

Strengthening Tuberculosis Control in Ukraine

Evaluating the Impact of the TB-HIV Integration Strategy on Treatment Outcomes

July 2018



ABSTRACT

This impact evaluation of the Strengthening Tuberculosis Control in Ukraine project examined the relationship between the strategy for integration of tuberculosis (TB) and HIV services and TB-HIV service use and mortality outcomes. The study employed a mixed-methods approach, with a quasi-experimental quantitative evaluation design, complemented by qualitative interviews to inform the findings. Using data abstracted from TB and HIV health facility records at baseline and end line, we employed a Coxproportional hazards model with a difference-in-differences approach to assess the impact of integration on diagnostic testing and treatment for TB and HIV at each health facility.

The qualitative study results suggested that the TB-HIV integration program affected several positive changes in the integration of services, especially around availability of diagnostic tests across facilities and the training of providers. Based on findings from data from both AIDS center records and data abstracted from TB dispensaries, the TB-HIV integration program was associated with a significant increase in the timely initiation of antiretroviral therapy. We did not find a statistically significant impact on survival based on data either from the TB or HIV facilities.

EVALUATION

Strengthening Tuberculosis Control in Ukraine

Evaluating the Impact of the TB-HIV Integration Strategy on Treatment Outcomes

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MEASURE Evaluation

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ABBREVIATIONS

AIDS	acquired immunodeficiency syndrome
ART	antiretroviral therapy
CI	confidence interval
СРТ	cotrimoxazole preventive therapy
СТ	computed tomography
DOTS	directly observed treatment, short-course
EIA	enzyme immunoassay
ELISA	enzyme-linked immunoassay
HF	health facility
HR	hazard ratio
HTC	HIV testing and counseling
ID	infectious disease
IPT	isoniazid preventive therapy
MDR-TB	multidrug resistant tuberculosis
NGO	nongovernmental organization
PCR	polymerase chain reaction
PLWH	people living with HIV/AIDS
PMDT	programmatic management of drug-resistant tuberculosis
PWID	people who inject drugs
S1, S2	Sample 1, Sample 2
STbCU	Strengthening Tuberculosis Control in Ukraine
ТВ	tuberculosis
VCT	voluntary counseling and testing
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNC-CH	University of North Carolina at Chapel Hill
USAID	United States Agency for International Development
URCS	Ukraine Red Cross Society
WHO	World Health Organization
XDR-TB	extensively drug-resistant tuberculosis

EXECUTIVE SUMMARY

Purpose and Background

Ukraine is one of 30 countries with the highest tuberculosis (TB) burden in the world, and one of 10 countries with the highest incidence of multidrug-resistant TB, making it one of the highest priority countries in the World Health Organization (WHO) European Region to fight TB. About one quarter of all patients with TB in Ukraine are estimated to also be HIV-positive. The treatment of TB-HIV coinfections is particularly challenging as TB becomes more virulent in the presence of HIV-associated immunosuppression. Given the complexities of treating coinfected patients, HIV and TB diagnostic and treatment regimens need to be closely aligned; specialized services for patients with coinfections need to be readily available at AIDS centers and TB dispensaries. Strengthening Tuberculosis Control in Ukraine (STbCU)—a project funded by the United States Agency for International Development (USAID)—aimed to strengthen the delivery of TB and HIV services, with the goal of improving timeliness of care and enhancing the life expectancy of patients with TB-HIV coinfections. The USAID mission in Ukraine commissioned MEASURE Evaluation—funded by USAID and the United States President's Emergency Plan for AIDS Relief (PEPFAR)—to conduct an impact evaluation of the STbCU project.

Strengthening Tuberculosis Control in Ukraine Program Overview

The STbCU project began in April 2012, and built on more than 10 years of USAID TB assistance in 10 geographic priority areas: Donetsk, Dnipropetrovsk, Kharkiv, Kherson, Luhansk, Odessa, the Crimea, and the cities of Kyiv and Sevastopol. In 2014, services were withdrawn from Crimea and Sevastopol due to the annexation of Crimea, and from Donetsk and Luhansk due to a security situation. However, by the end of 2015, STbCU expanded services to Lviv and Kirovohrad oblasts—two regions with high and medium levels of TB burden. The STbCU program had two strategies of interest: (1) targeting social support services to improve treatment adherence among people at high risk of treatment default, and (2) integrating services and referrals between TB facilities and HIV facilities to improve the timeliness of care and the treatment outcomes for coinfected people. This report focuses on the TB-HIV integration approach. A separate report presents findings from an evaluation of the social support services strategy (Charyeva, Curtis & Mullen, 2018). The STbCU TB-HIV integration strategy was designed to improve access to TB-HIV coinfection services at the national level and in USAID-supported areas, through these systemic interventions:

- Identifying gaps in TB-HIV coinfection services and building capacity to address them
- Ensuring HIV testing for TB patients and effective referrals of those found to be HIV-positive
- Providing TB screening of HIV patients and referrals to TB services for suspected TB cases

To achieve these objectives, the STbCU project undertook a range of activities, such as working with the government to institutionalize best practices for TB-HIV management; developing databases and protocols to support reporting and sharing of data across TB and HIV services; and providing numerous trainings to TB, HIV, and infectious disease (ID) specialists to improve care for TB-HIV coinfected patients. We expected that expanded services for screening, testing, and treating coinfected patients, and improved referral mechanisms within TB and HIV facilities would improve case detection, dual treatment, and subsequently decrease mortality.

Evaluation Questions

The TB-HIV Integration study aimed to evaluate the impact of the STbCU's TB-HIV integration strategy on early diagnosis, treatment, and survival of TB-HIV coinfected patients in Ukraine. The study aimed to answer the following key questions:

- A. Completion of TB-HIV service cascade: What proportion of TB and HIV/AIDS patients complete each step in the cascade of services from screening to receiving treatment, per national protocol?
- **B.** Factors affecting the use of TB-HIV services: What facilitates or impedes timely access to and use of testing and treatment for TB and HIV/AIDS patients?
- C. Impact of service integration on time to services: Do service integration, training, and support between TB and HIV/AIDS services decrease the time lag between each step of service (i.e., screening, testing, and dispensing treatment) for TB and HIV/AIDS patients?
- D. Impact of service integration on all-cause mortality: Do service integration, training, and support between TB and HIV/AIDS services decrease all-cause mortality among the TB-HIV coinfected patients?

Methods

The TB-HIV Integration study used a mixed-method approach with a quasi-experimental quantitative evaluation design, complemented by qualitative interviews to inform the findings. The study included a quantitative survey administered at TB dispensaries and AIDS centers at baseline in 2014 and at end line in 2016 in intervention and comparison oblasts (to answer evaluation questions A, C, and D) and qualitative interviews with medical providers at baseline, and providers and patients at end line (to answer question B and contextualize the findings). Additionally, facility-level data was collected to assess the availability of diagnostic supplies, training specialists and treatment services at the TB dispensaries and AIDS centers. The intervention oblasts, Kharkiv, Odessa, and Zaporizhzhya, were selected at baseline based on TB and HIV case counts and coinfection rates. The comparison oblasts, Kiev, Mykolaiv, and Zhytomyr, were loosely matched to the intervention oblasts on TB and HIV disease rates, population density, and level of socio-economic development.

For the quantitative study at baseline, data were abstracted from client records for a retrospective cohort of TB and HIV/AIDS patients from 2012. At end line, data were abstracted from client records for a retrospective cohort from the middle of 2014 to the middle of 2015. Target sample size calculations were powered on the expected change in probability of testing TB patients for HIV and testing HIV patients for TB from baseline (2012) to end line (2014–2015). Additional oversampling of coinfected patients at both TB and HIV facilities was done to provide power for the analysis of ART initiation and all-cause mortality among the coinfected. In total, 1,064 patient records were abstracted at baseline and 1,529 at end line from HIV facilities. Additionally, 1,427 patient records were abstracted at baseline and 1,448 at end line from TB facilities. To evaluate TB-HIV service integration, patient treatment cascades were created to illustrate the series of tests and services patients were offered at the facilities. Survival analyses assessed time to screening and receiving treatment for coinfected patients, using data separately from TB dispensaries and AIDS centers.

Finally, survival analyses were conducted using Cox proportional hazards models with a difference-indifferences approach to model the impact of the program on all-cause mortality over the program cycle, separately for data from TB dispensaries and AIDS centers.

At baseline, 18 in-depth qualitative interviews were completed with a sample of TB and ID specialists in the six study oblasts. At end line, a total of 53 in-depth interviews were analyzed across three stakeholder groups (30 interviews with patients, 17 interviews with providers, and 6 interviews with the STbCU project staff). Additionally, six focus group discussions with providers were conducted. Data were synthesized based on main themes that were identified using deductive and inductive coding; direct quotes are presented to support themes.

Findings

Table S1 summarizes the findings of the study by evaluation question and source of data.

Evaluation Question	AIDS Centers	TB Dispensaries
A: Completion of TB-HIV service cascade: What proportion of TB and HIV/AIDS patients completed each step in the cascade of services, from screening to receiving treatment, per national protocol?	 -TB testing increased from 63% to 85% in program areas and from 57% to 93% in comparison areas -TB treatment was universal among coinfected patients in both program and comparison areas at both baseline and end line. -ART initiation among coinfected patients increased from 41% to 76% in program areas and from 61% to 83% in comparison areas 	-HIV testing among patients not previously diagnosed with HIV increased from 91% to 99% in program areas and from 95% to 99% in comparison areas -ART initiation among coinfected patients increased from 20% to 47% in program areas and minimally changed from 47% to 46% in comparison areas
B: Factors affecting the use of TB- HIV services : What facilitates or impedes timely access to and use of tests and treatments for TB and HIV patients?	 Facilitators: improvements in diagnostic testing, coordination between HIV and TB providers, joint meetings and conferences for TB and HIV providers, enhanced TB services in HIV centers, high quality providers, and free ART. Barriers: stigma, emotional burden of TB and HIV diagnoses, side effects of medications, out-of-pocket and travel costs for treatment, long lines to receive services, confusion about where to go for treatment, staff shortages, infrastructure limitations, and inconsistent sharing of information across HIV and TB databases. 	
C: Impact of service integration on time to services: Do service integration, training and support between TB and HIV/AIDS services decrease the time lag	-Negative statistically significant program effect on time to TB testing. Time to TB testing decreased in both program and	-Positive, but not statistically significant, effect on time to HIV testing. Time to HIV testing decreased in both program and nonprogram areas. The

Table S 1. Summary of findings by evaluation question

Evaluation Question	AIDS Centers	TB Dispensaries
between each step of service (e.g., testing and treatment) for TB and HIV/AIDS patients?	comparison areas, but decrease was larger in comparison areas.	decrease was slightly greater in program areas, but not significantly greater.
	-Positive statistically significant program effect on time to ART initiation among coinfected. Time to ART initiation decreased in both program and comparison areas, but the decrease was larger in program areas.	-Positive statistically significant program effect on time to ART initiation among coinfected. Time to ART initiation decreased in both program and comparison areas, but the decrease was larger in program areas.
D: Impact of service integration on all-cause mortality: Do service integration, training and support between TB and HIV/AIDS services decrease all- cause mortality among the TB- HIV coinfected patients?	-No statistically significant program impact found. All-cause mortality decreased slightly in both program and comparison areas, but the declines were not statistically significant.	-No statistically significant program impact found. All-cause mortality decreased slightly in both program and comparison areas, but the declines were not statistically significant.

Conclusions

The qualitative study suggests that the TB-HIV integration program affected several positive changes in the integration of services, especially around the availability of diagnostic testing across facilities and the training of providers. The quantitative analysis shows that all integration outcomes improved between baseline and end line in both program and comparison areas; although, some improvements were not statistically significant. Improvements in outcomes were consistently larger in the area (program versus comparison) that had the poorer outcome at baseline, resulting in convergence in outcomes between program and comparison areas over time. The improvements both in the level and timing of ART initiation among coinfected patients were greater in program than comparison areas, indicating a significant program impact on this outcome. Although all-cause mortality declined slightly in both program and comparison areas, the declines were not statistically significant and there were no significant program impacts on this outcome despite the significant improvement in ART initiation. A number of factors might explain this: (1) demographic and disease characteristics data on patients in intervention and comparison AIDS centers suggest that at the time the patients entered the facility, those in the intervention facilities had more advanced disease stages, which would affect their mortality outcomes; (2) despite over-sampling coinfected patients, the number of deaths observed in the sampled records was small, giving us limited statistical power to detect statistically significant changes in mortality.

Key Messages

All integration outcomes examined improved between baseline and end line in both program and comparison areas; although, some improvements were not statistically significant.

- The improvements both in the level and timing of ART initiation among coinfected patients was greater in program than comparison areas, indicating a significant program impact on this outcome.
- Although all-cause mortality declined slightly in both program and comparison areas, the declines were not statistically significant and there were no significant program impacts on this outcome.
- Improvements were consistently larger in the area (program versus comparison) that had the poorer outcome at baseline, resulting in convergence in outcomes between program and comparison areas over time.
- The quality of the routinely collected data used for this evaluation improved between baseline and end line, but further improvements are needed both for patient management and program evaluation.

CHAPTER 1. INTRODUCTION

Evaluation Purpose and Questions

The USAID mission in Ukraine commissioned MEASURE Evaluation to conduct an impact evaluation of the STbCU project. The goal of the STbCU was to decrease the burden of TB in Ukraine in partnership with the Government of Ukraine, and national and international stakeholders. The project proposed implementation of strategic actions to improve the quality of TB services, including detection and treatment of TB and multi- and extensively drug-resistant TB (MDR-TB, XDR-TB, respectively), as well as prevention and treatment for the rapid increase of TB and HIV coinfection. The project began in April 2012, and built on over 10 years of USAID TB assistance in 10 geographic priority areas. Ukraine is one of several countries struggling with high treatment default rates and rising coinfection rates, and USAID is testing and investigating strategies to help combat these problems.

The impact evaluation examined the relationship between select intervention strategies implemented and changes in key outcomes. There were two strategies of interest: targeting social support services to improve treatment adherence among those at high risk of treatment default and integrating services and referrals between TB dispensaries and AIDS centers to improve the timeliness of care and the treatment outcomes for the coinfected. This report presents findings from the evaluation of integrating services and referrals between TB and HIV. A separate report was prepared on the findings from the evaluation of the targeting social support services strategy (Charyeva, Curtis, & Mullen, 2018).

To evaluate the effect of the TB-HIV Integration Program (henceforth, the TB-HIV Integration study), we aimed to answer the following questions:

- A. Completion of TB-HIV service cascade: What proportion of TB and HIV/AIDS patients complete each step in the cascade of services from screening to receiving treatment, per national protocol?
- **B.** Factors affecting the use of TB-HIV services: What facilitates or impedes timely access to and use of tests and treatments for TB and HIV/AIDS patients?
- C. Impact of service integration on time to services: Do service integration, training, and support between TB and HIV/AIDS services decrease the time lag between each step of service (i.e., screening, testing, and treating) for TB and HIV/AIDS patients?
- D. Impact of service integration on all-cause mortality: Do service integration, training, and support between TB and HIV/AIDS services decrease all-cause mortality among the TB-HIV coinfected patients?

Findings from this evaluation will not only have implications for follow-up interventions in Ukraine, but will also add to the evidence base for TB strategies more broadly. The USAID mission in Ukraine, along with incountry stakeholders, will use the evaluation findings to guide decision making on resource allocation and scaling-up of TB interventions in Ukraine.

Background

Ukraine is one of 30 countries with the highest TB burden in the world, and one of ten countries with the highest incidence rate of MDR-TB (WHO, 2017). Ukraine remains one of the high-priority countries in the WHO European Region to fight TB. The WHO Regional Office for Europe reports that in 2016, Ukraine had 9,000 patients with TB-HIV coinfections, second in the region only to Russia that has about 11,000 coinfected patients. About 22 percent of all patients with TB in Ukraine are estimated to also be infected with HIV, making successful treatment outcomes among TB patients even more challenging (WHO-Europe, 2017). The burden of TB-HIV coinfection continues to be disproportionally concentrated among socially marginalized populations, including people who inject drugs (PWID), sex workers, and prison populations (UNAIDS, 2013). Coinfection with TB and HIV can substantially influence mortality; in 2016, of the 9,000 newly diagnosed TB-HIV coinfected patients, about 25 percent died (WHO-Europe, 2016). Given the high incidence of HIV among TB patients and vice-versa, as well as the significant challenges of successfully treating patients with MDR-TB and HIV, it is important that patients suspected with coinfections are promptly diagnosed and appropriately treated. However, several technical and logistical challenges limit close collaborations between TB and HIV programs in Ukraine. For example, coverage of TB patients with HIV testing is not adequately monitored by either TB or HIV services, nationally; there are inconsistencies in guidelines for ART initiation for coinfected patients; and there is a lack of specialists with adequate training in treating coinfected patients (WHO-Europe, 2013).

In light of these challenges, USAIDsupported projects have focused on a number of initiatives to strengthen the delivery of services for TB and HIV. The STbCU was awarded to Chemonics International in partnership with Project HOPE and the New Jersey Medical School Global Tuberculosis Institute from 2012– 2017 (Chemonics International, Inc., 2017). This USAID-funded effort targets geographic priority areas in southeastern Ukraine to improve health outcomes for Ukrainians with TB and HIV. It aims to enable the Government of Ukraine to decrease the burden of TB by improving

STbCU Primary Objectives:

1. Improve the quality and expand availability of the WHO-recommended directly observed treatment, short-course (DOTS)-based TB services.

2. Enhance the safety of the medical environment through improved infection control and monitoring.

3. Increase the capacity to implement programmatic management of drug-resistant tuberculosis (PMDT) programs for MDR-TB and XDR-TB control.

4. Improve access to TB-HIV coinfection diagnostic and treatment services.

the quality of services and strengthening health systems for the delivery of services for routine TB, MDR-TB and XDR-TB, and TB-HIV coinfections.

The STbCU project started working in 10 USAID-supported regions, including Donetsk, Dnipropetrovsk, Kharkiv, Kherson, Luhansk, Odessa, and the Crimea, and the cities of Kyiv and Sevastopol. In 2014, it became impossible to continue working in Crimea and Sevastopol due to the annexation of Crimea, and in Donetsk and Luhansk due to a security situation. By the end of 2015, STbCU expanded services to Lviv and Kirovohrad oblasts—two regions with high and medium levels of TB burden.

TB-HIV Integration Strategy

The objective of STbCU was to improve access to and use of timely diagnostics and treatments for coinfected patients in an effort to decrease mortality. The STbCU strategy was to improve access to TB-HIV coinfection services at the national level and in USAID-supported areas by implementing a range of systemic interventions, as follows:

(1) Identifying gaps in TB-HIV coinfection services and building capacity to address them

Policy development and capacity building involved conducting gap analyses of TB-HIV coinfections services, facilitating institutionalization of international best practices in TB-HIV care, promoting the development of regulations to support referrals between TB-HIV services and providing training on effective referral mechanisms, making recommendations for the development of an electronic data management system for TB (i.e., E-TB Manager) and supporting the training of specialists to improve data entry and analysis in E-TB Manager, harmonizing indicators between TB dispensaries and AIDS centers, and establishing mentoring assistance in addressing challenges of collaboration between TB and HIV services.

Training involved cross-training TB and HIV providers in caring for coinfected patients; developing a TB-HIV module for primary healthcare doctors; developing training materials for nongovernmental organization (NGO) staff, social workers and psychologists; and developing the National Clinical Protocol for Case Management of TB-HIV and National Monitoring and Evaluation Plan for TB-HIV.

(2) Ensuring HIV testing for TB patients and effective referral of those found to be HIVpositive

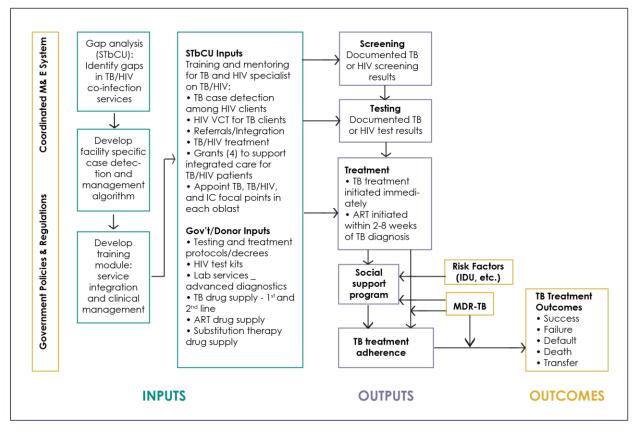
Following STbCU's recommendations, evidence-based approaches to diagnosing TB and HIV were introduced by the updated national TB and TB-HIV clinical protocols. To strengthen the TB-HIV testing reporting system, STbCU developed new recording and reporting forms for testing and counseling, and trained staff in TB dispensaries to use these forms.

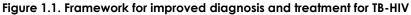
(3) Providing TB screening of HIV patients and referrals to TB services for suspected TB cases

A TB screening questionnaire was introduced in AIDS centers; clinical protocols for TB-HIV care were revised at the primary, secondary, and tertiary levels of healthcare; HIV specialists and ID specialists were trained in integrated TB-HIV services; a TB-HIV and referral monitoring database was developed for AIDS centers; informational materials were developed to appeal to people living with HIV (PLWH) to help them inform their doctors about TB symptoms; a grant was provided to a local NGO to support TB-HIV activities in correctional institutions; and several meetings and interregional informational workshops were conducted for ID specialists. The STbCU developed amendments to the Ukraine Ministry of Health's *Procedure for HIV Counseling and Testing* to facilitate early detection of TB-HIV coinfection and avoid loss to follow up during counseling, HIV testing, and registering at AIDS centers.

Development Hypotheses

Figure 1.1 illustrates the development hypotheses for this evaluation linking the interventions listed above with anticipated outputs and outcomes. It was expected that project activities would improve the proportion of TB and HIV/AIDS patients who were appropriately screened, tested, diagnosed, and treated in a timely manner. The primary outcome of interest was all-cause mortality. All-cause mortality was examined due to concerns related to inappropriate attributions of deaths to TB, HIV, or other causes.





Note: Risk factors such as comorbidity (e.g., a person who injects drugs) may moderate patients' efforts to adhere to treatment regimens.

*MDR-TB patients receive a longer treatment regimen and, as such, will likely be excluded from the final analysis.

CHAPTER 2. STUDY METHODS

Study Design

The integration study had a mixed-methods design. It included a quantitative survey at baseline and end line in intervention and comparison oblasts. It also included qualitative interviews with medical providers at baseline, and providers and patients at end line. Additionally, to contextualize our understanding of differences between availability of resources and services between oblasts, it includes facility-level data collected from TB dispensaries and AIDS centers in intervention and comparison oblasts. The quantitative surveys addressed evaluation questions A, C, and D, with retrospective medical record data abstraction from calendar year 2012 at baseline, and from April 2014 to June 2015 at end line, for a sample of newly diagnosed TB, HIV, and TB-HIV coinfected patients. Patient treatment cascades were created to illustrate the series of tests and services recommended for new patients. Survival analysis methods were used to assess time to treatment for the coinfected and survival analysis with a difference-in-differences approach used to model the impact of the program on all-cause mortality over the program cycle. Qualitative interviews with providers answered evaluation question B and offered insight into the existing policies and practices, vis-à-vis identifying and treating individuals coinfected with TB and HIV.

Sampling Design and Implementation

Quantitative Surveys (Evaluation Questions A, C, and D)

Oblasts: The oblasts were purposively chosen for this study: three intervention oblasts from USAIDsupported areas and three comparison oblasts from outside the USAID focus areas. The intervention oblasts, Kharkiv, Odessa, and Zaporizhzhya, were selected based on TB and HIV case counts and coinfection rates. The comparison oblasts, Kiev, Mykolaiv, and Zhytomyr, were loosely matched to intervention oblasts on TB and HIV disease rates, population density, and socio-economic status (MEASURE Evaluation, 2014).

Facilities: All AIDS centers and TB facilities offering inpatient intensive treatment in each oblast were selected for a facility survey at baseline and end line. We surveyed 18 TB and 9 HIV facilities at baseline and 17 TB and 8 HIV facilities at the end line. Respondents included facility administrators and directors or lead TB physicians.

Individuals: Individual medical record data were collected for two patient cohorts from each oblast: (1) TB patients starting TB intensive treatment during calendar year 2012 at baseline and from April 1, 2014 to June 30, 2015 at end line (if they completed TB treatment before Fall 2016), and (2) HIV patients newly registered at AIDS centers during calendar year 2012 at baseline and from April 1, 2014 to June 30, 2015 at end line. Each cohort (TB and HIV) was sampled independently. There was no way of de-duplicating patients in the medical records who were served by both types of facilities. Hence, the samples were collected and analyzed separately based on each patient's point of service.

Target sample size calculations were powered on the expected change in probability of testing TB patients for HIV and testing HIV patients for TB from baseline (2012) to end line (2014–2015). Additional oversampling of coinfected patients at both TB and HIV facilities was done to provide power for the

analysis of ART initiation and all-cause mortality among the coinfected. In total, 1,064 patient records were abstracted at baseline and 1,529 at end line from HIV facilities; from TB facilities, a total of 1,427 patient records were abstracted at baseline and 1,448 at end line. For the TB patient sampling, TB registries from each oblast were used. From these registries, the first random sample (S1) of patients was selected without replacement from all new TB patients in the baseline and end line study window, proportionate to the size of the oblast (not the facility). A second random sample (S2) was then selected from the remaining identified coinfected patients. For the HIV patient sampling, the oblast AIDS center stored all of the new HIV registration cards and kept a registration journal. The S1 was drawn without replacement from these registration of coinfected patients was more challenging, as that information was not always known at the time of initial patient registration. Instead of relying exclusively on the HIV registration cards, the ID specialists in each oblast reviewed patient records or HIV control cards or TB-09 records to provide a list of all coinfected patients in the oblast. For Odessa, after the S1 was selected, the S2 over-sample was drawn from the list of coinfected patients using systematic random sampling to get the desired sample size. For all other oblasts, data from all remaining charts of coinfected patients was abstracted.

Sample Implementation Success Rate

AIDS Centers

Sample implementation success rates for medical record abstraction for HIV services were very high at baseline and end line, and in the case of most oblasts, exceeded the target sample size (Appendix A, Table 2S.1). We abstracted more records at end line than the target sample due to a lower than expected number of coinfected patients at AIDS centers at baseline. Among intervention oblasts, over three times as many records were abstracted from Odessa (n=347 at baseline; n=536 at end line) compared to the other two oblasts. Among comparison oblasts, a much larger number of records were abstracted from Mykolaiv (n=241 at baseline; n=305 at end line). Sampling was proportionate to HIV caseload by oblasts to ensure that the data were representative of the set of oblasts studied, so the higher sample draws from Odessa and Mykolaiv reflected the fact that they had more HIV patients.

TB Dispensaries

The TB patient medical record abstraction rates were 98.5% at baseline and 100.0% at end line (Appendix A, Table 2S.2). At both baseline and end line the majority of medical records in intervention oblasts were extracted from Odessa (44%), followed by Kharkiv (31%) and Zaporizhzhya (25%). Medical record abstraction in comparison oblasts were approximately evenly split among Kiev, Mykolaiv, and Zhytomyr at both baseline and end line. Sampling was proportionate to TB caseload by oblast to obtain data that were representative of the six study oblasts.

Qualitative Interviews (Evaluation Question B)

At baseline, in-depth qualitative interviews were completed with a sample of TB and ID specialists in the six study oblasts. The provider interviews were conducted by different data collection agencies during different periods. The STbCU conducted provider interviews for a gap analysis of TB and HIV services in the intervention oblasts. The MEASURE Evaluation study team extracted data from all eight interviews, covering seven regional facilities in the intervention oblasts. Then, IFAK conducted 10 additional interviews in the comparison oblasts from June through September 2014 using the tools developed by STbCU. In total, 18 provider interviews were completed with providers working in the regional TB facilities and AIDS centers. Providers were selected using purposive sampling.

At end line, a total of 53 in-depth interviews were analyzed across three stakeholder groups (30 interviews with patients, 17 interviews with providers, and 6 interviews with coinfection specialists). Additionally, six focus group discussions with providers were conducted. Providers selected for interviews were the primary decision makers regarding the diagnosis, treatment, and referral of patients at their respective facilities. Interviews and focus group discussions with providers provided information on client and data flow, communication between TB and HIV services, and facilitators of and barriers to the provision of services to coinfected patients. Patient interviews provided a better understanding of patients' experiences accessing and using both TB and HIV services.

Data Collection and Instruments

A set of data abstraction instruments were developed to extract required information from medical records in AIDS centers and TB dispensaries (Appendix C). Data abstraction was led by IFAK in collaboration with the lead TB specialist and ID specialist in each oblast. The local staff provided deidentified client lists from each oblast and service facility registry. The IFAK used these client lists to randomly select the study sample, following the sampling protocol described above. The IFAK then trained lead TB and ID specialists on the two survey instruments, and these specialists completed the tools using data abstracted from the official client records (form TB-01, TB-03, HIV control card, HIV medical record, and electronic registry). The individual patient instrument collected basic sociodemographic characteristics; TB diagnosis, treatment, and outcomes; and HIV diagnosis, treatment, and status.

The facility surveys were completed by IFAK with the assistance of the facility director or administrator most knowledgeable about the TB and HIV policies and activities at the facility. Data collected in the facility survey instrument included basic facility characteristics, such as size and staffing; services and referrals provided; policies for screening, testing and treating of coinfected patients; and information on TB and HIV drug shortages in 2012 and mid-2014–mid-2015.

Qualitative interview guides covered tests, treatments, referral protocols, practices commonly used at each facility, and patients' experiences in accessing services at the facilities. Separate guides were developed for in-depth interviews and focus group discussions at TB dispensaries and AIDS centers. Interviews lasted typically 30–60 minutes and were conducted in Ukrainian or Russian. All discussions were digitally recorded, transcribed, and translated into English.

Data Entry, Processing, and Analysis

Completed facility surveys and individual record abstractions were returned to IFAK's main office in Kiev for processing, which included editing, coding, translation, data entry, and validation checks. Additional verification with oblast contacts was carried out as needed to assure accurate and complete data. Final Microsoft Excel files were forwarded to UNC-CH for analysis using Stata v12 (College Station, TX).

Analyses included descriptive analyses and multivariate survival analyses. We applied survey weights in all analyses. To address evaluation questions regarding intervention effects on service time lags, we present Kaplan-Meier survival curves, which estimated time (number of days) elapsed from when a patient entered into care at the HIV facility or TB dispensary until they experienced the outcome of interest (TB-HIV test, ART initiation, and all-cause mortality). We estimated the following Cox proportional hazards model for each outcome of interest at baseline and end line:

Eq. 1.
$$h(t) = h_0(t) \exp(\alpha_1 P + \alpha_2 X)$$

This model allowed us to examine the determinants of time to different outcomes of interest, comparing intervention and comparison oblasts separately, and controlling for observed characteristics, such as age, sex, and employment status. In Equation 1, h(t) was the hazard function for the outcome of interest; $h_0(t)$ was the baseline hazard function, t represented the time that the event had not occurred (i.e., the survival time); P was an indicator variable that was equal to one, if the patient resided in an intervention oblast, and equal to 0 if they resided in a comparison oblast; and X represented a vector of observed control variables. Estimated values of α_1 gave the effect of the program area on the time to the event, and α_2 gave the effect of the control variables on the time to event.

