EVALUATION

Strengthening Tuberculosis Control in Ukraine

Evaluation of the Impact of a Social Support Strategy on Treatment Outcomes

May 2018

USAID FROM THE AMERICAN PEOPLE

PEPFAR

MEASURE Evaluation

ABSTRACT

This impact evaluation of the Strengthening Tuberculosis Control in Ukraine project examines the relationship between the social support (SS) strategy and changes in tuberculosis (TB) treatment outcomes. The study employed a mixed methods approach, with a quasi-experimental quantitative evaluation design, complemented by qualitative interviews to inform the findings. We used a simple model to examine whether and by how much treatment default rates changed at the patient population level as the SS program was implemented or dropped. Data collection included surveys of medical facilities, patient chart abstractions, and interviews with patients, nurses, and program staff. Multivariate regression analyses produced estimates for the impact of the SS program on treatment default and death. The evaluation found that participation in the SS intervention improved TB treatment outcomes among high-risk (HR) patients. The intervention cohort had higher treatment success and lower likelihood of treatment default and dying than the other two HR comparison groups. The intervention cohort had similar TB treatment outcomes as low-risk (LR) cohorts. Modeling suggests that the 2014 SS program reduced the population-level default rate in the study regions by approximately 20 percent from what it might have been without it. The study identified outpatient treatment adherence barriers for patients at risk of treatment default in Ukraine, and described how the SS program worked to address most of the barriers. Based on the study findings, we recommend providing the SS program to HR patients to promote treatment adherence and improve treatment outcomes.

EVALUATION

Strengthening Tuberculosis Control in Ukraine

Evaluation of the Impact of a Social Support Strategy on Treatment Outcomes

Zulfiya Charyeva, PhD, Team Leader
Sian Curtis, PhD
Stephanie Mullen, PhD

May 2018

MEASURE Evaluation
University of North Carolina at Chapel Hill
123 W. Franklin Street, Suite 330
Chapel Hill, NC 27516 USA
Phone: +1 919-445-9350 | measure@unc.edu
www.measureevaluation.org

This publication was produced with the support of the United States Agency for International Development (USAID) under the terms of MEASURE Evaluation cooperative agreement AID-OAA-L-14-00004. MEASURE Evaluation is implemented by the Carolina Population Center, University of North Carolina at Chapel Hill in partnership with ICF International; John Snow, Inc.; Management Sciences for Health; Palladium; and Tulane University. Views expressed are not necessarily those of USAID or the United States government. This report was prepared independently by Zulfiya Charyeva, MEASURE Evaluation/Palladium (team leader), Sian Curtis, MEASURE Evaluation/UNC, and Stephanie Mullen, MEASURE Evaluation/JSI. TRE-18-007

ISBN: 978-1-64232-004-6

USAID FROM THE AMERICAN PEOPLE

PEPFAR

MEASURE Evaluation

ACKNOWLEDGMENTS

This impact evaluation of the Strengthening Tuberculosis Control in Ukraine (STbCU) project was conducted by MEASURE Evaluation—funded by the United States Agency for International Development (USAID) and the United States President's Emergency Plan for AIDS Relief (PEPFAR)—for the USAID mission in Ukraine. The principal investigator of the overall evaluation was Sian Curtis (University of North Carolina at Chapel Hill [UNC-CH]). The Ukraine-based research partner, the IFAK Institut, implemented the data collection and assisted with data analyses. Data analysis and report writing were supported by Palladium, UNC-CH, John Snow, Inc., and IFAK. Many individuals and organizations made important contributions to this report. They are listed below by institutional affiliation and in alphabetical order in each institution:

- IFAK: Sergey Govorukha, Natalya Romanenko, Tatyana Senik, and Olga Zaliznyak
- John Snow, Inc: Stephanie Mullen
- Palladium: Zulfiya Charyeva
- UNC-CH: Smisha Agarwal, Sian L. Curtis, Jessica Fehringer, Martha Priedman Skiles, and Chirayath M Suchindran
- USAID: Anna Blyumina, Ana Scholl, Erika Vitek

The authors recognize the contributions of several parties, without which this study would not have been possible. Our appreciation goes to the Government of Ukraine, the Ministry of Health, and its Public Health Center for their support of the study.

We also acknowledge the following contributions: Natalya Lytvinenko and Irina Novozhylova, of the Yanovskyi National Institute of Phthisiology and Pulmonology, who were instrumental in obtaining evaluation protocol approvals and permission to collect data from the oblasts and facilities; Dr. Alla Khabarova, the Secretary General of the Ukrainian Red Cross Society (URCS); and Zoya Pogorila, who provided in-depth background information on the mission and operations of the URCS. Many thanks to the excellent research team at IFAK, who worked tirelessly with the local authorities and facilities to collect the data.

We thank the tuberculosis and HIV/AIDS facilities, health providers, and the URCS, who gave their time to abstract data and to answer survey questions for this study. Our thanks also go to the patients, nurses, and STbCU staff who shared their social support program experiences.

Contact information
Zulfiya Charyeva (zulfiya.charyeva@thepalladiumgroup.com)
Sian Curtis (scurtis@email.unc.edu)
Stephanie Mullen (stephanie_mullen@jsi.com)

Suggested citation
MEASURE Evaluation. (2018). *Strengthening Tuberculosis Control in Ukraine: Evaluation of the Impact of a Social Support Strategy on Treatment Outcomes.* Chapel Hill, NC, USA: MEASURE Evaluation, University of North Carolina.

Cover illustration: Denise Todloski, MEASURE Evaluation

CONTENTS

FIGURES

TABLES

ABBREVIATIONS

ART	antiretroviral therapy
ARV	antiretroviral
CPT	cotrimoxazole preventative therapy
DOTS	directly observed treatment, short course
EQ	evaluation question
HF	health facility
HR	high-risk
IDI	in-depth interview
IPT	isoniazid preventive therapy
IRB	Institutional Review Board
LR	low-risk
M&E	monitoring and evaluation
MDR-TB	multidrug-resistant tuberculosis
PLWH	people living with HIV
PEPFAR	President's Emergency Plan for AIDS Relief
SS	social support
STbCU	Strengthening Tuberculosis Control in Ukraine
TB	tuberculosis
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	Ukrainian Red Cross Society
VCT	voluntary counseling and testing
WHO	World Health Organization

EXECUTIVE SUMMARY

Background

The United States Agency for International Development (USAID) mission in Ukraine is testing strategies to combat the problems posed by multidrug-resistant tuberculosis (MDR-TB) and HIV. One strategic mechanism was the Strengthening Tuberculosis Control in Ukraine (STbCU) project, which was implemented in partnership with the Government of Ukraine and national and international stakeholders, with additional funding from the United States President's Emergency Plan for AIDS Relief (PEPFAR). The project's goal was to decrease the country's TB burden and to improve the quality of TB services, including detection and treatment of TB, MDR-TB, and extensively drug-resistant TB. It also aimed to provide prevention and treatment support to counter the rapid growth of TB and HIV coinfection. The project started in March 2012 and ended in April 2017. It built on more than 10 years of USAID's TB assistance in 10 priority geographic areas of the country.

USAID/Ukraine commissioned MEASURE Evaluation to conduct an impact evaluation of the STbCU project. The impact evaluation examined the relationship between select intervention strategies that were implemented and changes in key outcomes. The two strategies of interest were targeting social support (SS) services to improve treatment adherence among those at high-risk (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 coinfected patients. This report presents findings from the impact evaluation of the SS strategy. A separate report has been prepared on the findings from the evaluation of the TB and HIV services integration strategy.

Findings from this evaluation have implications for follow-up interventions in Ukraine, and add to the evidence base for TB strategies more broadly. USAID/Ukraine, the Government of Ukraine, and in-country stakeholders will use the evaluation findings to guide decision making about resource allocation and scaling up TB interventions in Ukraine.

Evaluation Questions

The evaluation answered the following 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?

In Phase 1 of the evaluation (the baseline evaluation report is available at https://www.measureevaluation.org/resources/publications/tr-15-116), we found that the SS program reduced treatment default in the first year of its implementation in 2012. During this Phase 2 impact evaluation, we aimed to repeat the Phase 1 analysis to assess whether this effect held over time. We added a qualitative and modeling component to answer the remaining three evaluation questions (EQs).

Methods

The study employed a mixed methods approach, with a quasi-experimental quantitative evaluation design, complemented by qualitative interviews to inform the findings. We used a simple model to examine whether and by how much treatment default rates changed at the patient population level as the SS program was implemented or dropped. The study sites included Dnipropetrovsk, Kharkiv, and Odessa regions. Sampling included systematic random sampling for patient chart abstractions and purposive sampling for qualitative interviews. Data collection included surveys of medical facilities (N=48), patient chart abstractions (N=2,327), and interviews with patients (N=21), nurses (N=11), and program staff (N=4). TB diagnosis and treatment data were abstracted from medical records for five cohorts of TB patients: patients at high risk of defaulting (HR patients) in 2014 who received SS; HR patients in 2014 who did not receive SS; low-risk (LR) patients in 2014; HR patients in 2015 (when there was no SS program); and LR patients in 2015. Sampling for patient chart abstraction used a random selection of HR patients who received SS in 2014. A matching procedure was then used to select patients from the other four cohorts, matched to the randomly selected index cases. Multivariate regression analyses produced estimates for the impact of the SS program on treatment default and death. Qualitative data analysis was conducted with data from the interview transcripts.

Study Findings

The percentage of facilities providing SS referrals changed considerably, from 79 percent in 2014 to 33 percent in 2015 due to changes in funding between these periods. Over 70 percent of facilities that provided referrals for SS programs in 2014 required a minimum of one risk factor to consider someone as eligible for a referral. Drug shortages were reported in the Dnipropetrovsk region; one health facility (HF) experienced drug shortages lasting longer than 30 days during 2014 and four reported shortages in 2015.

The study populations shared similar demographic profiles across risk cohorts and years. During continuation treatment, HR intervention patients reported fewer interruptions, with 74.6 percent of the cohort reporting no treatment interruptions compared with 71.1 percent of the HR comparison group from 2014, and 54.7 percent of the HR comparison group from 2015.

The HR intervention cohort had much higher treatment success than the other two HR comparison groups (88.4 percent treatment success vs. 67.5 percent and 76.7 percent). TB treatment outcomes for the HR intervention group were very similar to the LR comparison cohorts in 2014 and 2015, with even lower treatment default in the intervention group (1 percent treatment default vs. 3.8 percent and 4.4 percent).

Logistic regression results found that the SS program had a protective effect on treatment default and death. Participation in the SS program lowered the predicted probability of default by 5.1 percentage points compared with the 2014 no intervention HR group, and by 7.8 percentage points compared with the 2015 no intervention HR group. Participation in the SS program lowered the predicted probability of dying by 4.6 percentage points compared with the 2014 no intervention group.

According to our modeling findings, the 2014 SS program reduced the population-level default rate in the three regions by about 20 percent from what it might have been without it. The URCS program in 2014 reduced the number of patients defaulting on treatment by 74 patients. Stopping the URCS program in 2015 was associated with an increase of 31.2 percent in the default rate, and 113 more patients defaulting on treatment compared with what it would have been if the program had been maintained.

In-depth interviews (IDIs) with patients and nurses revealed barriers to outpatient treatment adherence and the ways in which the SS program helped patients address the barriers. Aspects of outpatient TB treatment that made adherence particularly difficult for patients prior to joining the SS program included weakness and side effects from the medicine; length of time required daily to receive outpatient treatment at a HF; HF hours of operation; fear of getting reinfected with another TB strain at a HF; stigma; transportation expenses; and lack of motivation to get treated. The SS program addressed most of the treatment adherence barriers that patients faced when they received outpatient treatment at HFs. The program allowed patients to avoid travel to clinics, which addressed logistical barriers associated with travel time and costs, wait time at HFs, and stigma and fear of further infection. The SS program also supported patients with handling side effects and depression.

Two aspects of the SS program that patients indicated were the most important were convenience (because pills were brought to the patients daily) and support provided by the URCS nurses. Nurses provided emotional, informational, instrumental, and motivational support. It was important to patients that the nurses cared about their well-being and treated them as equals; that nurses provided information and encouraged and motivated them to stay on treatment; and that patients received individual attention from nurses. Patients appreciated and valued the SS program and felt that it helped them to stay in treatment. Patients were often isolated from society and felt lonely. It was important for them to have someone in their lives who cared about them. Most patients and nurses stated that it would be helpful to provide food parcels or food certificates to patients as part of the program.

Conclusions

This evaluation found that participation in the SS intervention improves TB treatment outcomes among HR patients. The Phase 1 and Phase 2 evaluations both found that the SS program has a protective effect on treatment default. The intervention cohort had higher treatment success and lower likelihood of treatment default and dying than the other two HR comparison groups. The intervention cohort had similar TB treatment outcomes as the LR cohorts. The study identifies outpatient treatment adherence barriers for patients at risk of treatment default in Ukraine and describes how the SS program worked to address most of the barriers.

Based on the findings of the study, SS is an effective strategy for reducing treatment default among HR patients and should be considered for all patients at HR of default. To improve this type of SS program in the future, we recommend offering food parcels or food certificates to program recipients to support their treatment. Future programs need to address TB-related stigma in society, to promote treatment adherence and improve the quality of life of patients with TB.

EVALUATION PURPOSE AND QUESTIONS

USAID/Ukraine is testing strategies to combat problems posed by TB and HIV. One strategic mechanism is the STbCU project, which was implemented in partnership with the Government of Ukraine, and national and international stakeholders, with additional funding from the PEPFAR. The project's goal was to decrease the country's TB burden and to improve the quality of TB services, including detection and treatment of TB, MDR-TB, and extensively drug-resistant TB. It also aimed to provide prevention and treatment support to counter the rapid growth of TB and HIV coinfection. The project began in March 2012 and ended in April 2017. It built on more than 10 years of USAID's TB assistance in 10 priority geographic areas of the country.

USAID/Ukraine commissioned MEASURE Evaluation to conduct an impact evaluation of the STbCU project. The impact evaluation examined the relationship between select intervention strategies implemented and changes in key outcomes. The two strategies of interest were 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. This report presents findings from the evaluation of the SS strategy. A separate report has been prepared on the findings from the evaluation of the TB and HIV services integration strategy.

Ukraine is one of several countries struggling with high TB treatment default rates, and USAID is one of the main donors implementing and testing strategies to help combat this problem. In Phase 1 of the evaluation, data were abstracted from client records for a retrospective cohort from 2011 and 2012 to examine whether participation in a SS program affected the likelihood of TB treatment default, treatment success, or treatment failure among HR patients. MEASURE Evaluation found that the SS program in 2012 had a protective effect on treatment default; those in the program were significantly less likely to default on TB treatment compared with HR patients not receiving SS services. (The Phase 1 baseline evaluation report is available at https://www.measureevaluation.org/resources/publications/tr-15-116.) During this Phase 2 impact evaluation, data were abstracted from client records for a retrospective cohort from 2014 and 2015 to examine whether the findings from Phase 1 held over time. In addition, we aimed to estimate the effect of the SS program on the treatment success rate at the population level. Last, we intended to obtain additional information on patients' and providers' perspectives regarding treatment adherence challenges and SS program experiences.

To evaluate the effect of the SS program on TB treatment adherence (henceforth called the SS study), we aimed to answer the following 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?

Findings from this evaluation have implications for follow-up interventions in Ukraine, and add to the evidence base for TB strategies more broadly. USAID/Ukraine, the Government of Ukraine, and in-country stakeholders will use the evaluation findings to guide decision making about resource allocation and scaling up TB interventions in Ukraine.

BACKGROUND

Ukraine is one of 30 countries with the highest burden of MDR-TB (World Health Organization [WHO], 2016). It had an estimated 22,000 new cases of MDR-TB in 2015 (WHO, 2016). Out of 30 countries with a high MDR-TB burden, only four, including Ukraine, had their incidence rate increase by 20 percent or more between 2014 and 2015 (WHO, 2016). Considering the epidemiologic landscape in Ukraine, USAID-supported projects have focused on expanding the availability and improving the quality of directly observed treatment, short course (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. Understanding the effect of efforts to improve treatment adherence and subsequent treatment outcomes among populations at HR for treatment default will provide evidence for improved policy and strategies in the future.

Project Description

The STbCU was a five-year, USAID-funded project designed to decrease the TB burden in Ukraine, leading to a reduction in TB morbidity and mortality. Broadly speaking, the project sought 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 worked with (1) HFs and laboratories to improve screening, diagnosis, and referrals for appropriate treatment, and to improve infection control for the protection of their workers; (2) SS agencies to improve treatment adherence, especially among marginalized populations; and (3) the health system to improve training, reporting, and procurement.

The intervention of interest to this impact evaluation report was the home-visiting program for TB patients vulnerable to treatment default, implemented by the Ukrainian Red Cross Society (URCS) under the STbCU Grant-01. Daily home visits provided delivery of DOTS, along with information materials to encourage full TB treatment adherence.

