patient during an active search for TB?

2. Are you always able to complete TB Intensive Case Finding among PLWHA? If no, why

3. Do you record the results of TB Intensive Case Finding?

Where do you record these results?

4. Are you always able to record the results of TB Intensive Case Finding among PLWHA?

B: Patients referral for TB control services

5. What do you do when a patient is thought to have TB?

- How do you ensure that the patient receives a diagnostic investigation of TB?
- What is the referral process for diagnostic evaluation?
- Where are patients referred for diagnostic evaluation?
- What are the forms or documentation that the patients are given for diagnostic evaluation?

6. Do you always get the results of TB suspect patients referred for TB services?

- What do you think could prevent patients from being successfully referred for diagnostic evaluation (referral and counter-referral)?
- What do you think could prevent referred suspect patients from receiving diagnostic evaluation?

7. When a TB suspect is referred to a CAT/CDT, how do you receive information about the services the patient has received?

- Does the CAT/CDT give you information directly or do you have to ask for that?
- How is this information communicated to you?
- Is it the patient that verbally reported this information? If so, why?
- Does the patient return with the documents issued by the CAT / CDT? (result under seal)

8. When a patient receives TB services, what do you do with the information you get from these services?

- Is this information recorded?
- How is this information recorded?
- Where is it recorded?
- Who records it?

9. What challenges do you face in recording information on TB services received by patients referred to CAT / CDT?

C. SUGGESTIONS

1. What do you suggest for improving systematic TB Intensive Case Finding among PLWHA?

2. What do you suggest so that referral and counter- referral occur successfully between your facility and CAT / CDT?

3. What are your suggestions for improving data reporting in TB Intensive Case Finding among PLWHA?

Annex 7: Informed consent form

INDIVIDUAL INFORMED CONSENT FORM FOR PARTICIPATION IN THE SURVEY

The Ministry of Health and the Fight Against AIDS (MSLS), in collaboration with the United States Centers for Disease Control and Prevention (CDC) and the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) through Family Health International 360 (FHI 360), are conducting research related to intensified tuberculosis case finding among people living with HIV/AIDS (PLWHA) in care and support centers in Côte d'Ivoire. The research involves two components:

- The first component consists of three independent surveys from the records of patients living with HIV.
- The second component consists of interviews of health personnel related to tuberculosis intensified case finding practices among PLWHA in care. A total of 42 health workers will take part in the interview.

I am asking you to participate in the interview. After I explain the interview, I will ask you whether you agree to participate or not and then I will ask you to sign a paper to document your decision. We will give you a copy of the information that I will read to you now. You can ask questions to clarify your understanding at any time.

Purpose of the Survey

The information collected during the survey will be used by the MSLS, CDC/PEPFAR, and other organizations working for HIV/AIDS control.

This information will be used to advocate for policies and programmatic actions to improve screening, diagnosis and treatment for TB among PLWHA, as well as data quality. It will also help decision-making at the government level to provide better services to PLWHA.

General Information About the Survey

For this study, 42 health centers, including yours, were randomly selected. In each of them, we invite two randomly selected health workers who are involved in the care and support of PLWHA to answer some questions about active tuberculosis case finding. To participate in this

study, an investigator will ask you some questions and write down your answers. There is no right or wrong answer in this interview. We need you to be as honest as possible. The answers you will provide will help the MSLS improve decision making. You can refuse to answer any questions you don't wish to answer. Your name will not be associated with your answers because your questionnaire will be identified by a number. Nobody from your department or your organization will know what you have said while answering our questions.

Your Part in This Study

If you agree to participate in the survey, you will be asked questions about the practices implemented in your center for TB screening for PLWHA and referral practices for presumptive TB patients. The interview will take between 30 and 45 minutes. You can decide to end the interview at any time without penalty.

Potential Risks

We are asking these questions in order to understand how health workers HIV care and treatment sites in Côte d'Ivoire conduct tuberculosis intensive case finding. If you do not want to answer a specific question, you are welcome to refuse. If the answers you share with us were to be released, some people might think that you said things you should not have. Others might say that you have exposed your service or organization through participating in the study.

However, in order to maintain your privacy, your answers will not be associated with your name and we will not specify the names of the responding health centers during the data analysis and presentation. Also, the content of our discussion will not be disclosed to your supervisors or patients.

Possible Advantages

In this study, there is no financial incentive for you as a participant.

However, the results of this evaluation will help improve active TB case finding practices among the population of PLWHA.

Thus, by helping improve the quality of TB screening and treatment among PLWHA in Côte d'Ivoire, you will help improve care and support for these people.

Non-participation in the Survey

You are free to decide whether you want to participate in this survey or not. Your decision will not affect the services or benefits that you normally receive as part of your work.

Confidentiality

Your name will not be written on any data collection forms. Your answers will be linked with a unique number that will be reported in other documents. Nobody other than the field team responsible for collecting information here today will be able to identify you from this number. The field team is not authorized to disclose the information you give. When the work is over the answers will be compiled for processing and the origin of the comments will not be disclosed.

When the results of this study are published, your name will not be disclosed because the survey is anonymous.

Compensation

As participation in this survey is voluntary, you will not receive any compensation for your participation.

Alternative to Participation

If you refuse to participate, you can leave the room now.