We modified Equation 1 to include a variable for the study year that was equal to 1 if the observation was from end line and 0 if it was from baseline, as well as an interaction of the year and intervention indicator variables. This difference-in-differences approach was the central identification strategy for providing estimates of program impacts on time to TB-HIV testing, ART initiation, and all-cause mortality.

Eq. 2.
$$h(t) = h_0(t)\exp(\beta_1 P + \beta_2 Y ear + \beta_3 P * Y ear + \beta_4 X)$$

In Equation 2, β_1 gave differences between intervention and comparison oblasts at baseline; β_2 gave the time trend in the hazard function in the comparison group; and the interaction term, β_3 , gave the differential trend in the program area, which can be interpreted as the change in the hazard function due to the oblast being exposed to the STbCU intervention. If β_3 was significant, we concluded that the change in the hazard function could be attributed to the intervention and there was an impact of the program. This equation could be used to calculate the differences-in-difference impact estimate for specific outcomes derived from the hazard function, such as the probability of experiencing a particular outcome (e.g., within six months).

We report hazard ratios (HR), not marginal effects or raw coefficients, for α and β in Equations 1 and 2. A HR greater than one indicated that the variable was positively associated with the probability of the event occurring, and therefore, was associated with a decrease in the time until the event occurred, while a HR equal to one indicated there was no effect of the variable.

At baseline, for the provider interviews, qualitative analysis was conducted to identify common themes and differences across oblasts and facilities using inductive and deductive coding. A table of these themes was constructed and used to draw out findings. At end line, qualitative transcripts were imported into ATLAS.ti, version 7.5.17 and analyzed. Qualitative data analysts read the transcripts multiple times and developed an initial codebook based on emergent themes and questions from interview and focus group discussion guides. The codebook was then pilot tested on interview transcripts of three patients (one from each region) and three providers (one from each region). The pilot testing allowed for the revising of the codebook—new codes were added, and some codes were collapsed. These codes were applied to the interview and focus groups discussion transcripts and a code report was run in ATLAS for each code across each stakeholder group (i.e., patients, providers). Individual summaries of each code were written with themes and sub-themes categorized across each code. Data were synthesized using direct quotes to support themes.

Ethical Review

All study protocols, consent forms, tools, and data security processes were reviewed and approved by the Institutional Review Board at UNC-CH. The ethics review board at the F.H. Yanovskyi Institute of Phthisiology and Pulmonology under the Academy of Medical Sciences of Ukraine also approved the study.

Strengths and Limitations

The evaluation design drew on a mixed-methods strategy to provide a multifaceted examination of the STbCU project's TB-HIV integration strategy. Survival analysis with difference-in-differences approach allowed us to account for preexisting differences in outcomes between intervention and comparison groups at baseline, as well as secular changes in both groups over the duration of the project, to isolate the impact of STbCU. The in-depth interviews of patients, providers, and STbCU project staff identified respondents' perspectives on barriers and facilitators for timely access to and use of tests and treatments for TB and HIV/AIDS patients to better interpret the quantitative findings and understand what was implemented and why the TB-HIV integration program did or did not work.

There are a few limitations to note. One concern was the contamination of comparison areas by other interventions that aimed to strengthen TB-HIV integration. In particular, the STbCU project expanded its TB-HIV integration activities to Mykolayiv, one of our comparison oblasts, beginning in 2016. Our end line data collection abstracts patient records from mid-2014 to mid-2015, before the expansion took place, which reduced the impact of this contamination on our quantitative findings. Also, the difference-in-differences approach assumed that the changes in the outcomes in the comparison areas represented the changes that would have been seen in the intervention areas in the absence of the program. Our comparison areas were purposively selected to be as similar as possible to the intervention oblasts, but there were differences between oblasts that could affect their underlying trends in outcomes.

Randomization was not possible in this context; however, this design represents the strongest one available to us.

Another issue was the effect of externalities on the outcomes of interest. For example, shortages of TB or ARV medications could have significant effects on treatment initiation and completion rates, or on strategies that intervention and comparison sites might have employed to offset these shortages. If the externalities are the same in the intervention and comparison areas, then they would not affect the results. However, if they were different, they would differentially contribute to the outcomes of interest across the oblasts. We collected data at the health facility level on some of the externalities (e.g., drug shortages) and assessed their potential role in our findings.

CHAPTER 3. DEMOGRAPHIC AND DISEASE CHARACTERISTICS

3.1. Findings From AIDS Centers

HIV Study Population Demographic Characteristics

Appendix A, Table 3S.1 presents the weighted background characteristics of the HIV patients in intervention and comparison sites at baseline and end line. Men comprised 50 percent of the sample in the intervention group at baseline and 60 percent at end line. The age distribution of the sample in the intervention group was roughly comparable between baseline and end line, with participants in age group 30-39 years constituting about 43 percent of the sample. More of the sample was unemployed at end line than at baseline. Substantially more patients were missing data on their employment status data at baseline compared to end line, which may account for some of this difference. Fifty-nine percent of the intervention baseline sample participants lived in urban areas compared with 65 percent at end line. The distribution of the sample by oblasts is broadly comparable between baseline and end line. At baseline, compared with the comparison group, the intervention group had fewer men (51% versus 64%, p<0.01), and significantly more unemployed patients (61% versus 22%, p<0.01). At end line, compared to the comparison group, the intervention group had significantly more unemployed patients (72% versus 49%, p<0.01), and more urban patients (65% versus 57%, p<0.01). The comparison group had more missing data on employment status than the intervention group at both baseline and end line, but the amount of missing data decreased over time.

HIV Patient Disease Characteristics

Appendix A, Table 3S.2 shows disease status for HIV-only patients and for those who are coinfected with TB among intervention and comparison groups at baseline and end line. At baseline, in the intervention group, over 50 percent of coinfected patients had missing data on numbers of visits, clinical stage, CD4 count, and injecting drugs status at the most recent visit, which made it difficult to interpret the findings regarding HIV disease status for these patients or compare disease characteristics between baseline and end line. The amount of missing data on all disease characteristics was substantially less at end line, at about 5 percent for all variables, except CD4 cell count which had 12–24 percent missing records for the intervention groups, and 27–31 percent missing for the comparison group at end line.

Nevertheless, across all groups, there was evidence of more advanced disease stage in patients with TB-HIV coinfections compared to those with HIV only, with a higher percentage of patients in stages 3 and 4 of HIV, and with lower CD4 cell counts. At end line, 12 percent of HIV-only patients, and 22 percent of coinfected patients in the intervention groups had four or more clinic visits in the past 12 months, compared with 32 percent of HIV-only patients and 37 percent of coinfected patients in the comparison groups.

At end line, three significant differences between the disease characteristics of intervention and comparison group patients were notable:

- Sixty-five percent of HIV-only patients in the intervention group were in advanced HIV clinical stages
 and 4 compared with 44 percent in the comparison group
- (2) Seventy-seven percent of coinfected patients in the intervention group had a CD4 cell count less than 350 cells/mm³ compared with 61 percent of the coinfected patients in the comparison groups
- (3) Seventy-three percent of HIV-only patients and 28 percent of coinfected patients in the intervention group versus 36 percent of HIV-only patients and 22 percent of coinfected patients in the comparison groups had no record of receiving ARV treatment.

These observations suggest that, in general, HIV patients in the intervention group may have been in more advanced disease stages, overall.

3.2. Findings from TB Dispensaries

TB Study Population Demographic Characteristics

The weighted demographic characteristics of TB patients at baseline and end line by intervention group are presented in Appendix A, Table 3S.3. Men accounted for 68 percent of both groups at end line; however, there were significantly more men in comparison oblasts than intervention oblasts at baseline (73% and 67%, p<0.05). Most patients were between ages 30 and 39 years at baseline and end line, and approximately five percent were ages 60 years or older. Unemployment rates were over 70 percent in both study rounds; while there was no significant difference in employment status between the intervention groups at baseline, 79 percent of patients in the intervention group were unemployed at end line, compared with 72 percent of patients in comparison oblasts (p<0.05). The distribution of the sample in rural and urban areas was stable over time, but differed significantly between intervention and comparison oblasts. Approximately 70 percent of the intervention sample resided in an urban area compared with 58 percent in comparison oblasts; this difference was significant during both study rounds (p<0.001). Just over half of the baseline sample resided in intervention oblasts (54%) compared with 66 percent at end line. While the sample distribution among intervention oblasts remained stable between baseline and end line, with the majority of patients in Odessa (64%), the proportion of subjects in Kiev and Mykolaiv shifted over time. At baseline, 33 percent of the comparison sample resided in Kiev compared with 58 percent at end line; 51 percent lived in Mykolaiv at baseline compared with 20 percent at end line.

No significant differences in background characteristics were detected between the intervention and comparison oblasts at baseline other than the proportion of men and urban residents discussed above. At end line, there was no significant difference in patient sex between intervention groups; however, there were more patients in the 30–39-year age group in comparison oblasts (p<0.001) and more patients in the unemployment category in the intervention oblasts (p<0.05); and the urban/rural distribution difference persisted.

TB Patient Disease Characteristics

Appendix A, Table 3S.4 presents disease status information for TB-only and coinfected patients seen at TB facilities at baseline and end line. Roughly 60 percent to 77 percent of TB-only and coinfected patients were diagnosed with TB for the first time during both study periods, followed by approximately 18 percent to 29 percent seeking retreatment (including reinitiation, treatment failure, and relapse). At baseline, coinfected patients in comparison oblasts exhibited more advanced disease (i.e., higher percentages of patients undergoing retreatment; and patients with chronic, extrapulmonary disease; and Category II treatment) than other groups. However, at end line the coinfected patients in intervention oblasts appeared to have more advanced disease stages overall, as evidenced by a high percentage of patients with both pulmonary and extrapulmonary TB clinical forms and a high percentage of patients diagnosed with MDR-TB (Category IV). Significantly more PWID were represented among the coinfected patients at baseline compared to end line, particularly in comparison oblasts (27% at baseline and 18% at end line).

There were several significant differences in disease status between TB and coinfected patients in intervention and comparison oblasts. Among TB-only patients at baseline, significantly more patients in the intervention than the comparison oblasts were diagnosed for the first time, while fewer were chronic TB or referral patients (p<0.001), and more were in treatment Category I. At end line there were no significant differences in patients with a first diagnosis, TB clinical form, treatment category, or injecting drugs between TB-only patients in intervention and comparison areas.

Among coinfected TB patients at baseline, significantly more patients in intervention than in comparison oblasts received a first diagnosis, more had pulmonary TB (p<0.05), fewer had extrapulmonary disease (p<0.05), more were in treatment Category I (p<0.001), and fewer reported injecting drugs (p<0.001). At end line significantly more coinfected patients in intervention than in comparison oblasts were diagnosed for the first time (p<0.01) compared to comparison oblasts, significantly fewer were in re-treatment (p<0.05), more had both clinical forms of TB (p<0.001), and significantly more were in Category IV (p<0.001). These observations suggest that coinfected patients in comparison oblasts had more advanced disease stages at baseline, but at end line coinfected patients in intervention oblasts appeared to have more advanced disease stages.

CHAPTER 4. COMPLETION OF TB-HIV SERVICE CASCADE

To illustrate results from question A on the proportion of TB and HIV/AIDS patients who completed each step in the cascade of services per national protocol, we present a series of bar graphs depicting the cascade of services received and drop-off (attrition) between services, using data from AIDS centers and TB dispensaries¹.

4.1. Findings From AIDS Centers

TB-HIV Service Cascade for HIV Patients

Appendix A, Table 4S.1 presents TB services received by patients at AIDS centers at baseline and end line among patients in S1 and S2 by intervention and comparison group. Figures 4.1 and 4.2 show the TB-HIV service cascades for all newly diagnosed HIV patients at the AIDS centers, by intervention and comparison oblasts. The cascade in Figure 4.1 is limited to the S1 selected randomly from all HIV patients, and excludes the oversampled coinfected patients. It shows the treatment cascade from the time the patient registered at the AIDS center until the time of TB confirmation. Figure 4.2 is limited to S2, comprising only coinfected patients, and shows the cascade of services received after a patient had been confirmed as coinfected with HIV and TB.

In Figure 4.1, we see an increase in the proportion of registered HIV patients that received TB diagnostic testing² between baseline and end line in both the intervention (63% at baseline versus 85% at end line) and comparison areas (57% at baseline versus 93% at end line). At baseline, a higher proportion of registered patients received diagnostic testing for TB in the intervention group than in the comparison group (63% versus 57%). At end line, a lower percentage of registered patients received diagnostic testing for TB in the intervention group (85% versus 93%). While comparison oblasts conducted more TB diagnostic tests at end line, their TB case confirmation rate among those patients who were tested was slightly lower than the rate in the intervention sites (15% for comparison versus 19% for intervention areas).

¹ Cascades of services do not present screening results due to the differences in data collection methods between baseline and end line. At baseline, the information on screening was abstracted based on the information on patients' complaints recorded in patients' charts; at end line it was abstracted based on the information on complaints or availability of completed screening questionnaire in patients' charts.

² Fluorography was documented as one of the TB diagnostic tests in this study.

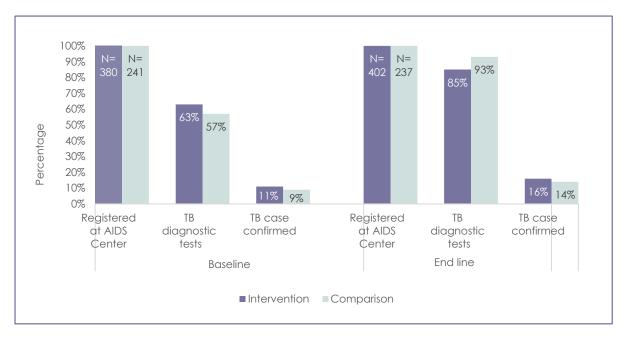
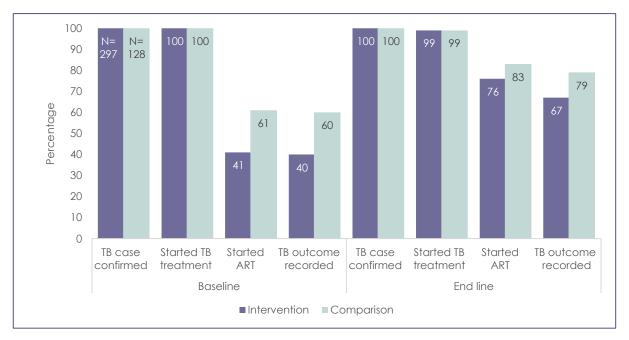


Figure 4.1. TB testing cascade for HIV patients (New TB cases) at baseline (2012) and end line (2015), by intervention status (Sample 1)

The cascade of services received by all coinfected patients (including the oversampled coinfected patients in S2) is presented in Figure 4.2. Almost all coinfected patients started TB treatment in both intervention and comparison groups at baseline and end line.

Figure 4.2. TB and HIV treatment cascade for HIV patients at baseline (2012) and end line (2015), by intervention status (coinfected patients)



At baseline, compared to the comparison group, a lower proportion of patients in the intervention group started ART (41% versus 61%) and had a TB outcome recorded (40% versus 60%). The proportion of coinfected patients who started ART and had TB outcome recorded increased significantly from baseline to end line for both intervention and comparison groups. At end line, compared to the comparison group, a lower proportion of patients in the intervention group started ART (76% versus 83%), and had a TB outcome recorded (67% versus 79%). The difference in proportion of patients who started ART between the intervention and comparison groups narrowed from baseline to end line.

4.2. Findings From TB Dispensaries

TB-HIV Service Cascade for TB Patients

Services for HIV testing and treatment received by TB patients in intervention and comparison oblasts at baseline and end line are presented in Appendix A, Table 4S.2. The TB-HIV service cascade for all new TB patients at TB dispensaries is presented in Figures 4.3 and 4.4. The HIV testing cascade (Figure 4.3) is restricted to the random sample of all TB patients (i.e., S1) and excludes the oversampled coinfected patients, whereas the HIV treatment cascade (Figure 4.4) includes both the S1 and S2 coinfected samples.

Figure 4.3 shows the HIV testing cascade for newly diagnosed TB patients in the S1 intervention and comparison groups at baseline and end line. At baseline, a higher proportion of new TB patients received HIV voluntary counseling and testing (VCT), and a lower percentage received a diagnostic HIV test in the intervention group than in the comparison group. At end line, almost all patients (99%) received VCT or HIV diagnostic tests, and there were no differences between comparison and intervention groups.

The percentage of TB patients in both intervention and comparison groups who received VCT increased over time from about 95 percent to 99 percent (see Appendix A, Table 4S.2). The percentage of TB patients receiving an HIV diagnostic test increased by eight percentage points for the intervention study group and by four percentage points for the comparison group, and reached 99 percent for both groups at end line. A larger percentage of TB patients were confirmed HIV-positive at end line (16%) compared to nine percent at baseline.

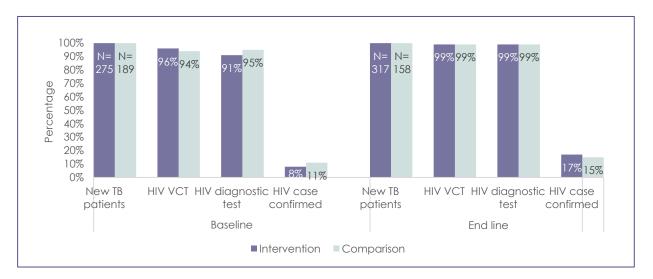


Figure 4.3. HIV testing cascade for newly diagnosed TB patients, by intervention group at baseline (2012) and end line (2015), Sample 1

The HIV treatment initiation for all coinfected TB patients (S1 and S2) is presented by intervention group and study round in Figure 4.4. At baseline, 47 percent of comparison group patients diagnosed with HIV initiated ART after starting TB treatment, compared with 20 percent in the intervention group. This percentage decreased by one point at end line to 46 percent in the comparison oblasts, but increased by 27 percentage points to 47 percent in intervention oblasts.

100% N= 221 N= N= 90% 108 115 80% 70% Percentage 60% 50% 47% 47% 40% 46% 30% 20% 10% 0% Started HIV case Started HIV case confirmed ART confirmed ART Baseline End line

■ Intervention ■ Comparison

Figure 4.4. Treatment initiation for HIV in coinfected TB patients at baseline (2012) and end line (2015), by intervention group (coinfected patients)

CHAPTER 5. FACTORS AFFECTING USE OF TB-HIV SERVICES

In this chapter, we address evaluation question B: What facilitates or impedes timely access to and use of tests and treatments for TB and HIV/AIDS patients?

5.1. Factors that Facilitate Access to and Use of Services

Providers mentioned several factors that facilitated access to TB services in the three regions: improving TB diagnostic testing, enhancing services for TB clients at HIV facilities, improving medication adherence by TB clients, expanding and updating clinics, improving tracking of TB clients who recovered, and revising laws. Four themes emerged from client interviews as examples of positive drivers of successful access to TB services: timely TB diagnostic testing, good communication between ID and TB specialists, mental preparedness of clients, and knowledgeable and professional doctors.

There's constant contact with an ID doctor who also interacts with a TB doctor. If she goes on vacation, she leaves the meds for me there. They call me. I come and pick them up. They can't just give them to me, though. One has to sign the log. [Patient]

Providers shared information on the ways in which they felt access to and use of HIV services have improved over the past several years. Key themes were faster and more accurate HIV diagnostic testing, well-staffed and well-trained medical teams, and improvements in the scope of HIV services offered to clients. Several themes emerged from the interviews with clients about factors that facilitated access to HIV services. Many clients echoed the providers in referencing the quality and professionalism of the medical providers and staff and faster and more accurate HIV testing. Other themes were the discretion of the medical staff around HIV to avoid offending patients and the fact that ART is free, available, and effective.

The facility-level data added further evidence regarding the availability of drugs and test kits According to facility surveys, there were no shortages of ARVs, medication-assisted therapy medications, or rapid test kits lasting for more than 30 days from April 01, 2014 to June 30, 2015. Only one TB facility in the intervention regions reported a TB drug shortage lasting more than 30 days (Appendix B).

5.2. Barriers to Timely Access to and Use of Services

The barriers to access to and use of TB services from the provider perspective may be categorized by the following themes: social factors; lack of client adherence to treatment; transportation issues; TB testing expenses; faulty or unavailable TB testing equipment; short-staffed facilities; and difficulty of diagnosing TB, especially in coinfected clients.

I came to work here in 2005, and the staff has not increased since that time, despite the fact that we have more and more patients. There should be 12 patients [per doctor], but in fact we have 36–40 [patients]. [Focus group discussion participant]

From the client interviews, the following themes emerged regarding challenges to receiving timely access to TB services: facilities lacked space and capacity to meet basic client needs, unsanitary and noisy conditions, side effects of TB medicines, inadequately integrated management of HIV and TB medications, inconvenience of daily travel to the dispensary for medical treatment, high travel costs, long hospital stays for TB inpatients, emotional burden, high out-of-pocket treatment expenses, medication shortages, and long lines to receive health services.

No, I don't get the treatment by the place of my residence, but in the facility of [X] district. My treatment costs me a penny. I spend around 100 UAH only to get here and around three hours at my best, and I have to make as much as three transport changing. I have to travel to receive my treatment every day, which is very inconvenient. [Patient]

Providers mentioned many barriers to effectively implementing HIV services in the coinfection program. The main themes were clients' unwillingness or inability to accept their HIV diagnosis and follow treatment instructions, lack of diagnostic testing, ability to overcome stigma, long lines to receive health services, and general infrastructure issues. Clients mentioned several barriers to their use of HIV services. The themes that overlapped with those reported by providers were ability to cope with the stigma of HIV; long lines; high costs associated with some laboratory work and medications; and the unavailability of diagnostic testing, such as CAT scans and magnetic resonance imaging. Other themes identified by clients were negative provider attitudes toward patients, confusion about the treatment process, and confusion about where to go to receive treatment.

5.3. Communication and Collaboration between TB and HIV Services

From the provider interviews, several themes described facilitators that improved effective integration of TB and HIV services: integrated meetings and conferences, recognized improvements in ID-TB communication, and assigned appointment cards given to patients.

As ID doctors, we see and feel these patients even better. But we have not had a good communication with TB doctors for many years. And now, the situation is different. We have norms and clinical protocols that clearly describe how diagnostics has to be done. [Focus group discussion participant]

... if he, the patient has a fever, or if there are any other symptoms, like cough, sweating, weight loss, and etcetera, I immediately connect TB doctor. Thanks God we have one in our facility. And, in general, it is very good, because when there was no TB doctor, it was very difficult for us in this respect. And now, right here we can make a common decision whether to do a CT or X-ray. [Provider]

Diagnostics became faster. New methods of sputum testing have appeared. Rapid tests for patients with coinfection. And Bactec and GeneXpert, in case of TB, ...informational support, laboratory diagnostics, methods of treatment—everything got systematized and improved. There has been integration of two services, and by now we have pretty good services. [Focus group discussion participant]

Providers mentioned several barriers to effective communication and collaboration between TB and HIV services: database inadequacies, challenges in referring patients to TB dispensaries during the diagnosis stage, lack of service integration at the rayon level, and the cost for patients to travel between HIV and TB facilities.

We have our own database and HIV service has their own. The only thing that would be worth doing is to merge the two existing databases... We don't need all of the information from their database. We just want to know status of our patients. And it would be good if we could enter last name of our patient and it [shows] in red or blue color. Red color would signify HIV-positive status. Because AIDS center can easily access all our data and we do not have possibility to see their data. They see everything about our patients, all their test results, treatment drugs they receive, resistance. And it would be good if we also had access to information that we need. [Focus group discussion participant]

5.4. Recommendations of Providers and Clients

Providers and clients made the following recommendations to improve TB- and HIV-integrated services:

- Providers recommended that TB-HIV coinfection treatment programs should address infrastructure issues, improve electronic health records and technology, address staffing and workload issues, conduct provider training, address equipment and supply needs, make legislative and protocol changes, and promote social change around TB and HIV.
- Client recommended improvements to the TB-HIV coinfection treatment program were to have at least a week's supply of TB medicines available; government subsidies for laboratory work and testing, such as computed tomography (CT) scans; more professional healthcare workers; and better communication regarding hospital services. Clients also recommended improvements in infrastructure, such as buildings repairs.

CHAPTER 6. IMPACT OF TB-HIV SERVICE INTEGRATION ON TIME LAG BETWEEN SERVICES

In this chapter, we address evaluation question C: whether service integration between TB and HIV/AIDS services combined with provider trainings decreased the time lag between each step of service (i.e., tests and treatments) for TB and HIV/AIDS patients.

6.1. Findings from AIDS Centers

Impact of TB-HIV Service Integration on TB Testing Based on Data from AIDS Centers

In Figure 6.1, we look at TB testing among HIV patients from S1 comparing intervention and comparison oblasts at baseline and end line. The figure shows the probability that patients are tested for TB at some point after each duration (in days) following registration at an AIDS Center. The end line curves are highly skewed to the left, because most testing occurred soon after registration. The curves drop more quickly and to a lower value at end line than at baseline indicating that more patients were tested and tested earlier at end line, in both intervention and comparison areas. Time to TB testing was shorter at the end line for patients in the comparison group compared to the intervention group. Overall, the improvements in time to TB testing were greater for patients in comparison areas compared to intervention areas. Both curves are statistically different at both baseline (p=0.0001) and at end line (p=0.0410).

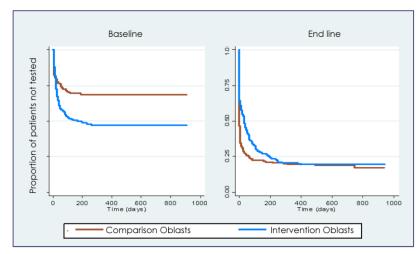




Table 6.1 shows the results of Cox proportional hazards models predicting TB testing among HIV patients (S1) at baseline and end line. Table 6.1 allowed us to assess the impact of the TB-HIV intervention strategy. Appendix A, Table 6S.1 includes oblast to assess whether there were differences in outcomes across oblasts.

At baseline, patients in the intervention group were twice as likely to be tested for TB compared to the comparison group (Table 6.1). Patients ages 30–49 years were more likely to be tested compared to those ages 18–29 years. When we included oblasts, we saw that patients in Kiev and Zhytomyr (both in the comparison group) were 95 percent (p<0.01) and 60 percent (p<0.01) less likely to be tested for TB compared to the referent oblast Mykolaiv (p<0.001) (Appendix A, Table 6S.1). Patients in Odessa and Kharkiv (both in the intervention group) were 54 percent (p<0.01) and 46 percent (p<0.05) less likely to be tested for TB than those in Mykolaiv. At end line, no significant difference was seen in TB testing between the intervention and comparison groups. When we included oblasts (Appendix A, Table 6S.1), we saw that patients in Kiev and Zhytomyr (both in the comparison groups) were 1.9 (p<0.01) and 2.5 (p<0.01) times more likely to be tested for TB than those in TB than those in Mykolaiv. TB than those in Mykolaiv. Patients in Odessa, an intervention oblast with a large number of records, were also 1.5 times more likely than those in Mykolaiv to be tested for TB.

The difference-in-differences model was consistent with our prior finding that the intervention group was significantly more likely at baseline to be tested for TB (HR=1.97, p<0.001) compared to the comparison group (Table 6.1). Over the course of the program, the hazard for TB testing improved by over four times between baseline and end line in the comparison group. Though an increase in TB testing was seen in the intervention group, as well, the net impact of the program on TB testing was negative because the improvement was lower in the intervention areas than in the comparison oblasts (HR=0.39, p<0.01).

Table 6.1. Cox proportional hazards model showing impact of the TB-HIV integration strategy on TB testing, using a difference-in-differences model for baseline and end line data (Sample 1)

		Baseline			End line		Diff	Difference-in-differences			
Variable	HR	(95% CI)	p-value	HR	(95% CI)	p-value	HR	(95% CI)	p-value		
Year X intervention group							0.39***	(0.27-0.57)	0.000		
Year											
Baseline							1				
End line							4.87***	(3.58-6.62)	0.000		
Intervention group											
Yes	2.05***	(1.50-2.81)	0.000	0.83	(0.67-1.03)	0.091	1.97***	(1.44-2.66)	0.000		
No	1			1			1				
Sex											
Male	0.99	(0.73-1.33)	0.924	1.11	(0.90-1.36)	0.326	1.12	(0.95-1.32)	0.166		
Female	1			1			1				
Age range, yrs											
18–29	1			1			1				
30–39	1.57*	(1.05-2.34)	0.027	1.16	(0.87-1.55)	0.314	1.30*	(1.03-1.64)	0.025		
40–49	2.82***	(1.87-4.27)	0.000	1.45*	(1.06-1.98)	0.019	1.86***	(1.45-2.39)	0.000		
50+	2.01	(1.07-3.79)	0.030	1.06	(0.73-1.56)	0.758	1.30	(0.93-1.80)	0.121		
Employment											
Employed	1			1			1				
Unemployed	0.74	(0.54-1.01)	0.055	0.86	(0.70-1.06)	0.161	0.83*	(0.70-0.99)	0.042		
Retired/disabled	1.62	(0.56-4.65)	0.372	1.42	(0.93-2.15)	0.101	1.34	(0.90-2.00)	0.148		
Student/other	0.87	(0.53-1.44)	0.587	1.16	(0.72-1.88)	0.536	1.02	(0.72-1.45)	0.902		
Total HIV patients	524			430			954				

CI, confidence interval; HR, Hazard ratio

*p<0.05, ***p<0.001

Impact of TB-HIV Service Integration on ART Initiation Based on Data from AIDS Centers

Kaplan-Meier estimates of the time until ART initiation among TB-HIV coinfected patients at AIDS centers (S1 and S2) are shown in Figure 6.2. The curves drop more quickly and to a lower value at end line than at baseline, particularly in intervention areas, demonstrating that more coinfected patients started ART, and that they started earlier in both intervention and comparison areas. The improvement in the probability of patients starting ART after each duration was greater in the intervention area, so the differences between the two areas narrowed over time.

Table 6.2 shows the results of Cox proportional hazards models predicting ART initiation among coinfected patients at baseline and end line. At baseline, patients in the intervention group were 37 percent less likely to begin ART compared to those in the comparison group. When oblasts are introduced in the model (Appendix A, Table 6S.2), it suggested that patients in Odessa, Zhytomyr and Kiev were 69, 62, and 39 percent, respectively, less likely to begin ART than those in Mykolaiv, after controlling for other factors in the model. At end line, intervention group patients were 22 percent less likely to initiate ART compared to patients in the comparison oblasts (Table 6.2). Patients in Kharkiv and Kiev were more than twice as likely to initiate ART compared to those in Mykolaiv, and patients in Zaporizhzhya and Zhytomyr were 76 percent and 81 percent, respectively, more likely than those in Mykolaiv to start ART (Appendix A, Table 6S.2).

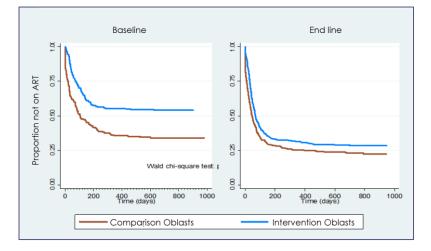


Figure 6.2. Time to ART initiation among coinfected patients, by intervention status

Finally, the difference-in-differences model corroborated our prior findings—at baseline, the intervention group was significantly less likely to initiate ART (p<0.001) compared to the comparison group. We found that the rate of testing among coinfected patients increased by 37 percent at end line (p<0.05) in comparison areas. The rate of ART initiation increased significantly more in intervention areas than in comparison areas (HR=1.49, p<0.05), indicating a significant positive impact of the STbCU project on the rate of coinfected patients initiating ART at AIDS centers.