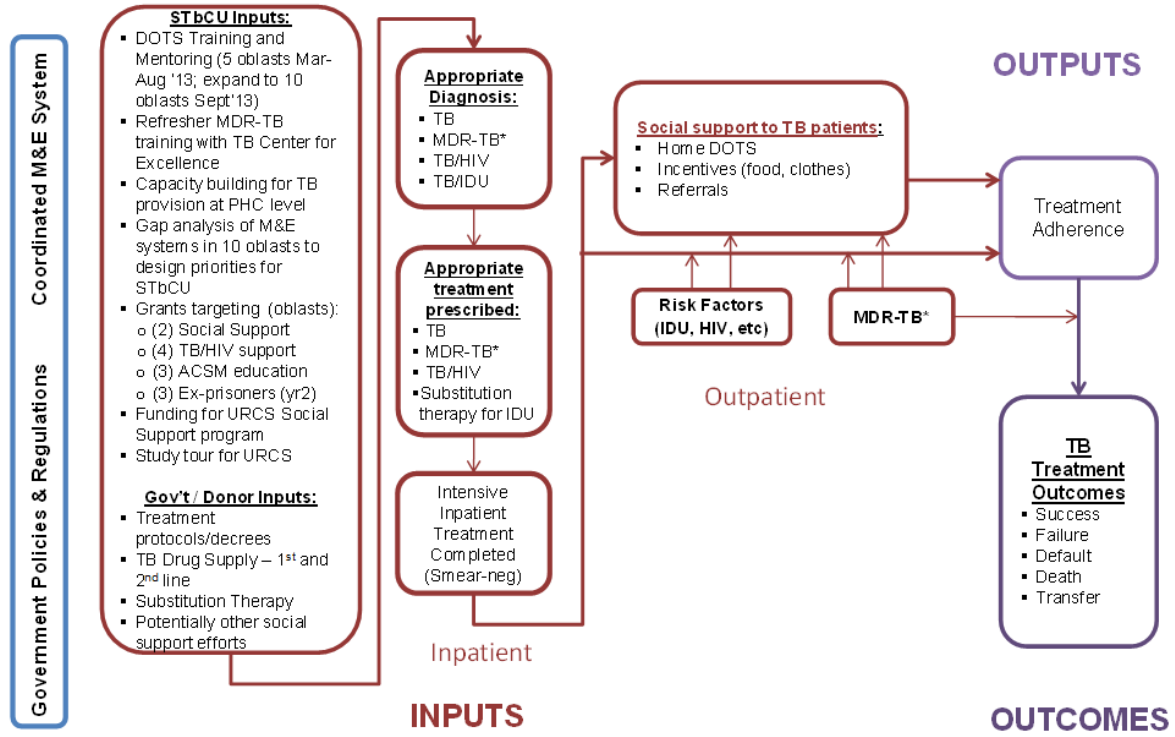
Targeting

The URCS implemented the SS program in five regions during 2012 to 2014. Three intervention oblasts were purposively chosen for the evaluation during Phase 1 to reflect oblasts with high treatment default rates and an adequate case load to study over time: Dnipropetrovsk, Kharkiv, and Odessa. An additional layer of targeting was used to select program participants for the URCS SS program to increase treatment adherence. The ten targeted HR groups for this intervention were HIV-positive, alcoholics, people who inject drugs, TB contacts, homeless, migrants, refugees, ex-prisoners, unemployed, persons with comorbidities, and others identified as HR by the health care provider. Risk screening was completed by the health care 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 services provided by the URCS.

Development Hypotheses

Figure 1 illustrates the development hypotheses linking the proposed interventions with the anticipated outputs and outcomes. The program input of primary interest was the outpatient URCS SS program that targeted patients vulnerable to treatment default. The primary outcome of interest was the rate of treatment default, which was hypothesized to decline among HR patients receiving SS compared with HR patients not receiving SS. Improved treatment adherence should lead to reduced mortality among TB patients. Secondary outcomes included the rate of death, which was hypothesized to be lower among HR patients receiving SS compared with HR patients not receiving SS.

Figure 1. Framework for improved treatment adherence and outcomes



Note: Risk factors, such as injecting drug use and HIV, may moderate patients' efforts to adhere to the treatment regimen. *MDR-TB patients received a longer treatment regimen and had a higher probability of failure.

METHODS

Study Design

The SS study was designed to measure program impact on select TB treatment outcomes using a mixed method, quasi-experimental design. The study design included a quantitative survey in Phase 1 and Phase 2, plus qualitative and modeling components in Phase 2. Table 1 provides a summary of methods for each evaluation question. Appendix B provides details on the study protocol.

The quantitative survey addressed EQ 1.1 with retrospective medical record data abstraction from 2011 and 2012 for Phase 1 and from 2014 and 2015 for Phase 2 for a sample of TB patients, stratified by risk of defaulting on TB treatment. The SS program was developed and piloted in 2010 in a few USAID-supported oblasts. A break in services occurred in 2011 for all sites. Then activities resumed in 2012 in oblasts across the country. The Phase 1 sampling design drew from 2011 (no intervention) and 2012 (intervention) time periods, and both HR and LR patients to allow for comparison to routine care for LR and HR patients. The SS program was implemented in 2014, but was scaled down in 2015. The Phase 2 sampling design drew from 2014 (intervention) and 2015 (no intervention) time periods, and both HR and LR patients to allow for comparison to routine care for LR and HR patients. We included LR patients from both intervention and comparison periods to strengthen confidence in the choice of comparison group. We hypothesized that LR patients in intervention and comparison periods would have similar treatment outcomes, while the HR patients in both periods would have different outcomes based on the SS received. Additional facility-level data were collected from TB facilities in the three selected intervention oblasts to inform our understanding of the differences seen among oblasts. During Phase 1, we demonstrated that the SS program reduced treatment default. In Phase 2, we aimed to repeat the Phase 1 analysis and assess whether this effect held over time.

The qualitative component addressed EQ 1.2 and 1.3. It included IDIs with patients, providers, and STbCU and URCS staff.

We used modeling to answer EQ 1.4. We calculated the weighted average of the risk cohort specific treatment default rates, where the weights were given by the estimated distribution of TB patients across the risk categories. We then changed these distributions (weights) to reflect different scenarios for the proportion of HR patients that received SS services. Appendix A, Table 13 provides more information on the modeling inputs and assumptions.

Table 1. Summary of methods for each evaluation question

Evaluation question	Method	Data collection method	Data sources	Sample	Sample size	Analysis	Limitations
1.1. Does participation in a SS program affect the likelihood of TB treatment default, treatment success, or treatment failure among HR patients?	Quantitative	Chart abstraction	Patient medical records; electronic TB manager	Systematic random sampling for chart abstraction	2,327 patient charts	Logistic regression model	Potential for selection bias
1.2. What aspects of outpatient TB treatment make adherence particularly difficult for patients in at-risk groups?	Qualitative	IDIs	Patients, providers, STbCU and URCS staff	Purposive	21 program beneficiaries, 11 nurses, and 4 STbCU and URCS program coordinators	Qualitative data analysis	Purposive sampling with implications for the generalizability of findings
1.3. What aspects of the SS program are most important to those receiving the program? What works best for ensuring adherence?	Qualitative	IDIs	Patients, providers, and STbCU and URCS staff	Purposive	21 program beneficiaries, 11 nurses, and 4 STbCU and URCS program coordinators	Qualitative data analysis	Purposive sampling with implications for the generalizability of findings
1.4. What is the estimated effect of the SS program on the treatment success rate at the population level?	Quantitative, Modeling	Chart abstraction	Patient medical records; electronic TB manager; findings on the effect of the SS program from EQ 1.1	Systematic random	1,030 patient charts	Analysis of frequencies; decom-position model using Excel	Modeling assumes that the URCS was the only SS program provider; no SS program in 2015; all HR patients would be willing to participate in the SS program
Program context	Quantitative	Facility survey	Facility lead doctors and administrators	All TB facilities in the three regions	48 HFs, 2 URCS regional offices	Descriptive statistics	Recall bias

Sampling Design and Implementation

Quantitative Component (EQ 1.1)

Oblasts: In Phase 2 we decided to study the same oblasts that were chosen for Phase 1: Dnipropetrovsk, Kharkiv, and Odessa. Funding for the URCS to offer SS services in Dnipropetrovsk, Kharkiv, and Odessa was available in 2014. In 2015, it was significantly reduced for Dnipropetrovsk and Odessa, and eliminated for Kharkiv. Whereas 1,564 patients received SS services in these regions in 2014, only 185 patients (11.8 percent) were supported in 2015.

Facilities: In Ukraine, TB patients typically receive intensive TB treatment at an inpatient facility, either at the oblast or city level. Once a patient is smear-negative, s/he is discharged and reassigned to a TB Cabinet for continuation treatment as an outpatient. Patients are evaluated at the TB Cabinet and may then be referred to the URCS for SS services. To better understand the referral and treatment processes at these facilities, every TB facility that served one of the TB patients selected for the study (see individual selection below), was selected for the facility survey (N=50). Two facilities refused to respond to survey questions. The response rate for the facility surveys was 96 percent. We also surveyed the Dnipropetrovsk and Odessa oblast regional URCS offices that implemented the SS program.

Individuals: For Phase 2, individual medical data were collected for five patient cohorts: HR patients receiving SS during January to December 2014; HR patients not enrolled in the SS program during September 2013 to December 2014; LR patients not enrolled in the SS program during September 2013 to December 2014; HR patients not enrolled in the SS program during October 2014 to December 2015; and LR patients not enrolled in the SS program during October 2014 to December 2015. (See Box 1 for the definitions of the study cohort risk groups.) The first three groups are 2014 cohorts and the last two are 2015 cohorts.

The target sample size calculations were powered on the expected change in probability of treatment default among the intervention and comparison cohorts. The target sample was 445 patients from each of the five cohorts (a total of 2,225 TB continuation treatment patients), selected by oblast proportionate to the size of their TB population. Based on our Phase 1 study experience, we further inflated this sample size by 105 charts (35 from each region) to address potential non-response due to missing data (a total of 2,330 TB continuation treatment patients). The selection of the study sample was based on program data from the URCS. A complete list of patients served by the URCS in each of the study oblasts in 2014 was provided. A random sample of HR intervention patients was first selected from each oblast from the list of patients served by the URCS during January to December 2014. Each TB facility where the patient was first assessed for continuation therapy served as the facility match point. Four charts from these facilities were then matched to this HR intervention patient: one HR comparison patient from 2014; one LR comparison patient from 2014; one HR comparison patient from 2015; and one LR comparison patient from 2015. Each additionally selected chart was matched to the primary case by day/month of TB continuation initiation, plus sex and age if more than one match was eligible. When any of the four matching charts were not available at a TB facility, the search for matches was extended first to other HFs that provided URCS intervention patients in the neighboring rayons, and then to other neighboring HFs that did not provide URCS intervention patients. (Appendix C provides details on the sampling procedures.)

The overall response rates for the chart abstraction across all oblasts and risk cohorts was 99.9 percent (Appendix A, Table A1). Matching on risk status and year at the facility level proved to be difficult, particularly in 2014 and at smaller facilities. In 2014, most patients received SS services, and in smaller facilities, everyone was referred for SS services, making it difficult to identify any HR or LR patients who did not receive SS. We achieved this high response rate by extending our window from September 1, 2013 to December 31, 2014 for patients in the 2014 cohorts, and from October 1, 2014 to December 31, 2015 for patients in the 2015 cohorts.

Box 1. Definition of Study Cohort Risk Groups

HR intervention patient: Everyone on the URCS patient list.

HR non-intervention patient: Any patient with one or more of the following risk factors who was not receiving SS services: HIV-positive, alcoholics, people who inject drugs, TB contacts, homeless, migrants, refugees, ex-prisoners, and persons with comorbidities.

LR non-intervention patient: Any patient without any risk factor, except for the unemployed.

Qualitative Component (EQ 1.2, 1.3)

Participant Selection and Data Collection Timeframe

Patient and provider interviews were completed with patients receiving and nurses providing URCS services in 2016. We interviewed respondents in two Phase 1 regions (Odessa and Dnipropetrovsk) because beginning in 2015, the URCS was not providing SS services to patients in Kharkiv. We aimed to interview at least 20 patients and 10 providers in two regions of the country. IDI respondents included both male and female patients to examine potential differences in barriers to treatment adherence, by sex, and the means of overcoming those barriers. We asked each URCS office to provide a list of nurses who worked in the SS program and then contacted 10 of those nurses to interview. Nurses nominated their patients for interviews. Nominated patients who had received home visits for at least two months or those patients who had completed the program no longer than two months previously were invited for interviews. Four program coordinator interviews were completed with the STbCU and URCS managers working on the SS program in both regions and in Kiev. All interviews were conducted in August and September 2016.

Modeling Component (EQ 1.4)

Oblasts: We abstracted patients charts in the three study regions: Dnipropetrovsk, Kharkiv, and Odessa. *Individuals*: To model the impact of cohort-specific treatment default rates on the treatment default rates in the population of TB patients, we needed the distribution of patients with drug-sensitive TB across the three study risk cohorts listed in Box 1. To obtain this distribution, we extracted records for a sample of all TB patients who started intensive treatment during November 2013 to March 2014, and a second sample of all TB patients who started intensive treatment during November 2014 to March 2015. Patients in each of these cohorts received continuation treatment during 2014 and 2015 years, respectively, corresponding to our samples for EQ1.1 described above. To estimate a proportion of 50 percent in a risk cohort with absolute precision of 0.04, the target sample was 567 patients from each of the two cohorts (a total of 1,134 TB patients). We inflated this number by 6 percent for non-response due to missing data, and sampled 1,200 charts, selected by oblast, using systematic random sampling proportionate to the size of their TB population.

Data Collection and Instruments

Quantitative and Modeling Components (EQ 1.1,1.4)

Data collection was led by our partner, the IFAK Institut, in collaboration with TB and infectious disease specialists in each oblast. The primary data source was patient medical records from which data were abstracted retrospectively. A data abstraction form was developed to record basic socio-demographic characteristics, TB diagnosis, treatment and outcomes, potential risk factors for defaulting on TB treatment, and participation in SS programs from official client records (form TB-01, TB-03).

The HF and URCS regional office surveys were completed by IFAK, with the assistance of the facility director or administrator most knowledgeable about the TB policies and activities at the facility. Data collected by the survey instruments included basic facility characteristics, such as size and staffing; services and referrals provided; drug shortages in 2014 and 2015; and eligibility criteria for offering SS services. (The data collection instruments are provided in Appendix D.)

Data collection took place during September to December 2016.

Qualitative Component (EQ 1.2, 1.3)

We developed tailored, semi-structured interview guides for program beneficiaries, providers, and program coordinators (Appendix D). All guides were translated into Ukrainian and Russian. Interviews were conducted in both languages, depending on the preference of the respondents. The guides were pre-tested with two patients and one nurse in Dnipropetrovsk, and minor changes were made to improve the clarity and intent of the questions.

We used patient, provider, and STbCU staff interviews to gather in-depth information on what services were provided, who was using those services and how, and to what extent services in the delivery models were working for the intended audience. To better understand the role of SS services in treatment adherence, in-depth patient interviews solicited information from HR patients on the primary barriers to treatment adherence and aspects of the SS program that helped them stay on their treatment regimen. We interviewed STbCU staff and URCS coordinators to learn about their experiences coordinating the SS program; specifically, the barriers to and facilitators of their work, and lessons learned that can be applied to future programs.

IFAK staff conducted the IDIs. MEASURE Evaluation conducted a three-day training for data collectors to familiarize them with the study aims, methods, and interview guides. The interviews lasted approximately one hour. Interviews were audio-recorded using digital recorders, and a separate consent to record was sought by the interviewers.

We conducted interviews with program beneficiaries in parks or in a private and quiet location in the local URCS offices, out of earshot of program staff. We informed participants of the study requirements, and obtained verbal informed consent prior to the interview. Interviews with nurses were conducted in their places of work. Interviews with the STbCU staff and URCS program coordinators were conducted in their offices in Kiev and in the Odessa and Dnipropetrovsk regions.

Data Entry, Processing, and Analysis

Quantitative and Modeling Components (EQ 1.1, 1.4)

Completed facility and individual surveys were returned to the IFAK's main office in Kiev for processing, which included office 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 MS Excel files were forwarded to UNC-CH for analysis using Stata v13 (College Station, TX). Analysis was conducted on the UNC-CH secure server, and included descriptive analyses and multivariate logistic regression modeling examining TB treatment default and outcomes, by intervention and risk status. Marginal effects were calculated to estimate the magnitude and direction of the effect of the SS program. Survey weights were calculated and applied to the analysis.

Data on outcomes for different risk groups collected over two years, combined with the data on risk distribution in the population, allowed us to use a simple decomposition model to estimate the effect of the SS program on the treatment success rates at the population level in 2014 to address EQ 1.4. We also estimated whether and by how much treatment default rates were likely to have increased after the SS program was phased out in 2015.

Qualitative Component (EQ 1.2, 1.3)

All interviews were transcribed and then translated into English. Transcripts were imported into ATLAS.ti, version 7.5.17 and analyzed. Study staff developed an initial codebook with topical codes based on questions from the interview guides. The codebook was then pilot tested on interview transcripts for two patients (one from each region) and two providers (one from each region). The pilot testing allowed for the revision of the codebook; new codes were added, and some initial codes were collapsed into existing codes.

Once the codebook was finalized, the transcribed interview files were imported into ATLAS.ti to facilitate analysis, and the codes from the revised codebook were applied to the interview transcripts. Once coding was completed, a code report was run in ATLAS for each code across each stakeholder group (patient interviews, provider interviews, project coordinator interviews). We reviewed the code reports, identified sub-themes in each code, and examined the evidence supporting the themes and sub-themes. Essential concepts and relationships between the different themes and sub-themes were formed. Data were synthesized, and findings communicated through the process of writing up and presenting the data, using direct quotes to support the themes.

Review

All study documents and data security processes were exempted from review by the Institutional Review Board (IRB) 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 approved the study.

Limitations

We extracted patient data from 2014 and 2015 records. Therefore, the facility and URCS surveys asked questions about services provided in 2014 and 2015, which is subject to recall bias. We were constrained in our analysis to variables that were available from the records and by the quality of those data. Participation in the SS program was selective; patients were referred by their provider, so the characteristics of HR patients that received SS may have been different from those of HR patients who did not receive SS. We were limited in our ability to control for this potential individual selection by the 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; however, owing to the closeout of the program, there were too few new patients planned to be able to recruit enough for a prospective design. The inclusion of cohorts from 2015 when virtually no SS intervention was implemented allowed us to explore the likely extent of selection bias. Another issue was the effect of externalities on the outcomes of interest. Shortages of TB medications, in particular, could have had significant effects on treatment completion rates; however, this would affect both intervention (SS) patients and comparison patients (HR patients not receiving SS and LR patients) so it would not necessarily affect differences between these groups. Additional data were collected on drug shortages at the facility level that could be used in the interpretation of the findings. We conducted interviews with patients, nurses, and providers to understand the patients' challenges to treatment adherence and their perception of the SS program. As with any modeling work, the findings on the effect of the SS program at the population level should be interpreted under the assumptions stated in the model.