Other questions

If you have any questions about the survey, please feel free to let us know If you have questions about the survey after the team has left the site you may contact:

- Dr. Hortense Angoran-Benie ; Tel : 22 40 50 10 / 05 57 14 41

or

- Dr. Guy Morineau ; Tel : 22 40 50 10 / 58 88 55 04

Your Rights as a Participant

This study has been examined and approved by the National Committee for Research Ethics in Côte d'Ivoire (CNERCI) and the Protection of Human Subjects Committee at FHI 360 (PHSC). These committees review research involving human subjects in order to protect participants. If you have any questions about your rights as a participant or believe that wrongdoing has occurred during this research, you may contact: the *CNERCI at 01 50 41 42*, and the *Protection*

of Human Subjects Committee of FHI 360, PO Box 21059, Durham, NC 27703, USA, 1-919-405-1445.

You are free to stop taking part at any time. You may quit without penalty.

• Do you agree to take part in this survey?

Yes, I agree to take part in it

□ No, I don't agree to take part in it

SIGNATURE

"I certify that the nature, purpose, potential benefits and risks associated with participation in this survey were explained to me. I understand all aspects of this study. I consent to participate in this study and state that I have not been forced into my choice."

"I understand that the study i take part in this study"	s voluntary and that it is not a work obligation to
"I understand that the study	is anonymous" 🗌
"I understand that the study provide will not be published which I work"	data are confidential and that the information I will together with the name of the health facility in
Particinant's Signature	 Date

«I certify that I have explained to the respondent the nature, purpose, potential benefits and risks associated with participation in this survey. I am sure he or she understands the activities of this survey».

Signature of the Study Staff

Date

Annex 8 : Investigators' confidentiality agreement

My name is I am working as an investigator in the evaluation of the Intensive Case Finding of tuberculosis in HIV care and treatment centers in Côte d'Ivoire. I understand that I will have some information on PLWHA cared for in centers selected for this study and others from tuberculosis control services where these patients were referred.

I will also have some information provided by participants about their TB screening and referral practices for presumptive TB patients.

I understand that this information is strictly confidential and I commit to protect the confidentiality of all participants and PLWHA whose records are used in this investigation.

I pledge to protect the confidentiality of participants and PLWHA whose records are used by not discussing, not disclosing, and not sharing their information, to or with any person, institution, or organization not directly involved in this study and not authorized to receive the information.

I understand the prejudice that can be caused to PLWHA participants if their records and identity are disclosed.

I understand that any voluntary disclosure of information about this study could result in administrative actions and lawsuits against me.

I undertake to comply with the standards provided above and survey procedures. Violation of these rules will be documented and reported immediately to the investigators.

I agree that any document to be redacted or destroyed because it contains identifying items will be processed in accordance with the existing procedures for managing the survey data.

Signature of the Study Staff

Date

Annex 9 : TB-ICF notification in Pre-ART Records

		Unique ID Number	Status New					Sex			Tuberculosis																
	Visit Date					Entry						Intensive Finding		ve g	Intensive Finding result					ТТТ ТВ							
N°			Newly enrolled	Transferred	Past	Point 1 (transferr ed, TB, PTME, CDV, others)	< 15 years	>= 15 years	F	М	HIV type	Done	Not done	TB Already	No sign	Suspected and referred	TB Suspected and sputum sample sent	to the lab	confirmed	TB diagnosis not confirmed	No TTT TB	TTT TB beginning	TTT TB progress	TTT TB stop	TTT TB end	Cured	Cured and referred

Annex 10 : TB-ICFnotification in patient's medical file

Patients N°: /____ /___/____/

Admittance Date: ____ / ____ / ____ ___.

ART start date: ____/ ___/ ____.

Date	Duration		Constant	s		IOs in progress and occurred since last visit								
	since ART					If yes, please check the box and specify other information								
	M)	Size (cm)	Weight	T°	ТА	TB Intensive Finding: 1-cough lasting for more than 3 weeks 2-night sweating 3-weight loss (involuntary loss of weight>3kg during last month) 4-night flu lasting more than 3 weeks 5-contact with a TB	Tuberculosis treatment 0=No TTT TB 1= TTT TB beginning 2= TTT TB progress 3= TTT TB stop 4= Not cured	IOS other than TB (date) 0=no IOS 1=Toxoplasmosis 2=Kaposi 3= 4=Pneumonia 5=Candidiasis 6=herpes zoster	Other IOS 0=No 1=Yes					
						intensive person	5=Cure							
						TB screening result: 1= No sign 2= Suspected and referred 3= TB Suspected and sputum sample sent to the lab 4= TB diagnosis confirmed	if 1, 2 specify the tuberculosis treatment	Date	If 1 : specify the disorder					
//_						1 2 3 4 5 1 2 3 4 5 1 1 1 1 1 0 1 2 3 3	012345	0 1 2 3 4 5 6	0 1					
//_									0 1					



Study report Assessment of the implementation, recording and reporting of intensified tuberculosis case-finding in HIV care and treatment settings in Côte d'Ivoire

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Annex 11 : Map of the HCC in Côte d'Ivoire (Health districts supported by PEPFAR and the Global Funds)

AUTHORS

This report was written by a team of FHI 360 and MSHP consisting of:

- Dr. Traore-Toure Fatoumata, Project Director/ Director of Science, FHI 360;
- Dr. Ouffoue Ange Fulgence, Monitoring & Evaluation Senior Technical Officer, FHI 360;
- Dr. Etheredge Gina, Strategic Information / Monitoring & Evaluation Senior Technical Advisor, Washington-USA, FHI 360;
- Dr. Yapo Adja Beaudrea, TB-HIV Focal Point at the PNLS, MSHP.