		Baseline			End line		Diffe	erence-in-differ	ences
Variable	HR	(95% CI)	p-value	HR	(95% CI)	p-value	HR	(95% CI)	p-value
Year X intervention group							1.49**	(1.10-2.01)	0.010
Year									
Baseline							1		
End line							1.37***	(1.10-1.71)	0.005
Intervention Group									
Yes	0.63*	(0.44-0.90)	0.010	0.78**	0.67-0.91)	0.002	0.53***	(0.40-0.70)	0.000
No	1			1			1		
Sex									
Male	0.83	(0.62-1.11)	0.202	0.88	(0.74-1.03)	0.114	0.85**	(0.74-0.98)	0.030
Female	1			1			1		
Age group, yrs									
18–29	1			1			1		
30–39	1.27	(0.79-2.04)	0.326	1.04	(0.84-1.30)	0.707	1.06	(0.87-1.29)	0.565
40–49	1.67*	(1.02-2.74)	0.042	1.00	(0.79-1.27)	0.982	1.10	(0.89-1.36)	0.383
50+	1.42	(0.77-2.61)	0.265	0.98	(0.72-1.33)	0.883	1.01	(0.77-1.33)	0.940
Employment									
Employed	1			1			1		
Unemployed	0.69	(0.48-1.00)	0.050	1.01	(0.84-1.21)	0.928	0.95	(0.81-1.12)	0.532
Retired/disabled	1.87	(0.97-3.57)	0.060	0.91	(0.63-1.32)	0.628	1.01	(0.72-1.41)	0.965
Student/other	1.19	(0.61-2.35)	0.605	0.98	(0.37-2.59)	0.971	1.27	(0.74-2.16)	0.385
Total coinfected patients	794			1529			2260		

Table 6.2. Cox proportional hazards model predicting ART initiation for patients from AIDS centers, Ukraine 2012 and 2015

CI, confidence interval; HR, Hazard ratio

*p<0.05, **p<0.01, ***p<0.001

6.2. Findings from TB Dispensaries

Impact of TB-HIV Service Integration on HIV Testing, Based on Data from TB Dispensaries

Figure 6.3 presents the graph of the Kaplan-Meier estimate of the time between TB diagnosis and HIV testing in S1. The curves are highly skewed at baseline and end line as most HIV testing occurred soon after TB diagnosis. At baseline, the probability of not having received an HIV test within the first month following TB diagnosis ranged from 15 percent to 35 percent, with a significant slowdown in testing thereafter. The difference between intervention and comparison areas was statistically significant (p<0.001), indicating significantly longer time to testing in intervention areas at baseline. The curves drop more quickly and to a lower value at end line than at baseline indicating that more patients were tested and tested earlier at end line in both intervention and comparison areas. However, the change was larger in the intervention group; at end line, the survivor function of the intervention group nearly caught up to that of the comparison group, although the difference between the two curves remained significant (p<0.001).

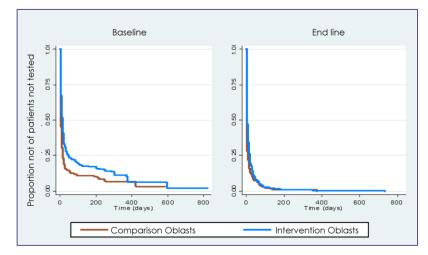




Table 6.3 presents estimates of Cox proportional hazards models predicting HIV testing among TB patients (S1) at baseline and end line, and also presents the difference-in-differences estimate of program impact. Appendix A, Table 6S.3 presents models of HIV testing, including oblast rather than intervention group in the models. The rate of HIV testing was 37 percent lower at baseline (p<0.001) and 22 percent lower at end line (p<0.01) among TB patients in intervention oblasts than among patients in comparison oblasts. We did not observe significant differences in the rate of receiving an HIV test by sex or age at baseline or end line; we did find that PWID were 45 percent more likely to be tested at end line (p<0.05).

The difference-in-differences model was consistent with our prior finding that the rate of HIV testing in the intervention group was significantly lower at baseline (HR=0.64, p<0.001) than that of the comparison group. We found that the HIV testing rate of TB patients increased by nearly 50 percent at end line (p<0.001) in the comparison group. We estimated a positive impact of the STbCU project on the HIV diagnostic testing rate of TB patients; however, this impact was not statistically significant (HR=1.20, p=0.135).

		Bo	aseline			End line		Difference-ir	n-differences
	HR	(95% CI)	p-value	HR	(95% CI)	p-value	HR	(95% CI)	p-value
Year x intervention group							1.20	(0.94-1.52)	0.135
Year									
Baseline							1		
End line							1.46***	(1.21-1.74)	0.000
Intervention group						·			
Yes	0.63***	(0.53-0.75)	0.000	0.78**	(0.66-0.93)	0.005	0.64***	(0.54-0.77)	0.000
No	1			1			1		
Sex									
Male	0.91	(0.76-1.10)	0.326	1.07	(0.89-1.30)	0.456	0.99	(0.87-1.13)	0.897
Female	1			1			1		
Age group, yrs						1			
18–29	1			1			1		
30–39	0.99	(0.77-1.26)	0.929	1.07	(0.82-1.40)	0.619	1.04	(0.88-1.24)	0.612
40–49	0.99	(0.76-1.29)	0.940	0.97	(0.76-1.24)	0.815	0.95	(0.80-1.14)	0.588
50+	0.85	(0.66-1.11)	0.238	1.08	(0.83-1.41)	0.562	0.96	(0.80-1.15)	0.669
Employment									

Table 6.3. Cox proportional hazard models predicting HIV testing for patients at TB dispensaries (Sample 1)

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		Bo	aseline		End line			Difference-in-differences		
Employed	1			1			1			
Unemployed	0.81	(0.64-1.02)	0.074	0.96	(0.78-1.18)	0.697	0.88	(0.76-1.03)	0.120	
Retired/disabled	0.85	(0.61-1.20)	0.363	0.94	(0.73-1.21)	0.643	0.90	(0.73-1.12)	0.339	
Student/other	0.80	(0.53-1.20)	0.274	0.74	(0.38-1.43)	0.370	0.85	(0.60-1.20)	0.344	
Person who injects drugs										
Yes	1.07	(0.51-2.23)	0.857	1.45*	(1.08-1.94)	0.012	1.18	(0.76-1.84)	0.460	
No	1			1			1			
Total TB patients	631			616			1247			

CI, confidence interval; HR, Hazard ratio

*p<0.05, **p<0.01, ***p<0.001

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Impact of TB-HIV Service Integration on ART Initiation Based on Data from TB Dispensaries

Kaplan-Meier estimates of the time from patient's HIV diagnosis until ART initiation among TB-HIV coinfected patients at TB dispensaries (S1 and S2) are shown in Figure 6.4. The survival curve for the comparison area indicated that the time between HIV diagnosis and treatment was significantly lower for comparison oblasts than intervention oblasts at baseline (p<0.001). The approximate median time³ until ART initiation was 125 days in comparison oblasts compared to over one year in intervention oblasts. Performance improved for both study groups at end line, with the improvement in intervention oblasts, outpacing that in comparison oblasts. The median time until ART initiation in the intervention group was roughly 50 days at end line, compared to roughly 75 days in comparison oblasts.

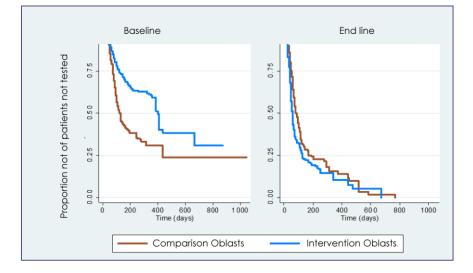


Figure 6.4. Time to ART initiation among coinfected patients at TB dispensaries, by intervention status

Cox proportional hazard models predicting ART initiation among coinfected patients at TB dispensaries are presented in Table 6.4 (Appendix A, Table 6S.4 includes oblast rather than intervention group in the models). The rate of ART initiation among patients in intervention oblasts was 53 percent lower than among patients in comparison oblasts at baseline (p<0.001), but was 35 percent higher than the comparison group at end line (p<0.01). We did not find evidence that the rate of ART initiation differed by sex, age, employment status, or injection-drug use in either study wave. Results from the difference-in-differences model demonstrate a strong and positive estimate of program impact on the rate of ART initiation (HR=2.91, p<0.001). We also found that the rate of initiating ART increased by nearly 70% between baseline and end line in the comparison group.

³ The median time to testing is the time at which the probability of being tested for TB is 0.5.

		Base	eline			End line		Difference-in-differences		
	HR	95% CI	p-value	HR	95% CI	p-value	HR	95% CI	p-value	
Year X intervention group						2.91*	***	(2.10-4.04)	0.000	
Year										
Baseline							1			
End line							1.68***	(1.36-2.07)	0.000	
Intervention group										
Yes	0.47***	(0.36-0.60)	0.000	1.35**	(1.10-1.66)	0.004	0.48***	(0.37-0.61)	0.000	
No	1			1			1			
Sex										
Male	1.03	(0.79-1.34)	0.823	0.96	(0.76-1.20)	0.705	0.98	(0.82-1.17)	0.808	
Female	1			1			1			
Age group, yrs										
18–29	1			1			1			
30–39	0.92	(0.65-1.29)	0.619	1.13	(0.80-1.60)	0.491	1.08	(0.84-1.40)	0.545	
40–49	0.95	(0.65-1.40)	0.798	1.33	(0.93-1.91)	0.119	1.19	(0.90-1.58)	0.213	
50+	0.74	(0.44-1.27)	0.275	0.94	(0.56-1.59)	0.816	0.88	(0.60-1.30)	0.529	
Employment										
Employed	1			1			1			

Table 6.4. Cox proportional hazards models predicting ART initiation among coinfected patients at TB dispensaries

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		Base	eline			End line		Difference-in-differences	
Unemployed	0.79	(0.58-1.10)	0.163	1.16	(0.84-1.59)	0.366	0.96	(0.76-1.22)	0.766
Retired/ disabled	0.84	(0.46-1.55)	0.575	1.38	(0.70-2.69)	0.351	1.06	(0.68-1.64)	0.800
Student/ other	0.69	(0.29-1.64)	0.399	0.32	(0.086-1.18)	0.087	0.49	(0.22-1.10)	0.084
Person who injects drugs									
Yes	0.90	(0.63-1.29)	0.567	1.02	(0.71-1.46)	0.915	0.93	(0.72-1.18)	0.539
No	1			1			1		
Total coinfected patients	1061			1280			2341		

CI, confidence interval; HR, Hazard ratio

p<0.01, *p<0.001

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CHAPTER 7. IMPACT OF TB-HIV SERVICE INTEGRATION ON ALL-CAUSE MORTALITY

This chapter addresses evaluation question D: the impact of service integration, and providing training and support between TB and HIV services on all-cause mortality among the TB-HIV coinfected patients.

7.1. Findings From AIDS Centers

Appendix A, Table 7S.2 presents HIV treatment outcomes for HIV patients by intervention group at baseline and end line. At baseline, 18 percent of patients in the intervention group versus 14 percent in the comparison group had interrupted TB treatment; 24 percent in the intervention group versus 18 percent in the comparison group died. At end line, 11 percent of patients in the intervention group versus 8 percent in the comparison group had interrupted TB treatment, and about 15 percent of patients in each area died.

The Kaplan-Meier survival curves in Figure 7.1 estimated the probability of surviving until the end of at least each period (in days) following registration at the HIV center among coinfected patients, by intervention status at baseline and end line. At baseline, survival was slightly better for patients in the comparison group compared to the intervention group, but the difference between groups was not significant. At end line, there was no substantial difference between the intervention and comparison group in survivor functions. Survival appears to have improved slightly in both groups at end line, particularly in the intervention group. However, the difference-in-differences model (Table 7.1) suggests that these differences in survival were not statistically significant: there was no significant differences between the intervention and comparison area or over time, and there was no significant impact of the program on mortality (HR=0.78, p-0.396).

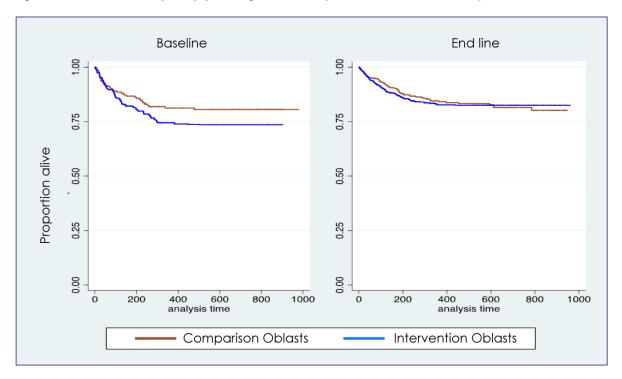


Figure 7.1. Time to death (in days) among coinfected patients at AIDS centers, by intervention status

Appendix A, Table 7S.3 presents the result of the Cox proportional hazards model predicting death among coinfected patients at AIDS centers, with ARV as a covariate. At baseline, there were no significant differences in time to death between intervention and comparison groups. However, as seen in Appendix A, Table 7S.2, patients in Zaporizhzhya were over 3.5 times more likely to die compared to those in Mykolaiv. In general, patients receiving ARV treatment were about 85 percent less likely to die compared to patients not receiving ARV treatment. At end line (Appendix A, Table 7S.3), patients in the intervention group were about 14 percent less likely to die compared to the comparison group; however, the difference was not statistically significant (HR=0.86, p=0.359). Again, coinfected patients receiving ARV treatment.

		Baseline			End line		Differe	nce-in-difference	es model
Variable	HR	(95% CI)	p-value	HR	(95% CI)	p-value	HR	(95% CI)	p-value
Year X intervention group							0.78	(0.46-1.36)	0.396
Year									
Baseline							1		
End line							0.82	(0.54-1.25)	0.36
Intervention group									
Yes	1.33	(0.79- 2.24)	0.274	0.97	(0.70-1.34)	0.849	1.26	(0.80-1.99)	0.322
No	1			1			1		
Sex									
Male	1.29	(0.77-2.14)	0.329	0.87	(0.60-1.27)	0.601	1.04	(0.79-1.38)	0.773
Female	1			1			1		
Age group, yrs									
18–29	1			1			1		
30–39	1.80	(0.76-4.24)	0.180	1.27	(0.72-2.23)	0.411	1.50	(0.94-2.39)	0.086
40–49	1.21	(0.48-3.06)	0.681	1.45	(0.81-2.62)	0.211	1.36	(0.84-2.22)	0.210
50+	1.11	(0.37-3.30)	0.852	1.49	(0.75-2.94)	0.255	1.47	(0.844-2.58)	0.172

Table 7.1. Cox proportional hazards model predicting time to death among coinfected patients at AIDS centers, Ukraine 2012 and 2015

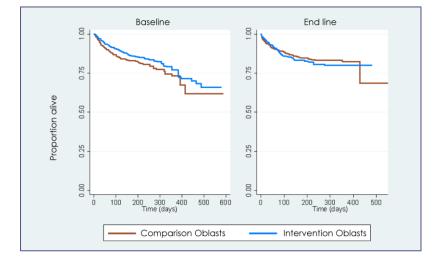
		Baseline			End line		Differe	ence-in-differenc	es model
Variable	HR	(95% CI)	p-value	HR	(95% CI)	p-value	HR	(95% CI)	p-value
Employment									
Employed	1			1			1		
Unemployed	1.26	(0.72-2.20)	0.426	1.59*	(1.05-2.43)	0.030	1.39	(1.00-1.92)	0.051
Retired/disabled	0.14	(0.018-1.08)	0.059	3.31**	(1.64-6.68)	0.001	2.06*	(1.17-3.65)	0.013
Student/other	0.28	(0.035-2.23)	0.229	0.74	(0.09-6.03)	0.774	0.35	(0.76-1.58)	0.172
Total coinfected patients	949			2,260			3209		
CI, confidence interval; HR, Hazard ratio									

*p<0.05, **p<0.01

7.2. Findings From TB Dispensaries

TB treatment outcomes among patients at TB dispensaries are presented in Appendix A, Table 7S.4 by intervention group at baseline and end line. There were no significant differences in treatment outcomes between intervention and comparison oblasts at baseline or end line. Treatment for TB was successful for half of the study subjects at baseline and end line. Between 16 percent and 20 percent of TB patients died during the baseline study period, compared with 14 percent of intervention and comparison subjects at end line. Treatment failure increased by more than 10 percentage points between baseline and end line in both study groups, from about 17 percent to about 30 percent.

Figure 7.2 presents Kaplan-Meier survival curves showing the probability of surviving until at least each period (in days) following TB diagnosis among coinfected patients at TB dispensaries, by intervention status at baseline and end line. Survival at end line was slightly better than at baseline for all subjects; there was no significant difference between the intervention and comparison group survivor functions at baseline or at end line.





We did not find evidence of a program effect on the risk of all-cause mortality among coinfected TB patients at baseline or end line, nor did we find evidence of a program impact on risk of death (Table 7.2). It is interesting to note that at baseline, injecting drug use was associated with a twofold increase in the likelihood of death (p<0.000), but this relationship was not significant at end line. Appendix A, Table 78.5 presents these models at baseline and end line, including oblast rather than intervention group in the model and adding ART as a time-varying covariate. Appendix A, Table 78.6 includes ART as a time-varying covariate in both the cross-sectional and difference-in-differences specifications.

		Baseline			End line			Difference-in- differences		
	HR	(95% CI)	p-value	HR	(95% CI)	p-value	HR	(95% CI)	p-value	
Year X intervention	group	1					1.32	(0.83-2.12)	0.243	
Year										
Baseline							1			
End line							0.84	(0.60-1.16)	0.286	
Intervention group										
Yes	0.86	(0.63-1.18)	0.356	1.07	(0.75-1.53)	0.715	0.85	(0.62-1.15)	0.296	
No	1			1			1			
Sex										
Male	0.98	(0.68-1.42)	0.924	0.87	(0.59-1.30)	0.501	0.95	(0.72-1.24)	0.684	
Female	1			1			1			
Age group, yrs										
18–29	1			1			1			
30–39	0.81	(0.51-1.27)	0.360	1.47	(0.75-2.88)	0.267	1.03	(0.71-1.50)	0.858	
40–49	1.14	(0.70-1.87)	0.588	1.38	(0.67-2.83)	0.376	1.21	(0.81-1.80)	0.349	
50+	0.95	(0.47-1.94)	0.894	2.03	(0.87-4.73)	0.102	1.33	(0.79-2.26)	0.286	
Employment										
Employed	1			1			1			
Unemployed	1.31	(0.79-2.18)	0.291	1.42	(0.74-2.73)	0.291	1.37	(0.91-2.05)	0.131	

Table 7.2. Cox proportional hazard models predicting time to death among coinfected patients at TB dispensaries

		Baseline		End line			Difference-in- differences		
	HR	(95% CI)	p-value	HR	(95% CI)	p-value	HR	(95% CI)	p-value
Retired/ disabled	0.71	(0.28-1.77)	0.456	0.83	(0.27-2.60)	0.755	0.79	(0.39-1.62)	0.521
Student/ other	1.17	(0.31-4.39)	0.814	1.93	(0.56-6.72)	0.300	1.49	(0.60-3.71)	0.390
Person who injects drugs	1	I							
Yes	2.11***	(1.46-3.05)	0.000	1.38	(0.79-2.42)	0.261	1.85***	(1.37-2.49)	0.000
No	1			1			1		
Total coinfected patients	1455			1870			3325		
CI, confidence interval; HR, H	lazard ratio	I				I		-	1
***p<0.001									

Appendix A, Table 7S.7 presents additional descriptive information on TB-specific versus non-TB mortality for coinfected patients in TB dispensaries who died by year, intervention status, and oblast. The numbers of deaths are small, especially at the oblast level, so results should be interpreted with caution. In general, the majority of deaths among coinfected patients were due to causes other than TB, particularly in intervention oblasts at end line.

CHAPTER 8. CONCLUSIONS AND RECOMMENDATIONS

Conclusions and Discussion

Table 8.1 summarizes the evaluation results for each evaluation question. All integration outcomes examined improved between baseline and end line in both program and comparison areas; although, some improvements were not statistically significant. For example, improvements in HIV testing at TB dispensaries were not statistically significant, likely in part, because the levels of HIV testing in TB dispensaries were high at baseline, leaving relatively little room for improvement. The improvements in both level and timing of ART initiation among coinfected patients were greater in program than comparison areas, indicating a significant program impact on this outcome. Although all-cause mortality declined slightly in both program and comparison areas, the declines were not statistically significant and there were no significant program impacts on this outcome despite the significant improvement in ART initiation.

Improvements in outcomes were consistently larger in the area (program versus comparison) that had the poorer outcome at baseline, resulting in convergence in outcomes between program and comparison areas over time. In particular, the improvements in TB testing were greater at AIDS centers in comparison areas than in intervention areas, even though HIV facility level data suggested that at end line, more AIDS centers in intervention oblasts had TB diagnostic services available on-site compared to the comparison oblasts (MEASURE Evaluation, 2014 and Appendix B). National TB-HIV integration efforts began in the entire country, including comparison areas, after 2012, so the national program and STbCU worked in the integration oblasts, while the national program supported by Global Fund worked in the comparison oblasts, which included a focus on improving TB testing services at AIDS centers. TB-HIV integration efforts started much earlier in the intervention oblasts (PATH worked there before STbCU), which might explain why the TB testing rates, which represent an early step in TB-HIV integration, were higher at baseline in intervention areas, but by end line comparison areas had caught up. For ART initiation, intervention areas were worse at baseline and saw bigger improvements. Intervention oblasts were selected by USAID due to their poor outcomes, historically. It takes time to train staff on ART initiation, which was a focus of the STbCU program, and intervention areas had more time to roll out training than comparison areas because integration efforts started there earlier.

Table 8.1. Summary of findings	, by evaluation question
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Evaluation Question	AIDS Center	TB Dispensary
A: Completion of TB-HIV service cascade: What proportion of TB and HIV/AIDS patients completed each step in the cascade of services from screening to treating, per national protocol?	-TB testing increased from 63% to 85% in program areas and from 57% to 93% in comparison areas -TB treatment was universal among coinfected patients in both program and comparison areas at both baseline and end line. -ART initiation among coinfected patients increased from 41% to 76% in program areas and from 61% to 83% in comparison areas	-HIV testing among patients not previously diagnosed with HIV increased from 91% to 99% in program areas and from 95% to 99% in comparison areas -ART initiation among coinfected patients increased from 20% to 47% in program areas and minimally changed from 47% to 46% in comparison areas
B: Factors affecting the use of TB-HIV services: What facilitates or impedes timely access to and use of tests and treatments for TB and HIV patients?	Facilitators: improvements in diag between HIV and TB providers; jo TB and HIV providers, enhanced quality providers, and free ART Barriers: stigma, emotional burde effects of medications, out-of-po treatment, long lines to receive se to find treatment, staff shortages, inconsistent sharing of information	int meetings and conferences for IB services in HIV centers, high- n of TB and HIV diagnoses, side cket and travel costs for ervices, confusion about where infrastructure limitations,
C: Impact of service integration on time to services: Does integrating service, and providing training and support between TB and HIV/AIDS services decrease the time lag between each step of service (tests and treatments) for TB and HIV/AIDS patients?	-Negative statistically significant program effect on time to TB testing. Time to TB testing decreased in both program and comparison areas, but decrease was larger in comparison areas. -Positive statistically significant program effect on time to ART initiation among coinfected. Time to ART initiation decreased in both program and comparison areas, but the decrease was larger in program areas.	-Positive but not statistically significant effect on time to HIV testing. Time to HIV testing decreased in both program and nonprogram areas. The decrease was slightly greater in program areas, but not significantly greater. -Positive statistically significant program effect on time to ART initiation among coinfected. Time to ART initiation decreased in both program and comparison areas, but the decrease was larger in program areas.
D: Impact of service integration on all-cause mortality: Does integrating service, and providing training and support between TB and HIV/AIDS services decrease all-cause mortality among the TB-HIV coinfected patients?	-No statistically significant program impact. All-cause mortality decreased slightly in both program and comparison areas, but the declines were not statistically significant.	-No statistically significant program impact. All-cause mortality decreased slightly in both program and comparison areas, but the declines were not statistically significant.

Interviews with patients and providers suggested that, while improvements in diagnostic testing and coordinating across TB and HIV facilities was well under way, several social factors, such as stigma both for TB and HIV, emotional burden, and adequate education to deal with the side effects of the medication still need to be addressed. Additionally, even though ART treatment is free, in-patient costs and travel costs pose a significant financial barrier to accessing care for TB-HIV coinfected patients. One of the key strategies of the STbCU project is a social support program that provided social support services to improve treatment adherence among those at high risk of treatment default. This intervention addressed several of the main factors that were identified as barriers to the use of services in this study. The impact evaluation of the social support program on reducing TB treatment default among patients at high risk of default (Charyeva, Curtis, & Mullen, 2018).

We would expect that more timely ART initiation would result in direct improvements in survival, particularly in the intervention areas where improvements in ART initiation were larger; however, no statistically significant improvements in mortality were observed at either TB dispensaries or AIDS centers. Demographic and disease characteristics data on patients in intervention and comparison AIDS centers suggested that at the time the patients entered the facility, those in the intervention facilities had more advanced disease stages. We were not able to control for disease severity variables, such as CD4 cell count or TB disease stage, in our impact models, due to the large amount of missing disease characteristic data at baseline, especially at AIDS centers. These variables are strong predictors of survival in coinfected patients. If it is indeed the case, that patients with more advanced disease stages were seeking care in facilities in intervention oblasts, we would expect to see this negatively impact mortality in intervention oblasts, despite improvements in treatment initiation. In addition, despite over-sampling coinfected patients, the number of deaths observed in the sampled records was small, giving us limited statistical power to detect statistically significant changes in mortality.

Finally, a note on missing data is warranted. In the intervention group AIDS centers, over 50 percent of coinfected patients had missing data on numbers of visits, clinical stage, CD4 count, and injecting drugs status at the most recent visit at baseline. At end line, the amount of missing data on all disease characteristics was substantially less, about 5 percent for all variables, except CD4 cell count, and on TB outcome status. This suggests that considerable progress has been made in addressing issues of data completeness and quality; however, more progress is necessary. At the individual level, having a complete record is critical to clinical decision making, and at the population level, it is not possible to understand how well interventions are working without complete data.

Recommendations

A number of recommendations emerged from the results of the quantitative study, as well as from indepth interviews with providers and patients. Many of the integration efforts have been successful in facilitating access to services. There has been progress, nationally, in TB testing of HIV patients, and HIV testing of TB patients, and in earlier initiation on ART. Existing efforts should continue and be further strengthened. Additional analysis (shown in Appendix A) suggests variability in outcomes across oblasts within program and comparison areas; factors associated with this variability should be further explored and best practices should be employed consistently across oblasts. Further investment is needed in interventions to alleviate social and logistical barriers to service use, such as social support services, to ensure that patients are retained in care.

The problem of missing data on disease characteristics may have multiple root causes. One that was identified in the discussions with providers was that a shared database was lacking between TB and HIV facilities, which substantially limited care coordination. Efforts to develop digital databases with protocols for sharing confidential patient information across facilities should be strengthened. Additionally, facility-level measures to ensure data completeness and quality control should be instituted. Additionally, the qualitative interviews also identified a number of staffing and workload issues that should be addressed.

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APPENDIX A. SUPPLEMENTARY RESULTS

Chapter 2 Supplementary Tables

Table 2S.1. HIV patient response rates at baseline and end line, by oblast

		2012		2015				
	HIV S	ervices, N (%)		HIV S	ervices, N (%)			
Intervention oblasts	Target Sample	Abstracted	Rate	Target Sample	Abstracted	Rate		
Kharkiv	95	110	(115.8)	95	104	(109.5)		
Odessa	343	347	(101.2)	343	536	(156.3)		
Zaporizhzhya	88	88	(100.0)	88	160	(181.8)		
Subtotal	526	545	(103.6)	524	800	(152.6)		
Comparison oblasts								
Kiev	180	174	(96.7)	180	276	(153.3)		
Mykolaiv	245	241	(98.4)	245	305	(124.5)		
Zhytomyr	101	104	(103.0)	101	148	(146.5)		
Subtotal	526	519	(98.7)	526	729	(138.6)		
Total HIV patients	1052	1064	(101.1)	1052	1529	(145.3)		

	le contra de la contra de	2012		2015				
	TB Se	ervices, N (%)		TB Services, N (%)				
Intervention oblast	Target sample	Abstracted	Rate	Target sample	Abstracted	Rate		
Kharkiv	226	224	(99.1)	226	226	(100.0)		
Odessa	317	314	(99.1)	317	317	(100.0)		
Zaporizhzhya	181	180	(99.4)	181	181	(100.0)		
Subtotal	724	718	(99.2)	724	724	(100.0)		
Kiev	238	237	(99.6)	238	238	(100.0)		
Mykolaiv	260	270	(103.8)	260	260	(100.0)		
Zhytomyr	226	202	(89.4)	226	226	(100.0)		
Subtotal	724	709	(97.9)	724	724	(100.0)		
Total TB patients	1448	1427	(98.5)	1448	1448	(100.0)		

Table 2S.2. TB patient response rates at baseline and end line, by oblast

Chapter 3 Supplementary Tables

Table 35.1. Demographic characteristics of patients from AIDS centers at baseline and end line, by intervention group

		20	12		2015						
		HIV Po	atients		HIV Patients						
	Interv	ention	Comp	oarison	Interv	ention	Comparison				
Background characteristics	N	(%)	N	(%)	N (%)		N	(%)			
Sex	1		l	1	1	1	1	1			
Male	343	(50.7)	246	(63.6)	606	(60.6)	312	(61.6)			
Female	315	(46.5)	141	(36.4)	394	(39.4)	194	(38.4)			
Missing	19	(2.8)									
Age group, years											
18–29	139	(20.5)	82	(21.2)	162	(16.1)	89	(17.7)			
30–39	291	(43.0)	176	(45.5)	420	(41.9)	236	(46.5)			
40-49	184	(27.2)	97	(25.1)	283	(28.3)	135	(26.7)			
50–59	53	(7.8)	30	(7.8)	108	(10.8)	38	(7.4)			
>60	10	(1.5)	2	(0.5)	28	(2.8)	9	(1.8)			
Employment											
Employed	122	(18.0)	71	(18.3)	167	(16.6)	113	(22.3)			
Unemployed	413	(61.0)	86	(22.2)	723	(72.3)	247	(48.7)			
Retired/person with disabilities	14	(2.1)	12	(3.1)	41	(4.1)	27	(5.2)			
Student/house wife/other	63	(9.3)	2	(0.5)	16	(1.6)	16	(3.2)			
Missing	65	(9.6)	216	(55.8)	54	(5.4)	105	(20.7)			

		20	12		2015				
Residence									
Urban	400	(59.1)	226	(58.4)	645	(64.5)	289	(57.0)	
Rural	266	(39.3)	160	(41.3)	353	(35.3)	210	(41.4)	
Missing	11	(1.6)	1	(0.3)	2	(0.2)	8	(1.6)	
Oblast									
Kharkiv	74	(10.9)			72	(7.2)			
Odessa	513	(75.8)			798	(79.7)			
Zaporizhzhya	90	(13.3)			131	(13.1)			
Kiev			143	(37.0)			196	(38.8)	
Mykolaiv			171	(44.2)			207	(40.8)	
Zhyłomyr			73	(18.9)			104	(20.5)	
Total HIV patients	677	(100)	387	(100)	1001		506.5		

Notes: Weighted counts and percentages. Statistically significant Pearson chi-square test statistics for differences between intervention and comparison groups at baseline include: Sex (p=0.0002 and employment (p=0.000). Significant differences at end line include: Employment (p=0.0000), and Residence (p=0.0000).