RESULTS

Program Context

Key Findings:

- The percentage of facilities providing SS referrals declined considerably, from 79 percent in 2014 to 33 percent in 2015, due to changes in funding between these periods.
- Only one HF experienced drug shortages lasting longer than 30 days during 2014 and four (8.6 percent) reported shortages in 2015.

TB Outpatient Facilities and Services

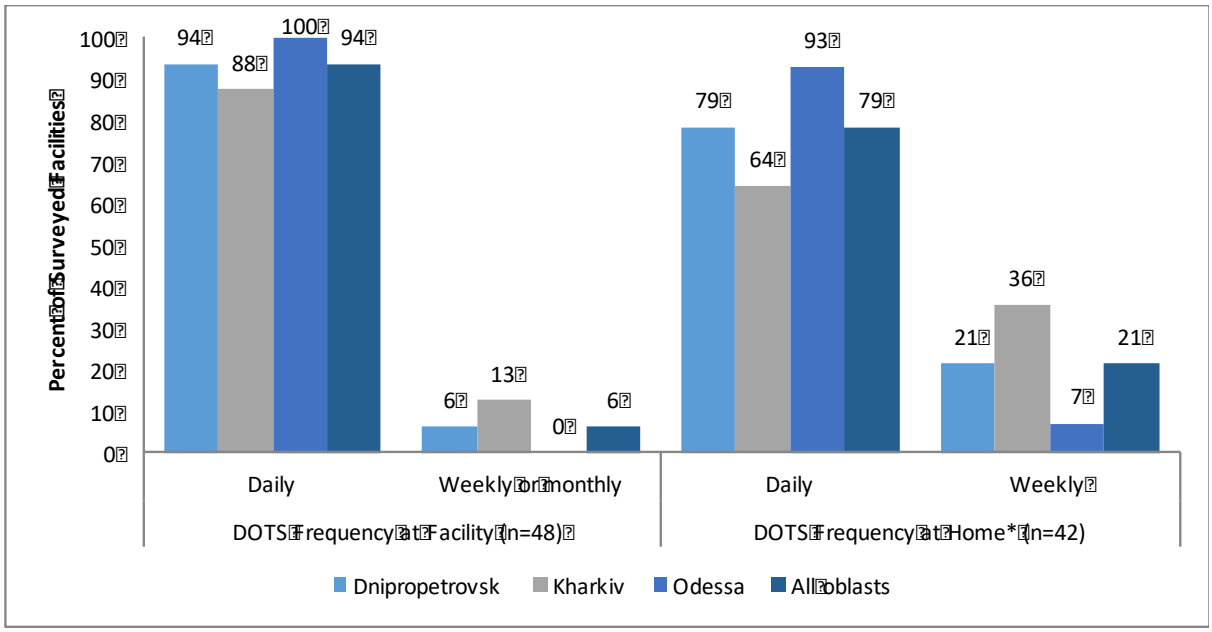
Facility Characteristics

Most of the TB facilities surveyed were either TB cabinets in a polyclinic or TB dispensaries/hospitals. Most facilities in the three regions were TB cabinets (Appendix A, Table A2). A wide range of services were offered at the TB facilities, including diagnostics, treatment, prevention, and counseling. All facilities provided TB diagnostic testing and TB outpatient treatment. Far fewer facilities provided inpatient treatment for TB (14.6 percent), especially in Odessa, were no surveyed facilities provided such treatment. Injecting drug use (IDU) substitution therapy was provided in one-quarter of the facilities, and psychological counseling was provided in less than 40 percent of the facilities (Appendix A, Table A2).

TB Treatment Strategies

The frequency of TB continuation treatment differed by location of DOTS treatment, and in some cases by region (Figure 2). Most facilities provided daily DOTS treatment in the facility (94 percent). This varied by region, with 100 percent of facilities in Odessa providing DOTS daily, compared with 94 percent in Dnipropetrovsk, and 88 percent in Kharkiv. The remaining facilities provided DOTS in the facility on a weekly or monthly basis. In facilities that had continuation treatment services available at home (N=42), nearly all facilities in Odessa reported that they were provided daily (93 percent), compared with 79 percent in Dnipropetrovsk, and 64 percent in Kharkiv.

Figure 2. Frequency of DOTS, by location and oblast, Ukraine 2016, n=48



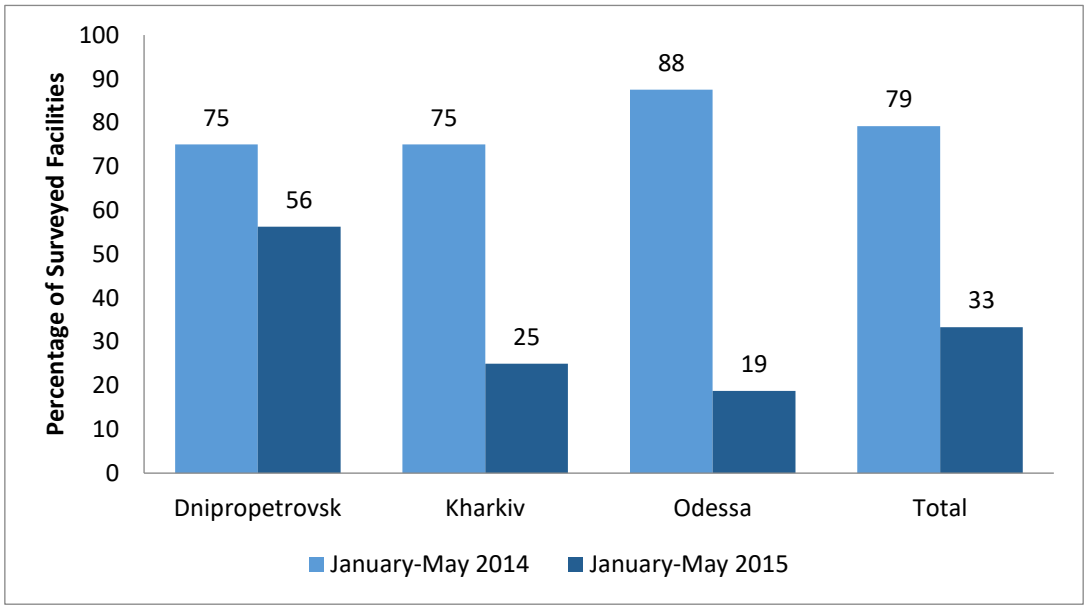
*Facilities not offering services are not shown.

SS Services

The percentage of facilities providing SS referrals declined considerably from 2014 (79 percent) to 2015 (33 percent) (Figure 3). This was expected because of changes in funding between these periods.

The URCS was the only provider of SS services in Odessa in 2014, and the primary provider in Dnipropetrovsk and Kharkiv. Only sixteen HFs provided SS referrals in 2015; half of these facilities provided referrals to the Ukrainian government and All-Ukrainian Network of People Living with HIV.

Figure 3. Percentage of surveyed facilities referring patients to SS programs for continuation treatment, Ukraine 2014 and 2015, n=48



Among the facilities providing referrals to the URCS or to the people living with HIV (PLWH) program in 2014 (N=35), 80 percent required a minimum of one risk factor to consider someone as eligible for a referral (Appendix A, Figure A1). In 2015, among the eight facilities providing such referrals, half had no minimum number of risk factors. The eligibility criteria used to refer for SS services were fairly similar across the two periods (Appendix A, Table A3). The most commonly used risk factors for both time periods were HIV-positive status and alcoholism (over 90 percent of facilities), although there were three facilities in 2014 that did not use HIV status as a criterion. Over 70 percent of facilities in 2014 reported using other risk factor criteria, such as an injecting drug user, unemployed person, or ex-prisoner. In both time periods, eligibility for SS was less often based on identification as a health care worker or refugee.

From the URCS office surveys, we learned that the presence of at least one of the risk criteria (HIV-positive, alcoholic, injecting drug user, comorbidity, homeless, unemployed, ex-prisoner, TB contact, migrant, refugee/immigrant) was sufficient to determine someone's eligibility for SS in both Odessa and Dnipropetrovsk regions. Health care worker and low income were additional eligibility criteria used in Odessa. HIV-positive, alcoholic, injecting drug user, and comorbidity were the most important criteria used for a patient's referral (data not shown).

Interactions and communication between the URCS and TB services in the patient selection process for the SS program were: a) the URCS provided the HF with the number of patients that could be referred to the SS program during a certain time period; b) the TB doctor/nurse informed the URCS about the patients that were eligible for the SS program; c) the URCS approved the selection of patients and made a final decision; d) the patient was informed by the URCS nurse about the program; if the patient agreed to participate in the program, the nurse started to provide services.

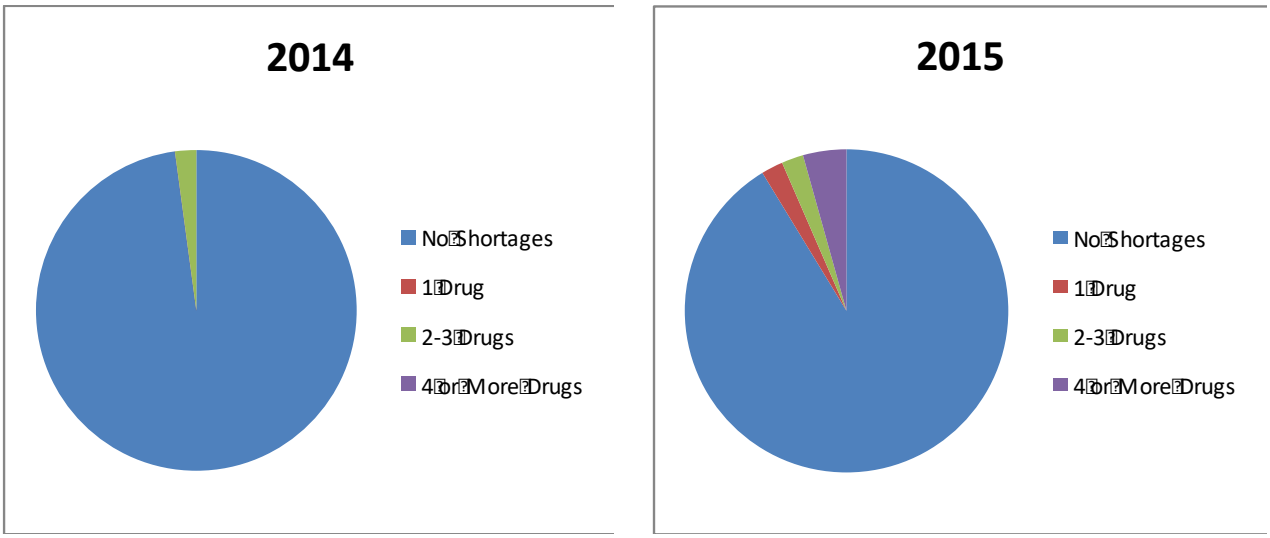
According to the HF surveys, SS services typically included daily DOTS provision at home, counseling, and food packages. Among the facilities offering SS, home visits were primarily conducted daily (Appendix A, Table A4). Across the regions, food packages were rarely offered to clients, usually only once every two to three months. Other types of SS, such as clothing or hygiene kits, transportation vouchers, and counseling, were not provided or were only provided upon request.

TB Drug Supply Shortages

Among the 47 facilities that responded to questions on drug shortages, only one experienced drug shortages lasting longer than 30 days during 2014 and four (8.6 percent) reported shortages in 2015 (Figure 4). One facility in the Dnipropetrovsk region experienced shortages of kanamycin and capreomycin in 2014. In 2015, drug shortages were experienced primarily in the Dnipropetrovsk region; they ranged from one to four or more drugs. The most commonly reported drug shortages in 2015 were for linezolid, levofloxacin, ethionamide, protomide, pyrazinamide, capreomycin, cycloserine, kanamycin, streptomycin, and ethambutol.

In all cases of drug shortages, the facilities reported that they waitlisted patients.

Figure 4. Percentage of facilities that reported a TB drug supply shortage lasting longer than 30 days in 2014 and 2015, n=47



Evaluation Question 1.1: Does Participation in a SS Program Improve TB Outcomes for HR Patients?

Key Findings:

- The study populations shared similar demographic profiles across risk cohorts and years. Approximately 60 percent of the patients were male in every risk group, three-quarters were under fifty years of age, and three-quarters lived in urban areas. However, fewer HR patients reported being employed.
- Among the HR cohorts, 54 percent to 71 percent reported between two and three factors putting them at risk for treatment default.
- During continuation treatment, HR intervention patients reported fewer interruptions, with 74.6 percent of the cohort reporting no treatment interruptions, compared with 71.1 percent of the HR comparison group from 2014, and 54.7 percent of the HR comparison group from 2015.
- The SS program had a protective effect on treatment default. Participation in the SS program lowered the predicted probability of default by 5.1 percentage points, compared with the 2014 no intervention HR group ($p<0.001$), and by 7.8 percentage points compared with the 2015 no intervention HR group ($p<0.001$).
- The SS program had a protective effect on death. Participation in the SS program (intervention group) lowered the predicted probability of dying by 4.6 percentage points,

TB Patients

Study Population

The study populations shared similar demographic profiles across risk cohorts and years (Appendix A, Table A5). Approximately 60 percent of the patients were male in every risk group, three-quarters were under fifty years of age, and three-quarters lived in urban areas. However, fewer HR patients reported being employed than LR patients. Differences in employment between the intervention group patients and patients in each of the comparison HR groups were not statistically significant at the 0.05 level. Among the HR cohorts, 54 percent to 71 percent reported between two and three factors putting them at risk for treatment default, while 3 percent to 4 percent reported four or more factors (Table 2). The most common risk factors reported were unemployment and being HIV-positive, followed by having disease comorbidity or being an alcoholic. About half of the LR patients reported no risk factors for treatment default, and among those who reported one risk factor, unemployment was the only risk cited. Notably, the proportion of patients who reported injection drug use as a risk factor in their records was very small, ranging from 4 percent to 8 percent among the HR cohort. Based on discussions with facility staff, we concluded that information on status and treatment of people who inject drugs was not routinely recorded in the TB records nor was it shared across TB cabinets due to concerns about confidentiality. Hence, the provider may have been unaware of the patient's status unless it was volunteered by the patient.

Table 2. TB patient risk profile, by sampled risk cohort and year. Ukraine, 2014 and 2015

	HR Patients						LR Patients				Total Patients	
	Intervention 2014		Comparison 2014		Comparison 2015		Comparison 2014		Comparison 2015			
Risk Profile	Number	(Percent)	Number	(Percent)	Number	(Percent)	Number	(Percent)	Number	(Percent)	Number	(Percent)
Risk Factor*												
HIV-positive	132	(28.4)	272	(58.5)	273	(58.6)	0	(0.0)	0	(0.0)	677	(29.1)
Alcoholic	118	(25.5)	123	(26.4)	105	(22.6)	0	(0.0)	0	(0.0)	346	(14.9)
Injecting Drug User	19	(4.1)	38	(8.2)	22	(4.6)	0	(0.0)	0	(0.0)	78	(3.4)
Comorbidity	127	(27.4)	109	(23.4)	98	(21.0)	0	(0.0)	0	(0.0)	334	(14.3)
Homeless	14	(3.1)	30	(6.5)	27	(5.8)	0	(0.0)	0	(0.0)	72	(3.1)
Unemployed	276	(59.5)	284	(61.1)	271	(58.1)	236	(50.7)	206	(44.3)	1274	(54.7)
Contact to Case	24	(5.1)	20	(4.4)	14	(3.0)	0	(0.0)	0	(0.0)	58	(2.5)
Ex-Prisoner	15	(3.2)	16	(3.4)	15	(3.1)	0	(0.0)	0	(0.0)	45	(1.9)
Health Care Worker	7	(1.6)	7	(1.4)	9	(2.0)	0	(0.0)	0	(0.0)	23	(1.0)
Migrant	1	(0.2)	0	(0.0)	2	(0.5)	0	(0.0)	0	(0.0)	3	(0.1)
Refugee / Immigrant	0	(0.0)	0	(0.0)	4	(0.9)	0	(0.0)	0	(0.0)	4	(0.2)
Other	69	(14.9)	52	(11.2)	49	(10.5)	0	(0.0)	0	(0.0)	170	(7.3)
Number of Risk Factors												
No risk factors	12	(2.7)	0	(0.0)	0	(0.0)	229	(49.3)	260	(55.7)	501	(21.5)
1	186	(40.1)	118	(25.3)	142	(30.5)	236	(50.7)	206	(44.3)	888	(38.2)
2-3	249	(53.7)	328	(70.5)	308	(66.2)	0	(0.0)	0	(0.0)	886	(38.1)
4 or more	16	(3.5)	20	(4.3)	15	(3.3)	0	(0.0)	0	(0.0)	52	(2.2)
Total Patients	464	(100.0)	465	(100.0)	466	(100.0)	465	(100.0)	466	(100.0)	2327	(100.0)

*Multiple responses possible, may not sum to 100%.

TB Status and Treatment

Overall, 74.3 percent of the TB patients were seen for first diagnosis, although among the HR cohorts, a few more were reinitiating treatment after earlier failure or relapse, compared with the LR cohorts (Appendix A, Table A6). Most cases were pulmonary TB (86.5 percent) and most cases fit a Category I classification (68.9 percent), followed by Category II (24.3 percent).

For almost two-thirds of patients (1433), intensive treatment lasted two to three months on average, and about one-third completed intensive treatment in less than two months (Table 3). A spread in treatment times was seen during continuation therapy across HR groups, with comparison groups having more patients with shorter continuation treatment durations. Thus, for more than 13 percent of patients in comparison groups, the recorded duration of continuation treatment for all outcomes was less than two months, compared with 2 percent in the intervention group, which is indicative of dropping out in the comparison groups. During continuation treatment, the HR intervention patients reported fewer interruptions, with 74.6 percent of the cohort reporting no treatment interruptions, compared with 71.1 percent of the HR comparison group from 2014, and 54.7 percent of the HR comparison group from 2015. All cohorts reported a substantial proportion of patients with one to three interruptions during continuation treatment, ranging from 18.9 percent among the 2014 HR intervention group to 27.0 percent among the HR comparison group from 2015. Among those with interrupted care, over half reported less than a one-week interruption and about one-quarter reported a one- to two-week interruption.

The HR intervention cohort had much higher treatment success than the other two HR comparison groups (88.4 percent treatment success vs. 67.5 percent and 76.7 percent, $p<0.0001$ for both HR comparison groups (Table 3). The HR intervention cohort had lower treatment default than the other two HR comparison groups (1 percent treatment default vs. 5.7 percent and 8.2 percent, $p<0.0001$ for both comparisons). The HR intervention cohort had a lower proportion of patients who died compared with the other two HR comparison groups (2 percent vs. 6.7 percent and 4.2 percent, $p=0.0004$ for the 2014 HR groups comparison; not a significant difference between 2014 intervention and 2015 HR comparison groups). Both LR comparison cohorts in 2014 and 2015 reported over 80 percent treatment success, and fewer than five percent defaulting on treatment. TB treatment outcomes for the HR intervention group were very similar to the LR comparison cohorts in 2014 and 2015, with even lower treatment default in the intervention group (1 percent treatment default vs. 3.8 percent and 4.4 percent, $p<0.01$ for both LR comparison groups).

Table 3. TB patient treatment duration and outcome, by risk cohort and year. Ukraine, 2014 and 2015

Treatment and Outcome	HR Patients						LR Patients				Total	
	Intervention 2014		Comparison 2014		Comparison 2015		Comparison 2014		Comparison 2015			
	Number	(Percent)	*Number*	(Percent)	*Number*	(Percent)	*Number*	(Percent)	*Number*	(Percent)	*Number*	(Percent)
Intensive Treatment Duration												
< 2 months	152	(32.6)	146	(31.4)	157	(33.6)	142	(30.6)	165	(35.5)	762	(32.7)
2 - 3 months	280	(60.4)	291	(62.4)	287	(61.6)	298	(64.0)	278	(59.6)	1433	(61.6)
4 - 5 months	22	(4.7)	24	(5.1)	21	(4.5)	24	(5.1)	22	(4.8)	112	(4.8)
≥ 6 months	8	(1.8)	5	(1.1)	1	(0.3)	2	(0.4)	1	(0.2)	17	(0.7)
Missing	2	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)
Continuation Treatment Duration												
< 2 months	9	(1.9)	92	(19.8)	64	(13.7)	54	(11.7)	30	(6.4)	264	(11.3)
2 - 3 months	116	(25.1)	178	(38.3)	170	(36.4)	193	(41.5)	190	(40.7)	941	(40.5)
4 - 5 months	222	(47.8)	153	(32.8)	181	(38.8)	191	(41.1)	211	(45.3)	928	(39.9)
6 - 8 months	69	(14.9)	33	(7.0)	33	(7.0)	21	(4.5)	24	(5.2)	140	(6.0)
≥ 9 months	17	(3.6)	9	(2.0)	19	(4.1)	6	(1.2)	11	(2.4)	54	(2.3)
Number of interruptions during continuation treatment												
None	346	(74.6)	331	(71.1)	255	(54.7)	345	(74.0)	306	(65.6)	1583	(68.0)
1	60	13.0)	57	(12.2)	74	(15.8)	58	(12.4)	59	(12.8)	308	(13.2)
2-3	27	(5.9)	43	(9.3)	52	(11.2)	33	(7.1)	29	(6.3)	185	(8.0)
4 or more	24	(5.2)	33	(7.1)	85	(18.2)	30	(6.5)	70	(14.9)	242	(10.4)
Missing	6	(1.3)	2	(0.4)	0	(0.0)	0	(0.0)	2	(0.4)	10	(0.4)
Duration of longest interruption during continuation treatment among those with any interruptions	(n= 119)		(n=134)		(n=210)		(n=120)		(n=160)		(n=743)	
< 1 week	64	(53.9)	58	(43.6)	124	(59.2)	63	(52.7)	112	(69.8)	422	(56.8)
1-2 weeks	33	(28.0)	33	(24.4)	48	(22.9)	28	(23.3)	30	(18.7)	172	(23.1)
3-4 weeks	7	(6.3)	15	(11.2)	13	(6.2)	14	(11.3)	7	(4.7)	56	(7.6)

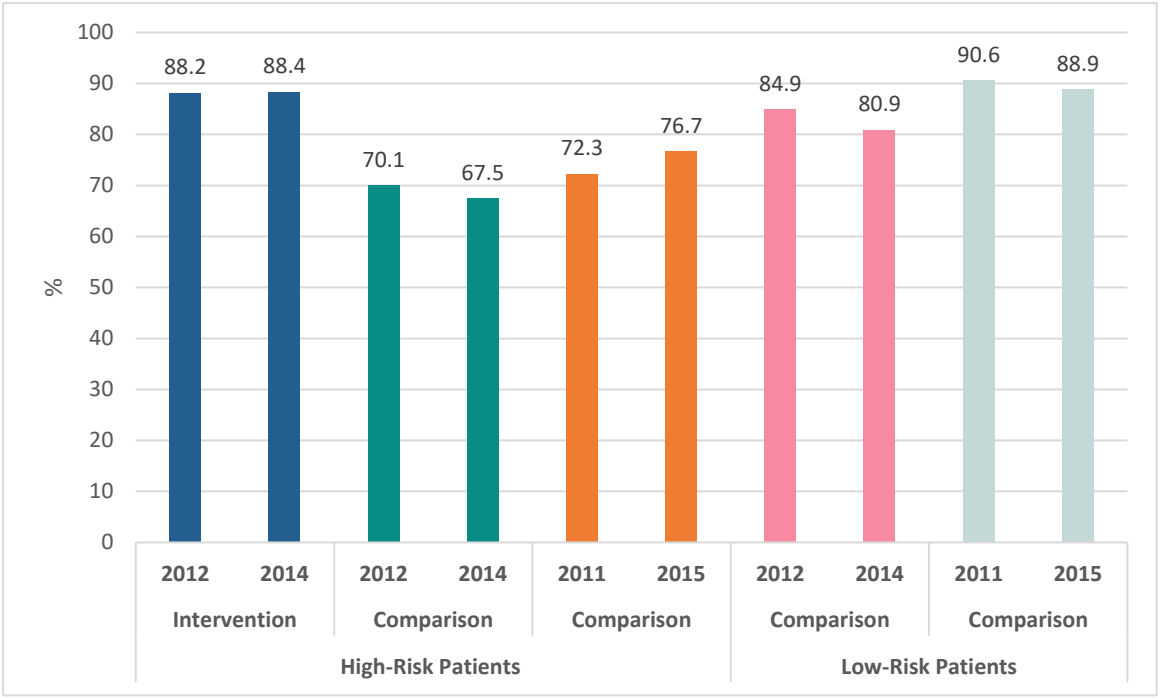
Treatment and Outcome	HR Patients						LR Patients				Total	
	Intervention 2014		Comparison 2014		Comparison 2015		Comparison 2014		Comparison 2015			
	Number	(Percent)	*Number*	(Percent)	*Number*	(Percent)	*Number*	(Percent)	*Number*	(Percent)	*Number*	(Percent)
≥ 5 weeks	14	(11.4)	28	(21.2)	25	(11.7)	15	(12.8)	10	(6.5)	92	(12.4)
TB Treatment Outcome												
Success*	410	(88.4)	314	(67.5)	357	(76.7)	376	(80.9)	414	(88.9)	1872	(80.4)
Died	9	(2.0)	31	(6.7)	19	(4.2)	7	(1.5)	3	(0.7)	70	(3.0)
Treatment failed	39	(8.4)	92	(19.8)	51	(10.9)	64	(13.7)	28	(6.0)	274	(11.8)
Treatment interrupted (Default)	5	(1.0)	27	(5.7)	38	(8.2)	18	(3.8)	21	(4.4)	108	(4.6)
Transferred	1	(0.2)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)
Total Patients	**464**	**(100.0)**	**465**	**(100.0)**	**466**	**(100.0)**	**465**	**(100.0)**	**466**	**(100.0)**	**2327**	**(100.0)**

Note: Table excludes two presumed cases when the TB diagnosis was cancelled.

*Includes those cured and those who completed treatment.

These results were similar to the Phase 1 study findings on TB treatment outcomes (see Phase 1 report, Table 3.13). At Phase 1, the HR intervention cohort had much higher treatment success and lower treatment default than the other two HR comparison groups (88.2 percent treatment success vs. 70.1 percent and 72.3 percent; 1.9 percent treatment default vs. 11 percent and 13.1 percent). Both LR comparison cohorts in 2011 and 2012 reported over 85 percent treatment success, and fewer than five percent defaulting on treatment. Figure 5 provides a comparison of treatment success, by risk cohort and year for both Phase 1 and Phase 2 studies. The figure shows that treatment success remained the same for the two intervention groups (HR 2012 at Phase 1 and HR 2014 at Phase 2), and it was very similar for each of the comparison groups.

Figure 5. Treatment success, by risk cohort and year, % (Phase 1 and Phase 2 results)



SS Program Results

To evaluate the results of the SS program, we looked at two outcomes: TB treatment default and mortality. We ran logistic regressions using the three cohorts—2014 HR intervention, 2014 HR comparison, and 2015 HR comparison—controlling for age, sex, and residence, and we also stratified by oblast to identify any oblast-specific differences. Predicted probabilities and marginal effects of the intervention were calculated to understand the magnitude and direction of the effect of the SS program.

Probability of Defaulting on TB Treatment

Table 4 presents the predicted probability of defaulting on TB treatment for participants from each of the cohorts. For the combined oblast results, we found that participants in the HR intervention group had the lowest probability of defaulting on treatment (0.6 percent compared with a 5.8 percent probability of default for the 2014 HR comparison cohort, and 8.5 percent probability for the 2015 HR comparison cohort). By oblast, the HR comparison groups from both 2014 and 2015 had similar probabilities of defaulting on treatment, and the probabilities were substantially higher than the intervention group. Dnipropetrovsk had the highest defaults among the HR patients who received no intervention in both 2014 and 2015, 7.5 percent and 11 percent, respectively. This could be partially explained by drug shortages that the HFs experienced in this region in both years (see the section on context, above).

Table 4. Predicted probability of treatment default, by intervention and oblast, n=1375

	HR Intervention 2014			HR Comparison 2014			HR Comparison 2015		
Oblast	Predicted Probability	(SE)	Confidence Interval	Predicted Probability	(SE)	Confidence Interval	Predicted Probability	(SE)	Confidence Interval
All Oblasts	0.006	0.003	(0.000, 0.012)	0.058	0.012	(0.035, 0.080)	0.085	0.014	(0.057, 0.112)
Dnipropetrovsk	0.008	0.005	(0.000, 0.017)	0.075	0.016	(0.045, 0.106)	0.110	0.020	(0.070, 0.150)
Kharkiv	0.006	0.003	(0.000, 0.012)	0.053	0.017	(0.020, 0.087)	0.079	0.022	(0.036, 0.121)
Odessa	0.005	0.003	(0.000, 0.010)	0.046	0.014	(0.019, 0.073)	0.069	0.019	(0.032, 0.105)

Marginal Effects of the Intervention on the Probability of Treatment Default

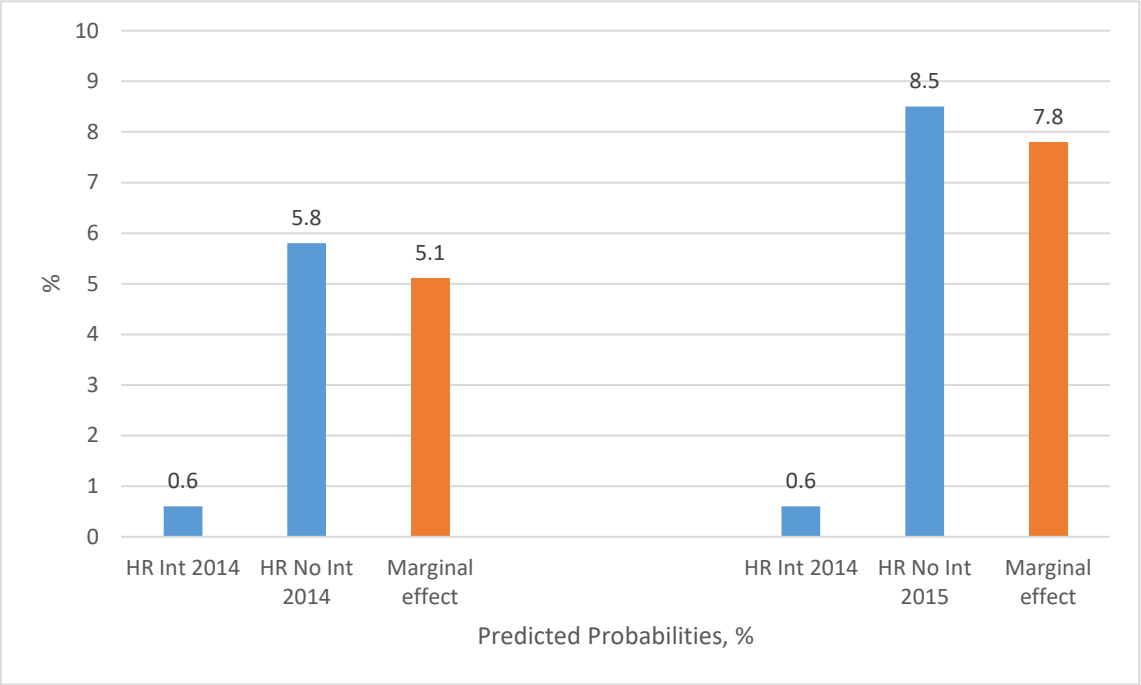
Marginal effects are the difference between predicted probabilities of defaulting between the groups of interest. We found that participation in the SS program (intervention group) lowered the predicted probability of default by 5.1 percentage points compared with the 2014 no intervention HR group ($p<0.001$), and by 7.8 percentage points compared with the 2015 no intervention HR group ($p<0.001$) (Table 5 and Figure 6). By oblast, we saw a similar pattern of marginal effects, with Dnipropetrovsk having the highest marginal effects for both comparisons.

Table 5. Marginal effect of the intervention on the probability of default among HR groups, n=1375

	HR intervention 2014 compared with HR no intervention 2014				HR intervention 2014 compared with HR no intervention 2015			
Oblast	Marginal Effect		(SE)	Confidence Interval	Marginal Effect		(SE)	Confidence Interval
All Oblasts	-0.051	***	0.012	(-0.075, -0.028)	-0.078	***	0.015	(-0.107, -0.050)
Dnipropetrovsk	-0.067	***	0.015	(-0.097, -0.037)	-0.102	***	0.020	(-0.140, -0.063)
Kharkiv	-0.048	**	0.016	(-0.079, -0.016)	-0.073	***	0.021	(-0.113, -0.032)
Odessa	-0.041	**	0.014	(-0.068, -0.015)	-0.064	**	0.018	(-0.100, -0.028)

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

Figure 6. Predicted probability of treatment default and marginal effects of the intervention, all oblasts



Probability of Dying

Improved treatment adherence should lead to reduced mortality among TB patients. We looked at mortality by risk cohort and oblast (Table 6). We found that participants in the HR intervention group had the lowest probability of dying (2.1 percent probability of dying compared with a 6.7 percent probability of dying for 2014 HR comparison cohort, and 4.3 percent probability for the 2015 comparison HR cohort). By oblast, the HR comparison groups from both years had similar probabilities of dying, and the probabilities were higher than the intervention group. Dnipropetrovsk had the highest probability of dying among the HR patients who received no intervention in both 2014 and 2015, 7.9 and 5.1 percent, respectively. This finding for Dnipropetrovsk was similar to the findings on treatment default.

Table 6. Predicted probability of dying, by intervention group and oblast, n=1375

	HR Intervention 2014			HR Comparison 2014			HR Comparison 2015		
Oblast	Predicted Probability	(SE)	Confidence Interval	Predicted Probability	(SE)	Confidence Interval	Predicted Probability	(SE)	Confidence Interval
All Oblasts	0.021	0.007	(0.007, 0.035)	0.067	0.014	(0.040, 0.093)	0.043	0.010	(0.023, 0.064)
Dnipropetrovsk	0.025	0.009	(0.008, 0.042)	0.079	0.016	(0.047, 0.111)	0.051	0.015	(0.022, 0.081)
Kharkiv	0.008	0.004	(0.000, 0.017)	0.025	0.012	(0.002, 0.048)	0.016	0.008	(0.001, 0.031)
Odessa	0.023	0.009	(0.005, 0.040)	0.072	0.021	(0.032, 0.113)	0.047	0.014	(0.020, 0.074)

Marginal Effects of the Intervention on the Probability of Dying

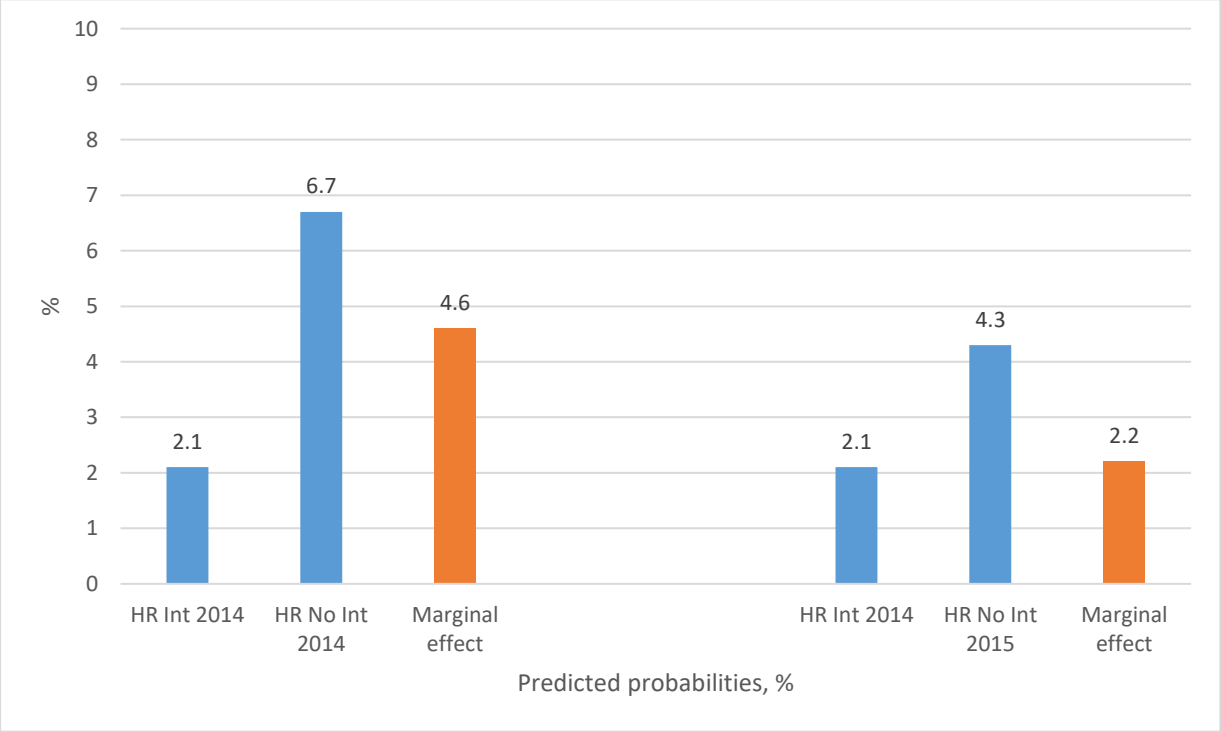
Participation in the SS program (intervention group) lowered the predicted probability of dying by 4.6 percentage points, compared with the 2014 no intervention group ($p<0.01$), and by 2.2 percentage points compared with the 2015 no intervention HR group (results are not statistically significant) (Table 7 and Figure 7). By oblast, we saw significant effects of the intervention on reducing the probability of dying in Dnipropetrovsk and Odessa in 2014 (5.4 and 5 percentage points, respectively).