Table 3S.2. Disease status of HIV patients at baseline and end line, by coinfection status and intervention group

		20	12		2015				
	Interventi	Intervention Oblasts		on Oblasts	Interventi	on Oblasts	Comparison Oblasts		
	HIV Only	Coinfected	HIV Only	Coinfected	HIV Only	Coinfected	HIV Only	Coinfected	
HIV status	N(%)	N(%)	N(%)	N(%)	N(%)	N(%)	N(%)	N(%)	
Number of visits in past 12 month	S								
1	156(47.4)	101 (29.0)	103(46.6)	56(33.7)	189(63.2)	275(39.3)	55(34.8)	98(28.2)	
2	72(21.9)	36(10.3)	48(21.7)	33(19.9)	49(16.4)	177(25.2)	29(18.5)	72(20.6)	
3	32(9.7)	15(4.3)	30(13.6)	31(18.7)	12(3.9)	57(8.1)	21(13.1)	50(14.5)	
4 or more	25(7.6)	14(4.0)	23(10.4)	37(22.3)	35(11.8)	153(21.8)	50(31.6)	127(36.5)	
Missing	44(13.4)	182(52.3)	17(7.7)	9(5.4)	14(4.8)	39(5.6)	3(1.9)	1 (0.2)	
HIV clinical stage (most recent vi	isit)								
Stage 1	104(31.6)	0(0.0)	85(38.5)	3(1.8)	77(25.7)	15(2.2)	62(39.2)	28(8.1)	
Stage 2	67 (20.4)	5(1.4)	33(14.9)	3(1.8)	14(4.5)	13(1.8)	23(14.6)	8(2.4)	
Stage 3	77(23.4)	27(7.8)	43(19.5)	41 (24.7)	85(28.3)	80(11.4)	34(21.3)	17(4.8)	
Stage 4	31 (9.4)	132(37.9)	40(18.1)	110(66.3)	110(36.7)	553(78.9)	36(23.0)	294(84.5)	
Missing	50(15.2)	184(52.9)	20(9.0)	9(5.4)	14(4.8)	40(5.7)	3(1.9)	1 (0.2)	

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		20	12		2015								
	Interventi	on Oblasts	Comparis	on Oblasts	In	Intervention Oblasts				omparis	on Oł	olasts	
	HIV Only	Coinfected	HIV Only	Coinfected	HIV Only		Coir	Coinfected		/ Only	Coinfecte		
HIV status	N(%)	N(%)	N(%)	N(%)	N	N(%)				N(%)		N(%)	
CD4 count (most recent visit)													
<50 cells/mm ³	73(22.2)	58(16.7)	88(39.8)	72(43.4)	52	(17.3)	265	(37.7)	58	(36.7)	146	(41.9)	
50-349 cells/mm ³	71(21.6)	93(26.7)	39 (17.6)	68 (41.0)	92	(30.8)	270	(38.5)	16	(9.9)	67	(19.2)	
≥350 cells/mm³	142(43.2)	15(4.3)	77 (34.8)	17(10.2)	83	83(27.6)		84(12.0)		84(12.0) 35(22.3)		40(11.5)	
Missing	43(13.1)	182(52.3)	17(7.7)	9(5.4) 73(24.3)		83	(11.8)	49	(31.2)	95	(27.4)		
ARV treatment													
Yes, known treatment	170(51.7)	166(47.7)	89(40.3)	111(66.9)	80	(26.8)	504	504(71.9) 10		1 (63.7)	272(78.0)		
No record of treatment	159(48.3)	182(52.3)	132(59.7)	55(33.1)	219	9(73.2)	197	197(28.1) 58(36.3)		77(22.0)			
PWID													
Yes*	20(6.1)	11(3.2)	18(8.1)	18(10.8)	37	37(12.3) 79(11.3)		24	(14.9)	30	D(8.7)		
No	263(79.9)	154(44.3)	179(81.0)	135(81.3) 249(8		9(83.0)	581	(82.9)	128	8(81.0)	302	2(86.6)	
Missing	46(14.0)	183(52.6)	24(10.9)	13(7.8)	14	4(4.8) 41(5.9)		(5.9)	7	(4.1)	10	6(4.7)	
Total HIV patients	329(100)	348(100)	221(100)	166(100)		300		701		158		348	

		20)12			2015				
		TB Pc	itients			TB Pc	atients			
	Inter	vention	Com	parison	Inter	vention	Comparison			
Background characteristics	N	(%)	N	(%)	N	(%)	N	(%)		
Sex			1	1		1		1		
Male	518	(66.7)	476	(73.1)	651	(68.4)	335	(67.7)		
Female	258	(33.3)	175	(26.9)	301	(31.6)	160	(32.3)		
Missing	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)		
Age group, years			1	1		1		1		
18–29	157	(20.2)	111	(17.1)	145	(15.2)	66	(13.4)		
30–39	308	(39.7)	259	(39.7)	373	(39.2)	235	(47.5)		
40–49	193	(24.8)	167	(25.7)	275	(28.9)	120	(24.2)		
50–59	74	(9.6)	76	(11.6)	112	(11.8)	45	(9.1)		
>60	39	(5.0)	38	(5.9)	48	(5.0)	29	(5.9)		
Missing	5	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)		
Employment										
Employed	91	(11.7)	89	(13.6)	113	(11.9)	73	(14.7)		
Unemployed	576	(74.3)	468	(71.8)	756	(79.3)	355	(71.7)		
Retired/disabled	71	(9.1)	80	(12.2)	65	(6.8)	52	(10.5)		
Student/housewife/other	22	(2.8)	15	(2.3)	17	(1.8)	12	(2.3)		
Missing	16	(2.1)	1	(0.1)	2	(0.2)	4	(0.7)		
Residence										
Urban	563	(72.6)	377	(57.8)	662	(69.5)	287	(57.9)		
Rural	213	(27.4)	268	(41.2)	288	(30.2)	205	(41.3)		
Missing	0	(0.0)	7	(1.0)	3	(0.3)	4	(0.8)		
Oblast										
Kharkiv	131	(16.9)			153	(16.1)				
Odessa	490	(63.2)			610	(64.1)				
Zaporizhzhya	155	(19.9)			189	(19.8)				
Kiev			214	(32.8)			288	(58.2)		

Table 35.3. Demographic characteristics of TB patients at baseline and end line, by intervention group

		2012		2015 TB Patients					
		TB Patients							
Mykolaiv		333	(51.2)		97	(19.5)			
Zhytomyr		105	(16.0)		110	(22.2)			
Total TB patients	776	651		953	495				

Notes: Weighted counts and percentages. Statistically significant Pearson chi-square test statistics for differences between intervention and comparison groups at baseline include: Sex (*p*=0.0153) and Residence (*p*=0.0000). Significant differences at end line include: Age (*p*=0.0311), Employment (*p*=0.0277), and Residence (*p*=0.0004).

Table 3S.4. Disease status of TB patients at baseline and end line, by coinfection status and intervention group

				20)12				2015							
		Intervent	ion Oblo	asts		Compari	son Obl	asts		Interventi	on Obl	asts	Comparison Oblasts			asts
	ТВ	Only	Coir	nfected	ТВ	Only	Coiı	nfected	ТВ	Only	Coiı	nfected	ТВ	Only	Coir	fected
TB status	N	(%)	1	1(%)	N	(%)	1	√(%)	N	I(%)	1	√(%)	N	(%)	N(%)	
TB classification	-		-		-		-		-							
First diagnosis	249	(76.9)	341	(75.4)	164	(65.2)	229	9(60.3)	264	(78.1)	440	6(72.6)	134	(71.1)	194	4(63.0)
Retreatmenta	69 (21.2)	83	(18.3)	53(21.1)	114	4(25.7)	59	(17.4)	14	1 (23.0)	45(23.9)	89	(29.1)
Chronic TB ^b	0(0.0)	0	(0.0)	18	(7.0)	35	5(8.1)								
Referral/other	6(1.8)	28	3(6.3)	17	(6.7)	23	3(6.0)	15	(4.5)	27	7(4.4)	9(5.0)	24	4(7.9)
TB clinical form	-		-		-		-		-			-				-
Pulmonary	305	(94.4)	401	(88.8)	234	(93.0)	330	(82.4)	320	(94.5)	381	(62.0)	171	(90.7)	217	(70.6)
Extrapulmonary	14	(4.5)	36	(7.9)	16	(6.3)	56	(13.9)	12	(3.5)	96	(15.6)	10	(5.5)	64	(20.8)
Both	4	(1.1)	15	(3.3)	2	(0.7)	15	(3.7)	7	(2.0)	138	(22.4)	7	(3.8)	26	(8.5)
TB treatment categ	ory		-		-		-		-			-				
Category I	215	(66.6)	317	(70.1)	138	(55.1)	219	(54.7)	241	(71.3)	406	(66.1)	118	(62.9)	184	(59.8)
Category II	69	(21.2)	109	(24.2)	87	(34.5)	166	(41.4)	65	(19.1)	111	(18.1)	45	(24.0)	108	(35.0)
Category III	39	(12.2)	25	(5.5)	25	(10.0)	12	(2.9)	17	(5.1)	11	(1.7)	16	(8.4)	6	(1.8)
Category IV ^c									15	(4.6)	87	(14.1)	9	(4.7)	10	(3.4)
Other/missing	0	(0.0)	1	(0.3)	1	(0.4)	4	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
PWID																
Yes	4	(1.1)	61	(13.5)	4	(1.5)	109	(27.2)	2	(0.7)	22	(3.6)	1	(0.4)	56	(18.2)

	2012							2015								
No	320	(98.9)	391	(86.5)	247	(98.5)	291	(72.8)	336	(99.3)	592	(96.4)	187	(99.7)	251	(81.8)
Total HIV patients	324		452		251		400		339		614		188		307	
Total HIV patients 324 452 251 400 339 614 188 307 Notes: Weighted counts and percentages. •Includes reinitiation, treatment failure, and relapse •Includes reinitiation, treatment failure, and relapse •Includes reported for chronic TB category at end line																
°Category IV includes patients diagnosed with multidrug-resistant TB within one week from date of admission to TB facility and was not measured at baseline.																

Chapter 4 Supplementary Tables

	Base	line	End	Line
	Intervention, n	Comparison, n	Intervention, n	Comparison, n
SAMPLE 1: HIV patients without pr	ior TB			
Registered at AIDS Center	380	241	402	237
TB diagnostic tests	239	137	342	220
TB case confirmed	40	22	66	33
COINFECTED SAMPLE: HIV patient	s with prior TB and n	o prior TB combine	d	
TB case confirmed	297	128	565	275
Started TB treatment	297	128	561	271
Started ART	121	78	429	228
TB outcome recorded	119	77	377	217
ART, antiretroviral treatment				

Table 4S.1. Services received by HIV patients at baseline and end line, Samples 1 and coinfected patients

Table 4S.2. Services received by TB patients at baseline and end line for sample 1 and coinfected patient sample

	Base	line	End	Line
	Intervention, n	Comparison, n	Intervention, n	Comparison, n
SAMPLE 1: TB Patients w	ith no prior HIV			
New TB patients	275	189	317	158
HIV VCT	265	178	315	156
HIV diagnostic test	251	179	315	156
HIV case confirmed	22	21	53	24
COINFECTED SAMPLE: TI	B patients with prior HIV	V and with no prior HI	V combined	
HIV case confirmed	105	108	221	115
HIV registration	40	84	142	82
Started ART	21	51	103	53
TB outcome recorded	21	51	103	53

ART, antiretroviral treatment; VCT, voluntary counseling and testing

Chapter 6 Supplementary Tables

			2012		2015								
Variable	HR		(95% CI)	p-value	HR		(95% CI)	p-value					
Oblast													
Kharkiv	0.54	*	(0.31-0.96)	0.034	0.59		(0.34-1.04)	0.069					
Odessa	0.46	**	(0.27-0.78)	0.004	1.48	*	(1.01-2.17)	0.046					
Zaporizhzhya	0.88		(0.46-1.67)	0.694	0.70		(0.35-1.41)	0.320					
Kiev	0.05	***	(0.02-0.12)	0.000	1.87	**	(1.22-2.87)	0.004					
Zhytomyr	0.40	**	(0.22-0.73)	0.003	2.49	***	(1.45-4.26)	0.001					
Mykolaiv	1				1								
Sex													
Male	1.05		(0.77-1.44)	0.762	1.09		(0.88-1.34)	0.440					
Female	1				1								
Age group, years													
18–29	1				1								
30–39	1.54	*	(1.03-2.29)	0.035	1.14		(0.85-1.53)	0.374					
40–49	2.55	***	(1.67-3.91)	0.000	1.48	*	(1.11-2.00)	0.011					
50+	1.49		(0.73-3.04)	0.273	1.09		(0.74-1.61)	0.652					
Employment													
Employed	1				1								
Unemployed	0.96		(0.66-1.42)	0.856	0.93		(0.75-1.16)	0.524					
Retired/disabled	1.24		(0.40-4.18)	0.725	1.53	*	(1.02-2.31)	0.042					
Student/other	1.10		(0.62-1.93)	0.751	1.02		(0.63-1.67)	0.926					
Total HIV patients	524				430								

Table 6S.1. Cox proportional hazard models predicting TB testing among HIV patients (\$1 sample) at baseline (2012) and end line (2015), controlling for oblasts

*CI, confidence interval; HR, Hazard ratio

*p<0.05, **p<0.01, ***p<0.001

Table 6S.2. Cox proportional hazards models predicting ART initiation among coinfected patients presenting at AIDS centers at baseline (2012) and end line (2015), controlling for oblasts

	2012			2015								
Variable	HR	(95% CI)	p-value	HR	(95% CI)	p-value						
Oblast												
Kharkiv	0.59*	(0.37-0.93)	0.024	2.02***	(1.38-2.94)	0.000						
Odessa	0.31***	(0.19-0.50)	0.000	1.05	(0.84-1.31)	0.656						
Zaporizhzhya	1.29	(0.75-2.22)	0.356	1.76***	(1.26-2.48)	0.001						
Kiev	0.61*	(0.40-0.92)	0.020	2.13***	(1.64-2.77)	0.000						
Zhytomyr	0.38***	(0.24-0.60)	0.000	1.81***	(1.36-2.40)	0.000						
Mykolaiv	1			1								
Sex												
Male	0.88	(0.65-1.19)	0.398	0.88	(0.74-1.03)	0.115						
Female	1			1								
Age group, years												
18–29	1			1								
30–39	1.31	(0.83-2.06)	0.250	0.98	(0.78-1.22)	0.826						
40–49	1.61	(1.00-2.60)	0.050	1.00	(0.78-1.26)	0.935						
50+	1.52	(0.84-2.77)	0.169	1.00	(0.73-1.36)	0.992						
Employment												
Employed	1			1								
Unemployed	0.84	(0.57-1.24)	0.375	1.05	(0.87-1.26)	0.634						
Retired/disabled	1.32	(0.75-2.34)	0.335	0.89	(0.62-1.26)	0.503						
Student/other	1.76	(0.85-3.67)	0.130	1.04	(0.39-2.74)	0.939						
Total coinfected HIV patients	794			1529								

*CI, confidence interval; HR, Hazard ratio

*p<0.05, **p<0.01, ***p<0.001

Table 6S.3. Cox proportional hazard models predicting HIV testing among TB patients (Sample 1) at baseline (2012) and end line (2015), controlling for oblasts

		Baseline			End Line	
	HR	(95% CI)	p-value	HR	(95% CI)	p-value
Oblast						
Mykolaiv	1.00			1		
Kharkiv	0.72*	(0.54-0.95)	0.020	0.70**	(0.54-0.91)	0.007
Odessa	0.51***	(0.67-0.69)	0.000	1.16	(0.86-1.55)	0.341
Zaporizhzhya	0.69**	(0.53-0.91)	0.008	0.89	(0.69-1.15)	0.380
Kiev	0.66**	(0.49-0.88)	0.004	0.91	(0.68-1.22)	0.525
Zhytomyr	2.56***	(1.76-3.72)	0.000	2.46***	(1.83-3.32)	0.000
Sex						
Male	0.94	(0.78-1.14)	0.524	1.07	(0.87-1.30)	0.525
Female	1.00			1		
Age group, year	ſS					
18–29	1.00			1		
30–39	0.97	(0.77-1.23)	0.806	1.07	(0.82-1.38)	0.619
40–49	1.00	(0.78-1.29)	0.992	0.97	(0.76-1.22)	0.767
50+	0.78	(0.60-1.01)	0.056	0.98	(0.76-1.27)	0.883
Employment						
Employed	1.00			1		
Unemployed	0.83	(0.65-1.06)	0.135	0.91	(0.74-1.12)	0.363
Retired/	0.94	(0.66-1.33)	0.718	0.99	(0.76-1.29)	0.929
disabled						
Student/	0.76	(0.50-1.16)	0.205	0.87	(0.46-1.66)	0.677
other						
Person who injec	cts drugs					
Yes	0.86	(0.38-1.97)	0.726	1.55*	(1.08-2.24)	0.018
No	1.00			1		
Ν	631				616	

CI, confidence interval; HR, Hazard ratio

*p<0.05, **p<0.01, ***p<0.001

Table 6S.4. Cox proportional hazard models predicting ART initiation among coinfected TB patients at baseline (2012) and end line (2015), controlling for oblasts

		Baseline			End Line	
	HR	(95% CI)	p-value	HR	(95% CI)	p-value
Oblast						
Mykolaiv	1			1		
Kharkiv	0.42***	(0.29-0.60)	0.000	1.30	(0.90-1.88)	0.166
Odessa	0.33***	(0.23-0.47)	0.000	1.37*	(1.03-1.84)	0.033
Zaporizhzhya	0.49**	(0.31-0.77)	0.002	1.38	(0.96-1.98)	0.084
Kiev	0.50***	(0.35-0.72)	0.000	0.96	(0.71-1.30)	0.777
Zhytomyr	0.51***	(0.35-0.75)	0.001	1.29	(0.92-1.81)	0.138
Sex						
Male	1.05	(0.80-1.37)	0.744	0.96	(0.76-1.20)	0.704
Female	1			1		
Age group, years	5					
18–29	1			1		
30–39	0.87	(0.62-1.23)	0.440	1.13	(0.80-1.61)	0.481
40–49	0.86	(0.58-1.28)	0.464	1.33	(0.92-1.90)	0.126
50+	0.68	(0.40-1.16)	0.154	0.93	(0.55-1.57)	0.775
Employment						
Employed	1			1		
Unemployed	0.87	(0.61-1.24)	0.444	1.16	(0.84-1.60)	0.372
Retired/ disabled	0.94	(0.50-1.75)	0.846	1.37	(0.69-2.69)	0.367
Student/ other	0.70	(0.31-1.56)	0.383	0.33	(0.087-1.22)	0.096
Person who injec	ts drugs					
Yes	0.88	(0.61-1.29)	0.523	1.04	(0.72-1.49)	0.851
No						
N	1061			1280		

CI, confidence interval; HR, Hazard ratio

*p<0.05, **p<0.01, ***p<0.001

Chapter 7 Supplementary Tables

	20	12		2015					
Interventio	on Oblasts	Comparis	on Oblasts	Interventi	on Oblasts	Comparis	on Oblasts		
N	(%)	N	(%)	N	(%)	N	(%)		
116	(33.3)	53	(31.9)	272	(38.8)	166	(47.7)		
30	(8.6)	11	(6.6)	47	(6.7)	19	(5.5)		
62	(17.8)	23	(13.9)	75 (10.6)		28	(8.0)		
83	(23.9)	30	(18.1)	109	(15.5)	50	(14.5)		
2	(0.6)	10	(6.0)	0	(0.0)	2	(0.5)		
55	(15.8)	39	(23.5)	199	(28.3)	83	(23.9)		
348		166		701	(100.0)	348	100.0		
	N 116 30 62 83 2 55	Intervention Oblasts N (%) 116 (33.3) 30 (8.6) 62 (17.8) 83 (23.9) 2 (0.6) 55 (15.8)	N (%) N 116 (33.3) 53 30 (8.6) 11 62 (17.8) 23 83 (23.9) 30 2 (0.6) 10 55 (15.8) 39	Intervention Oblasts Comparison Oblasts N $(\%)$ N $(\%)$ 116 (33.3) 53 (31.9) 30 (8.6) 11 (6.6) 62 (17.8) 23 (13.9) 83 (23.9) 30 (18.1) 2 (0.6) 10 (6.0) 55 (15.8) 39 (23.5)	Intervention Oblasts Comparison Oblasts Intervention N $(\%)$ N $(\%)$ N 116 (33.3) 53 (31.9) 272 30 (8.6) 11 (6.6) 47 62 (17.8) 23 (13.9) 75 83 (23.9) 30 (18.1) 109 2 (0.6) 10 (6.0) 0 55 (15.8) 39 (23.5) 199	Intervention Oblasts Intervention Oblasts N $(\%)$ N $(\%)$ N $(\%)$ 116 (33.3) 53 (31.9) 272 (38.8) 30 (8.6) 11 (6.6) 47 (6.7) 62 (17.8) 23 (13.9) 75 (10.6) 83 (23.9) 30 (18.1) 109 (15.5) 2 (0.6) 10 (6.0) 0 (0.0) 55 (15.8) 39 (23.5) 199 (28.3)	Intervention Oblasts Comparison Oblasts Intervention Oblasts Comparison Oblasts Comparison Oblasts Comparison Oblasts N $(\%)$ N $(\%)$ N $(\%)$ N $(\%)$ N 116 (33.3) 53 (31.9) 272 (38.8) 166 30 (8.6) 11 (6.6) 47 (6.7) 19 62 (17.8) 23 (13.9) 75 (10.6) 28 83 (23.9) 30 (18.1) 109 (15.5) 50 2 (0.6) 10 (6.0) 0 (0.0) 2 55 (15.8) 39 (23.5) 199 (28.3) 83		

Table 75.1. TB treatment outcome among HIV patients at baseline (2012) and end line (2015)

Table 7S.2. Cox proportional hazard model predicting death among coinfected patients from AIDS centers, controlling for oblasts and ARV

			Baseline				End Line	
Variable	HR		(95% CI)	p-value	HR		(95% CI)	p-value
Oblast				1				1
Kharkiv	1.79		(0.70-4.54)	0.222	0.55		0.21-1.44)	0.220
Odessa	1.12		(0.48-2.62)	0.795	1.04		(0.65-1.67)	0.866
Zaporizhzhya	3.56	**	(1.42-8.95)	0.007	1.25		(0.66-2.35)	0.496
Kiev	1.64		(0.72-3.75)	0.241	1.33		(0.76-2.33)	0.311
Zhytomyr	0.91		(0.32-2.59)	0.857	1.58		(0.85-2.96)	0.151
Mykolaiv	1.00				1.00			
Sex		I						
Male	1.20		(0.72-2.01)	0.479	0.81		(0.55-1.19)	0.286
Female	1				1			
Age group, years				1				
18–29	1				1			
30–39	2.08		(0.84-5.11)	0.111	1.34		(0.75-2.38)	0.320
40–49	1.51		(0.59-3.88)	0.394	1.53		(0.84-2.78)	0.162
50+	1.25		(0.42-3.76)	0.689	1.50		(0.74-3.05)	0.264
Employment		1		1				1
Employed	1				1			
Unemployed	0.96		(0.52-1.80)	0.908	1.69	*	(1.09-2.61)	0.020
Retired/disabled	0.14		(0.02-1.11)	0.063	3.65	**	(1.75-7.63)	0.001
Student/other	0.25		(0.03-2.06)	0.199	0.85		(0.10-6.97)	0.882
On ARVs								
Yes	0.14	***	(0.08-0.23)	0.000	0.29	***	(0.21-0.42)	0.000
No	1				1			
Ν	980				2260			

CI, confidence interval; HR, Hazard ratio

*p<0.05, **p<0.01, ***p<0.001

Table 7S.3. Cox proportional hazard model predicting death among coinfected patients from AIDS centers, with ARV as a covariate, using difference-in-differences analysis

		Baseline			End Line		Differ	ence-in-Differe	ences
Variable	HR	(95% CI)	p- value	HR	(95% CI)	p- value	HR	(95% CI)	p- value
Year X intervent	ion group	1			1		0.90	(0.511-1.60)	0.728
Year									
Baseline							1		
End line							0.90	(0.59-1.38)	0.632
Intervention gro	up	1			1	1	1	1	
Yes	1.00	(0.57-1.76)	0.986	0.86	(0.62-1.19)	0.359	0.95	(0.59-1.52)	0.824
No	1			1			1		
Sex									
Male	1.21	(0.73-1.99)	0.458	0.79	0.54-1.17)	0.238	0.94	(0.71-1.25)	0.693
Female	1			1			1		
Age group, yea	rs		-	-		-	-		
18–29	1			1			1		
30–39	2.17	(0.88-5.31)	0.091	1.36	(0.76-2.42)	0.297	1.64*	(1.02-2.64)	0.041
40–49	1.53	(0.59-3.97)	0.379	1.54	(0.85-2.80)	0.154	1.51	(0.93-2.47)	0.097
50+	1.34	(0.44-4.05)	0.609	1.45	(0.71-2.96)	0.303	1.51	(0.86-2.66)	0.156
Employment									
Employed	1			1			1		
Unemployed	0.95	(0.52-1.73)	0.860	1.61	(1.05-2.48)	0.030	1.31	(0.94-1.82)	0.112
Retired/	0.16	(0.02-1.29)	0.086	3.70**	(1.77-7.76)	0.001	2.29**	(1.27-4.15)	0.006
disabled									
Student/other	0.23	(0.03-1.80)	0.161	0.89	(0.11-7.12)	0.910	0.35	(0.08-1.57)	0.17
On ARVs									
Yes	0.16***	(0.10-0.27)	0.000	0.30***	(0.21-0.42)	0.000	0.25***	(0.19-0.33)	0
No	1			1			1		
N	980			2,260			3209		

CI, confidence interval; HR, Hazard ratio

*p<0.05, **p<0.01, ***p<0.001

Table 7S.4. TB treatment outcome among TB patients at baseline (2012) and end line (2015)

		Base	eline		End Line					
	Interv	vention	Com	parison	Interv	vention	Com	oarison		
	N	%	N	%	N	%	N	%		
Treatment success*	396	51.1	324	49.8	439	46.1	252	50.9		
Treatment failed	147	18.9	105	16.1	300	31.6	144	29.1		
Treatment interrupted	91	11.7	85	13.0	75	7.9	29	5.8		
Died	124	15.9	127	19.4	137	14.4	69	14.0		
Transferred out	18	2.3	11	1.7	0	0.0	1	0.2		
Total TB patients	776		651		953		495			

*Success included cured and completed

Table 7S.5. Cox proportional hazard models predicting death among coinfected TB patients, controlling for oblasts and ARV

		Baseline			End Line	
Variable	HR	(95% CI)	p-value	HR	(95% CI)	p-value
Oblast						
Kharkiv	0.41**	(0.23-0.73)	0.002	0.57	(0.27-1.23)	0.15
Odessa	0.53**	(0.35-0.81)	0.003	1.29	(0.76-2.20)	0.34
Zaporizhzhya	0.52*	(0.30-0.92)	0.025	1.13	(0.61-2.08)	0.700
Kiev	0.57*	(0.36-0.93)	0.023	0.98	(0.55-1.77)	0.954
Zhytomyr	0.39***	(0.22-0.68)	0.001	1.30	(0.69-2.45)	0.414
Mykolaiv	1			1		
Sex						
Male	0.87	(0.59-1.28)	0.482	0.74	(0.49-1.11)	0.140
Female	1			1		
Age group, years				I		
18–29	1			1		
30–39	0.81	(0.52-1.28)	0.371	1.38	(0.72-2.66)	0.334
40–49	1.08	(0.65-1.79)	0.774	1.57	(0.78-3.17)	0.205
50+	0.78	(0.37-1.63)	0.501	1.43	(0.57-3.57)	0.442

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		Baseline			End Line	
Employment						
Employed	1			1		
Unemployed	1.14	(0.68-1.90)	0.626	1.43	(0.73-2.83)	0.300
Retired/disabled	0.68	(0.27-1.71)	0.409	0.96	(0.26-3.55)	0.949
Student/other	0.92	(0.22-3.80)	0.908	0.87	(0.24-3.18)	0.831
On ARVs						
Yes	0.22***	(0.15-0.31)	0.000	0.10***	(0.069-0.16)	0.000
No	1			1		
Total coinfected patients	1455			1870		

Cl, confidence interval; HR, Hazard ratio

*p<0.05, **p<0.01, ***p<0.001

		Baseline			End Line		Diff	ierence-in-Differe	ences
Variable	HR	(95% CI)	p-value	HR	(95% CI)	p-value	HR	(95% CI)	p-value
Year X intervention group							1.90**	(1.18-3.04)	0.008
Year									
Baseline							1		
End line							1.09	(0.77-1.52)	0.634
Intervention group									
Yes	0.67*	(0.49 0.93)	0.015	1.15	(0.81-1.65)	0.432	0.62**	(0.45-0.85)	0.003
No	1			1			1		
Sex									
Male	0.89	(0.61 1.31)	0.551	0.75	(0.50-1.11)	0.151	0.85	(0.64-1.12)	0.241
Female	1			1			1		
Age group, years									
18–29	1			1			1		
30–39	0.85	(0.54-1.34)	0.495	1.39	(0.72-2.69)	0.323	1.05	(0.73-1.52)	0.786
40–49	1.20	(0.73-1.97)	0.477	1.61	(0.80-3.26)	0.184	1.30	(0.87-1.94)	0.195
50+	0.83	(0.40-1.72)	0.624	1.51	(0.61-3.73)	0.376	1.14	(0.66-1.97)	0.628
Employment							1.05	(0.73-1.52)	
Employed	1			1			1		
Unemployed	1.21	(0.73-1.99)	0.460	1.40	(0.71-2.78)	0.330	1.24	(0.83-1.85)	0.294

Table 75.6. Cox proportional hazard model predicting death among coinfected patients from TB dispensaries, with ARV as time-varying covariate

	Baseline			End Line			Difference-in-Differences			
Retired/disabled	0.75	(0.30-1.85)	0.530	0.93	(0.26-3.34)	0.915	0.82	(0.40-1.67)	0.580	
Student/other	1.01	(0.24-4.22)	0.986	0.84	(0.23-3.02)	0.788	1.01	(0.39-2.58)	0.988	
Person who injects drugs										
Yes	1.97***	(1.35-2.87)	0.000	1.30	(0.80-2.13)	0.292	1.81***	(1.34-2.43)	0.000	
No	1			1			1			
On ARVs										
Yes	0.23***	(0.16-0.34)	0.000	0.11***	(0.071-0.16)	0.000	0.18***	(0.14-0.24)	0.000	
No	1			1			1			
Total coinfected patients	1455			1870			3325			

*p<0.05, **p<0.01, ***p<0.001

Table 7S.7. TB-related mortality among all TB patients at baseline (2012) and end line (2015), by oblast (S1 and coinfected samples)

		Baseline Mortality						En	d Line	Mortalit	у	
	TB-S	pecific	No	n-TB	All-	Cause	TB-S	pecific	No	n-TB	All-	Cause
	N	%	N	%	N	%	N	%	N	%	N	%
Intervention oblasts												
Kharkiv	3	27.3	9	72.7	12	100.0	3	27.1	7	72.9	10	100.0
Odessa	17	18.0	78	82.0	95	100.0	5	4.8	92	95.2	96	100.0
Zaporizhzhya	3	20.3	13	79.7	17	100.0	2	6.8	28	93.2	31	100.0
Subtotal	24	19.2	100	80.8	124	100.0	9	6.9	127	93.1	137	100.0
Comparison oblasts												
Kiev	11	32.4	23	67.6	34	100.0	15	33.9	29	66.1	43	100.0
Mykolaiv	5	6.0	77	94.0	82	100.0	2	13.5	12	86.5	14	100.0
Zhytomyr	5	41.7	7	58.3	11	100.0	9	72.9	3	27.1	12	100.0
Subtotal	21	16.2	106	83.8	127	100.0	25	36.5	44	63.6	69	100.0
Total TB patients	44	17.7	206	82.3	250	100.0	35	16.9	172	83.2	206	100.0

APPENDIX B. HEALTH FACILITY SURVEY RESULTS

HIV Facility Surveys

HIV Facilities and Services

Facility surveys and provider interviews were conducted at the oblast AIDS centers and city AIDS centers. We administered eight facility surveys; five in intervention oblasts and three in comparison oblasts (Table B1).

Table B1. TB and HIV facility surveys	at end line, by oblast	. Ukraine, 2016
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Intervention Oblast	Tb Dispensary Su	HIV Center Surveys, n	
Kharkiv	6		1
Odessa	2		2
Zaporizhzhya	3		2
Subtotal: intervention	11		5
Comparison oblast			
Kiev	3		1
Mykolayiv	2		1
Zhytomyr	1		1
Subtotal: comparison	6		3
Total	17		8

AIDS Centers' Capacity and Services

None of the AIDS centers had exclusive beds for inpatient TB treatment; five centers (four in the intervention and one in comparison regions) had beds for HIV patients and only three (one in the comparison and two in the intervention regions) had beds for coinfected patients. Number of beds ranged from zero to 50 (Table B2).

The majority of new patients were HIV patients. Comparison facilities had lower median number of new HIV patients than intervention facilities. The number of new coinfected patients was a fraction of the total number of new patients, and comparison facilities had a median number of new coinfected patients two times that of intervention facilities. Numbers varied widely by facility for all types of patients.

	Interv	ention	Comp	oarison		
	Median	(Range)	Median	(Range)		
Beds for inpatient treatment						
HIV/AIDS patients	5	(0-50)	0	(0-30)		
TB-HIV coinfected patients	0	(0-50)	0	(0-30)		
New patients, April 01, 2014–June 30, 2015						
HIV/AIDS patients	587	(142-3,233)	424	(390-790)		
TB-HIV coinfected patients	66	(21-802)	130	(98-147)		
Staffing for HIV services						
Administrative	4	(2-8)	2	(1-3)		
Nurses	15	(4-32)	7	(4-28)		
Doctors	17	(3-32)	9	(7-17)		
Staffing for TB services						
Administrative	4	(2-8)	2	(1-3)		
Nurses	15	(1-32)	4	(3-28)		
Doctors	13	(1-32)	7	(3-17)		
Number of AIDS centers	5		3			

Table B2. AIDS center staffing and capacity, by intervention status, Ukraine, 2016

Staffing in AIDS Centers

Typically, AIDS center staff includes administrative personnel, ID specialists, psychologists, inpatient nurses and laboratory assistants. Staffing for HIV services differed between intervention and comparison sites, with the median number of administrative staff, nurses and doctors at intervention sites about double that of the comparison sites. Overall, there were many more staff for TB services at AIDS centers in the intervention oblasts, with twice as many administrative staff and doctors and about four times as many nurses as in comparison sites. (Table B2).

HIV Diagnostics

The process for HIV diagnostics begins with HIV counseling and testing, rapid tests, and enzyme-linked immunosorbent assay (ELISA) test for confirmation, and other tests, such as the Western blot and polymerase chain reaction (PCR), as needed. All eight of the AIDS centers provided HIV testing and counseling and offered rapid testing at the AIDS center (Table B3). Two of the five intervention AIDS centers offered ELISA at the facility; the other two centers collected the specimen and sent it out for

analysis. All three comparison AIDS centers conducted the ELISA test on site. Western blot and PCR tests were also offered, but less frequently. About half to two-thirds of the AIDS centers offered Western blot and the PCR test in-house; the remaining centers collected specimens and sent them out for analysis or referred patients elsewhere.

Table B3. HIV diagnostic and analytic services offered at AIDS centers, by intervention status, Ukraine, 2016

		Intervention Oblasts				Comparison Oblasts				
Services	Available at facility			Specimen collected and sent out	Patient referred	Not provided				
Diagnostics										
HIV counseling	5	0	0	0	3	0	0	0		
Rapid test	5	0	0	0	3	0	0	0		
ELISA test	3	2	0	0	3	0	0	0		
Western blot	2	1	1	1	2	0	0	1		
PCR test	3	1	1	0	2	1	0	0		
Analytics										
CD4 count (Pima)	3	0	0	2	3	0	0	0		
CD4 count (multiparameter flow	4	1	0	0	1	2	0	0		
fluorometer)										
Viral load	3	2	0	0	2	0	0			
Number of AIDS centers		5	5		3					

ELISA, enzyme-linked immunosorbent assay; PCR, polymerase chain reaction

The period between when the sample was taken and when the results were received varied by test type (Figure B1). Rapid tests, when offered, produced results the same day; ELISA, Western blot, and PCR test results were typically returned within one to two weeks.

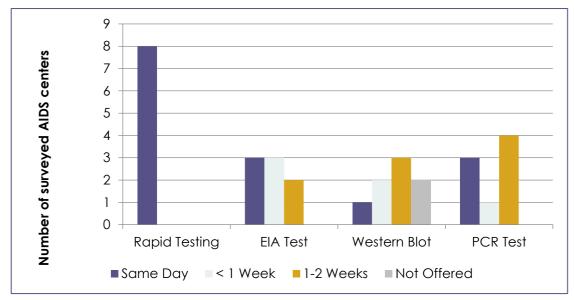


Figure B1. Time between HIV testing and receipt of results at AIDS centers, Ukraine, 2016

EIA, enzyme immunoassay; PCR, polymerase chain reaction

If there was a positive HIV test, a blood analysis was conducted to determine CD4 counts and viral load. Six AIDS centers conducted CD4 count using Pima, and five AIDS centers conducted CD4 count using multiparameter flow fluorometer. Half the centers conducted viral load analyses at the facility; the remaining four collected the specimen and sent it to a laboratory for analysis (Table B3). CD4 counts via Pima were usually provided the same day. Centers varied in the length of time to receive CD4 counts using multiparameter flow fluorometer, which could take from one day to two weeks. Viral load results took longer, up to one to two weeks (Figure B2). Some facilities were able to provide results more quickly.

For smear-positive coinfected patients, ART was provided in seven of eight facilities. For coinfected patients who were smear-negative, all eight AIDS centers offered ART. For HIV-positive patients with no TB diagnosis, all AIDS centers provided ART.

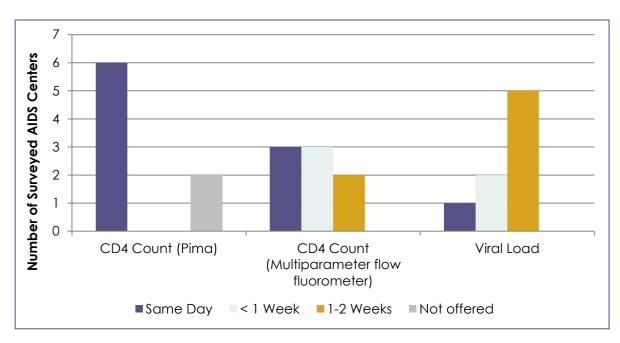


Figure B2. Time between blood draw and receipt of results at AIDS centers, Ukraine, 2016

TB Diagnostics and Treatment at AIDS Centers

All eight AIDS centers surveyed conducted TB symptom screening and seven conducted clinical evaluation on site (Table B4). Seven of eight AIDS centers referred patients for chest x-rays. Laboratory diagnostics included TB sputum microscopy (which is the mandatory minimum diagnostic procedure for patients with suspected pulmonary TB), Xpert[®], and TB cultures. Half of the AIDS centers conducted the sputum microscopy on site; the remaining facilities either collected and sent specimens for analysis or referred for testing. Most of the AIDS centers collected samples for Xpert[®] and TB cultures and sent them out for analysis.

Table B4. TB diagnostic services offered at AIDS centers and intervention status, Ukraine, 2016

		Intervention Comparison					on	
Diagnostics	Available at facility	Specimen collected and sent out	Patient referred	Not provided	Available at facility	Specimen collected and sent out	Patient referred	Not provided
TB symptom screening	5	0	0	0	3	0	0	0
TB spułum microscopy	3	1	1	0	1	1	1	0
Xpert®	1	3	1	0	1	2	0	0
TB culture	0	3	2	0	0	1	1	1
Chest X-ray	1	0	4	0	0	0	3	0
Clinical evaluation	4	0	1	0	3	0	0	0
Number of AIDS centers		5				3		

The time between testing and receiving results varied by type of TB test (Figure B3). For TB symptom screening tests, results were provided on the same day. Chest x-ray results were available on the same day in half of the facilities and within a week in the remaining facilities. For most centers, the timing of x-ray results depended on when the patient brought the x-rays from the x-ray site. All but one AIDS center provided TB sputum results in less than a week; in one facility it took more than 2 weeks. The majority of facilities received Xpert[©] results within a week. For TB liquid cultures, results overall took the greatest length of time to receive, in most cases it took one–two weeks.

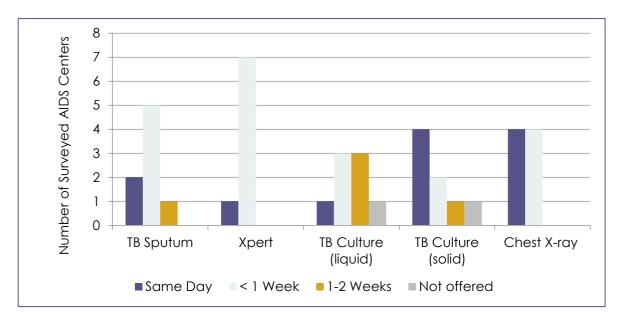


Figure B3. Time between TB diagnostic testing and receiving results at AIDS centers, Ukraine, 2016

TB Treatment at AIDS Centers

Only one AIDS center provided inpatient intensive TB treatment for coinfected patients, and only three provided TB outpatient treatment and DOTS (Table B5). Psychological counseling was provided at six of the AIDS centers. For patients with HIV or TB-HIV coinfection who inject drugs, only three AIDS centers offered medication-assisted therapy.

	Intervention	Comparison	Total
Services offered	N	N	N
TB inpatient treatment	1	0	1
TB outpatient treatment	2	1	3
DOTS at facility	1	1	2

	Intervention	Comparison	Total
DOTS at home	1	0	1
Self-management	3	2	5
Psychological counseling	3	3	6
Medication-assisted therapy	3	0	3
Number of AIDS centers	5	3	8

Preventive Measures in AIDS Centers

Facility surveys provided additional information on the availability of cotrimoxazole preventative therapy (CPT) and isoniazid preventive therapy (IPT) in AIDS centers. All AIDS centers provided IPT and seven of eight provided CP.

Drug and Equipment Shortages

None of the eight facilities that administered a survey reported drug shortages lasting more than 30 days from April 01, 2014 to June 30, 2015.

TB Facility Surveys

Facility Surveys

Facility surveys were administered in 17 TB dispensaries where patients received intensive TB treatment at the rayon and oblast level. Table B1 shows the distribution of facilities across the six study oblasts.

Facility Capacity and Services

All facilities provided inpatient TB intensive treatment. The median number of beds used for inpatient treatment for coinfected patients was smaller than the number of beds for TB patients in both intervention and comparison sites, suggesting that a distinction had been made between beds for TB patients and coinfected patients (Table B6). The number of beds varied extensively by facility, with some facilities having less than 20 beds and others over 500.

	Inte	ervention	Cor	nparison
	Median	(Range)	Median	(Range)
Beds for inpatient treatment				
TB patients	125		175	(15-540)
TB-HIV coinfected patients	80	(19-510)	125	(15-540)
New patients, April 01, 2014–June 3	80, 2015			
TB patients	214	(47-1,952)	1124	(101-2,061)
TB-HIV coinfected patients	41	(2-851)	138	(1-562)
Staffing for TB services	1			
Administrative	3	(1-10)	3	(2-21)
Nurses	40	(6-147)	77	(14-120)
Doctors	13	(3-54)	29	(4-45)
Staffing for HIV services	1			
Administrative	3	(1-10)	3	(2-21)
Nurses	40	(6-147)	52	(9-120)
Doctors	13	(3-54)	12	(4-45)
Number of TB facilities	10		6	

Table B6. TB facility capacity and staffing, by intervention status, Ukraine, 2016

The median number of new patients (TB patients and coinfected patients) from April 2014 to June 2015 was higher at comparison than intervention facilities, likely due to larger facilities and populations in those areas. The number of new patients varied considerably with some facilities having only one coinfected patient and others serving over 800. The majority of new patients were TB patients and comparison facilities had a median number of new patients five times that of intervention facilities. Numbers varied widely by facility for all types of patients.

Staffing in TB Facilities

Medical personnel at TB dispensaries were regulated by relevant national protocols and orders approved by the Ukraine Ministry of Health. Typical TB dispensary staff included administrative personnel, TB specialists, nurses, and laboratory assistants. Administrative staffing of intervention and comparison TB facilities was similar, with a median of three administrative staff providing services (Table B6). The median number of nurses and doctors providing TB services in comparison facilities was two times that of intervention facilities reflecting the greater number of patients served in comparison sites. The range for the number of nurses and doctors per TB facility varied widely, from 6 to 147 nurses and 3 to 54 doctors. In intervention area facilities, most doctors and nurses provided both TB and HIV services, but in comparison areas a few nurses and doctors provided TB services, but not HIV services.

TB Diagnostics

Diagnosis of TB patients involved TB symptom screening, laboratory testing, x-rays and clinical evaluation. Nearly all of the 17 TB facilities reported providing TB sputum microscopy, x-rays, and clinical evaluation at their facility. Xpert[®] testing was provided in only six health facilities, seven facilities provided sputum sample for liquid culture, and 12 facilities provided sputum sample for solid cultures. Xpert[®], and other tests using nucleic acid amplification technology, provided advanced testing for MDR-TB and more sensitive testing for TB-HIV coinfected patients. In two-thirds of the facilities surveyed, specimens for Xpert[®] were collected at the facility and sent to an off-site laboratory for analysis.

The average amount of time from testing to receiving diagnostic results differed depending on the type of test (Figure B4). Results of chest x-rays, clinical evaluations, and sputum microscopy were routine diagnostics typically received the same day of the test. Xpert[©] and TB cultures took longer. In most cases, Xpert[©] and TB solid culture results were returned in less than a week, while TB liquid cultures typically took two weeks or longer.

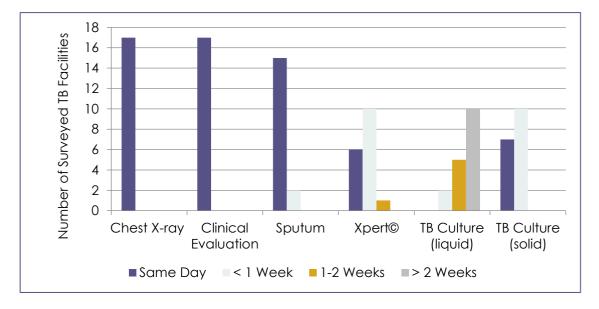


Figure B4. Time from TB test to receipt of results, TB dispensaries, Ukraine, 2016

TB Treatment

All TB facilities provided TB intensive therapy, and 13 facilities provided continuation treatment (Table B7). For smear-positive TB patients, all 17 TB facilities provided inpatient TB intensive therapy, and two of the facilities provided both inpatient and outpatient therapy. For smear-negative TB patients, all but two TB facilities provided intensive therapy through outpatient (n=nine), and both inpatient and

outpatient care (n=six). All but five of the TB facilities provided TB continuation therapy, one provided inpatient care, 10 provided outpatient care, and one provided both inpatient and outpatient care.

	Interver	ntion Oblasts	Compa	Comparison Oblasts Tota		
Services offered	Number	Percentage	Number	Percentage	Number	Percentage
TB intensive	11	(100.0)	6	(100.0)	17	(100.0)
treatment TB continuation treatment	7	(63.6)	6	(100.0)	13	(76.5)
Antiretroviral therapy	11	(100.0)	5	(83.3)	16	(94.1)
Isoniazid prevention	4	(36.4)	2	(33.3)	6	(35.3)
therapy Cotrimoxazole prevention therapy	8	(72.7)	5	(83.3)	13	(76.5)
Medication- assisted therapy	6	(50.0)	2	(20.0)	8	(44.4)
Number of TB facilities	11	(100)	6	(100)	17	(100)

Table B7. Treatment offered by intervention status. TB dispensaries, Ukraine, 2016

For smear-positive coinfected HIV patients, all TB facilities provided inpatient TB intensive therapy (n=14), or both inpatient and outpatient services (n=three). For smear-negative coinfected HIV patients, all but three TB facilities provided TB intensive therapy through outpatient care (n=seven), or both inpatient and outpatient services (n=seven). All but four of the TB facilities provided TB continuation therapy; some provided inpatient care (n=three), some provided outpatient care (n=nine), and one provided both inpatient and outpatient care. Most of the facilities provided cotrimoxazole prevention therapy. About one-third of the facilities provided isoniazid prevention and medication-assisted therapy for patients (Table B7).

HIV Diagnostics

Of TB facilities surveyed to document the HIV diagnostics available, all 17 reported offering HIV counseling and testing (Table B8). Three-quarters of those facilities reported conducting rapid tests at the facility. Among the remaining facilities, three in the intervention sites referred patients somewhere and one in the comparison sites collected blood and sent it to an outside lab. For the remaining HIV

diagnostics (EIA/ELISA, Western blot, and PCR), none of the TB facilities offered the tests on site. Samples were either collected at the facility and sent to the AIDS center or patients were referred to an HIV facility for the test. Samples were collected and sent out for ELISA at 14 facilities, Western blot at 3, and PCR at 6 of the 17 facilities.

	Intervention Oblasts Compariso						on Oblasts		
Diagnostic services	Available at facility	Specimen collected and sent out	Patient referred	Not provided	Available facility		Specimen collected and sent out	Patient referred	Not provided
HIV counseling	11	0	0	0	6		0	0	0
Rapid testing	8	0	3	0	6		0	0	0
EIA test	0	8	2	1	0		6	0	0
Western blot	0	2	2	7	0		1	0	5
PCR test	0	4	2	5	0		2	0	4
CD4 count (Pima)	0	0	0	11	0		0	0	6
CD4 count (multiparameter flow fluorometer)	0	8	2	1	0		6	0	0
Viral load	0	8	2	1	0		6	0	0
Number of TB facilities	11	11	11	11	6		6	6	6

Table B8. HIV diagnostic services offered at TB dispensaries by intervention status, Ukraine, 2016

EIA, enzyme immunoassay; PCR, polymerase chain reaction

The amount of time it took for TB facilities to receive HIV test results varied depending on the type of test (Figure B5). All rapid tests yielded results on the same day. Results for ELISA tests were typically returned in less than two weeks, though three facilities did not receive results until after a two-week period. Facilities received test results for Western blot and PCR within two weeks.

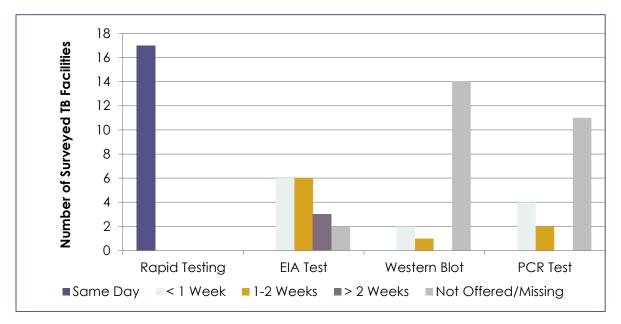


Figure B5. Time between HIV test and receipt of results at TB dispensaries, Ukraine, 2016

HIV Treatment

In the 17 TB facilities surveyed, ART treatment for coinfected patients was provided to coinfected patients in all intervention facilities (n=11) and in five of the six comparison facilities. No TB facility provided testing for CD4 count or viral load on site; although, 14 facilities collected specimens and sent them out for CD4 count using multiparameter flow flurometer and for viral load determination (Table **B**8). The amount of time it took to receive CD4 count and viral load results varied from less than one week to more than two weeks and depended on the established protocol between facilities (Figure B6).

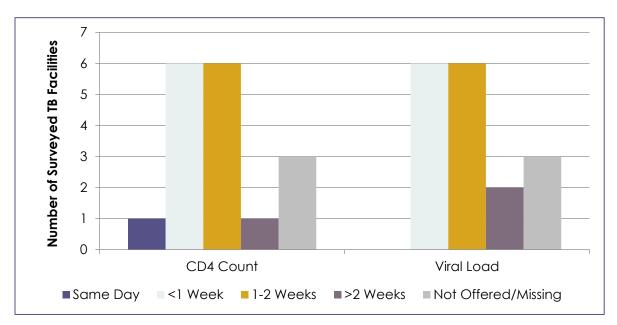


Figure B6. Time between blood draw and results, Ukraine, 2016

According to provider interviews, patients with HIV-associated TB received HIV treatment services in an inpatient department of the TB dispensary during the intensive phase of TB treatment. During the follow-up or continuation phase, patients were provided with HIV treatment at the place of residence or at the regional AIDS center.

Drug and Equipment Shortages

Few drug shortages were reported in TB facilities from April 01, 2014 to June 30, 2015. Of 17 facilities, one intervention and one comparison facility reported a TB drug shortage lasting more than 30 days. The intervention group facility reported shortages of pyrazinamide from March to May, 2015. Patients purchased this drug out-of-pocket. The comparison group facility reported a shortage on second-line drugs, such as linezolid, ciprofloxacin, ethionamide, moxifloxacin, levofloxacin, and capreomycin in September and October 2014. During these times, the facility waitlisted patients for treatment. No TB facilities among those providing the service, reported any shortages of ARVs, medication-assisted therapy medications, or rapid test kits lasting more than 30 days from April 01, 2014 to June 30, 2015.

APPENDIX C. STUDY PROTOCOL



MEASURE Evaluation Phase IV

Protocol for Impact Evaluation: Strengthening Tuberculosis Control in Ukraine, Phase 2

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Evaluation Purpose

USAID/Ukraine commissioned MEASURE Evaluation to conduct an impact evaluation of the Strengthening Tuberculosis Control in Ukraine (STbCU) project. The goal of the STbCU is to decrease the burden of tuberculosis (TB) in Ukraine, in partnership with the Government of Ukraine, and national and international stakeholders. The project proposes the implementation of strategic actions to improve the quality of TB services, including detection and treatment of TB and multi- and extensively-drug resistant TB (MDR-TB, XDR-TB), and their prevention and treatment for the rapid growth of TB and human immunodeficiency virus (HIV) coinfection. The project began in April 2012 and builds on over 10 years of USAID TB assistance in 10 geographic priority areas.

The impact evaluation will examine the relationship between select intervention strategies implemented and changes in key outcomes. The two strategies of interest are targeting SS services to improve treatment adherence among those at HR of treatment default; and integrating services and referrals between TB facilities and HIV facilities to improve the timeliness of care and the treatment outcomes for the coinfected. Ukraine is one of several countries struggling with high treatment default rates and rising coinfection rates, and USAID is one of many donors testing and investigating strategies to help combat these problems. In Phase 1 of the evaluation, data were abstracted from client records for a retrospective cohort from 2011 and 2012 to provide a baseline measure of key outcomes. During Phase 2, data will be abstracted from client records for a retrospective cohort from 2014 and 2015 to provide end line measures of key outcomes.

Findings from this evaluation will not only have implications for the STbCU project and follow-up interventions in Ukraine, but will also add to the evidence base for TB and TB/HIV strategies more broadly. USAID/Ukraine, along with in-country stakeholders, will use the evaluation finding to measure the extent of the impact attributable to the strategies implemented. This will guide decision making on resource allocation and/or scaling up of TB interventions in Ukraine.

Background

Ukraine is one of 27 countries with the high burden of MDR-TB (Acosta et al., 2014; WHO, n.d.). It has an estimated 40,000 cases of TB each year (PATH, n.d.), with 7,855 new cases of MDR-TB in 2014 alone (Ukrainian national TB statistics, 2014). Among European and Central Asian countries, it also has one of the highest numbers of people living with HIV (PLWH), with an estimated 210,000 PLWH (range: 180,000-250,000) (UNAIDS, 2013). HIV fuels the transmission of TB, resulting in a higher number of deaths. TB is the most common opportunistic infection among PLWH. The burden of HIV/TB coinfection in Ukraine is high at 16/100,000 population, and is disproportionately concentrated in marginalized groups, such as sex workers, prison populations, and injecting drug users. Nearly 40% of deaths among PLWH are associated with TB (UNAIDS, 2013). Despite the adoption of appropriate TB control programs, their components have been inadequately implemented. To address the existing challenges in TB control, there has been an increasing focus on integrating and streamlining HIV and TB services such that individuals who present at TB clinics can also be tested and treated for HIV (WHO, 2012) and vice versa.

Considering the epidemiologic landscape in Ukraine, USAID-supported projects have focused on expanding the availability and improving the quality of DOTS services for the population, while concurrently working at the policy level to create a service environment with fewer barriers to accessing quality case detection and treatment. According to PATH, 50% of the population now has access to quality TB care. Case detection rates have increased to 73%, exceeding the minimum recommendations from WHO (PATH, 2012). However, only 59.9% were treated successfully in 2011 in the 10 project areas, which is well below the 85% WHO recommendation (PATH, 2012; WHO, 2002). Emerging MDR-TB and the difficulty in treating TB/HIV coinfection have further complicated effective treatment. Understanding the effect of efforts to improve timely diagnosis, treatment adherence, and subsequent treatment outcomes among heterogeneous target populations will provide evidence for improved policy and strategies in the future.

Project Description

The STbCU is a five-year, USAID-funded project designed to decrease the TB burden in Ukraine, leading to a reduction of TB morbidity and mortality. Broadly speaking, the project seeks to improve the quality and availability of DOTS-based services, build capacity for programmatic management of drug-resistant TB, improve access to TB/HIV coinfection services, and improve infection control practices to provide a safer medical environment for workers. STbCU is working with i) health facilities and laboratories to improve screening, diagnosis, and referrals for appropriate treatment, and improving infection control for the protection of their workers; ii) SS agencies to improve treatment adherence, particularly among marginalized populations; and iii) the health system to improve training, reporting, and procurement.

The interventions of interest to this evaluation are:

Home-visiting program for TB patients vulnerable to treatment default, implemented by the Ukrainian Red Cross Society (URCS). Periodic home visits provide delivery and direct observation of treatment with incentives (e.g., food, clothing) to encourage full TB treatment adherence.

Expanded screening, testing, and treatment for HIV among TB patients and for TB among HIV patients. Protocols, diagnostic supplies, and referral mechanisms in TB facilities and HIV facilities will improve case detection, dual treatment, and subsequently decrease mortality.

STbCU builds on a history of USAID-supported TB work in 10 administrative target areas: seven oblasts (Dnipropetrovsk, Donetsk, Kharkiv, Kherson, Luhansk, Odessa, and Zaporizhya); two cities (Kiev and Sevastopol); and one autonomous republic (Republic of Crimea) (Figure B1a). In these 10 areas, PATH selected facilities to pilot and scale up their interventions from 2007 to 2012. STbCU inherited these same areas for interventions in Years 1 and 2. As of June 2014, when data collection for Phase 1 of the evaluation began, the STbCU program was no longer working in the Autonomous Republic of Crimea and Sevastopol. Donetsk and Luhansk were also removed from the list of potential oblasts for study selection per USAID/Kiev. The project expanded its activities to Lviv and Kirovograd oblasts in Year 3 (Figure B1b).



Figure B1a. Ukraine map of USAID-supported TB intervention areas, 2013

Figure B1b. Ukraine map of USAID-supported TB intervention areas, November 2014



Targeting

The selection criteria for the project areas were based on the TB and HIV disease burden, the availability of DOTS services, geographic location, concentration of vulnerable populations, nongovernmental organizations already operating in areas, and desire of local government officials to participate (PATH, 2012). In the project intervention areas, the operating assumption was that every TB and HIV facility would receive some baseline project intervention, including some training, supplies, and mentoring. Additional interventions would be tested and rolled out over the life of the project, with select services targeted by area.

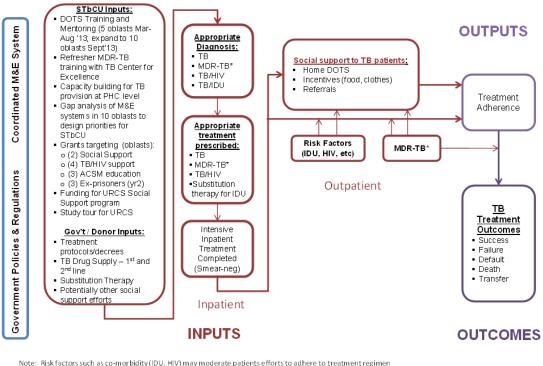
An additional layer of targeting would be used to select program participants for the URCS SS program to increase treatment adherence. The 10 key target HR groups for this intervention included alcoholics, people who inject drugs, TB contacts, homeless, migrants, refugees, ex-prisoners, unemployed, persons with comorbidities, and others identified as HR by the healthcare provider. Risk screening was completed by the healthcare provider at time of discharge from inpatient treatment or at the start of continuation therapy. Those considered at HR for treatment default were eligible for SS provided by the outpatient facility responsible for their continued treatment. The underlying assumption was that refusal of SS support would be negligible.

Development Hypotheses

Figures B2 and B3 below illustrate the development hypotheses linking proposed interventions with anticipated outputs and outcomes. Figure B2 lists program inputs by the STbCU, the government, and other donors that contribute to appropriate inpatient and outpatient treatment. The program input of primary interest is the outpatient URCS SS program that targets patients vulnerable to treatment default. The URCS program provides home-based DOTS; incentives, such as food kits; and assistance in connecting with other support programs for these HR populations. This individualized, home-based care is intended to improve adherence to the outpatient TB treatment regimen, which will subsequently improve TB treatment outcomes. The primary outcome of interest is the rate of treatment default, which is hypothesized to decline among HR patients receiving SS compared with HR patients not receiving support. Secondary outcomes are treatment success versus treatment failure among those who adhere.