Table 7. Marginal effect of the intervention on the probability of dying among HR groups, n=1375

	HR intervention 2014 compared with HR no intervention 2014				HR intervention 2014 compared with HR no intervention 2015		
Oblast	Marginal Effect		(SE)	Confidence Interval	Marginal Effect	(SE)	Confidence Interval
All Oblasts	-0.046	**	0.015	(-0.076, -0.016)	-0.022	0.013	(-0.047, 0.002)
Dnipropetrovsk	-0.054	**	0.018	(-0.090, -0.019)	-0.027	0.016	(-0.058, 0.005)
Kharkiv	-0.018		0.009	(-0.036, 0.000)	-0.008	0.005	(-0.119, 0.002)
Odessa	-0.050	*	0.019	(-0.088, -0.012)	-0.024	0.014	(-0.051, 0.003)

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

Figure 7. Predicted probability of dying and marginal effects of the intervention, all oblasts



Appendix A, Tables A7 to A10 provide information from Phase 1 results on predicted probabilities and marginal effects of the intervention.

SS Program Targeting

The aim of the SS program conducted by the URCS was to improve TB treatment adherence, thereby increasing treatment success. As noted above, the URCS program offered home DOTS services to those patients identified to be at higher risk for defaulting on continuation treatment. In 2014, the program served patients in all three oblasts; however, the demand for the SS services often exceeded their capacity to provide care to all HR patients. The URCS, along with its funders and the government, established the risk criteria for SS referrals, which, according to the facility surveys, were applied with some variability by facility (Appendix A, Table A3). The lead TB physician was the decision maker for referrals to the URCS at most facilities.

From the evaluation standpoint, it is important to understand the application of the criteria to the referrals received by the URCS, particularly when some but not all HR patients in 2014 were referred. If patients were selectively referred for treatment, the impact of the program could be underestimated (if selected patients were higher risk than other HR patients) or overestimated (if selected patients were lower risk). Looking only at the HR 2014 patients, we first tested whether any risk factors were predictive of receipt of SS among the HR patients compared with the patients that did not receive SS services. For many risk factors (IDUs, ex-prisoner, presence of comorbidities, health care workers, contacts to cases, and migrants), there was no difference in distribution between intervention and comparison cohorts (data not shown). That is, the intervention and comparison cohorts in 2014 were comparable across these risk categories. Among the remaining risk factors, HIV-positive patients and homeless were less likely to receive the intervention, while abusing alcohol and "other" risk factors were predictive of receiving the intervention. The homeless population was very small in our sample, only 5.1 percent. We also know from facility surveys that this risk factor was not always prioritized. However, HIV coinfection was cited by 91.4 percent of the facilities as an important referral consideration in 2014, and 43.5 percent of the total sample of HR patients in 2014 reported coinfection. One possible reason for the lower referrals among HIV-positive patients was the higher proportion (25.5 percent) of these cases that had extra-pulmonary TB, compared with 8.5 percent of the TB-only patients. The URCS provided limited services to patients with extra-pulmonary TB.

Controlling for these four risk factors in the multivariate logistic regression model (HIV-positive, alcohol use, homeless, and other) did not influence our results from regression analysis, which strengthens the credibility of the main results. Tables A11 and A12 in Appendix A provide more information on the model comparisons. In addition, we compared the treatment outcomes across the five cohorts (Table 3) and found that high-risk nonintervention cohorts had similar default rates in 2014 and 2015 (5.7% in 2014, 8.2% in 2015, p-value=0.16). This strengthens our argument that the difference in outcome for the intervention cohort is attributable to the social support intervention.

Conclusions

The Phase 2 study results are consistent with the Phase 1 findings. Participation in the SS intervention improves TB treatment outcomes among HR patients. The intervention cohort has higher treatment success and lower likelihood of treatment default and dying than the other two HR comparison groups. The intervention cohort has similar TB treatment outcomes as the LR cohorts.

The Effect of the SS Program on the Treatment Success Rate at the Population Level (EQ 1.4)

Key findings:

- The 2014 SS program reduced the population-level default rate by approximately 20 percent from what it might have been without it. In 2014, the URCS program reduced the number of patients defaulting on treatment by 74 patients (reduction from 362 to 288 patients).
- If the URCS program had been continued and expanded to cover all HR patients in 2015, the estimated default rate was 2.65 percent, which translates to 198 patients with default.
- Stopping the URCS program in 2015 was associated with an increase of 31.2 percent in the default rate, compared with what it would have been if the program had been maintained. Stopping the URCS program in 2015 was associated with 113 more patients defaulting on treatment (increase from 362 to 475 patients).

The impact of the SS program at the population level depends not only on the magnitude of the effect of the program for HR patients but also on the coverage of the intervention among HR patients and the prevalence of HR patients in the population of all TB patients. Table 8 provides modeling inputs, data sources, and assumptions. Detailed information on the calculations is provided in Appendix A, Tables A13 and A14. To assess the distribution of risk factors in the population of patients with TB, we analyzed data from 1,030 patient charts sampled from all three regions. With 1,134 charts planned for abstraction, we achieved a 91 percent response rate. Nine percent of charts were excluded, because initiated continuation treatment under the treatment category IV or patients were outside of the determined time interval for the continuation treatment (see Appendix C for details on sampling procedures). There were 50.4 percent HR patients in the 2014 sample, and 51.4 percent HR patients in the 2015 sample. With 7,611 new patients with drug-sensitive TB in the three regions, our estimated coverage of the URCS program in 2014 was 20.6 percent of all TB patients in the oblasts, or 40.8 percent of HR patients. The treatment default rate estimated for 2014, given our study default rates for the different groups and our estimated distribution of these three groups (HR with SS, HR without SS, LR) in the population, was 3.79 percent.

Table 8. Modeling inputs, data sources, and assumptions

Inputs	Year		Data source	Assumptions/Considerations
	2014	2015		
Number of URCS patients	1,564	0	URCS program data	No SS program was provided in 2015
Number of new patients with drug-sensitive TB in the three regions	7,611	7,482	TB Reference Book, Public Health Center of the Ministry of Health of Ukraine http://phc.org.ua	
Proportion of HR patients in the population	50.4	51.4	Patients charts, N=1,027	Unemployment was not considered a risk factor
Proportion of LR patients in the population	49.6	48.6	Patients charts, N=1,027	
Number of HR patients in the population	3,835	3,846	Calculated based on the number of new patients with drug-sensitive TB and proportion of HR patients in the population	
Proportion of HR patients who received the SS program	40.8	0	Calculated based on the number of URCS patients out of the total number of HR patients in the population	No SS program was provided in 2015
Proportion of HR patients who did not receive the SS program	59.2	100.0		No SS program was provided in 2015
Distribution of patients across risk categories and SS program received:				
HR intervention group	20.5	0	URCS program data, TB Reference Book, patients charts, N=1,027	No SS program was provided in 2015
HR no intervention group	29.8	51.4	Patients charts, N=1,027	No SS program was provided in 2015
LR no intervention group	49.6	48.6	Patients charts, N=1,027	
Proportion of patients with treatment default:				
HR intervention group	1.0	1.0	Patients charts, see Table 3	HR patients not on SS would have experienced default rates estimated for HR patients on SS in 2014, if the SS was provided in 2015
HR no intervention group	5.7	8.2	Patients charts, see Table 3	
LR no intervention group	3.8	4.4	Patients charts, see Table 3	

Figure 8 provides the estimated impact of the URCS program, by different scenarios of program coverage. To estimate the population-level impact of the URCS program in 2014, we simulated what would have happened if it had not existed and if all the HR patients that got SS experienced the default rates of other HR patients. Doing that gives a default rate for 2014 of 4.76 percent. Therefore, under this model, the 2014 SS program reduced the population-level default rate by about 20 percent from what it might have been without it ((4.76-3.79)/4.76). In terms of the number of defaulters, the URCS program in 2014 reduced the number of patients defaulting on treatment by 74 patients (reduction from 362 to

288 patients; calculations are based on the number of new patients with drug-sensitive TB in the three regions in 2014, Table 8).

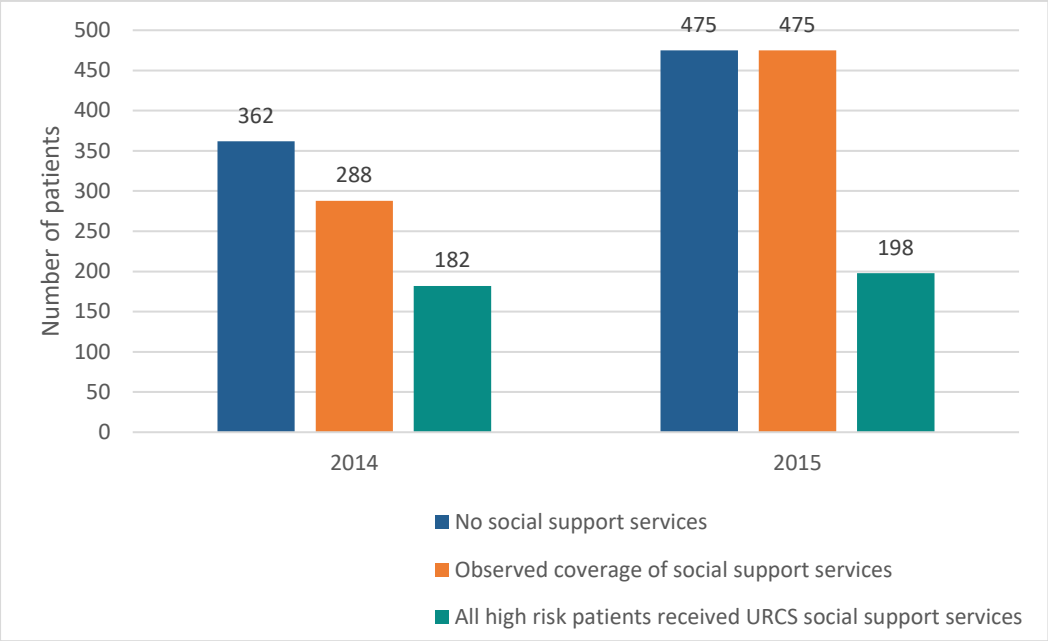
If the URCS program had been expanded to cover all HR patients, the estimated default rate was 2.39 percent. That is the maximum impact we could have expected of the program, which translates to 182 patients with default.

Similarly, in 2015, when there was no SS program, we estimated that the default rate in the population was 6.35 percent. This higher rate was associated with both HR patients not receiving SS and higher default rates in the 2015 cohort.

If we simulate what would have happened if the SS had continued to operate as it had in 2014, covering about 40.8 percent of the HR population but with the higher default rates, we found in 2015 that the default rate that we estimated for the population was 4.84 percent. In other words, in 2015, stopping the URCS program was potentially associated with an increase of 31.2 percent in the default rate compared with what it would have been if the program had been maintained ((6.35-4.84)/4.84). In terms of the number of defaulters, stopping the URCS program in 2015 was associated with 113 more patients defaulting on treatment (increase from 362 to 475 patients; calculations are based on the number of new patients with drug-sensitive TB in the three regions in 2015, Table 8).

If the URCS program had been continued and expanded to cover all HR patients in 2015, the estimated default rate was 2.65 percent. That is the maximum impact we could have expected of the program in 2015, which translates to 198 patients with default.

Figure 8. Number of patients with treatment default, by SS program coverage and year (results from modeling)



Barriers to Treatment Adherence and What Works Best for Ensuring Adherence (EQ1.2 and 1.3)

Study Participants

We interviewed 21 patients and 11 SS program providers/nurses from four cities in two regions of Ukraine. Eight patients were female. All providers were female. Nine nurses worked full time for the URCS and two nurses worked at a TB HF. We also interviewed one STbCU staff member and three URCS coordinators. Table 9 provides more information about the number of patients, nurses, and coordinators interviewed, by city and region.

Table 9. Geographic distribution of the participants

City	Region	Number of patients interviewed	Number of providers interviewed	Number of program coordinators
Odessa	Odessa	10	5	1
Dnipro	Dnipropetrovsk	4	2	1
Kryvyi Rih	Dnipropetrovsk	5	2	
Nikopol	Dnipropetrovsk	2	2	
Kiev	Kiev			2
Total		21	11	4

We did not find any sex differences in barriers to adherence reported by patients. Therefore, the findings presented below are for all patients.

Barriers to Outpatient TB Treatment Adherence for Patients in At-Risk Groups (EQ1.2)

Key Findings:

- Aspects of outpatient TB treatment that made adherence particularly difficult for patients prior to joining the SS program included weakness and side effects from medicine; length of time required daily to receive outpatient treatment at a HF; HF hours of operation; fear of getting reinfected with another TB strain at a HF; stigma; transportation expenses; and lack of motivation to get treated.
- The SS program addressed most of the treatment adherence barriers that patients faced when they received outpatient treatment at HFs. The program allowed patients to avoid travel to clinics, which addressed logistical barriers associated with travel time and costs, wait time at HFs, and stigma and fear of further infection. The program also supported patients to handle side effects and depression.

Challenges to Adherence that Patients Faced Prior to Participation in the SS Program

Several themes emerged from the patient interviews about aspects of outpatient TB treatment that made adherence particularly difficult prior to joining the SS program. These themes included weakness and side effects from the medicine; length of time required daily to receive outpatient treatment at a HF; HF hours of operation; fear of getting reinfected with another TB strain at a HF; transportation expenses; and lack of motivation to get treated.

> *I started treatment in May ….From the very beginning of treatment, I started having nausea and I was very sleepy. As I kept taking pills, my condition worsened. … It was a long way to a HF. I had to wait for the minivan. I felt dizzy from the crowd in the minivan too. I felt weak and almost fainted from these pills… Sometimes I missed my stops when I was riding a minivan. I did not feel well. ….There were a few days when I could not get to the HF because I could not make myself get up and go. This was because of the side effects from the pills. These are strong pills.* (Patient)

> *This* [visits to HF] *takes time. In my case, I have to walk to a tram stop for 15 minutes, then it takes time to get there* [to the HF], *to take the pills, to come back. At the end it takes about two hours. Time goes fast. However, there are other things in life that I have to do, go somewhere. I don't want to spend so much time for HF visits every day.* (Patient)

We noted that stigma related to having TB was a cross-cutting theme discussed by respondents in all categories. In addition to being one of the barriers to treatment adherence, stigma negatively influenced the clients' quality of life and their well-being.

> *Odessa is very big communal apartment. It is like a very big village.… when somebody sees you in the hospital he says: "Why is he going to the tuberculosis dispensary?" Most conclude that probably he has tuberculosis. If you show up in the hospital, it becomes clear that something is wrong with you. It goes without saying, because you go to the tuberculosis dispensary. In our city, this hospital specializes only in tuberculosis. There is one in every city, in every district. So, it is important from the psychological point of view. And in public opinion. I really care about it.* (Patient)

They also worry a lot. They go to the TB dispensary and take their pills, but they live in constant fear that they will be seen there by someone. (Nurse)

Challenges to Adherence that Patients Faced while Participating in the SS Program

The SS program addressed most of these barriers by bringing pills to patients' homes. Side effects of the medicine remained one of the biggest challenges for patients involved in the program; however, program participants reported that participation in the home visit program made it easier for them to handle some of the side effects.

I get nauseous from time to time. But I am home, so I go, lay down. I often have a headache. Nausea not so much. Mainly, it is a headache and sleepiness. That is why it was difficult for me to get there [to the HF]. *This way, I am close to home. I climb up to my floor, lay down and it no longer matters whether I am sleepy or not, have a headache or not. I am near my home— I take the pills, go upstairs, and I am at home. I no longer need to overcome a commute. To stand there waiting for the minivan. In this crowd you also get a headache. Sometimes you also get sick from these pills.* (Patient)

Several other challenges to treatment adherence were reported by providers and patients, including alcohol abuse; length of the regimen; patients feeling better in the course of treatment; denial of having TB; depression; and loss of hope.