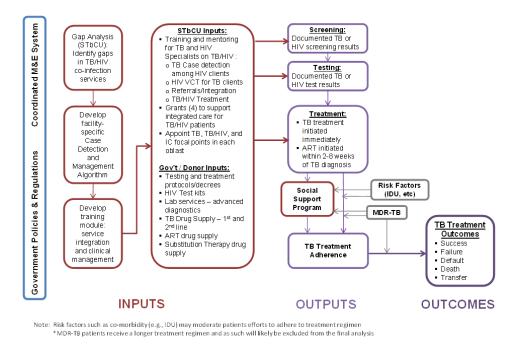
Figure B3 focuses on the collaboration between TB and HIV programs. Almost 17% of new TB cases are infected with HIV and 40% of the AIDS deaths are attributable to TB, yet the government services providing TB and HIV care remain vertical, with minimal collaboration across programs. The STbCU, through policy work, training, and mentoring, and implementation of model integration strategies, aims to facilitate improved TB testing among HIV patients and improved HIV testing among TB patients. Additionally, among the coinfected, antiretroviral therapy (ART) should be introduced during the primary two to eight weeks of TB treatment to reduce mortality among the coinfected. The process outputs of interest are the proportion of TB and HIV/AIDS patients who receive the appropriate screening, testing, diagnosis, and treatment in a timely manner. The primary outcome of interest is mortality, which will include all-cause mortality to minimize the complications from reporting anomalies that may inappropriately attribute death to TB, HIV, or other causes.

Figure B2. Framework for improved treatment adherence and outcomes



2: Risk factors such as co-morbidity (IDU, HIV) may moderate patients efforts to adhere to treatment regimen *MDR-TB patients receive a longer treatment regimen and higher probability of failure, as such will be excluded from the final analysis

Figure B3. Framework for improved diagnosis and treatment for TB/HIV Evaluation Protocol



The impact evaluation encompasses two programmatic priorities: i) treatment adherence and outcomes among those receiving SS; and ii) decline in mortality due to early diagnosis and early treatment among TB/HIV coinfected patients served by programs. For each priority area, evaluation questions, study design, and methods are detailed below. Please see Appendix A for the updates on the study protocol in Phase 2.

Tuberculosis Treatment Adherence/Social Support Study

A mixed methods approach with a quasi-experimental quantitative evaluation design complemented by qualitative descriptive work to inform the findings will be completed over two phases. In Phase 1, data were abstracted from client records for a retrospective cohort of TB patients from 2011 and 2012 to provide a baseline measure of key outcomes. During Phase 2, data will be abstracted from client records for a retrospective cohort of TB patients from client records for a retrospective cohort of TB patients from client records for a retrospective cohort of TB patients from client records for a retrospective cohort of TB patients from client records for a retrospective cohort of TB patients from 2014 and 2015. To measure program impact, different comparison groups will be identified to estimate outcomes in the absence of SS interventions.

Evaluation Questions

1.1 Does participation in a SS program affect the likelihood of TB treatment default, treatment success, or treatment failure among HR patients?

1.2 What aspects of outpatient TB treatment make adherence particularly difficult for patients in at-risk groups?

1.3 What aspects of the SS program are most important to those receiving the program? What works best for ensuring adherence?

1.4 What is the estimated effect of the SS program on the treatment success rate at the population level?

Quantitative Design

Evaluation question 1.1 will be evaluated quantitatively using survival analysis. In Phase 2, data will be abstracted from client records for a retrospective cohort of TB patients from 2014 and 2015. We will use modeling to answer evaluation question 1.4. To estimate a proportion of Low Risk (LR) and High Risk (HR) patients in the population of all TB patients (one of the parameters for the model), we will work with a separate random sample of TB patients from 2011, 2012, 2014, and 2015 years.

Counterfactual

For the evaluation question 1.1, a counterfactual is needed to represent what would have happened in the absence of treatment. In the case of TB treatment adherence, we want to compare treatment outcomes between those who receive SS and those who do not. Ideally one would measure two outcomes for each individual: the treatment outcome when the TB patient receives SS and the outcome when the same individual does not receive SS. As this scenario is impossible, the evaluation design needs to create a comparison group that is as similar as possible to the intervention group on observable and unobservable characteristics.

The primary intervention population for the treatment adherence intervention (RQ1.1) is TB patients at HR for treatment default during continuation treatment who receive SS services from the URCS. The SS program was developed and piloted in 2010; a break in services occurred in 2011 for all sites; then activities resumed in 2012; and the program scaled down in 2015. In Phase 1, a quasi-experimental design sampled from 2011 (no intervention) and 2012 (intervention) time periods, with both HR and LR patients sampled to allow for comparison to routine care for LR and HR patients. Similarly, five groups will be sampled in Phase 2: HR patients receiving the intervention in 2014 (the intervention group); HR patients not receiving the intervention in 2014; HR patients not receiving the intervention in 2015; LR patients not receiving the intervention in 2014; and LR patients not receiving the intervention in 2015. The inclusion of LR patients from both intervention and comparison periods will provide additional evidence of the adequacy of the comparisons across time and the identification of HR patients. For example, we hypothesize that LR patients will have similar treatment outcomes across four years (2011, 2012, 2014, and 2015), while the HR patients in intervention and comparison groups in 2012 and 2014 will have different outcomes based on the SS received. This scenario will strengthen confidence in the choice of comparison group.

Sampling

The target population for the SS evaluation is TB outpatients. The sampling will be stratified at three levels: year, oblast, and risk group. For Phase 2, retrospective data collection will include patients initiating TB outpatient treatment between January and May 2014 and January and May 2015 in Dnipropetrovsk, Kharkiv, and Odessa oblasts. For each oblast, we will obtain a list of patients receiving SS services from the URCS between January and May 2014 by TB facility, and we will apply probability proportionate to size sampling to select the HR intervention sample. The selection of the 2014 non-intervention comparison patients will be driven by the HR intervention sample. For each HR intervention patient from 2014, a HR non-intervention patient and a LR non-intervention patient from 2014 will be selected based on the date of treatment initiation, sex, and age. Additionally, a HR non-intervention and LR non-intervention patient from 2015 will also be selected from the same facility, but seen one year later when no URCS services were offered. For each facility that provided patients for the 2014 HR intervention sample, all TB patients initiating continuation treatment between January and May 2015 who meet the HR criteria, but have not received SS services, will form the 2015 HR patient sampling frame. For each patient in the 2014 HR intervention sample, one 2015 HR non-intervention patient will be randomly selected for the 2015 HR non-intervention sample. For each patient in the 2015 HR non-intervention sample, a LR non-intervention patient from 2015 will be selected based on the date of treatment initiation, sex, and age (Table B1).

Table B1. Sample size estimates for SS Study

	Dniprop	Kharkiv	Odessa	Totals						
2014 HR Intervention (URCS)	230	100	115	445						
2014 HR Non-Intervention	230	100	115	445						
2014 LR Non-Intervention	230	100	115	445						
2014 Subtotal:	690	300	345	1335						
2015 HR Non-Intervention	230	100	115	445						
2015 LR Non-Intervention	230	100	115	445						
2015 Subtotal:	460	200	230	890						
TOTAL by Oblast: 1150 500 575 2225										
Test and Assumptions:										
5% one-sided log-rank test, 80% power, 1.2 d	esign effect									
HR Nonintervention Default = 9%; HR Inter =18%	vention, LR Non	-Intervention D	0efault = 4%, (Censoring						

Notes: Estimated with Stata SE 12, Stata Corp. (College Station, TX), stpower logrank command.

Powered on the assumption that the primary effect will be due to intervention, hence comparison group will not see measurable change in rates.

In addition, to estimate risk distribution in the population, we will randomly sample 300 patients' charts (100 per region) for each of the four years (2011, 2012, 2014, and 2015), 1200 in total. This sample size will allow us to estimate the percentage of TB patients that have at least one risk factor for receiving SS services. Assuming 50% of patients having at least one risk factor, a sample size of 300 gives us 5.7 points for margin of error, and a sample size of 1200 gives us 2.8 points for margin of error.

Data Requirements and Data Collection

Data required for the quantitative component of the evaluation will be collected from mid-2016 to early 2017, and will include individual, program, and facility data. Data collection includes:

<u>Individual Data</u>: TB diagnosis and treatment, program participation (include participants, eligible not participating, eligible not offered), confounding health factors (injecting drug use, alcohol use, smoking, HIV, diabetes), socio-demographics (age, sex, education, marital status, and employment). Data will be collected from the medical records.

<u>Program Data</u>: Frequency and intensity of program intervention (what was received, how often, by whom), start date of program.

<u>Facility Data</u>: Implementation details of DOTS strategy, type of facility, availability of services (TB diagnostics, TB inpatient/outpatient treatment, isoniazid-preventive therapy, etc.), drug shortages, eligibility criteria for offering SS services.

The primary data source is patient medical records from which data will be abstracted retrospectively. Routine management information systems data from the TB treatment facilities follow the WHOrecommended Basic Management Unit TB Register, and record data on diagnostics, treatment, treatment outcome, HIV tests, and treatment prescribed and received. A facility survey will also be used to collect information about services, volume, and externalities.

Estimation Strategy and Analytic Plan

TB therapy can lead to different treatment outcomes or exit events with varying duration times from entry to exit; hence, the data lend themselves to survival analysis. Basic survival analysis or time-to-event analysis includes censored data, cases for which data are incomplete, or timing of an exit event is unknown (Guo, 2006). Using data from complete and censored cases, survival curves will be generated to estimate the time to exit event for different treatment groups, with log-rank statistical tests to test differences in the survival functions. Bivariate analysis using the Kaplan-Meier test will be used to estimate median time to event. Events include treatment default, success, and failure for TB adherence.

Competing risk analysis extends survival analysis to allow for comparisons across multiple, mutually exclusive outcomes by treatment group. Using discrete-time hazard modeling with a multinomial logit (MNL), we can estimate the effect of SS on duration of TB treatment, by type of exit event for different comparison groups (Guo, 2006). In the case of TB treatment adherence, the different treatment exits of interest are default, success, and failure; with treatment success serving as the reference group for the MNL. Other events, such as death, transfer, and status not yet evaluated, will be censored. Analysis groups will include HR TB patients receiving SS in 2012 and 2014; HR TB patients receiving routine care (no SS) in 2011, 2012, 2014, and 2015; and LR TB patients receiving routine care in 2011, 2012, 2014, and 2015. In our analysis in Phase 2, we will examine whether participation in the SS program (HR-SS arm) in 2014 is associated with better outcomes (the likelihood of TB treatment default, treatment success, or treatment failure) compared with those who do not participate (HR-No SS, LR arms) and if the strength of this association is similar to that observed in 2012. In addition, we will examine changes in the likelihood of TB treatment success, or treatment default, treatment success, or treatment failure in each of the arms (HR-SS, HR-NSS, LR) over time (2012 and 2014 for HR-SS; 2011, 2012, 2014, 2014, 2015 for HR-NSS, LR).

Data on outcomes for different risk groups collected over four years, combined with the data on risk distribution in the population, will allow us to use a simple decomposition model to estimate whether and by how much treatment default rates are likely to have increased after the SS program was phased out in 2015 to address question 1.4.

Qualitative Design

Evaluation questions 1.2 and 1.3 will be answered using qualitative methods. We will use patient, provider, and STbCU staff interviews to provide an in-depth picture of what services are provided, who is using those services and how, and what services in the delivery models may or may not be working for the intended audience. Patient and provider interviewing will be completed with patients receiving and providers providing URCS services in 2016. Patients who have been receiving home visits for at least two months and those who have completed the program no longer than two months ago will be invited for interviews. STbCU staff interviews will be completed with staff working on the SS program.

To better understand the role of SS in treatment adherence, in-depth patient interviews will solicit information from HR patients regarding i) primary barriers to treatment adherence; ii) aspects of the SS program that helped them stay on the treatment regimen; and iii) ways to overcome barriers to treatment adherence. Barriers to treatment adherence and the means of overcoming those barriers may differ by men and women. In-depth interview (IDI) respondents will include both male and female patients. Also, since 2015, the URCS has not been providing SS services to patients in Kharkiv. Therefore, in 2016, we will interview patients receiving URCS services in two other remaining baseline regions: Odessa and Dnipropetrovsk.

We will interview STbCU staff members to learn about their experiences coordinating the SS program, barriers, facilitators for their work, and lessons learned for future programs.

Sample

Approximately 20 patients and 10 providers participating in the home visits program in 2016 will be interviewed for the TB adherence work in Dnipropetrovsk and Odessa (RQ1.2, 1.3). Interview participants will be purposively selected from a mix of urban and rural treatment facilities, with attention to including both men and women. We will interview two to three STbCU staff from the office in Kiev (Table B2).

Method	# of respondents	Eligibility Criteria	Location	Notes
In-depth interviews (IDI) with patients	20	Patients receiving URCS services in 2016. Specifically, we will include: -Patients who have been receiving home visits for at least two months -Patients who have completed the program no longer than two months ago	Dnipropetrovsk and Odessa (approximately 10 respondents in each)	In each region, we aim to interview about three to four females and five to six males. We will select patients from both urban and rural areas. Since there are only urban residents in Odessa, we will aim to interview 10 urban residents in this region and five rural and five urban residents in Dnipropetrovsk.
IDIs with providers	10	URCS nurses and social workers providing home visits in 2016	Dnipropetrovsk and Odessa (approximately 5 respondents in each)	We aim to include providers from both urban and rural areas. Since there are only urban providers in Odessa, we plan to interview two to three providers working in rural areas in Dnipropetrovsk.
IDIs with STbCU staff	2-3	STbCU project staff working on managing/coordinating the SS study grant with the URCS	Kiev office	

Table B2. Selection of respondents for qualitative study, TB Adherence/SS Study

Evaluation Design Strengths and Limitations

The evaluation design draws on a mixed methods strategy to provide a comprehensive examination of the SS strategy being implemented under the STbCU project. The analysis will estimate and compare different treatment outcomes and time with exit events for different treatment groups. We will be able to conclude whether participation in the SS program in 2014 is associated with better outcomes compared with those who do not participate, and if the strength of this association is similar to that observed in 2012. Including multiple comparison groups over time will reinforce our ability to draw conclusions. Data on outcomes collected over four years, combined with the data on risk distribution in the population, will allow us to model the effect of the SS program on the treatment success rate at the population level. The IDIs of current home visit recipients, providers, and STbCU project staff will facilitate an understanding of individual and system-level barriers and facilitators to patient treatment adherence, and will provide suggestions on the ways to improve future programs.

There are a few limitations to note. We plan to extract patient data from 2014 and 2015 records. Therefore, the facility and URCS surveys will ask questions about services provided in 2014 and 2015, which is subject to recall bias. Another limitation is that we are constrained in our analysis to variables that are available from the records. Participation in the SS program is selective –patients are referred by their provider –so the characteristics of HR patients that receive SS may be different from those of HR patients who do not receive SS. We are limited in our ability to control for this potential individual selection by the limited range of characteristics available in the medical records. We considered a prospective study that would allow us to collect and control for a wider range of the patient characteristics, but due to the closing out of the program, there were too few new patients planned to be able to recruit enough for a prospective design. Another issue is the effect of externalities on the outcomes of interest. In particular, shortages of TB medications could have significant effects on treatment completion rates. Additional data will be collected on drug shortages so that they can be controlled for in the analysis.

TB/HIV Integration Study

A mixed methods approach, with a quasi-experimental quantitative evaluation design complemented by qualitative descriptive work to inform the findings, will be completed over two phases (baseline and end line).

Evaluation Questions

2.1 What proportion of TB and HIV/AIDS patients completes each step in the cascade of services, from screening to treatment per national protocol?

2.2 What facilitates or impedes timely access and use of testing and treatment for TB and HIV/AIDS patients?

2.3 Do service integration, training, and support between TB and HIV/AIDS services decrease the time lag between each step of service (screening, testing, treatment) for TB and HIV/AIDS patients?

2.4 Do service integration, training, and support between TB and HIV/AIDS services decrease all-cause mortality among the TB/HIV coinfected?

Quantitative Design

Evaluation question 2.1 will be addressed with a descriptive quantitative analysis of the proportion of TB and HIV/AIDS cases that complete the cascade of services per protocol. Questions 2.3 and 2.4 will be evaluated quantitatively using survival analysis within a difference in differences framework. In Phase 1, data were abstracted from client records for a retrospective cohort of TB and HIV/AIDS patients from 2012 to provide a baseline measure of key outcomes. During Phase 2, data will be abstracted from client records for a retrospective cohort from the middle of 2014 to the middle of 2015. To measure program impact, comparison groups will be identified to represent the counterfactual.

Counterfactual

For the impact evaluations questions 2.3 and 2.4, a counterfactual is needed to represent what would have happened in the absence of the integration interventions. In the case of TB/HIV integration, we want to compare the use and timing of services (screening, testing, treatment), treatment outcomes, and survival between those who receive services from TB and HIV facilities participating in the integration strengthening activities. Ideally one would measure two outcomes for each individual: the outcomes when the TB/HIV patient receives HIV and TB services from facilities participating in the integration strengthening activities and the outcomes when the same individual receives HIV and TB services from facilities each individual receives from facilities with no integration strengthening activities. As this scenario is impossible, the evaluation design needs to create a comparison group that is as similar as possible to the intervention group on observable and unobservable characteristics.

The primary intervention population for the integrated TB/HIV services is coinfected patients at a TB or HIV facility in the STbCU target areas. The evaluation will be conducted in three intervention oblasts (Kharkiv, Odessa, and Zaporizhzhya) and three comparison oblasts (Kiev, Mykolayiv, and Zhytomyr). The comparison oblasts were purposively selected because they were not supported by USAID in 2012 during baseline data collection, and had similar HIV and TB incidence rates and facilities providing TB and/or HIV testing and treatment services. We hypothesize that patients in comparison areas will have similar or slightly different treatment outcomes in Phases 1 and 2 (baseline and end line), while patients in intervention areas will have improved outcomes in Phase 2 compared with Phase 1, and that the changes in the intervention group will be greater than the changes in the comparison group.

Sampling

The target populations for the integration study are new TB patients, new HIV patients, and newly diagnosed coinfected TB/HIV patients seen in the six study oblasts during July 2014 to June 2015.

Two questions motivate the sampling for the integration study:

To measure the change in the proportion of patients tested for HIV/AIDS (in TB facilities) or TB (in HIV/AIDS facilities) from 2012 to 2015 between intervention and comparison populations seen at either TB or HIV/AIDS facilities (S1).

To measure the change in the proportion of newly diagnosed coinfected patients who begin antiretroviral treatment from 2012 to 2015 between intervention and comparison populations seen at either TB or HIV/AIDS facilities (S2).

For question 1, Sample 1 (S1=1460) is selected from TB and HIV/AIDS facilities. For the Phase 2 sample, we will apply systematic random equal probability sampling from all TB facilities in each oblast to select 730 patients who initiated TB continuation treatment in TB facilities from July 1, 2014 to June 30, 2015. We will use systematic random equal probability sampling from all AIDS centers in each oblast to select 730 patients in total who initiated HIV treatment in AIDS centers from July 1, 2014 to June 30, 2015. Differential outcomes for men and women patients were not found at baseline; hence, the sample size will not be powered to estimate differences in outcomes by sex for Phase 2 data collection.

For question 2, an additional oversample of coinfected patients (Sample 2 [S2=1040]) will be selected from TB and HIV/AIDS facilities. All TB/HIV coinfected patients initiating TB and/or HIV/AIDS treatment between July 1, 2014 and June 30, 2015 who were not selected in Sample 1 will be the sampling frame for Sample 2. We will apply systematic random sampling to select 718 coinfected patients from TB facilities and 322 coinfected patients from AIDS centers. To calculate the sample sizes needed for S2, we assumed that 20% of TB-positive clients are coinfected and 60% of HIV-positive clients are coinfected; we also will supplement the S2 sample with the coinfected patients identified in S1 (Table B3).

	TB Facilities		HIV Facilities	
Oblast	S1: TB+	S2: TB/HIV	S1: HIV+	S2: TB/-HIV
Kharkiv	114	112	66	29
Odessa	160	157	238	105
Zaporizhzhya	91	90	61	27
Intervention	365	359	365	161
Kiev Oblast	120	118	125	55
Mykolayiv	131	129	170	75
Zhytomyr	114	112	70	31
Control	365	359	365	161
TOTALS	730	718	730	322

Table B3. Sample size estimates for TB/HIV Integration Study

Test and Assumptions:

5% one-sided log-rank test, 80% power, 1.8 Design Effect

Mortality rate = 15%; Mortality rate among intervention=10%; Censoring=13%

Notes: Estimated with Stata SE 12, Stata Corp. (College Station, TX), stpower logrank command.

Powered on the assumption that the primary effect will be due to the intervention, hence, a comparison group will not see measurable change in rates.

Data Requirements and Data Collection

Data required for the quantitative component of the evaluation will be collected from mid-2016 to early 2017, and will include individual and facility data. Data collection includes:

Individual Data: Diagnosis, treatment, and outcomes; program participation; confounding health factors (injecting drug use, alcohol use, smoking, diabetes); and socio-demographics (age, sex, education, marital status, and employment). Data will be collected from the medical records.

<u>Facility Data</u>: Type of facility; availability of services (TB and HIV screening, testing and treatment services, isoniazid-preventive therapy, etc.); referral mechanisms; average time from test to results received; and drug shortages.

The primary data source is patient medical records from which data will be abstracted retrospectively. Routine management information systems data from the TB and HIV treatment facilities follow the WHOrecommended Basic Management Unit TB Register, and record data on diagnostics, treatment, treatment outcome, HIV tests, and treatment prescribed and received. A facility survey will also be used to collect information about services, volume, and externalities.

Estimation Strategy and Analytic Plan

To evaluate TB/HIV service integration, a descriptive analysis will quantify the proportion of TB and HIV/AIDS cases that receive the cascade of screening, testing, and treatment services in 2014/2015, and draw comparisons to the national diagnostic protocols (RQ2.1). Also, we will compare the results from the descriptive analysis conducted in Phase 1 and Phase 2 to assess changes over time in the cascade of screening, testing, and treatment services in intervention and comparison areas. The data from intervention and comparison oblasts and from Phase 1 and Phase 2 of the study will be merged, and discrete time hazard models will be run separately for each outcome in the service cascade. These hazard models will be individual logit models, with time and intervention area included as covariates. Of particular interest for the difference in differences analysis will allow us to measure whether participants in the integration treatment oblasts received key services in a timelier manner compared with the comparison oblasts, indicating program effects (RQ2.3). Among those patients who are coinfected, a separate similar hazards model will model all-cause mortality events. (RQ2.4).

Qualitative Design

For the TB/HIV integration interventions, the intent is to improve the timeliness of patient screening, testing, and treatment initiation for those coinfected. To answer evaluation question 2.2, we will use patient and provider interviews, and small group discussions with providers to learn about the barriers and facilitators

to timely access and use of testing and treatment for TB and HIV/AIDS patients. Mapping the cascade of services during IDIs and small group discussions will identify where coinfected patients are falling through the cracks. Patient interviews will add to our understanding of patients' experiences accessing and using both TB and HIV services. Provider interviews and small group discussions will provide additional information on patient and data flow, ways of communication between TB and HIV services, and barriers and facilitators to providing services to coinfected patients. We will include both male and female respondents in the interviews to explore differences in the experiences of men and women. We will conduct IDIs with TB/HIV integration staff of the STbCU project to learn more about the implementation of the integration activities in the intervention sites, in particular, what was planned and what was done, barriers and facilitators, and lessons learned. This additional process information will allow us to better interpret the findings of the impact analysis.

Sample

We will select patients and providers for the qualitative study from intervention sites only. Approximately 10 to 12 providers, 30 patients, three STbCU staff interviews, and six small group discussions with providers will be conducted in the three intervention sites. An additional four to five interviews will be conducted with the STbCU project staff working in the Kiev office and intervention regions. The selection of patients will be purposive, with attention to sex, age, and initial disease diagnosis. Coinfected patients who are currently receiving continuation phase TB treatment for at least two months or who completed the continuation phase TB treatment no longer than two months ago will be invited for interviews. A purposive sample of providers for interviews and small group discussions and STbCU staff interviews will also be selected (Table B4).

Method	# of respondents	Eligibility Criteria	Location	Notes
IDIs with patients	30	TB/HIV coinfected patients who are currently receiving continuation phase TB treatment for at least two months or completed the continuation phase TB treatment no longer than two months ago	Intervention oblasts: Kharkiv, Odessa, Zaporizhzhya (10 respondents in each oblast)	In each region, we will interview five patients who were first diagnosed with TB and five patients who were first diagnosed with HIV. Also, in each region, we aim to interview about three to four females and five to six males. If possible, we want to interview both rural and urban residents, but the priority for selection is given to the first two criteria (1. disease diagnosis and 2. sex).
IDIs with providers	12	-TB providers treating coinfected patients -HIV providers treating coinfected patients	Intervention oblasts: Kharkiv, Odessa, Zaporizhzhya (two TB and two HIV providers in each oblast)	Providers from the same health facility or AIDS center should take part in each discussion.
Small group discussions with providers	Six groups, five to six participants in each	-TB providers treating coinfected patients -HIV providers treating coinfected patients	Intervention oblasts: Kharkiv, Odessa, Zaporizhzhya (one discussion with TB and one with HIV providers in each oblast)	IDI participants will not be invited to the small group discussions.
IDIs with STbCU staff	Four to five	STbCU project staff working on coordinating and/or implementing integration activities	Kiev office (two respondents), Intervention oblasts: Kharkiv, Odessa, Zaporizhzhya (one coordinator in each)	

Table B4. Selection of respondents for qualitative study, TB/HIV Integration Study

Evaluation Design Strengths and Limitations

The evaluation design draws on a mixed methods strategy to provide a comprehensive examination of the TB/HIV integration strategy being implemented under the STbCU project. We have used survival analyses to quantify pre-existing difference in outcomes between intervention and comparison groups at baseline. At end line, the survival analysis will produce estimates of the effect of the intervention among patients living in intervention areas. Including a comparison group over time provides a relatively strong evaluation design to estimate program impact. The IDIs of patients and providers will identify respondents' perspectives on barriers and facilitators for timely access and use of testing and treatment for TB and HIV/AIDS patients to better interpret the quantitative findings and improve future interventions. The IDIs with STbCU project staff will facilitate our understanding of what was implemented and why the TB/HIV integration program did or did not work.

There are a few limitations to note. One concern is the contamination of comparison areas by other interventions that aim to strengthen TB/HIV integration. In particular, the STbCU project expanded its TB/HIV integration activities to Mykolayiv, one of our comparison oblasts, beginning in 2016. Our Phase 2 data collection abstracts patient records from mid-2014 to mid-2015, before the expansion took place, which should reduce the impact of this contamination on our quantitative findings (some longer-term outcomes like survival may fall into 2016). We will also include controls for oblast in our models. We will conduct interviews with the STbCU project staff to document what integration activities took place in Mykolayiv since baseline and when each of these activities took place. Depending on the intensity and timing of these activities in 2016, we will adjust the analysis accordingly. Also, the difference in differences approach assumes that the changes in the outcomes in the comparison areas represent the changes that would have been seen in the intervention areas in the absence of the program. Our comparison areas were purposively selected to be as similar as possible to the intervention oblasts, but there are differences between oblasts that could affect their underlying trends in outcomes. Randomization was not possible in this context, however, and this design represents the strongest one available to us.

Another issue is the effect of externalities on the outcomes of interest. In particular, shortages of TB or antiretroviral medications could have significant effects on treatment initiation and completion rates or on strategies that intervention and comparison sites might have employed to offset these shortages. Additional data will be collected on drug shortages so that they can be considered in the analysis.

Protection of Human Subjects and Security

Protection of Human Subjects

Human subjects review and approval of the complete study protocol and data collection instruments from the UNC-Chapel Hill IRB and the appropriate review board in the Ukraine will be obtained prior to data collection. For all interviews, verbal informed consent will be documented. Special population considerations may be necessary for TB and/or HIV patients, health records data, vulnerable populations (e.g., HIV-positive, poor, ex-prisoners).

Data Security

Data extracted from patient records, and routine health information systems will be encrypted by the implementing partner in Ukraine and sent via secure data link to MEASURE Evaluation where it will be stored on a secure server. Data from IDIs and small group discussions will not contain any personal identifiers. All original data collection instruments and data, including audio recordings from interviews and group discussions, will be destroyed by the sub-contractor at the end of the study and will be stored securely until that time. The data collection subcontractor contract will comply with the requirements of the UNC data security policies and IRB requirements. A contract between the subcontractor and the MEASURE Evaluation project will detail the data sharing agreement between respective parties. De-identified data will be available to USAID and provided via a secure data link upon request.

Deliverables, Dissemination, and Data Use

The evaluation deliverables are listed below; timelines associated with each deliverable are detailed in Table B5.

MEASURE Evaluation will submit the following deliverables to USAID:

Final impact evaluation report with a synthesis of quantitative and qualitative findings. This report will follow the guidance specified in the USAID Evaluation Policy: *Criteria to Ensure the Quality of the Evaluation Report* (USAID, 2011).

Dissemination and data use workshop and report summarizing feedback and recommendations provided by workshop participants/stakeholders.

Following the review of the final impact evaluations report by all relevant stakeholders, MEASURE Evaluation will hold a workshop to disseminate and facilitate use of the study findings. The evaluation team, including local contractors, will be involved in designing and conducting the dissemination/data use workshop. The workshop will entail presentation and discussion of key findings, and will also include sessions to solicit recommendations from stakeholders and potential action steps for TB and TB/HIV policy and programming based on the evaluation.

Evaluation Team and Stakeholders

The evaluation team includes international development specialists from MEASURE Evaluation who have substantial knowledge and experience in 1) evaluation design and implementation; 2) TB and HIV program implementation and monitoring and evaluation (M&E); 3) quantitative and qualitative methodologies; and 4) data analysis and use. Key personnel for this scope of work include a TB M&E Specialist, two Evaluation Specialists, and a Data Use Specialist. Below is a summary of their skills and roles in the evaluation:

Stephanie Mullen, Dr.PH, TB M&E Specialist

MEASURE Evaluation, John Snow, Inc.

Dr. Mullen has 18 years of experience working in international health managing and evaluating tuberculosis, HIV/AIDS, and reproductive health programs. Her technical areas of expertise are M&E of health programs and building capacity of local organizations and individuals in the areas of tuberculosis, HIV/AIDS, and reproductive health M&E. She has provided technical assistance on M&E, data collection, and data analysis in Southeast Asia, Eastern Europe, Sub-Saharan Africa, Latin America, and the Caribbean. She has experience conducting regional, national, provincial, and district-level training courses on M&E of HIV/AIDS and TB programs, in collaboration with local training institutions, with support from USAID, Centers for Disease Control and Prevention, the Joint United Nations Programme on HIV/AIDS (UNAIDS), and WHO. She has supervised a multi-country initiative to develop an M&E strategy for global TB programs with STOP TB partners in Southeast Asia, Latin America, Eastern Europe, and Africa. Dr. Mullen has both quantitative and qualitative evaluation experience.

Siân Curtis, Ph.D., Evaluation Specialist

MEASURE Evaluation, Carolina Population Center, UNC

Siân Curtis is Research Associate Professor in the Department of Maternal and Child Health at the Gillings School of Global Public Health, University of North Carolina, and is a Faculty Fellow at the Carolina Population Center. Currently Dr. Curtis is senior evaluation advisor for the USAID-funded MEASURE Evaluation and FEEDBACK Projects. Until November 2012, she served as Director of the MEASURE Evaluation Project. Previously, Dr. Curtis was a senior research associate at Macro International where she served as a senior analyst for the Demographic and Health Survey project. Dr. Curtis was awarded her Ph.D. in Social Statistics and M.Sc. in Statistics with Applications in Medicine from the University of Southampton, U.K. Her research focuses on M&E of international population and health programs and food security and nutrition programs, contraceptive use dynamics, maternal health, and infant mortality. Current research includes an impact evaluation for an maternal and child health service delivery project in Bangladesh; an impact evaluation of the gendered outcomes of a groundnut value chain intervention in Zambia; and a threecountry comparative study on using verbal autopsy methods to measure maternal mortality. She has published widely in peer-reviewed journals, including *Demography, Studies in Family Planning, Health Policy and Planning, AIDS Care, Sexually Transmitted Infections, British Medical Journal,* and the *Journal of Biosocial Science,* among others. Dr. Curtis was a member of the 2012 Family Planning Summit Monitoring and Accountability Advisory Group and Technical Working Group, the UNAIDS Monitoring and Evaluation Reference Group, and the Health Metrics Network Technical Advisory Group, and has served as a member of the Board of the Routine Health Information Network.

Zulfiya Charyeva, Ph.D., Evaluation Specialist

MEASURE Evaluation, Palladium

Dr. Charyeva is an expert in data collection and analysis, M&E, training, and research. Over the past 13 years, she has focused on helping counterparts by conducting evaluations and providing recommendations for strengthening standards of care for reproductive health and HIV/AIDS programs. Under the MEASURE Evaluation project, Dr. Charyeva collaborated on the development of the UNAIDS Technical Working Group Monitoring and Evaluation Guidelines for HIV Prevention for sex workers, men who have sex with men, and people who inject drugs. She also developed curricula and conducted training on M&E, qualitative and quantitative data analysis, and data quality assessments. Dr. Charyeva designed and led data quality assessments for USAID-funded projects in Ukraine. She wrote data analysis plans for the MEASURE Evaluation outcomes measurement toolkit for orphans and vulnerable children programs. Dr. Charyeva served as operations research technical backstop for the Targeted States High Impact Project, a five-year project designed to increase the use of high impact integrated maternal, newborn, and child health and family planning/reproductive health services in two northern Nigerian states. Her current projects include an impact evaluation of a savings and internal lending communities on child and household well-being in Zambia. Dr. Charyeva is a proficient Russian speaker.

Nicole Judice, Data Use Specialist

MEASURE Evaluation, Palladium

Nicole Ross Judice has extensive experience as a technical expert, trainer, and project manager working on international projects focused on HIV/AIDS, maternal and child health, family planning, and reproductive health. She has technical expertise in such areas as policy, data use, strategic planning, M&E, individual and organizational capacity development, and costing. Currently, Ms. Judice is M&E Director for the global Health Policy Project, and is Country Activity Manager to the Health Policy Project country program in Kenya. She led a team to conduct an HIV policy assessment in Ukraine, and has designed and conducted

several studies in Ukraine and Russia, including a costing study of reproductive health interventions, a study on the efficiency of use of health sector resources, a study to test approaches to preventing congenital syphilis, and a situational analysis of the use of naltrexone to reduce opiate dependence. Ms. Judice has spent the last two years working closely with the Central Asian Association of PLWH to strengthen capacity in policy advocacy and using evidence to inform decision making. Ms. Judice is a proficient Russian speaker.

The Evaluation Team has contracted IFAK, a local Ukrainian research organization, for study coordination and data collection. IFAK has detailed knowledge of Ukraine's public health sector, TB and HIV/AIDS implementation, relevant governmental and nongovernmental institutions, and experience in conducting evaluations, including data collection, cleaning, and analysis. IFAK served as the local implementing partner for the baseline data collection for this evaluation.

Participation of Relevant Stakeholders in the Design or Conduct of the Evaluation

USAID/Ukraine staff will provide feedback on the evaluation design to ensure that the information they need for future planning and implementation of TB programs will be produced by the evaluation. Ongoing dialogue is anticipated during the implementation of the study to ensure that USAID/Ukraine staff are fully informed throughout the process.

Implementing partners, such as the Ukrainian Red Cross Society and Chemonics International, will be consulted to inform the evaluation design in terms of how and where the SS and TB/HIV integration programs are being implemented in the Ukraine. Furthermore, their feedback is critical to gain a better understanding of how the evaluation can be designed to maximize the relevance and use of the data by these programs while remaining true to its primary objectives.

National counterparts, such as the State Service for Socially Dangerous Diseases, the TB Institute, and HIV/ADIS Centers, will be consulted to gain a greater understanding of the context of TB programs in the Ukraine, how this evaluation can help inform TB and TB/HIV programing, and how to maximize the relevance and use of the evaluation findings. Collaboration with these organizations will also be necessary to understand how data are collected at TB facilities and HIV/AIDS Centers, and to gain access to information collected from TB and TB/HIV coinfected patients through their routine data collection systems.

The evaluation, including data collection and analysis, will be conducted by MEASURE Evaluation staff and by the local research organization, IFAK. These organization are not directly involved in the implementation of TB programs in Ukraine to minimize any biases.

Timeline

Table B5 details the proposed timeline for study design, data collection, analysis, and report writing for Phase 2. For the qualitative study, the implementation time is approximately 10 months. It is included in the calendar, but the timing of this activity is negotiable depending on the schedule of the qualitative researchers. Since the URCS finishes patient enrollment in the SS program in June 2016, all key IDIs with patients and providers for this study will need to be completed by the end of 2016.

Table B5. Activity	y implementation	timeline for Phase 2, ST	bCU project in	npact evaluation

Tasks/Timeline	20	16											2017											
	Ja	Fe	Ма	Ар	Ma	Ju	Ju	Au	Se	Oc	No	De	Ja	Fe	Ma	Ар	Ma	Ju	Ju	Au	Se	Oc	No	De
Work on protocol and instruments																								
Sub-contract local researchers																								
Obtain Ministry of Health permission																								
IRB application and approval UNC / Ukraine																								
Quantitative Evaluation Plan		1	1							1		L	1	L	1	L	1	1	1					
Define sampling plan for treatment / comparisons																								
Pilot test instruments																								
Train data collectors and study coordinators																								

Tasks/Timeline	20	16											2017	7										
	Ja	Fe	Ma	Ар	Ma	Ju	Ju	Au	Se	Oc	No	De	Ja	Fe	Ма	Ар	Ма	Ju	Ju	Au	Se	Oc	No	De
Trip: Train data collectors and study coordinators																								
Collect data –chart and facility surveys (SS Study)																								
Collect data –chart (IB/HIV Integration Study) abstraction																								
Process and analyze data																								
Draft preliminary report																								
Qualitative Study –timeline for qu	alitati	ive stı	ıdy cou	ld shif	t per sc	hedul	e of s	ubcont	racto	ſ				-										
Define sampling plan																								
Train data collectors																								
Trip: Training, Data Collection																								

Tasks/Timeline	201	16											2017											
	Ja	Fe	Ма	Ар	Ma	Ju	Ju	Au	Se	Oc	No	De	Ja	Fe	Ма	Ар	Ma	Ju	Ju	Au	Se	Oc	No	De
Collect data																								
Process and analyze data																								
Draft preliminary report																								
Final Evaluation Findings Dissemi	natio	on																						
Produce combined report																								
Review by stakeholders																								
Dissemination/Data Use Workshop																								
Trip: Dissemination/Data Use Workshop																								
Produce the workshop report with recommendations																								

Tasks/Timeline	20	16											2017											
	Ja	Fe	Ma	Ар	Ma	Ju	Ju	Au	Se	Oc	No	De	Ja	Fe	Ma	Ар	Ma	Ju	Ju	Au	Se	Oc	No	De
Revise and publish final impact evaluation report																								

Caveat: All timelines are dependent on getting IRB and other approvals in a timely way. These approvals can be subject to external delays outside of the control of MEASURE Evaluation.

STUDY PROTOCOL REFERENCES

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Updates to the Study Protocol in Phase 2

Several changes have been made to the protocol for Phase 2 of the evaluation compared with what was planned in the original evaluation protocol developed prior to Phase 1 (baseline) data collection. The revisions reflect changes in the program between Phase 1 and Phase 2, and lesson learned from the baseline data collection. For reference, Table B7 details the changes to the study design in Phase 2 of the evaluation compared with the original protocol.

#	Proposed in the original protocol	Changes to the original protocol	Notes/Explanation
For	the SS Study:		
1	Prospective enrollment of TB patients for end line	Retrospectively extract data from 2014 and 2015 records in Dnipropetrovsk, Odessa, and Kharkiv as we did in Phase 1. Replication of Phase 1 design.	Enrollment in the SS program has been decreasing. In 2015, STbCU reports that they only recruited 376 patients for SS with the URCS. This is much lower than the volume of SS referrals we had in 2012 when we were able to identify at least 445 HR-SS clients in January to May 2012 from lists provided by the URCS. Prospective enrollment is not feasible with this reduced number of beneficiaries. The geographic coverage of STbCU has changed. Kharkiv has been dropped as a site for STbCU SS referrals in 2015 and two new oblasts have been added in 2012 (Zaporizhzhia and Kherson) so there are no new patients to recruit in Kharkiv.
2	Three evaluation questions for the SS study	Add evaluation question 1.4 on the effect of the SS program on the treatment success rate at the population level. We will use modeling to answer this evaluation question.	We will have data for 2011 (no SS program), 2012 (yes SS program), 2014 (yes SS program), and 2015 (no SS program) to answer this evaluation question.

Table B7. Changes to the study design in Phase 2

#	Proposed in the original protocol	Changes to the original protocol	Notes/Explanation
		Collect data on risk distribution in the population of patients in 2011, 2012, 2014, and 2015 to allow us to use a decomposition model to examine whether and by how much treatment default rates change at the patient population level as the SS program is implemented or dropped.	
3	IDIs with 30 HR patients, IDIs with 10 providers in all three SS intervention sites to answer questions 1.2 and 1.3.	Conduct IDIs with 20 HR patients, IDIs with 10 providers as planned in the original protocol with 2016 new patients in Dnipropetrovsk and Odessa to answer questions 1.2 and 1.3. We will not conduct interviews in Kharkiv.	The geographic coverage of STbCU has changed. Kharkiv has been dropped as a site for STbCU SS referrals in 2015.
For	the TB/HIV Integration	a Study:	
4	Prospective enrollment of TB and HIV patients	Extract medical outcomes retrospectively from records of TB and HIV patients who initiated services during the mid-2014 to mid- 2015 time period. We need a minimum of a 14 to 15 month period following initiation of treatment to observe treatment outcomes, so we will start data collection in October 2016 and have all data collected and cleaned ready for the analysis in March 2017.	To conduct the difference in differences analysis, we do not need to enroll study participants prospectively. Instead, to be consistent with the baseline methods, we should rely on retrospective data collection from medical records.
5	No plans for small group discussions with providers	To answer evaluation question 2.2, we will use small group discussions with providers in addition to patients, and conduct provider interviews to learn about the barriers and facilitators to timely access and use of testing and treatment for TB and HIV/AIDS patients.	Group discussions with providers from the same facility will provide an environment for brainstorming ideas and further facilitate our understanding of patient and data flow. Mapping the cascade of services will identify where coinfected patients are falling through the cracks and what can be done to promote integration between TB and HIV services.

#	Proposed in the original protocol	Changes to the original protocol	Notes/Explanation
6	No plans for IDIs with STbCU staff	Conduct four to five IDIs with TB/HIV integration staff of the STbCU project to learn more about implementation of the integration activities in the intervention sites (what was planned and what was done, barriers and facilitators, lessons learned).	This additional process information will allow us to better interpret the findings of the impact analysis.

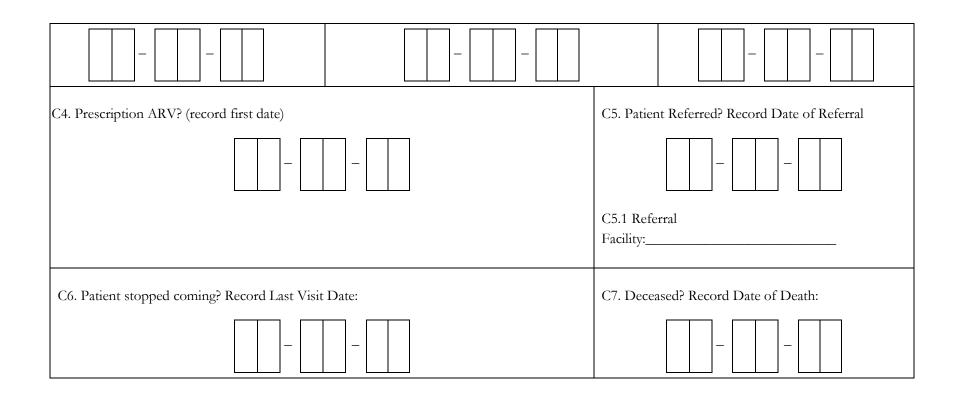
APPENDIX D. STUDY QUESTIONNAIRES

D.1. HIV Facility patient Chart Abstraction Form

HIV DATA ABSTRACTION FORM –Integration Study FINAL: September 19, 2016

PLEASE PAY YOUR ATTENTION TO THE FOLLOWING CODING:				
	SERVICE WAS NOT PROVIDED IS '0'			
INFORMATION IS NOT AVAILABLE OR UNKNOWN IS '9'				
A. Facility Identification				
A1. Today's Date: (DD-MM-YY)	A2. Data Collector ID:	A3. Rayon		
A4. Oblast	A5. Facility Name:			
B. Patient Identification				

B1. Patient's Code:					
PLEASE, INSERT THREE FIRST LETTERS BIRTH	S OF PATIENTS SURNAME, FIRS	ST LETTER OF PAT	IENTS FIRST NAME AND DATE OF		
B2. Sex:	B3. Date of Birth:	B4. Age (years)	B5. Residence:		
Male2	DD - MM - YY	<if <18="" end<br="" years="">SURVEY></if>	Urban1 Rural2		
B6. Employment:	Retired	3	Housewife6		
Employed1	Person with Disabilities4	Other7			
Unemployed2	Student	Information not available9			
C. HIV Registration and Testing [HIV Control Card]					
C1. HIV Registration Date	C2. HIV Date of Diagnosis	C3. Date of Most Recent Visit			

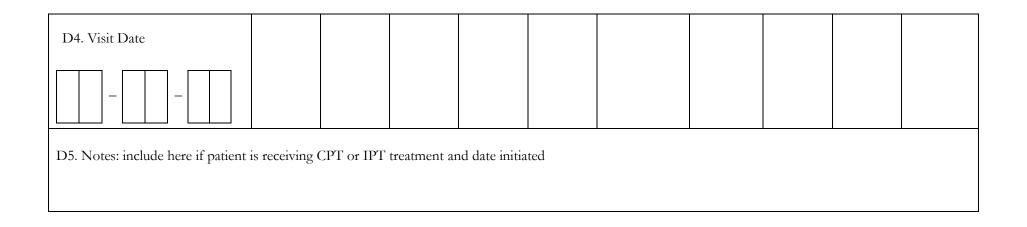


D. Health Status and HIV Treatment [HIV Control Card –Form 030-5/o]

REVIEW ALL PATIENT VISITS BETWEEN April 01, 2014 – June 30, 2015. STARTING IN MARCH 2015 AND WORKING BACKWARDS,

COMPLETE TABLE INFORMATION FOR UP TO 4 VISITS DURING PERIOD. IF MORE THAN 4 VISITS, SELECT THOSE VISITS WITH DATA ON ARV OR OTHER HEALTH STATUS (TB, PREGNANT, IDU, ETC).

Visit Date	Clinical Stage	CD4 Count (absolute)	Viral Load (copies/ml)	Pregnant (Yes / No)	Functional Status (P, A, L)	IDU (C1-C5)	TB (T1-T7)	Viral Hepatitis (H1-H14)
D1. Visit Date								
D2. Visit Date								
D3. Visit Date								



E. TB Screening and Referral [HIV Control Card, TB09, medical record]						
ASK ABOUT AVAILABILITY OF EAC PROVIDED, THEN RECORD THE DA	IF YES: Date Initiated (DD-MM-YY)					
E1. Was patient <u>screened</u> for TB sympton sweats, weight loss) at this facility? Yes, screening provided No						
E1.1. Did patient undergo any additional TB diagnostic Yes No SURVEY> Don't know						
EVALUATING A SUSPECT TB CASE MAY INCLUDE MULTIPLE TESTS TO ESTABLISH A DIAGNOSIS. FOR EACH OF THE FOLLOWING, NOTE IF THE TEST OR EXAM WAS PERFORMED AND THE DATE INITIATED.						
TEST:	(a) Where evaluated	(b) Date of evaluation or referral				
E2. Sputum microscopy	This facility					
E3. Culture	This facility1					

	Referred to TB Facility2 Previously at other facility3 Service was not provided0	
E4. X-ray	This facility1 Referred to TB Facility2 Previously at other facility3 Service was not provided0	
E5. Clinical Evaluation	This facility1 Referred to TB Facility2 Previously at other facility3 Service was not provided0	
E6. Other	This facility1 Referred to TB Facility2 Previously at other facility3 Service was not provided0	

E7. Diagnostic evaluation concluded patient is:	
Confirmed TB Case1	
TB ruled-out2 <end SURVEY></end 	
TB status unknown9	
IF TB DIAGNOSIS RULED-OUT	<end survey<="" td=""></end>
IF TB CONFIRMED OR UNKNOWN:	
F. Treatments [TB-09]	
F1. Did patient start Intensive TB Treatment?	
Yes, at this facility1 < <i>complet</i> <i>date</i> >	e
Yes, treated at other facility	
Unknown, referred to other facility for treatment3 < complete date>	
No	4>
Don't know	4>

Patient Record Number:





F1.1. Diagnosis: Clinical form Lung1 Extra-pulmonary	2				
F2. Did patient finish Intensive TB Treatment?					
Yes, at this facility1 < <i>complete date</i> >					
Yes, finished at other facility					
Unknown, referred to other facility for treatment3					
No					
Don't know9 < <i>skip to</i> F4>					
F2.1. Treatment Category: CATEGORY I1					
CATEGORY II	2				
CATEGORY III	3				
Other:6					
IF IN QUESTION F1 CIRCLED OPTIONS 2 OR 3 THEN COMPLETE QUESTION F3					
F3. Name of facility where patient was referred:					
F4. Did patient start anti-retroviral therapy (ART)?					
Yes, at this facility1 < complete date>					
Yes, treated at other facility					
Unknown, referred to other facility for treatment3 < complete date>					
No					
Don't know9 < <i>skip to</i> F6>					





IF IN QUESTION F4 CIRCLED OPTIONS 2 OR 3 THAN COMPLETE QUESTION F	4.1
F4.1 Name of facility where patient was referred:	
F5. Did patient start Continuation (or Follow-up) TB Treatment?	
Yes, at this facility1 < <i>complete date</i> >	
Yes, treated at other facility	
Unknown, referred to other facility for treatment3 < complete date>	
No	
Don't know	
F6. Did patient finish Continuation TB Treatment?	
Yes, at this facility1 < <i>complete date</i> >	
Yes, finished at other facility	
Unknown, referred to other facility for treatment3 < complete date>	
No	
Don't know	
IF IN QUESTION F5 CIRCLED OPTIONS 2 OR 3 THAN COMPLETE QUESTION F	6.1
F6.1 Name of facility where patient was referred:	
F7. Is patient an Injection Drug User?	
Yes1	





No.....0 < skip to G >

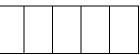
Don't know......9 <*skip to* G>

F8. Notes:





G. TB Treatment Outcome [TB09 or TB01]	
G1. Outcome of TB Treatment: < <i>CIRCLE ONE</i> > Cured	G2. Treatment Outcome Date
1 Treatment complete2	(DD-MM-YY)
Died from TB3 Died (non-TB cause)4	
Treatment failed-smear/culture5 Treatment failed -xray/clinical	
Treatment failed –MDR-TB (transfer to Cat IV)7	
Treatment Interrupted	
G3. Notes [include additional key information on diagnosis, treatment or outcome	
U.S. Proces [intimate automate Key information on autoproses, inclument of outcome	
END SURVEY	





D.2. TB Facility Patient Chart Abstraction Form

TB Data Abstraction Form –Integration Study

FINAL: Sept 19, 2016

PLEASE PAY YOUR ATTENTION TO THE FOLLOWING CODING:

SERVICE WAS NOT PROVIDED IS '0'

INFORMATION IS NOT AVAILABLE OR UNKNOWN IS '9'

F. Facility Identification (WRITE NAME OF THE FACILITY)				
A1. Today's Date: (DD-MM-YY)	A2. Data Collec	ctor ID:	A3. Facility Name (Intensive Phase):	
A4. Oblast	A5. Raion		A6. Facility Name (Continuation Phase):	
G. Patient Identification				
B1. Patient Name			B2. Patient Record Number:	
Last (SURNAME):				
B3. Date of Birth:	B4. Age (years)	B5. Sex:	B6. Residence:	
		Male 1	Urban1	

Patient	Record	Num	ber:



D D M M Y Y	[if <18 years END SURVEY]	Female2	Rural	2
B7. Employment:				
Employed 1		Student		5
	2	Housewife		6
Unemployed	2	Other		
Retired3		Information no	ot available	9
Person with Disabilities	4			
B8. Patient's Code:				
PLEASE, INSERT THREE FIRS NAME AND DATE OF BIRTH	T LETTERS OF PAT	IENTS SURNAME	E, FIRST L	ETTER OF PATIENTS FIRST
H. TB Case Initiation				
C1. TB detected due to:	C2. Date of E	mergence of first sy	mptoms:	C3. Date of First TB visit:
Own				
initiative	1			
Occupational screening	2			

Patient Record Number:



C4. Beginning Treatment Date:	C5. Hospital Admission Date: [if not hospitalized, enter 00-00-00]	C6. Hospital Discharge Date: [if not hospitalized, enter 00-00-00]
I. TB Diagnosis		
D1. Date of first smear (DD-MM-YY)	D2. Date of first culture (DD-MM-YY)	D3. Date of first x-ray (DD-MM-YY)
D4. Diagnosis: Type of case		
First Diagnosis		5
Re-initiation following interruption .	Other:	6
Treatment failure	3	
Relapse4		
D5. Diagnosis: Clinical form		
Lung		2





J. TB Treatment: Intensive Phase	
E1. Intensive Phase TB treatment was provided as:	Inpatient
E2. Treatment Category: CATEGORY I	1
CATEGORY II	2
CATEGORY III	
Other:	6
E3. Intensive Treatment Start Date:	E4. Intensive Treatment End Date:
E5. Was direct observation of use of TB drugs recorded (regrelatives of the patient)? Yes1 No	
E5.1 Number of Planned Doses (doses planned)	
E5.2 Number of Doses Received (doses patient received	d)
E5.3 Number of Interruptions (number of periods whe	n no drugs received)
E5.4 Duration of longest interruption	



K. TB Treatment: Continuation / Follow-up Phase			
F1. Did patient start Follow-up phase? Yes1 No2 < <i>skip to G1></i>			
F2.Follow-up Treatment start date:	F3. Follow-up Treatment end date:		
F4. Was direct observation of use of TB drugs recorded (regardless whether it was observed within the facility or by relatives of the patient)? Yes1 No			
F4.1 Number of Planned Doses (doses planned)			
F4.2 Number of Doses Received (doses patient received	d)		
F4.3 Number of Interruptions (number of periods whe	n no drugs received)		
F4.4 Duration of longest interruption			



L. Treatment Outcome	
G1. Outcome of treatment: <i><circle one=""></circle></i>	G2. Treatment Outcome Date
Cured1	(DD-MM-YY)
Treatment complete2	
Died from TB3	
Died (non-TB cause)4	
Treatment failed-smear/culture5	
Treatment failed –xray/clinical6	
Treatment failed –MDR-TB (transfer to Cat IV)7	
Treatment Interrupted	
TB diagnosis cancelled9	
Transferred:	
G3. Notes [include additional key information on diagnosis, treatment or outcome]	
M. actors that affect Course of Illness and Treatment	
H1. Factors (CIRCLE ALL THAT APPLY):	(DD - MM - YY)
H1.1 HIV positive1 \rightarrow 1.1.a Date of VCT H1.2 Alcoholic2 1.1.b Date of Testing	
1.1.D Date of Testing	

Patient Record	Number:
----------------	---------



Data Collector ID Number:



		-				1
H1.3 Injection Drug User3	1.1.c Date of ART		-	-]_[
H1.4 Contact with a case4	1.1.d Date of CPT					
H1.5 Comorbidities5	→ IF CoMorbidities List:		-	-		
H1.6			-	-	_	
Homeless6						
H1.7						
Unemployed7					 	
H1.8 Health Care Worker8					 	
H1.9					 	
Migrant9						
H1.10 Refugee/Immigrant10						
H1.11 Ex-						
Prisoner11						
H1.12 Other12						
H1.13 No known risk factors 13						
H2. Referral for Social Support during continuation treatment?	Yes	1				
No2						
Don't Know9						



N. HIV Screening, Testing, Referral and Treatment	
I1. Was patient diagnosed with HIV before TB diagnosis?	
Yes, HIV positive1 < <i>skip to I6></i>	
No2	
Don't know9	
ASK ABOUT AVAILABILITY OF EACH SERVICE. IF OFFERED AND/OR PROVIDED, THEN RECORD THE DATE WHEN SERVICE INITIATED.	IF YES: Date Initiated (DD-MM-YY)
I2. Was HIV pre-test counseling provided? Yes, provided	
I3. Were HIV diagnostic tests completed? Yes, tests provided1 < <i>complete date</i> >	
Yes, offered but not accepted	
Not offered0 < <i>skip to I5</i> >	
I4. Diagnostic test confirms patient is:	
HIV-positive1	
HIV-negative2 <end SURVEY></end 	

Patient Record Number:





HIV status unknown9	
	IF YES: Keep date (DD-MM-YY)
15. Was HIV Registration Card filled out for patient?	
Yes1 < complete date>	
No0	
Don't know9	
I6. Did patient start anti-retroviral therapy (ART)?	
Yes, at this facility1 < <i>complete date</i> >	
Yes, treated at other facility	
Unknown, referred to other facility for treatment3 < complete date>	
No	
Don't know9 <end survey></end 	
IF IN QUESTION I6 CIRCLED OPTIONS 2 or 3 COMPLETE I6.1:	

Patient Record	Number:
----------------	---------





I6.1 Facility name where patient was referred: _____

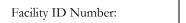
NOTES:

J. Health Status and HIV Treatment

REVIEW ALL PATIENT VISITS BETWEEN April 01, 2014 AND TODAY. STARTING TODAY AND WORKING BACKWARDS,

COMPLETE TABLE INFORMATION FOR UP TO 4 VISITS DURING PERIOD. IF MORE THAN 4 VISITS, SELECT THOSE VISITS WITH DATA ON CLINICAL STAGE, CD4 COUNT OR ARV.

Clinical Stage	CD4 Count (absolute)	Viral load (copies/ml)	ARV (Yes/No)
J1. Date	J1. Date	J1. Date	J1. Date
Stage	Count	Viral load	ARV (Yes/No)
J2. Date	J2. Date	J2. Date	J2. Date
Stage	Count	Viral load	ARV (Yes/No)







J3. Date J3. Date J3. Date J3. Date ARV (Yes/No) Count Viral load Stage J4. Date J4. Date J4. Date J4. Date Viral load ARV (Yes/No) Stage Count J5. Notes: include here if patient is receiving CPT or IPT treatment and date initiated

End of Survey

D.3. Health Facility Questionnaire

TB AND HIV FACILITY SURVEY

FACILITY SURVEY: TB and/or HIV Services		FINAL	A	August 25, 2016			
A. Facility Identification							
A1. Today's Date: (DD-MM-YY)	A2. Oblast	A3. Raion		A4 Data Co	ollector	r ID:	
A5. Facility (where data collected):	A6. Facilit	y ID N	Number:				
A7. Facility type (circle one):		A8. Facility Authority (circle one):					
HIV / AIDS Center	HIV / AIDS Center1			Public facility (government)1			
TB Dispensary		Non-profit / NGO facility2					
2		Private For-profit facility3					
Other	Other6			6			
A9. [<i>START INTERVIEW</i>] I will read a list of "yes" if a patient can receive the service he referrals.		0		•		say	
		Referrals Provided	Org	anization Na	ame		





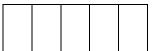
	Yes	No	Yes	No	for Referrals	
	1	0	1	0		
TB Symptom Screening						
TB Diagnostics (lab, xray, clinical)						
TB Outpatient Treatment						
HIV Voluntary Counseling and Testing (VCT)						
IPT for the prevention of TB disease (isoniazid-preventive therapy)						
CPT (Cotrimoxazole preventative therapy)						
ARV or ART (Antiretroviral therapy)						
Medication assisted therapy						
Psychological Counseling						

A10. Next I will list treatment adherence support strategies, identify the one that best describes the facility strategy for TB and HIV therapy?