Bad habits… only bad habits. A person may get drunk and then sleep the whole day. They are just not available. And then, for example, I have to call up his daughter who lives not too far and we go to his house together. We come over and wake him up. (Provider)

Initially, I was very depressed. It was hard for me to understand that I had to follow the regimen, that I am depending on it, that my health depends on it. It was difficult, because I felt miserable. (Patient)

Most Important Aspects of the SS Program for Patients. What Worked Best for Ensuring Adherence (EQ1.3)

Key Findings:

- Two aspects of the SS program that patients indicated as the most important were convenience, since pills were brought to the patients daily, and support provided by the URCS nurses.
- Nurses provided emotional, informational, instrumental, and motivational support. It was important to patients that nurses cared about their well-being and treated them as equals; that nurses provided information, and encouraged and motivated them to stay on treatment; and that patients received individual attention from nurses.
- Patients appreciated and valued the SS program and felt that it helped them to stay on treatment. Often patients were isolated from society and felt lonely. It was very important for them to have someone in their lives who cared about them.

Two aspects of the SS program that patients indicated as the most important were convenience, since pills were brought to the patients daily, and support provided by the URCS nurses. Themes describing convenience for patients included time, effort, and money saved; help dealing with side effects; minimized number of visits to the HF; flexibility in the time of day and place for meetings with nurses; and the opportunity to have uninterrupted treatment.

> [The nurse] *brings the pills to my home, so that you don't have to go there, to be stuck in traffic. Even today you witnessed this. This is the norm for us. You will definitely not be on time, it is pure stress. This is not treatment, it is only stress.* (Patient)

> *It is more convenient for me to meet with the nurse rather than go to the TB hospital. Everything works for me because it is a convenient time, a convenient location. We are always able to find a good fit. If I am unable to, then she will work around my schedule. I can also work around her schedule. That is what was most fitting for me--that you could always find a solution.* (Patient)

Patients equally appreciated the support provided by nurses. Nurses provided emotional, informational, instrumental (i.e., providing tangible assistance), and motivational support. It was important to patients that nurses cared about their well-being and treated them as equals; that nurses provided information, and encouraged and motivated them to stay on treatment; and that patients received individual attention from nurses.

> *Simply, it's pleasant to receive someone's attention. She will calm me down, will say, "It's okay. Everything will be ok. You will heal." You know, it is very hard to have this disease. We all think that none of us will be affected. Things happen in life. None of us are protected from it. With her I was able to talk about this, I was able to open up to her and express my worries. She would calm me down.* (Patient)

> *Tuberculosis is not a flu, but a sickness with which you need support. See, with another disease, you can talk to somebody, can share. With this disease, I cannot just talk to someone and pour my heart out. I was able to talk with the nurse, she knows.* (Patient)

> *Such a program should exist because in such a program…. Many ill patients who get treatment in the hospital do not have the motivation to go through the treatment to get better. But here they encourage and support you, tell you that treatment is necessary, they explain it. And for me, I want to live, and I want to undergo the treatment.* (Patient)

Another important aspect of the SS program that patients mentioned was the importance of understanding the consequences of not getting treated and motivation to stay free of MDR-TB. Last, patients expressed their appreciation for the SS program, for its efforts to treat patients successfully, and consequently, reduce the TB epidemic in the country.

> *I consider this to be a very good program. It does not allow the patient to interrupt treatment. He gets better, he will not infect others, he will not discontinue treatment. At the same time, it improves patients' well-being.* (Patient)

Patients described the program as successful and attributed this success primarily to the dedication and efforts of the nurses. Both patients and nurses described their relationship as open and based on trust and

mutual respect. Many patients considered a nurse as their close friend or a family member who they could trust.

> *Yes, it turns out that you are needed to this organization. The nurse stands behind you with her support, as for family. Right now, there are families in which the members talk and help each other rarely. This, I consider, helps. She brings the pills, talks, and provides advice.* (Patient)

Patients described nurses as open, sincere, approachable, responsible, flexible in scheduling, open to communication, being "positive", and having good energy. Other main themes were excellent interpersonal communication skills; caring about patients and wanting to help them; gaining patients' trust and building rapport; using individual approaches to patients; building patients' self-esteem; and treating them as equals. While nurses felt they had good interpersonal communication skills, they expressed the need for additional training in psychology and counseling. They hoped additional training would help them to understand patients better and come up with new strategies to ensure patient adherence.

To improve this type of SS program in the future, all groups of respondents suggested that food parcels or food certificates be offered to patients to support their treatment. Food certificates could be limited to food items and exclude alcohol and tobacco products. This way a patient would have the choice to buy or not, since tastes differ. In addition, providing food certificates would eliminate many logistics issues associated with the storage and distribution of food parcels.

> *I would love to receive food parcels since I don't have enough food. I can't earn money since I can't get a job. I am not able to get a temporary job requiring physical work due to my health issues. It would be very helpful to have food parcels.* (Patient)

> *You know, if only it was possible to give some kind of groceries to these people. It would be truly effective and easy, that the person would have received something… Even a minimum, you understand? Otherwise, I visit and always think what to come up with, what to do.* (Nurse)

RECOMMENDATIONS

We offer the following recommendations to the Government of Ukraine, USAID, and other stakeholder agencies involved in TB control efforts in Ukraine and internationally:

1. SS is an effective strategy for reducing treatment default and mortality among HR patients and should be considered for all patients at HR of default.
2. If the program is to be replicated or scaled up, staff in SS programs in the future need to be trained to gain the trust of patients, build a close relationship with them, and have skills and qualities similar to those of nurses working for the URCS SS program.
3. To improve this type of SS program in the future, offering food parcels or food certificates to program recipients should be considered, to support their treatment.
4. Future programs need to address TB-related stigma in society, to promote treatment adherence and improve the quality of life of patients with TB.

CONCLUSIONS

The impact evaluation found that participation in the SS intervention improves TB treatment outcomes among HR patients. Both Phase 1 and Phase 2 studies found that the SS program has a protective effect on treatment default. In addition, the evaluation demonstrates the potential impact of the SS program at the population level, taking program coverage and effectiveness into account. The evaluation identifies outpatient treatment adherence barriers for patients at risk of treatment default in Ukraine. This information will be useful in future program planning to promote patients' treatment adherence. The evaluation also describes how the SS program addressed most of the treatment adherence barriers that patients face when they receive outpatient treatment at HFs. This information will be important for program replication or scale up in other areas of the country and globally. Beyond the effect on treatment default, the SS program appears to have a big impact on the quality of life of all TB patients, whether or not they default on treatment, which is another outcome to consider when weighing the costs and benefits of the program.

REFERENCES

MEASURE Evaluation. (2014). *Strengthening Tuberculosis Control in Ukraine: Impact Evaluation Baseline Survey, Ukraine 2014 (tr-15-116)*. Chapel Hill, NC: MEASURE Evaluation, University of North Carolina. Retrieved from https://www.measureevaluation.org/resources/publications/tr-15-116.

World Health Organization. (2016). *Global TB report 2016*. Geneva, Switzerland: WHO. Retrieved from http://apps.who.int/iris/bitstream/10665/250441/1/9789241565394-eng.pdf?ua=1.

APPENDIX A. SUPPLEMENTAL TABLES AND FIGURES FOR THE EVALUATION REPORT

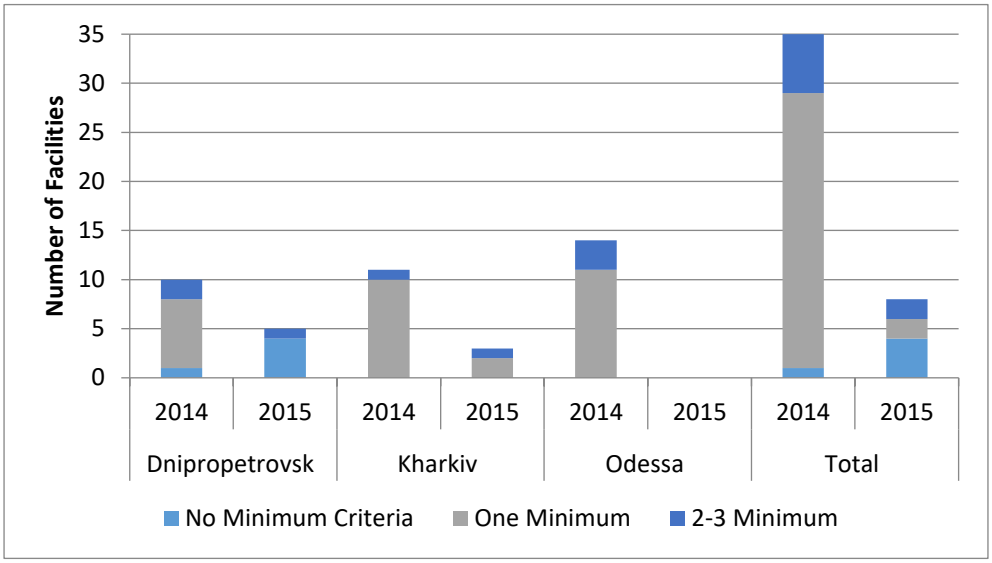
Table A1. TB patients' response rates by risk cohort and intervention group per oblast. Ukraine, 2014 and 2015

	2014			2015			*Total*		
Oblast and Risk Group	Sample	Abstracted	Rate	Sample	Abstracted	Rate	Sample	Abstracted	Rate
Dnipropetrovsk Oblast									
HR intervention	237	237	100.0	NA	NA	NA	237	237	100.0
HR non-intervention	237	236	99.6	237	237	100.0	474	473	99.8
LR non-intervention	237	236	99.6	237	237	100.0	474	473	99.8
Sub-Total	711	709	99.7	474	474	100.0	1185	1183	99.8
Kharkiv Oblast									
HR intervention	107	107	100.0	NA	NA	NA	107	107	100.0
HR non-intervention	107	107	100.0	107	107	100.0	214	214	100.0
LR non-intervention	107	107	100.0	107	107	100.0	214	214	100.0
Sub-Total	321	321	100.0	214	214	100.0	535	535	100.0
Odessa Oblast									
HR intervention	122	121	99.2	NA	NA	NA	122	121	99.2
HR non-intervention	122	122	100.0	122	122	100.0	244	244	100.0
LR non-intervention	122	122	100.0	122	122	100.0	244	244	100.0
Sub-Total	366	365	99.7	244	244	100.0	610	609	99.8
Total Patients	**1398**	**1395**	**99.8**	**932**	**932**	**100.0**	**2330**	**2327**	**99.9**

Table A2. TB facilities surveyed, by type, services offered, and oblast. Ukraine, 2016

	Dnipropetrovsk		Kharkiv		Odessa		Total	
Facility Characteristics	*Number*	(Percent)	*Number*	(Percent)	*Number*	(Percent)	*Number*	(Percent)
Facility Type								
DOT Cabinet	1	(6.3)	0	(0.0)	2	(12.5)	3	(6.3)
TB Cabinet in a polyclinic	11	(68.8)	10	(62.5)	13	(81.3)	34	(70.8)
TB Dispensary / Hospital	4	(25.0)	6	(37.5)	0	(0.0)	10	(20.8)
Other	0	(0.0)	0	(0.0)	1	(6.3)	1	(2.1)
Services Offered								
TB symptom screening	14	(87.5)	16	(100.0)	16	(100.0)	46	(95.8)
TB diagnostic testing	16	(100.0)	16	(100.0)	16	(100.0)	48	(100.0)
TB inpatient treatment	4	(25.0)	3	(18.8)	0	(0.0)	7	(14.6)
TB outpatient treatment	16	(100.0)	16	(100.0)	16	(100.0)	48	(100.0)
HIV voluntary counseling and testing	16	(100.0)	16	(100.0)	16	(100.0)	48	(100.0)
Isoniazid preventive therapy	14	(87.5)	15	(93.8)	16	(100.0)	45	(93.8)
Cotrimoxazole preventive therapy	10	(62.5)	8	(50.0)	11	(68.8)	29	(60.4)
Antiretroviral therapy	8	(50.0)	8	(50.0)	8	(50.0)	24	(50.0)
Injecting drug use (IDU) substitution therapy	6	(37.5)	3	(18.8)	3	(18.8)	12	(25.0)
Psychological counseling	7	(43.8)	5	(31.3)	6	(37.5)	18	(37.5)
Total Facilities	**16**	**(100.0)**	**16**	**(100.0)**	**16**	**(100.0)**	**48**	**(100.0)**

Figure A1. Minimum number of risk factors required to be eligible for referral to a SS program, among facilities providing referrals, by oblast and year. Ukraine, 2014 and 2015*



*Includes only facilities providing referrals to the URCS or PLWH program in 2014 (n=35) and 2015 (n=8). Odessa only referred to the Government of Ukraine in 2015.

Table A3. Risk factors used by surveyed facilities that provide SS program referrals to determine eligibility for referrals, by time period*. Ukraine, 2014 and 2015

	Factor Used for Referrals			
	Jan-May 2014		Jan-May 2015	
Risk Factors	Number	(Percent)	Number	(Percent)
HIV-positive	32	(91.4)	8	(100.0)
Alcoholic	33	(94.3)	8	(100.0)
Injecting Drug User	27	(77.1)	8	(100.0)
Comorbidity	24	(68.6)	6	(75.0)
Homeless	30	(85.7)	7	(87.5)
Unemployed	30	(85.7)	8	(100.0)
Contact with case	22	(62.9)	5	(62.5)
Ex-prisoner	26	(74.3)	8	(100.0)
Health Care Worker	15	(42.9)	2	(25.0)
Migrant	18	(51.4)	3	(37.5)
Refugee / Immigrant	17	(48.6)	3	(37.5)
Low income	24	(68.6)	7	(87.5)
Total Facilities	**35**	**(100.0)**	**8**	**(100.0)**

*Among facilities providing referrals to the URCS and PLWH programs.

Table A4. SS services offered according to referral facilities in 2014 and 2015*. Ukraine, 2014 and 2015

Patient Incentives	Jan-May 2014		Jan-May 2015	
	Number	(Percent)	Number	(Percent)
Home Visits				
Daily	33	(94.3)	5	(62.5)
Weekly	2	(5.7)	3	(37.5)
Food Packages (total quantity for the reporting period)				
1	5	(14.3)	2	(25.0)
2	22	(62.9)	5	(62.5)
3 or more	3	(8.6)	0	(0.0)
Not offered	3	(8.6)	0	(0.0)
Missing	2	(5.7)	1	(12.5)
Total Facilities	**35**	**(100.0)**	**8**	**(100.0)**

*Among facilities providing referrals to the URCS and PLWH programs.

Table A5. Background characteristics of TB patients, by risk cohort and year. Ukraine, 2014 and 2015

	HR Patients						LR Patients				Total	
	Intervention 2014		Comparison 2014		Comparison 2015		Comparison 2014		Comparison 2015			
Background characteristics	Number	(Percent)	Number	(Percent)	Number	(Percent)	Number	(Percent)	Number	(Percent)	Number	(Percent)
Sex												
Female	188	(40.4)	179	(38.4)	179	(38.5)	187	(40.1)	190	(40.9)	923	(39.6)
Male	277	(59.6)	287	(61.6)	287	(61.5)	279	(59.9)	276	(59.1)	1404	(60.3)
Age												
18-29 years	102	(22.0)	64	(13.7)	46	(9.9)	120	(25.8)	127	(27.3)	459	(19.7)
30-39 years	136	(29.2)	163	(34.9)	201	(43.2)	111	(23.7)	131	(28.1)	741	(31.8)
40-49 years	98	(21.1)	136	(29.2)	130	(27.8)	89	(19.1)	91	(19.5)	543	(23.3)
50-59 years	84	(18.2)	74	(15.9)	65	(14.0)	92	(19.8)	61	(13.1)	377	(16.2)
60-69 years	30	(6.6)	20	(4.3)	16	(3.4)	41	(8.8)	35	(7.5)	142	(6.1)
70 and older	14	(3.0)	9	(1.9)	8	(1.7)	13	(2.8)	21	(4.5)	65	(2.8)
Employment												
Employed	64	(13.8)	47	(10.0)	70	(15.0)	96	(20.6)	120	(25.8)	397	(17.1)
Unemployed	324	(69.7)	352	(75.7)	338	(72.5)	293	(62.9)	261	(55.9)	1567	(67.3)
Retired/Disabled	59	(12.7)	54	(11.6)	47	(10.1)	51	(10.9)	57	(12.1)	267	(11.5)
Student/Housewife/Other	14	(2.9)	8	(1.8)	4	(0.9)	18	(3.9)	20	(4.3)	64	(2.8)
Missing	4	(0.8)	4	(0.9)	7	(1.5)	8	(1.7)	9	(1.8)	32	(1.4)
Residence												
Rural	108	(23.2)	125	(26.8)	111	(23.8)	117	(25.2)	117	(25.1)	577	(24.8)
Urban	345	(74.4)	337	(72.3)	343	(73.7)	337	(72.4)	339	(72.8)	1701	(73.1)
Missing	11	(2.4)	4	(0.9)	12	(2.6)	11	(2.4)	10	(2.1)	48	(2.1)
Oblast												
Dnipropetrovsk	167	(36.0)	167	(35.8)	167	(35.9)	167	(35.8)	167	(35.9)	835	(35.9)
Kharkiv	82	(17.6)	82	(17.5)	82	(17.5)	82	(17.5)	82	(17.5)	408	(17.5)
Odessa	215	(46.4)	217	(46.7)	217	(46.6)	217	(46.7)	217	(46.6)	1084	(46.6)
Total Patients	464	(100.0)	465	(100.0)	466	(100.0)	465	(100.0)	466	(100.0)	2327	(100.0)

Table A6. TB patient's disease status, by risk cohort and year. Ukraine, 2014 and 2015

	HR Patients						LR Patients				Total	
	Intervention 2014		Comparison 2014		Comparison 2015		Comparison 2014		Comparison 2015			
Disease Status	Number	(Percent)	Number	(Percent)	Number	(Percent)	Number	(Percent)	Number	(Percent)	Number	(Percent)
TB Classification												
First Diagnosis	343	(73.9)	313	(67.3)	341	(73.1)	352	(75.6)	381	(81.8)	1729	(74.3)
Reinitiation*	94	(20.3)	111	(23.9)	69	(14.8)	77	(16.6)	28	(6.1)	380	(16.3)
Relapse	26	(5.7)	41	(8.8)	57	(12.1)	36	(7.8)	56	(12.1)	217	(9.3)
Missing	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
TB Clinical Form												
Pulmonary	431	(92.8)	377	(81.0)	383	(82.2)	416	(89.4)	406	(87.1)	2014	(86.5)
Extra-Pulmonary	17	(3.7)	57	(12.3)	51	(10.9)	36	(7.7)	53	(11.4)	214	(9.3)
Both Pulmonary and Extra-Pulmonary	16	(3.4)	31	(6.7)	32	(6.9)	13	(2.8)	7	(1.5)	99	(4.2)
TB Treatment Category												
Category I	318	(68.5)	300	(64.6)	327	(70.3)	319	(68.5)	340	(72.9)	1604	(68.9)
Category II	115	(24.9)	143	(30.8)	121	(25.9)	112	(24.0)	75	(16.0)	566	(24.3)
Category III	30	(6.5)	22	(4.7)	18	(3.9)	35	(7.4)	52	(11.1)	157	(6.7)
Missing	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Total Patients	464	**(100.0)**	465	**(100.0)**	466	**(100.0)**	465	**(100.0)**	466	**(100.0)**	2327	**(100.0)**

***** Includes reinitiated treatment, treatment failure, and those with previous TB but no documentation available.

Table A7. Phase 1 predicted probability of treatment default, by intervention and oblast, n=1188

	HR Intervention 2012			HR Comparison 2012			HR Comparison 2011		
Oblast	Predicted Probability	(SE)	Confidence Interval	Predicted Probability	(SE)	Confidence Interval	Predicted Probability	(SE)	Confidence Interval
All Oblasts	0.019	0.007	(0.006, 0.032)	0.111	0.016	(0.079, 0.144)	0.128	0.017	(0.096, 0.161)
Dnipropetrovsk	0.018	0.007	(0.005, 0.031)	0.113	0.021	(0.073, 0.154)	0.125	0.022	(0.083 0.168)
Kharkiv	0.010	0.004	(0.002, 0.018)	0.063	0.019	(0.026, 0.100)	0.070	0.020	(0.032, 0.109)
Odessa	0.026	0.010	(0.006, 0.047)	0.155	0.030	(0.096, 0.214)	0.170	0.030	(0.111, 0.230)

Table A8. Phase 1 marginal effect of the intervention on the probability of default among HR groups, n=1188

	HR intervention 2012 compared with HR no intervention 2012				HR intervention 2012 compared with HR no intervention 2011			
Oblast	Marginal Effect		(SE)	Confidence Interval	Marginal Effect		(SE)	Confidence Interval
All Oblasts	-0.093	***	0.018	(-0128, -0.058)	-0.109	***	0.018	(-0.144, -0.074)
Dnipropetrovsk	-0.095	***	0.021	(-0.135, -0.054)	-0.107	***	0.021	(-0.149, -0.065)
Kharkiv	-0.053	**	0.017	(-0.087, -0.020)	-0.061	**	0.018	(-0.096, -0.025)
Odessa	-0.128	***	0.028	(-0.184, -0.073)	-0.144	***	0.028	(-0.199, -0.089)

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

Table A9. Phase 1 predicted probability of dying, by intervention and oblast, n=1188

	HR Intervention 2012			HR Comparison 2012			HR Comparison 2011		
Oblast	Predicted Probability	(SE)	Confidence Interval	Predicted Probability	(SE)	Confidence Interval	Predicted Probability	(SE)	Confidence Interval
All Oblasts	0.019	0.007	(0.006, 0.031)	0.074	0.014	(0.047, 0.101)	0.044	0.010	(0.024, 0.064)
Dnipropetrovsk	0.015	0.007	(0.002, 0.028)	0.064	0.015	(0.035, 0.093)	0.035	0.010	(0.016, 0.054)
Kharkiv	0.007	0.004	(0.000, 0.014)	0.029	0.014	(0.002, 0.056)	0.016	0.008	(0.001, 0.031)
Odessa	0.038	0.013	(0.012, 0.062)	0.147	0.034	(0.081, 0.214)	0.085	0.024	(0.037, 0.133)

Table A10. Phase 1 marginal effect of the intervention on the probability of dying among HR groups, n=1188

	HR intervention 2012 compared with HR no intervention 2012				HR intervention 2012 compared with HR no intervention 2011			
Oblast	Marginal Effect		(SE)	Confidence Interval	Marginal Effect		(SE)	Confidence Interval
All Oblasts	-0.055	***	0.015	(-0.085, -0.025)	-0.025	*	0.012	(-0.050, -0.001)
Dnipropetrovsk	-0.049	***	0.014	(-0.075, -0.022)	-0.020	*	0.010	(-0.039, -0.001)
Kharkiv	-0.022		0.012	(-0.045, 0.000)	-0.009		0.006	(-0.021, 0.003)
Odessa	-0.110	**	0.035	(-0.177, -0.042)	-0.047		0.026	(-0.097, 0.003)

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

Table A11. Predicted probability of treatment default and death, by intervention and model, n=1375

	HR Intervention 2014			HR Comparison 2014			HR Comparison 2015		
Models	Predicted Probability	(SE)	Confidence Interval	Predicted Probability	(SE)	Confidence Interval	Predicted Probability	(SE)	Confidence Interval
Probability of treatment default									
Model 1	0.006	0.003	(0.000, 0.012)	0.058	0.012	(0.035, 0.080)	0.085	0.014	(0.057, 0.112)
Model 2	0.007	0.003	(0.000, 0.013)	0.056	0.011	(0.034, 0.078)	0.084	0.014	(0.057, 0.111)
Probability of death									
Model 1	0.021	0.007	(0.007, 0.035)	0.067	0.014	(0.040, 0.093)	0.043	0.010	(0.023, 0.064)
Model 2	0.026	0.008	(0.010, 0.043)	0.061	0.012	(0.037, 0.085)	0.039	0.009	(0.021, 0.056)

Model 1: Logistic regression controlling for age, sex, and place of residence.
Model 2: Logistic regression controlling for age, sex, place of residence, and HR factors (HIV-positive, alcohol abuse, homeless, other).

Table A12. Marginal effects of the intervention on the probability of default and death among HR groups for different models, n=1375

	HR intervention 2014 compared with HR no intervention 2014				HR intervention 2014 compared with HR no intervention 2015			
Models	Marginal Effect		(SE)	Confidence Interval	Marginal Effect		(SE)	Confidence Interval
Probability of treatment default								
Model 1	-0.051	***	0.012	(-0.075, -0.028)	-0.078	***	0.015	(-0.107, -0.050)
Model 2	-0.067	***	0.015	(-0.097, -0.037)	-0.102	***	0.020	(-0.140, -0.063)
Probability of death								
Model 1	-0.046	**	0.015	(-0.076, -0.016)	-0.022		0.013	(-0.047, 0.002)
Model 2	0.035	*	0.015	(-0.063, -0.006)	-0.013		0.012	(-0.036, 0.011)

*p<0.05, **p<0.01, ***p<0.001
Model 1: Logistic regression controlling for age, sex, and place of residence.
Model 2: Logistic regression controlling for age, sex, place of residence, and HR factors (HIV-positive, alcohol abuse, homeless, other).

Table A13. Modeling inputs, data sources, and assumptions

Inputs	Year				Data source	Assumptions/Considerations
	2014	Calculations	2015	Calculations		
Number of URCS patients	1,564		0		URCS	No SS program was provided in 2015
Number of new patients with drug-sensitive TB in the three regions	7,611		7,482		TB Reference Book, Public Health Center of the Ministry of Health of Ukraine http://phc.org.ua	
Proportion of HR patients in the population	50.4		51.4		Patients charts, N=1,027	Unemployment was not considered as a risk factor
Proportion of LR patients in the population	49.6		48.6		Patients charts, N=1,027	
Number of HR patients in the population	3,835	equals 50.4% of 7611	3,846	equals 51.4% of 7,482	Calculated based on the number of new patients with drug-sensitive TB and proportion of HR patients in the population	
Proportion of HR patients who received SS program	40.8	equals proportion of 1564 patients out of 3835	0		Calculated based on the number of URCS patients out of the total number of HR patients in the population	No SS program was provided in 2015
Proportion of HR patients who did not receive SS program	59.2	equals 100% minus 40.78%	100			No SS program was provided in 2015
Distribution of patients across risk categories and SS program received:						
HR intervention group	20.5	equals 40.8% out of 50.4% of HR patients in the population	0		URCS program data, TB Reference Book, patients charts, N=1,027	No SS program was provided in 2015
HR no intervention group	29.8	equals 59.2% out of 50.4% of HR patients in the population	51.4		Patients charts, N=1,027	No SS program was provided in 2015
LR no intervention group	49.6		48.6		Patients charts, N=1,027	
Proportion of patients with treatment default:						
HR intervention group	1.0		1.0		Patients charts, see Table 3 in the report	HR patients not on SS would have experienced the default rates we estimated for HR patients on SS in 2014
HR no intervention group	5.7		8.2		Patients charts, see Table 3 in the report	
LR no intervention group	3.8		4.4		Patients charts, see Table 3 in the report	

Table A14. Calculation for the default rate at population level, by year

	2014, SS is provided			2015, no SS is provided		
	Proportion of patients with treatment default	Proportion in the population/ weights	Contribution to the weighted average of the risk cohort specific rates*	Proportion of patients with treatment default	Proportion in the population/ weights	Contribution to the weighted average of the risk cohort specific rates*
Population groups:						
HR intervention group	1	20.5	0.21	n/a	0	0
HR no intervention group	5.7	29.8	1.70	8.2	51.4	4.21
LR no intervention group	3.8	49.6	1.89	4.4	48.6	2.14
Weighted default rate for the population			**3.79****			**6.35****

* Equals the proportion of patients with default multiplied by individual cohort weights and divided by 100.

**Equals the sum of contributions from each risk cohort.

APPENDIX B. STUDY PROTOCOL

MEASURE Evaluation Phase IV

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

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 endline 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.

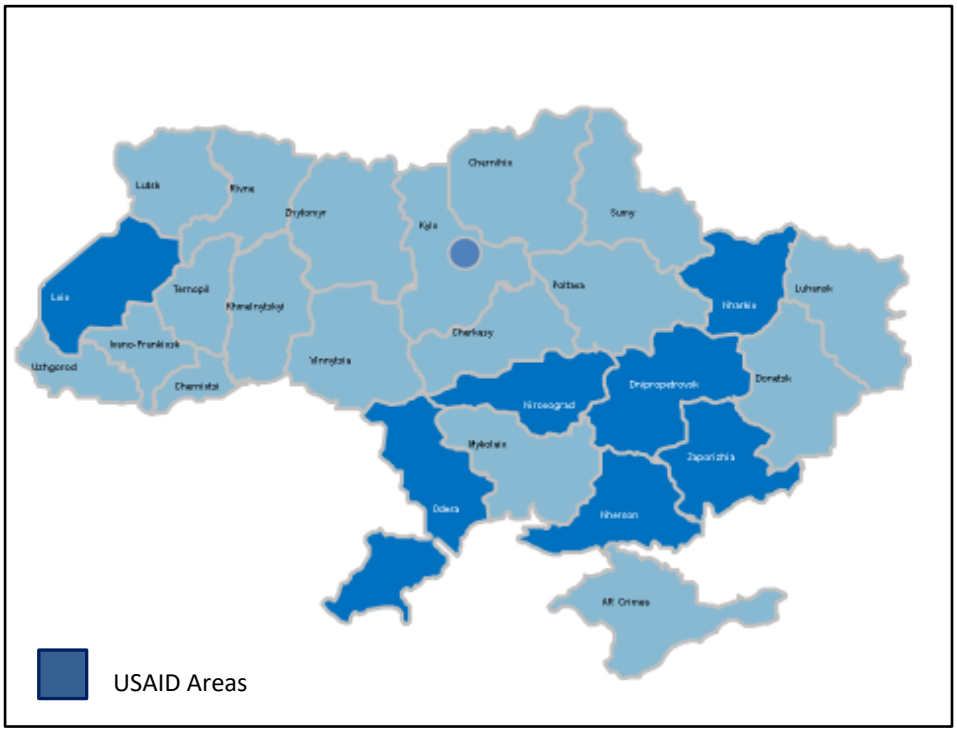
The interventions of interest to this evaluation are:

- 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.

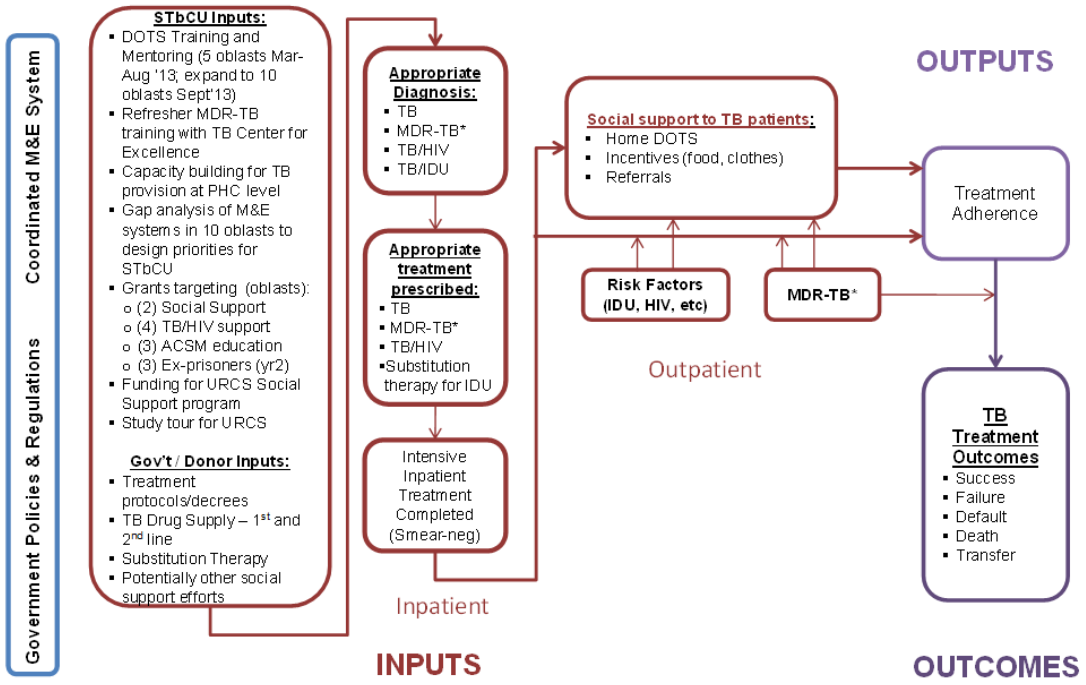
An additional layer of targeting would be used to select program participants for the URCS SS program to increase treatment adherence. The 10 key target HR groups for this intervention included alcoholics, people who inject drugs, TB contacts, homeless, migrants, refugees, ex-prisoners, unemployed, persons with comorbidities, and others identified as HR by the health care provider. Risk screening was completed by the health care 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.

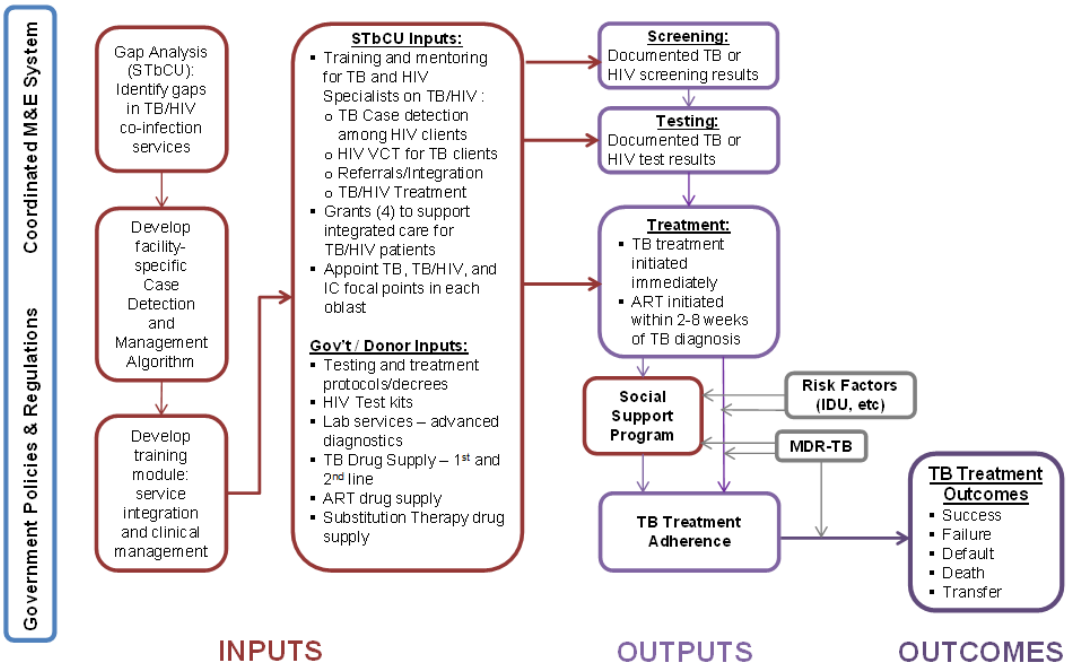
Figure B3 focuses on the collaboration between TB and HIV programs. Almost 17% of new TB cases are infected with HIV and 40% of the AIDS deaths are attributable to TB, yet the government services providing TB and HIV care remain vertical, with minimal collaboration across programs. The STbCU, through 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



Note: 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



Note: Risk factors such as co-morbidity (e.g., IDU) may moderate patients efforts to adhere to treatment regimen
*MDR-TB patients receive a longer treatment regimen and as such will likely be excluded from the final analysis

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 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 LR and 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 (EQ1.1) 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 Sub-Total:	690	300	345	1335
2015 HR Non-Intervention	230	100	115	445
2015 LR Non-Intervention	230	100	115	445
2015 Sub-Total:	460	200	230	890
TOTAL by Oblast:	**1150**	**500**	**575**	**2225**

Test and Assumptions:

5% one-sided log-rank test, 80% power, 1.2 design effect

HR Nonintervention Default = 9%; HR Intervention, LR Non-Intervention Default = 4%, Censoring =18%

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:

Individual Data: 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.