10.1 <u>TB Treatment</u> 10.2 <u>HIV/AIDS Treatment</u>

Directly observed therapy (DOTS) at facility......11

Directly observed therapy (DOTS) at patient's home22





B. TB and HIV/AIDS Services							
How many staff at this facility provide TB and HIV/AIDS services? Consider administrative staff, nurses and doctors separately.	(a) TB Services	(b) HIV/AIDS Services	(c) Services for the Coinfected				
B1.1. Administrative							
B1.2. Nurses							
B1.3. Doctor							
B2. How many beds are available for inpatient treatment for each service?							
During the following time periods, record the number of TB patients, Newly Registered HIV patients and those coinfected served at this facility	(a) TB Patients receiving Intensive Treatment	(b) Newly Registered HIV Patients	(c) TB-HIV Coinfected Patients				
B3.1. In the past 30 days							
B3.2. April 01, 2014 –June 30, 2015							







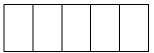


For the following TB screening and testing services , identify availability and average time from testing to receiving results:	(a) Availability	(b) Average time from test to results received
B4. TB Symptom Screening –when patient is evaluated for cough, fever, night sweats, and weight loss, per protocol	Yes, at this facility1 No, not at this facility0	Same day1 < 1 week2 1-2 weeks3 > 2 weeks4
B5. TB sputum microscopy–sputum sample examined to determine smear-positive or smear-negative TB	Yes, at this facility1 Specimen collected and sent to outside lab2 Patient referred elsewhere3	Same day1 < 1 week2 1-2 weeks3 > 2 weeks4
B6. <i>Xpert</i> (or other nucleic acid amplification test NAAT) –sputum sample analyzed with <i>Xpert</i> to identify TB and drug resistant TB	Yes, at this facility1 Specimen collected and sent to outside lab2 Patient referred elsewhere3	Same day1 < 1 week2 1-2 weeks3 > 2 weeks4
B7. TB culture–sputum sample cultured to identify active TB	Yes, at this facility1 Specimen collected and sent to outside lab2 Patient referred elsewhere3	Same day1 < 1 week2 1-2 weeks3 > 2 weeks4
B8. X-Ray –chest xray performed to identify TB pulmonary infection	Yes, at this facility1 Specimen collected and	Same day1 < 1 week2





	sent to outside lab2	1-2 weeks
	Patient referred elsewhere3	> 2 weeks4
		Same day1
B9. Clinical Evaluation –physical	Yes, at this facility1	< 1 week2
examination to determine TB diagnosis	Patient referred elsewhere3	1-2 weeks3
		> 2 weeks4
P10 Other TP Discretion	Yes, at this facility1	Same day1
B10. Other TB Diagnostics:	Specimen collected and	< 1 week2
	sent to outside lab2	1-2 weeks3
	Patient referred elsewhere3	> 2 weeks4



Data Collector ID Number:



For the following HIV screening and testing services , identify availability and average time from testing to receiving results:	(a) Availability	(b) Average time from test to results received
B11. HIV Voluntary Counseling	Yes, at this facility1 Patient referred elsewhere3	Same day1 < 1 week2 1-2 weeks3 > 2 weeks4
B12. HIV Voluntary Testing with rapid HIV antibody test (R <i>apid Test Kit</i>)	Yes, at this facility1 Specimen collected and sent to outside lab2 Patient referred elsewhere3	Same day1 < 1 week2 1-2 weeks3 > 2 weeks4
B13. HIV Voluntary Testing with Enzyme immunoassay (ELA) test	Yes, at this facility1 Specimen collected and sent to outside lab2 Patient referred elsewhere3	Same day1 < 1 week2 1-2 weeks3 > 2 weeks4
B14. HIV Voluntary Testing with Western Blot test	Yes, at this facility1 Specimen collected and sent to outside lab2 Patient referred elsewhere3	Same day1 < 1 week2 1-2 weeks3 > 2 weeks4
B15. HIV Voluntary Testing with PCR (Polymerase chain reaction) test	Yes, at this facility1 Specimen collected and	Same day1 < 1 week2





	sent to outside lab2	1-2 weeks3
	Patient referred elsewhere3	> 2 weeks4
	Yes, at this facility1	Same day1
	Specimen collected and	< 1 week2
B16. CD4 Count	sent to outside lab2	1-2 weeks3
	Patient referred elsewhere3	> 2 weeks4
	Yes, at this facility1	Same day1
	Specimen collected and	< 1 week2
B17. Viral Load	sent to outside lab2	1-2 weeks
	Patient referred elsewhere3	> 2 weeks4





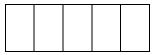
For the following treatments, identify availability	For the following treatments, identify availability at facility by disease diagnosis:													
Diagnosis:	(a)	(b)	(c)	(d)	(e)									
Treatment:	Smear-Positive TB	Smear-Neg TB	Smear-Positive TB	Smear-Neg TB	No TB Diagnosed									
	HIV-Negative	HIV-Negative	HIV-Positive	HIV-Positive	HIV-Positive									
B18. Is TB Intensive Treatment offered to patients at this facility? Yes1 < <i>complete table</i> >	Inpatient1	Inpatient1	Inpatient1	Inpatient1										
No0 < <i>skip to B19></i>	Outpatient2	Outpatient2	Outpatient2	Outpatient2										
B19. Is TB Continuation Treatment offered to patients at this facility? Yes1 < <i>complete table</i> > No0 < <i>skip to B20</i> >	Inpatient1 Outpatient2	Inpatient1 Outpatient2	Inpatient1 Outpatient2	Inpatient1 Outpatient2										
B20. Is Antiretroviral Therapy (ART/ARV) offered to patients at this facility? Yes1 < <i>complete table</i> >			Inpatient1 Outpatient2	Inpatient1 Outpatient2	Inpatient1 Outpatient2									



Data Collector ID Number:



No0 < <i>skip to B21></i>					
B21. Is Isoniazid Prevention Therapy (IPT) offered to patients at this facility? Yes1 < complete table> No0 < skip to B22>					Inpatient1 Outpatient2
B22. Is Cotrimoxazole Prevention Therapy (CPT) offered to patients at this facility? Yes1 < complete table> No0 < skip to B23>			Inpatient1 Outpatient2	Inpatient1 Outpatient2	Inpatient1 Outpatient2
 B23. Is Medication assisted therapy offered to patients at this facility? Yes1 < complete table> No0 < skip to C1> 	Inpatient1 Outpatient2	Inpatient1 Outpatient2	Inpatient1 Outpatient2	Inpatient1 Outpatient2	Inpatient1 Outpatient2





C. Drug Shortages

C1. Did this facility experience any drug shortages lasting more than 30 days in April 01, 2014 –June 30, 2015? This includes a situation where the number of patients eligible for treatment exceeds the drug supply

		Yes No	Don't Know	
C1.1	TB Intensive Treatment 1 0	8		
C1.2	2 Medication assisted therapy 1 0 8	5		
C1.3	3 Antiretroviral therapy 1 0 8	3		
C1.4	HIV Test Kits 1 0	8		
< if yes i	to any of the above, then complete drug shortage table> <if "0"="" i<="" no="" td="" then=""><td>END SURV</td><td>/EY></td><td></td></if>	END SURV	/EY>	

C2. Complete if this facility experienced <u>TB drug shortages</u> that lasted longer than 30 days in April 01, 2014 – June 30, 2015.

YEAR: April 01, 2014 –June 30,			Mo	nths	suff	erin	g fro	Consequence of Shortage						
2015 Drug shortage >30 days	J	F	М	А	М	J	J	А	S	Ο	Ν	D	<code></code>	Other: describe
TB Drug 1														
TB Drug 2														
TB Drug 3														
TB Drug 4														

Facility ID Number:							Data Collector ID Number:									
TB Other																
Coding for Conseque	ence	of sh	ortag	ge:												
Waitlisted patient					 		1 1	Refer	red p	atient	to ai	nother fac	llity		 4	ł
Switched treatment dru	1gs				 	2		Other						••••	 	•
Stopped treatment					 	3			· · · · · · ·	0						



C3. Complete if this facility experienced <u>Medication Assisted Therapy drug shortages</u> that lasted longer than 30 days in April 01, 2014 –June 30, 2015.

YEAR: April 01, 2014 –June 30,			Мо	nths	suff	erin	Consequence of Shortage							
2015			20	014					20	15				
Drug shortage >30 days	J	А	S	0	N	D	J	F	М	А	М	J	<code></code>	Other: describe
Substitution Drug 1														
Substitution Drug 2														
Substitution Drug 3														
Coding for Conseque	ence	of sh	ortag	ge:										
Waitlisted patient							••••	.1]	Refer	red p	atien	t to a	nother facil	ity4
Switched treatment dru	1gs						2							
Stopped treatment														

C4. Complete if this facility experienced <u>ARV drug shortages</u> that lasted longer than 30 days in April 01, 2014 – June 30, 2015 or if a lack of ARV drugs limited the initiation of therapy during April 01, 2014 – June 30, 2015?

YEAR: April 01,			Mo	nths	suff	erin	g fro	Con	sequence of Shortage					
2014 –June 30, 2015	2014							20	15					
Drug limitations	J	А	S	0	Ν	D	J	F	М	А	М	J	<code></code>	Other: describe
ARV Drug 1														





ARV Drug 2														
ARV Drug 3														
ARV Drug 4														
Coding for Consequence of shortage:														
Waitlisted patient4 Referred patient to another facility														
						Other								
Stopped treatment6														

C5. Complete if this facility experienced <u>HIV Test Kit shortages</u> that lasted longer than 30 days in April 01, 2014 –June 30, 2015

YEAR: April 01, 2014 –June 30,		Months suffering from shortages											Consequence of Shortage		
2015	2014						2015								
Drug shortage >30 days	J	А	S	0	N	D	J	F	М	А	М	J	<code></code>	Other: describe	
HIV Test Kits															
Coding for Consequence of shortage:															
Waitlisted patient															
Switched test Other															

D.4. Qualitative Interview Guides

Patient Interview Guide

In-depth interview with coinfected patients, Integration study								
Date of Interview:	Start Time:	AM	PM					
Name of Interviewer:								

Section I: Socio-Demographic Characteristics of Patient

(Extract from medical records/Patient Card)

First diagno	osis: I	HIV	ТВ
Sex:	Female	Male	
Location:	Rural	U	rban
City:			

Section II: Mapping Access to TB/HIV Treatment and Care (Instruction for an Interviewer: please see the map guide below)

Interviewer:

First of all, thank you for your willingness to take part in this interview. Your answers will help us to improve services for the people who live with TB and HIV in Ukraine.

*Warm up questions

How are you doing today?

What are some of the things you enjoy doing? (Possible follow-ups: How often do you get to do that these days? What would make it easier for you to do this more often? What is your best memory of doing that? What do you usually do when you have free time?)

I would like to learn more about the process or steps you have gone through to receive TB and HIV services. I'm going to record them on this "map" so we can walk through the steps together.

Let's start from the beginning, how did you know you had TB or HIV? What happened next? (Probe for first visit to a health facility and go to POINT A on map)

Instruction for an Interviewer: Based on the respondent's description, draw a path from starting point to Point A on the diagram, share it with the respondent and use to facilitate further discussion.

Point A:

- 1. What was the name and location of this facility?
- 2. How long did it take go get here?
- 3. What kind of services did you receive here?
- 4. Were you satisfied with the services? Why or why not?
- 5. What could have been done better?
- 6. What happened next? If referred to a different facility go to "Point B"

Point B:

- 1. What was the name and location of this facility?
- 2. How many hours/days between the services you received at Point A & Point B?

*Repeat remaining questions 2-6 as above in Point A

Instruction for an Interviewer: Continue with asking what was next and recording the various points on the diagram until the patient says they have shared the last step in the process. If they skip a key step in the pathway (testing, starting treatment, etc.), probe by asking whether they received that service and, if so, at what point in the process this was.

Ask the following questions regarding access to and use of both HIV and TB services if they were not discussed during the discussion on the process diagram.

1. How easy/difficult is it for you to access both services? Please explain.

2. How easy/difficult is it for you to use both services? Please explain.

3. How easy/difficult is it for you to receive ARV and TB drugs? Please explain.

4. Do HIV and TB providers communicate with each other regarding your treatment? If yes, how do they communicate?)

Section III: Reflections on mapping

Interviewer:

Thank you for taking us through these important steps. Reflecting on your experience do you have any additional thoughts on how services can be improved for patients like yourself when you need both TB and HIV services?

Do you have any questions for me?

Thank you very much.

End Time: _____ AM PM

Map Guide for Interviewers

*Need to confirm in-country

TB Providers Interview Guide

In depth interview with TB providers, TB/HIV Integration Study								
Date of Interview:	Start Time:	_AM PM						
Name of Interviewer:								
Sex: MaleFemale								
Location: Rural Urban								
Organization:								
Job title:								
Length of time in current position:								
City:								

For TB Facility:

т	36 .	1		C		•
	Manning	out the	nrocess	tor	providing	services.
1.	- mapping	out the	process	TOT	providing	001 10000

Please describe a typical process for providing services at your facility when a patient comes in from start to finish

Instruction for an Interviewer: Based on the respondent's description, draw a diagram, share it with the respondent (you may draw it together or you may draw as the respondent talks) and use to facilitate further discussion.

Ask the following questions:

At point A:

-Who are your patients? How do they end up coming to your facility? Who refers them? Where do they come first in your facility? What services do they receive at this point? What prevents/might prevent patients from receiving services at Point A? How is this different, if at all, for different groups of patients (e.g., homeless, alcoholics, etc.)?

-What helps patients to receive services at Point A? How is this different, if at all, for different groups of patients (e.g., homeless, alcoholics, etc.)?

Where do they go next?

Ask these same set of questions for all points on the diagram:

When a patient goes from point A to point B, what services does he/she receive at point B? Is there any place different that he/she may go? (i.e., is it always B that they go to?) If not, what is/are the other possible place(s)? What services does he/she receive there?

-What prevents/might prevent patients from accessing services at Point B? How is this different, if at all, for different groups of patients (e.g., homeless, alcoholics, etc.)?

-What helps patients to access services at Point B? How is this different, if at all, for different groups of patients (e.g., homeless, alcoholics, etc.)?

-Think back to how the process was five years ago-Please describe for me any differences compared to then?-How could things be improved?

Once you have gone through the process diagram and talked through all the questions for each point, move on to the next sections. Ask only those questions that were not discussed during the work on the process diagram.

II. <u>Policy</u>

Now I have some questions for you related to laws, policies, and protocols.

Are there any laws or regulations that prevent you from providing appropriate TB/HIV diagnosis and treatment services? What are those laws or regulations?

Are there any additional laws or regulations that are needed for providing appropriate TB/HIV diagnosis and treatment services? What are those laws or regulations?

Do you have a protocol or policy that you follow for <u>screening</u>, <u>diagnosis and treatment</u> of HIV in TB patients? Could you please show me this protocol/policy?

Do you have a protocol or policy that you follow for <u>referring TB patients to HIV facilities</u> for testing or treatment? Could you please show where the protocol is?

Overall, how do you think the current referral system is working?

What would you do to improve the referral system between TB and HIV services?

III. Training/mentoring

The next few questions I have are on any training, mentoring, or supportive supervision you may have received.

Please describe any training you have received on integration of TB/HIV services? (*Probe on when/who/what/etc.*) How, if at all, was the training helpful? (*if not mentioned, probe*: how, if at all, did it help you in patient treatment? How satisfied are you with this training? Please describe any additional training or refresher training needs on this topic.

Please describe for me any other training (in addition to what you have already described) you think would be helpful for you. (*if they name something else, probe on how they think it would help them*)

Please describe for me any mentoring/supportive supervision visits you have received? (probe: who, what, where, etc.) How satisfied are you with these visits? What additional support do you need?

What support have you received from the STbCU project over the last five years? (*Interviewer: Please ask about any type of support, including trainings and mentoring visits*). What is your opinion on this support?

IV. Information System

Do TB registers reflect patients HIV status? If yes, since when have they reflected patients HIV status?

Does the patient card include both TB and HIV treatment information? If yes, since when has the patient card included both TB and HIV treatment information? How do you receive HIV treatment information (what is the source, who provides with this information, how frequently)? Are there regular meetings between TB and HIV services, either general or specific to patient management? If yes, how often do you meet?

What is your opinion on communication between services?

How (if relevant) communication between services could be improved?

Is there a regular collaborative review of recorded data between TB facilities and AIDS Centers?

- Number of patients seen from either system, referred, followed up, etc.?
- Do you receive routine supervisory visits to examine registers, look at referrals, etc.? By whom (TB or HIV supervisors)? How often?
- Are these visits generally supportive or punitive?
- Is mentoring provided as part of this?

Do you have a TB/HIV referral monitoring database? What is your opinion on its utility?

V. <u>Patient data flow (ask these questions if time allows)</u>

Please describe the process of recording patient data at your health facility. What data are being recorded and to what document?

What data are being recorded in patients' charts? What additional data are being recorded? Who records these data and how often?

When new information is entered, is it shared with the other service; if so, how? (face to face meetings, phone calls, mail, email, shared database, etc.)

Please describe the process of recording patient data at your health facility five years ago. What changed in the last five years?

These are the only questions that I have for you today. Is there anything else you would like to tell me?

Do you have any questions for me?

Thank you very much for your time and for speaking with me about your work on the intervention.

End Time: _____ AM PM

HIV Providers Interview Guide

In depth interview with HIV providers, TB/HIV Integration Study

Date of Interview: _____ AM PM

180 Evaluation of the Impact of the TB-HIV Integration Strategy on Treatment Outcomes

Name of Interviewer:				
Sex: MaleFemale				
Location: Rural Urban				
Organization:				
Job title:				
Length of time in current position:				
City:				

For HIV Facility:

VI. Mapping out the process for providing services

Please describe a typical process for providing services at your facility when a patient comes in from start to finish

Instruction for an Interviewer: Based on the respondent's description, draw a diagram, share it with the respondent (you may draw it together or you may draw as the respondent talks) and use to facilitate further discussion.

Ask the following questions:

At point A:

-Who are your patients? How do they end up coming to your facility? Who refers them? Where do they come first in your facility? What services do they receive at this point? What prevents/might prevent patients from receiving services at Point A? How is this different, if at all, for different groups of patients (e.g., homeless, alcoholics, etc.)?

-What helps patients to receive services at Point A? How is this different, if at all, for different groups of patients (e.g., homeless, alcoholics, etc.)?

Where do they go next?

Ask these same set of questions for all points on the diagram:

When a patient goes from point A to point B, what services does he/she receive at point B? Is there any place different that he/she may go? (i.e., is it always B that they go to?) If not, what is/are the other possible place(s)? What services does he/she receive there?

-What prevents/might prevent patients from accessing services at Point B? How is this different, if at all, for different groups of patients (e.g., homeless, alcoholics, etc.)?

-What helps patients to access services at Point B? How is this different, if at all, for different groups of patients (e.g., homeless, alcoholics, etc.)?

-Think back to how the process was five years ago-Please describe for me any differences compared to then?-How could things be improved?

Once you have gone through the process diagram and talked through all the questions for each point, move on to the next sections. Ask only those questions that were not discussed during the work on the process diagram.

VII. <u>Policy</u>

Now I have some questions for you related to laws, policies, and protocols.

Are there any laws or regulations that prevent you from providing appropriate HIV/TB diagnosis and treatment services? What are those laws or regulations?

Are there any additional laws or regulations that are needed for providing appropriate HIV/TB diagnosis and treatment services? What are those laws or regulations?

Do you have a protocol or policy that you follow for <u>screening</u>, <u>diagnosis and treatment</u> of TB in HIV patients? Could you please show me this protocol/policy?

Do you have a protocol or policy that you follow for <u>referring HIV patients to TB facilities</u> for testing or treatment? Could you please show where the protocol is?

Overall, how do you think the current referral system is working?

What would you do to improve the referral system between HIV and TB services?

VIII. <u>Training/mentoring</u>

The next few questions I have are on any training, mentoring, or supportive supervision you may have received.

Please describe any training you have received on integration of HIV/TB services? (*Probe on when/who/what/etc.*) How, if at all, was the training helpful? (*if not mentioned, probe*: how, if at all, did it help you in patient treatment? How satisfied are you with this training? Please describe any additional training or refresher training needs on this topic.

Please describe for me any other training (in addition to what you have already described) you think would be helpful for you. (*if they name something else, probe on how they think it would help them*)

Please describe for me any mentoring/supportive supervision visits you have received? (probe: who, what, where, etc.) How satisfied are you with these visits? What additional support do you need?

What support have you received from the STbCU project over the last five years? (*Interviewer: Please ask about any type of support, including trainings and mentoring visits*). What is your opinion on this support?

IX. Information System

Do HIV registers reflect patients TB status? If yes, since when have they reflected patients TB status?

Does the patient card include both HIV and TB treatment information? If yes, since when has the patient card included both HIV and TB treatment information? How do you receive TB treatment information (what is the source, who provides with this information, how frequently)? Are there regular meetings between HIV and TB services, either general or specific to patient management? If yes, how often do you meet?

What is your opinion on communication between services?

How (if relevant) communication between services could be improved?

Is there a regular collaborative review of recorded data between AIDS Centers and TB facilities?

- Number of patients seen from either system, referred, followed up, etc.?
- Do you receive routine supervisory visits to examine registers, look at referrals, etc.? By whom (HIV or TB supervisors)? How often?
- Are these visits generally supportive or punitive?
- Is mentoring provided as part of this?

Do you have a TB/HIV and referral monitoring database? What is your opinion on its utility?

X. <u>Patient data flow (ask these questions if time allows)</u>

Please describe the process of recording patient data at your health facility. What data are being recorded and to what document?

What data are being recorded in patients' charts? What additional data are being recorded? Who records these data and how often?

When new information is entered, is it shared with the other service; if so, how? (face to face meetings, phone calls, mail, email, shared database, etc.)

Please describe the process of recording patient data at your health facility five years ago. What changed in the last five years?

These are the only questions that I have for you today. Is there anything else you would like to tell me?

Do you have any questions for me?

Thank you very much for your time and for speaking with me about your work on the intervention.

End Time: _____ AM PM

Small Group Discussion with TB Providers Guide

Small group discussions with TB providers, TB/	HIV Integration Study		
Date of group discussion:	Start Time:	AM	РМ
Name of facilitator:			_

Health facility type: TB HIV

Health facility name: _____

City: _____

Welcome. Thank you for participating in this discussion. My name is ______ and assisting me is ______ (*name*). We are from IFAK. We have asked you to participate in this discussion because you are provided services to patients with TB and coinfected patients. We would like to hear from you about practices related to screening, diagnosis and treatment in your facility. We would like to spend 60-90 minutes talking with you about these topics.

I am the moderator and I will be guiding our discussion today. It is my job to make sure that we get to all of the topics that we would like to cover. My assistant will be taking notes on our discussion. We will not be writing down your name, so everything that you say during the discussion today will remain anonymous. We will not identify anyone by name in our report.

For TB Facility:

XI. Mapping out the process for providing services to patients

Supplies needed: flipcharts or white board and markers.

Ask the participants to prepare a visual presentation of a typical process for providing services at their facility when a patient comes in from start to finish.

Ask the group to show all the points of the process that they can think of.

Ask the group to list all services that patients receive at each point. Labels or symbols can be used to identify different services.

Allow the group to prepare the diagram on their own, and observe the process.

Once the diagram is ready, ask a volunteer to describe the process using the flow diagram.

Ask the following questions:

At point A:

-Who are your patients? How do they end up coming to your facility? Who refers them? Where do they come first in your facility? What services do they receive at this point? What prevents/might prevent patients from receiving services at Point A? How is this different, if at all, for different groups of patients (e.g., homeless, alcoholics, etc.)?

-What helps patients to receive services at Point A? How is this different, if at all, for different groups of patients (e.g., homeless, alcoholics, etc.)?

Where do they go next?

Ask these same set of questions for all points on the diagram:

When a patient goes from point A to point B, what services does he/she receive at point B? Is there any place different that he/she may go? (i.e., is it always B that they go to?) If not, what is/are the other possible place(s)? What services does he/she receive there?

-What prevents/might prevent patients from accessing services at Point B? How is this different, if at all, for different groups of patients (e.g., homeless, alcoholics, etc.)?

-What helps patients to access services at Point B? How is this different, if at all, for different groups of patients (e.g., homeless, alcoholics, etc.)?

-Think back to how the process was five years ago-Please describe for me any differences compared to then?

-How could things be improved?

Once you have gone through the process diagram and talked through all the questions for each point, move on to the next sections. Ask only those questions that were not discussed during the work on the process diagram.

XII. <u>Policy</u>

Please describe any laws or regulations that prevent you from providing appropriate TB/HIV diagnosis and treatment services? (*probe for additional laws/regulations*)

Overall, how do you think the current referral system is working?

Probe, depending on response(s): Please describe why you think it is working well? Please describe why you think it is not working?

What would you do, if anything, to improve the referral system between TB and HIV services?

XIII. <u>Training</u>

Please describe any training that is provided for TB service staff providing HIV screening, diagnosis and treatment? How does this training help staff, if at all, to better treat patients?

Please describe any training staff receive on provider-initiated HIV testing and counseling? How has this training help staff to better treat patients?

What additional training do you think is needed?

Please describe any mentoring/supportive supervision visits staff receive? (*Probe on frequency, satisfaction in general, etc.*) What, if any, additional support do staff need?

What support have staff received from the STbCU project over the last five years? (*Interviewer: Please ask about any type of support, including trainings and mentoring visits.*) How helpful has this support been? What do you think should be done differently in the future?

XIV. Information System

Do TB registers reflect patients HIV status? If yes, since when have they reflected patients HIV status?

Does the patient card include both TB and HIV treatment information? If yes, since when has the patient card included both TB and HIV treatment information? How do you receive HIV treatment information (what is the source, who provides with this information, how frequently)? Are there regular meetings between TB and HIV services, either general or specific to patient management? If yes, how often do you meet?

What is your opinion on communication between services?

How (if relevant) communication between services could be improved?

Is there a regular collaborative review of recorded data between TB facilities and AIDS Centers?

• Number of patients seen from either system, referred, followed up, etc.?

- Do you receive routine supervisory visits to examine registers, look at referrals, etc.? By whom (TB or HIV supervisors)? How often?
- Are these visits generally supportive or punitive?
- Is mentoring provided as part of this?

Do you have a TB/HIV referral monitoring database? What is your opinion on its utility?

XV. <u>Patient data flow (ask these questions if time allows)</u>

Please describe the process of recording patient data at your health facility. What data are being recorded and to what document?

What data are being recorded in patients' charts? What additional data are being recorded? Who records these data and how often?

When new information is entered, is it shared with the other service; if so, how? (face to face meetings, phone calls, mail, email, shared database, etc.)

Please describe the process of recording patient data at your health facility five years ago. What changed in the last five years?

These are the only questions that I have for you today. Is there anything else you would like to tell me?

Do you have any questions for me?

Thank you very much for your time and for speaking with me about your work on the intervention.

End Time: _____ AM PM

Small Group Discussion with HIV Providers Guide

Small group discussio	ons with HIV providers, TB/HI	V Integration Study		
Date of group discuss	ion:	Start Time:	_AM	PM
Name of facilitator:				-
Health facility type:	TB HIV			
Health facility name:				
City:				

Welcome. Thank you for participating in this discussion. My name is _______ and assisting me is ______ (*name*). We are from IFAK. We have asked you to participate in this discussion because you are provided services to patients with HIV and coinfected patients. We would like to hear from you about practices related to screening, diagnosis and treatment in your facility. We would like to spend 60-90 minutes talking with you about these topics.

I am the moderator and I will be guiding our discussion today. It is my job to make sure that we get to all of the topics that we would like to cover. My assistant will be taking notes on our discussion. We will not be writing down your name, so everything that you say during the discussion today will remain anonymous. We will not identify anyone by name in our report.

For TB Facility:

XVI. Mapping out the process for providing services to patients

Supplies needed: flipcharts or white board and markers.

Ask the participants to prepare a visual presentation of a typical process for providing services at their facility when a patient comes in from start to finish.

Ask the group to show all the points of the process that they can think of.

Ask the group to list all services that patients receive at each point. Labels or symbols can be used to identify different services.

Allow the group to prepare the diagram on their own, and observe the process.

Once the diagram is ready, ask a volunteer to describe the process using the flow diagram.

Ask the following questions:

At point A:

-Who are your patients? How do they end up coming to your facility? Who refers them? Where do they come first in your facility? What services do they receive at this point? What prevents/might prevent patients from receiving services at Point A? How is this different, if at all, for different groups of patients (e.g., homeless, alcoholics, etc.)?

-What helps patients to receive services at Point A? How is this different, if at all, for different groups of patients (e.g., homeless, alcoholics, etc.)?

Where do they go next?

Ask these same set of questions for all points on the diagram:

When a patient goes from point A to point B, what services does he/she receive at point B? Is there any place different that he/she may go? (i.e., is it always B that they go to?) If not, what is/are the other possible place(s)? What services does he/she receive there?

-What prevents/might prevent patients from accessing services at Point B? How is this different, if at all, for different groups of patients (e.g., homeless, alcoholics, etc.)?

-What helps patients to access services at Point B? How is this different, if at all, for different groups of patients (e.g., homeless, alcoholics, etc.)?

-Think back to how the process was five years ago-Please describe for me any differences compared to then?

How could things be improved?

Once you have gone through the process diagram and talked through all the questions for each point, move on to the next sections. Ask only those questions that were not discussed during the work on the process diagram.

XVII. Policy

Please describe any laws or regulations that prevent you from providing appropriate HIV/TB diagnosis and treatment services? (*probe for additional laws/regulations*)

Overall, how do you think the current referral system is working?

Probe, depending on response(s): Please describe why you think it is working well? Please describe why you think it is not working?

What would you do, if anything, to improve the referral system between HIV and TB services?

XVIII. <u>Training</u>

Please describe any training that is provided for HIV service staff providing TB screening, diagnosis and treatment? How does this training help staff, if at all, to better treat patients?

What additional training do you think is needed?

Please describe any mentoring/supportive supervision visits staff receive? (*Probe on frequency, satisfaction in general, etc.*) What, if any, additional support do staff need?

What support have staff received from the STbCU project over the last five years? (*Interviewer: Please ask about any type of support, including trainings and mentoring visits.*) How helpful has this support been? What do you think should be done differently in the future?

XIX. Information System

Do HIV registers reflect patients TB status? If yes, since when have they reflected patients TB status?

Does the patient card include both HIV and TB treatment information? If yes, since when has the patient card included both HIV and TB treatment information? How do you receive TB treatment information (what is the source, who provides with this information, how frequently)? Are there regular meetings between HIV and TB services, either general or specific to patient management? If yes, how often do you meet?

What is your opinion on communication between services?

How (if relevant) communication between services could be improved?

Is there a regular collaborative review of recorded data between AIDS Centers and TB facilities?

- Number of patients seen from either system, referred, followed up, etc.?
- Do you receive routine supervisory visits to examine registers, look at referrals, etc.? By whom (HIV or TB supervisors)? How often?
- Are these visits generally supportive or punitive?
- Is mentoring provided as part of this?

Do you have an HIV/TB referral monitoring database? What is your opinion on its utility?

XX. <u>Patient data flow (ask these questions if time allows)</u>

Please describe the process of recording patient data at your health facility. What data are being recorded and to what document?

What data are being recorded in patients' charts? What additional data are being recorded? Who records these data and how often?

When new information is entered, is it shared with the other service; if so, how? (face to face meetings, phone calls, mail, email, shared database, etc.)

Please describe the process of recording patient data at your health facility five years ago. What changed in the last five years?

These are the only questions that I have for you today. Is there anything else you would like to tell me?

Do you have any questions for me?

Thank you very much for your time and for speaking with me about your work on the intervention.

End Time: _____ AM PM

STbCU Project Coordinators Interview Guide

In-depth interview with the STbCU project staff, Integration Study					
Date of Interview:	Start Time:	AM PM			
Name of Interviewer:					
Sex: Female Male					
Organization:					
Job title:					
Length of time in current position:	:				
City:					

You are working on promoting integration between TB and HIV services. Today, we would like to understand more about your experiences in working in this area.

1. First, I would like to know more about your responsibilities at STbCU.

1.a. What are your overall responsibilities at STbCU?

1.b. How long have you been working for STbCU?

2. Please describe your responsibilities related to TB-HIV integration.

3. Please tell us what activities were planned in order to strengthen integration of TB and HIV services.

4. In your experience, how did the integration work go?

4.a. What worked well? Please share a specific example.

4.b. What did not work well? Please share a specific example?

4.c. Please describe any adaptations you made to planned activities? (what/when/why?)

4.d. What are some challenges that you encountered in your work promoting integration between services? (Probes: Law/legislation, system constraints, providers, support from the project, lack of time, etc.)

4.d.i. What aspects of the integration program are most difficult to implement?

4.d.ii. What barriers exist for providing high quality integration services?

5. What are some facilitators that help you do your job? (What helps you do your job well?)

6. What makes it difficult to do your job? Why?

7. If you had a chance to work on promoting TB-HIV integration again, what would you do differently?

8. What suggestions do you have for those who are planning to conduct integration activities?

9. How could the integration be enhanced to improve patients' health?

10. These are the only questions that I have for you today. Is there anything else you would like to tell me?

11. Do you have any questions for me?

Thank you very much for your time and for speaking with me about your work on the integration.

End Time: _____ AM PM

MEASURE Evaluation

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