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

Facility Data: 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 WHO-recommended 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 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, 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 (EQ1.2, 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).

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

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	

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 endline).

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 and those who receive services from facilities that are not 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 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 endline), 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:

1. 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).
2. 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).

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

Oblast	TB Facilities		HIV Facilities	
	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**
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.

Facility Data: 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 WHO-recommended 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 (EQ2.1). 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 are the interaction terms between the study phase and the intervention group in these models. This analysis will allow us to measure whether participants in the integration treatment oblasts received key services in a timelier manner compared with the comparison group, and whether these outcomes have improved over time more in intervention oblasts than in the comparison oblasts, indicating program effects (EQ2.3). Among those patients who are coinfected, a separate similar hazards model will model all-cause mortality events. (EQ2.4).

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).

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

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)	

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:

1) 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).
2) 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 three-country 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 for an orphans and vulnerable children project in Uganda, and 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 implementation timeline for Phase 2, STbCU project impact evaluation

Tasks/Timeline	2016												2017											
	Ja	Fe	Ma	Ap	Ma	Ju	Ju	Au	Se	Oc	No	De	Ja	Fe	Ma	Ap	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																								
Define sampling plan for treatment / comparisons																								
Pilot test instruments																								
Train data collectors and study coordinators																								
Trip: Train data collectors and study coordinators																								
Collect data – chart and facility surveys (SS Study)																								
Collect data – chart (TB/HIV Integration Study) abstraction																								
Process and analyze data																								
Draft preliminary report																								
Qualitative Study – timeline for qualitative study could shift per schedule of subcontractor																								
Define sampling plan																								

Tasks/Timeline	2016												2017											
	Ja	Fe	Ma	Ap	Ma	Ju	Ju	Au	Se	Oc	No	De	Ja	Fe	Ma	Ap	Ma	Ju	Ju	Au	Se	Oc	No	De
Train data collectors																								
Trip: Training, Data Collection																								
Collect data																								
Process and analyze data																								
Draft preliminary report																								
Final Evaluation Findings Dissemination																								
Produce combined report																								
Review by stakeholders																								
Dissemination/Data Use Workshop																								
Trip: Dissemination/Data Use Workshop																								
Produce the workshop report with recommendations																								
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

Acosta, C.D., Kaluski, D.N. & Dara, M. (2014). Conflict and drug-resistant tuberculosis in Ukraine. *The Lancet*, 384(9953), pp.1500–1501. Retrived from http://linkinghub.elsevier.com/retrieve/pii/S0140673614619140.

Guo, S., Barth, R.P., Gibbons, C. (2006). Propensity score matching strategies for evaluating substance abuse services for child welfare clients. *Children and Youth Services Review,* 28(4):357-83. Retrieved from http://www.sciencedirect.com/science/article/pii/S0190740905001143.

PATH. (n.d.) Ukraine TB and TB/HIV Projects. Retrived from http://www.path.org/publications/files/HIV-AIDS_Ukraine_tb_fs.pdf.

PATH. (2012). Ukraine Tuberculosis Control Partnership Project: Final Report, May 15, 2012. Retrieved from http://pdf.usaid.gov/pdf_docs/pdacu009.pdf.

UNAIDS. (2013). Ukraine Harmonized AIDSResponse Progress Report. Retrieved from http://www.unaids.org/sites/default/files/country/documents//UKR_narrative_report_2014.pdf.

USAID. (2011). USAID Evaluation Policy. Washington, D.C. Retrieved from http://pdf.usaid.gov/pdf_docs/Pdacq800.pdf.

Ukraine National Tuberculosis Statistics. (2014). Ukrainian Center for Disease Control website. Retrieved from http://ucdc.gov.ua/pages/diseases/tuberculosis/surveillance/statistical-information. Table 44.

WHO. (2016). Ukraine Tuberculosis Brief. Retrieved from http://www.euro.who.int/en/health-topics/communicable-diseases/tuberculosis/country-work/ukraine.

World Health Organization. (2002). *An expanded DOTS framework for effective tuberculosis control.* Geneva, Switzerland: WHO. Retrieved from http://apps.who.int/iris/bitstream/10665/67232/1/WHO_CDS_TB_2002.297.pdf.

World Health Organization. (2012). *WHO policy on collaborative TB/HIV activities- Guidelines for national programmes and other stakeholders.* Geneva, Switzerland: WHO. Retrieved from http://www.who.int/tb/publications/2012/tb_hiv_policy_9789241503006/en/.

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.

Table B7. Changes to the study design in Phase 2

#	Proposed in the original protocol	Changes to the original protocol	Notes/Explanation
For the SS Study:			
1	Prospective enrollment of TB patients for endline	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. 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.	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.

#	Proposed in the original protocol	Changes to the original protocol	Notes/Explanation
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 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.
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 C. SAMPLE SIZE AND SAMPLING PROCEDURES

Sample size calculation for patient chart abstraction, EQ 1.1

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 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 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 C1).

Table C1. 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 Sub-Total:	690	300	345	1335
2015 HR Non-Intervention	230	100	115	445
2015 LR Non-Intervention	230	100	115	445
2015 Sub-Total:	460	200	230	890
TOTAL by Oblast:	**1150**	**500**	**575**	**2225**
Test and Assumptions:				
5% one-sided log-rank test, 80% power, 1.2 Design Effect				
HR Non-Intervention Default = 9%; HR Intervention, LR Non-Intervention Default=4%, Censoring=18%				

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, the comparison group will not see measurable change in rates.

Sampling procedures for sample selection for chart abstraction, EQ 1.1

We need to abstract data from a total of 2,225 TB records: 1,335 records from 2014 and 890 from 2015. For 2014, 445 patients who received URCS SS services will be matched with 445 HR who did not receive SS and 445 LR patients who did not receive SS. This sample of non-intervention patients will be matched on treatment facility, initiation date for continuation treatment, sex, and age. For 2015, 445 HR and 445 LR patients matched on treatment facility, initiation date for continuation treatment, sex, and age will be sampled.

Table C2. Sample sizes

	HR Intervention	HR Non-Intervention	LR, Non-Intervention	**TOTAL**
Jan – May 2014	445	445	445	**1335**
Jan – May 2015		445	445	**890**

We are sampling from three oblasts—Dnipropetrovsk, Kharkiv, and Odessa—with sampling proportional to TB outpatients per facility, or proportionate to size. Each of the three oblasts received some funding from USAID and the Global Fund for SS services provided by the URCS in 2014. The URCS served 581 patients in Dnipropetrovsk, 714 patients in Odessa, and 269 patients in Kharkiv in 2014. Assuming that the number of new cases receiving SS is evenly distributed across the year, we estimate needing to select all HR records of patients receiving SS services from the URCS from a five-month period, January to May 2014 in Dnipropetrovsk and Kharkiv, and a sample of these patients in Odessa. The number of HR and LR records for abstraction by oblast is estimated below (Table C3).

Table C3. Sample per oblast

	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 Sub-Total:	690	300	345	1335
2015 HR Non-Intervention	230	100	115	445
2015 LR Non-Intervention	230	100	115	445
2011 Sub-Total:	460	200	230	890
TOTAL by Oblast:	**1150**	**500**	**575**	**2225**

Note for the purposes of sample selection, our definitions are as follows:

URCS Intervention Patient: Everyone on the URCS patient list.

HR Non-Intervention Patient: Any patient with one or more of the following risk factors who is not receiving SS services: alcoholics, IDUs, TB contacts, homeless, migrants, refugees, ex-prisoners, and persons with comorbidities.

LR Non-Intervention Patient: Exclude all risk factors, except for unemployed.

To select the sample, we will start with a list of all patients who received SS services from the URCS in each Oblast between January and May 2014. The list will include both USAID- and Global Fund-funded non-MDR-TB patients in 2014. The list from the URCS will be sorted by the date outpatient treatment was initiated. It will include patient name, date of birth, facility, medical record number, and risk factor. Starting with January 1, 2014, we will go down the list of the URCS patients chronologically and select the total number needed to meet the 2014 HR intervention sample for Dnipropetrovsk and Kharkiv oblasts. For Odessa oblast, we will apply systematic random sampling to select 115 patients from the sampling frame of patients who received SS from the URCS during January to May 2014. (See the instruction on implementing systematic random sampling below.) This sample of 2014 HR URCS patients will determine the TB Cabinets we will select for the remaining sample. Each TB Cabinet on the URCS 2014 sample list will be visited and the sample steps below will be followed.

FOR 2014:

Overall note: To meet the sample size requirements, we can extend the timeframe for finding matches from January to May 2014 to January to September 2014. Also, we can look for matches in the neighboring health facilities in the same rayon.

1. Start first with the patient TB Register from 2014. Beginning with January 2014, find every **patient** on the URCS list that started treatment during January at that facility. Select those patients who were part of the sample of 2014 HR URCS patients (see above). Confirm the patients' medical record numbers.
2. For each sampled URCS patient, we need to select a **LR patient** seen at the same facility during the same time period. Once you have identified the first sampled URCS patient in the Register, next select one record for a LR patient who initiated treatment on the same day, matching on sex (male or female). If more than one LR patient initiated treatment on the same day, then further match to one closest in age. If no LR patient of the same sex initiated treatment on the same day, then select a LR patient of the same sex who started treatment as close to the same day as possible. Record the LR patient's name and medical record number.
3. For each sampled URCS patient, we need to select a **HR patient** seen at the same facility during the same time period, but one who did not receive the SS program. Once you have identified the first sampled URCS patient in the Register, next select one record for a HR patient who initiated treatment on the same day, matching on sex (male or female). If more than one HR patient initiated treatment on the same day, then further match to one closest in age. If no HR patient of the same sex initiated treatment on the same day, then select a HR patient of the same sex who started treatment as close to the same day as possible. Record the HR patient's name and medical record number.
4. Continue selection following steps 1 to 3 above for February, March, April, and May.

FOR 2015:

Overall note: To meet the sample size requirements, we can extend the timeframe for finding matches from January to May 2015 to January to September 2015. Also, we can look for matches in the neighboring health facilities in the same rayon.

1. We will not use a list of HR patients from the URCS for January to May 2015 because the URCS provided limited services in 2015. Only 106 patients in Dnipropetrovsk and 79 patients in Odessa received services from the URCS in 2015. However, we need to sample patients with risk factors that would make them *eligible* for a referral if the service had been available. We will sample these patients from the same facilities that provided a sample of 2014 HR patients receiving the SS program. We want to select the same number of HR non-intervention patients from each TB Cabinet in January to May 2015 as was selected from that Cabinet in January to May 2014.
2. For the 2015 samples, exclude any patient who is noted on the URCS patient list as having received the SS program at any time. Also, exclude any patient who received SS services from the Network of People Living with HIV.
3. Repeat step 1 for the 2014 sample above, i.e., start first with the patient TB Register from 2014. Beginning with January 2014, find every **patient** on the URCS list that started treatment during January 2014 at that facility. Select those patients who were part of the sample of 2014 HR URCS patients (see above). Confirm the patients' medical record numbers.
4. For each sampled URCS patient in 2014, we need to select a **LR patient** seen at the same facility during the same time period in 2015. Once you have identified the first sampled 2014 URCS patient in the Register, next select one record for a LR patient who initiated treatment on the same day in 2015, matching on sex (male or female). If more than one LR patient initiated treatment on the same day, then further match to one closest in age. If no LR patient of the same sex initiated treatment on the same day, then select a LR patient of the same sex who started treatment as close to the same day as possible. Record the LR patient's name and medical record number.
5. For each sampled URCS patient in 2014, we need to select a **HR patient** seen at the same facility during the same time period in 2015, but one who did not receive the SS program. Once you have identified the first sampled URCS patient in the 2014 Register, next select one record for a HR patient who initiated treatment on the same day in 2015, matching on sex (male or female). If more than one HR patient initiated treatment on the same day, then further match to one closest in age. If no HR patient of the same sex initiated treatment on the same day, then select a HR patient of the same sex who started treatment as close to the same day as possible. Record the HR patient's name and medical record number.
6. Continue selection following steps 4 to 5 above for February, March, April, and May to select the full sample.

Once the sample for 2014 and 2015 has been selected, proceed with pulling the medical record for each case and abstracting the data using the TB Data Abstraction Form.

<u>Additional guidance on selecting matches for the SS program to address difficulties in finding matches in the HR no intervention group:</u>

1. Extend the timeframe to January to December for each year, 2014 and 2015. If needed, extend the windows to a few months in the previous years.
2. Step 1. Try to find matches in the same HF that provides the URCS intervention patient. Find the matches seen during the same time of year, match on sex, then select the one closest on age. If there are no matches to be found, go to the next step (see below).
3. Step 2. Find matches in the same HF that provides the URCS intervention patient. Find the matches seen during the same time of year, select opposite sex, then select the one closest on age. If there are no matches to be found, go to the next step (see below).
4. Step 3. Search for matches in the other HFs that provide the URCS intervention patients. Find the matches seen during the same time of year, match on sex, then select the one closest on age. If there are no matches to be found, go to the next step (see below).
5. Step 4. Search for matches in the other HFs that provide the URCS intervention patients. Find the matches seen during the same time of year, select opposite sex, then select the one closest on age. If there are no matches to be found, go to the next step (see below).
6. Step 5. Search for matches in the other neighboring HFs that do not provide the URCS intervention patients. Find the matches seen during the same time of year, match on sex, then select the one closest on age. If there are no matches to be found, stop your search.

Please make sure to include the health facility ID numbers for all patients in our sample so that we can use this information in the analysis.

Sampling procedures for the risk distribution modeling, EQ 1.4

SAMPLE SIZE: In total 600 records (in three oblasts) per each year (2014, 2015). Total sample for two years: 1200 records.
GEOGRAPHY: Dnipropetrovsk, Odessa, and Kharkov oblasts
STUDY SAMPLE SELECTION:
To determine a sample per each year, we should start with obtaining the list of patients who started treatment in each targeted oblast in the following timeframe:

List 1. Patients who started treatment during the period November 1, 2013 to March 31, 2014
List 2. Patients who started treatment during the period November 1, 2014 to March 31, 2015

For each oblast, a separate list per each year will be obtained, checked for repeats, and after that, the sample will be determined.

ALL PATIENTS should:

1) **Be 18 years old and older at the time of treatment initiation**
2) **Refer to the** I-III **category at the time of treatment initiation**

The list should include the following information: full name, date of birth, treatment initiation date, facility name (where medical record is kept), patient ID number (from both the TB Register and paper records). Additionally, a unique sequential number must be assigned, in other words, the list should have a consecutive numbering.

SAMPLING PROCEDURE:
A systematic probability sample proportional to the size of the population in each region SHOULD BE APPLIED. The sample WILL BE determined separately for each year and region.
To determine the sample for each region (per each year):
Calculate the sample size per each oblast by year. For example, if in Kharkiv in 2014 there were 2000 patients (20%), in Odessa, 5000 patients (50%), and in Dnipropetrovsk, 3000 patients (30%), then our sample size for Kharkiv is 120 records (20%), for Odessa, 300 (50%), and for Dnipropetrovsk, 180 (30%).

1. To select the sample, the list in the oblast should be sorted by the date of treatment initiation. For each list, we need to identify the selection interval by dividing the total number of patients in the oblast per year by the number of records needed. For example, if the total number of patients in the oblast is 2050 patients, and in this oblast we need to select 112 records, then our interval will be 2050/112=18.303.
2. Select the start point by generating a random number between (0 – 18.303).
3. The start point will provide the first selection from the patient list of 2014. Then we should add our interval (18.303) to the start point to arrive at the second selection from the registry. Continue advancing by the same interval (18.303) until we select 112 records.
4. RULE OF ROUNDING: First, obtain the list of the numbers of the selected records without applying a rounding rule. For example, for the selection of the first five records with the starting point 2.91, you will obtain the following numbers: 2,91; 506.24; 1009.57; 1512.9. Then adopt a rule of

rounding down to the nearest integer values and it will be numbers for selecting the actual record for the first list: 2, 506, 1009, 1512, 2016.

5. Then apply the same sampling procedure for determining the sample for each oblast per each year.

PARTICULAR FEATURES OF PROCESSING OF SELECTED RECORDS

As soon as the processing of medical records is started, the following should be noted:

1. First, we should verify whether the patient started the continuation phase of treatment. If patient did not start the continuation phase for any reason or was referred to another category after completing the intensive phase treatment I-III, the chart abstraction tool should not be completed for such cases. These cases must be marked in the sample and the reason for excluding them from the sampling list must be recorded (patient died, referred to the IV category, etc.)
2. Then we must verify the date of the continuation phase treatment initiation. The date of the beginning of the continuation phase for cases from the list of 2013 to 2014 should be in the timeframe of January 1 to May 31, 2014; cases from the list of 2014 to 2015 should be in the timeframe of January 1 to May 31, 2015. All cases when the date does not match the selected timeframe should be excluded from the sample. The excluded cases must be marked in the sampling list and the actual date of the continuation phase initiation should be recorded.
3. Consequently, chart abstraction tools must be completed only for those patients who initiated the continuation phase treatment being under I-III category and only in the determined time interval (January 1 to May 31, 2014, January 1 to May 31, 2015).

4. FINALLY, FROM THE LIST OF 600 PATIENTS, SOME CASES MIGHT BE EXCLUDED FOR DIFFERENT REASONS, AND THE TOTAL NUMBER OF COMPLETED CHART ABSTRACTION TOOLS WILL BE LESS THAN 1200.

APPENDIX D. DATA COLLECTION INSTRUMENTS

TB FACILITY SURVEY

FACILITY SURVEY: TB Outpatient Services

A. Facility Identification			
A1. Today's Date: (DD-MM-YY) ☐☐ - ☐☐ - ☐☐	A2. Oblast ☐☐	A3. Rayon ☐☐☐	A4 Data Collector ID: ☐☐☐
A5. Facility Name: _____		A6. Facility ID Number: ☐☐☐☐☐☐	
A7. Facility type <*circle one*>: DOT Cabinet ……..……..1 TB Cabinet ……2 TB Dispensary/Hospital……..……3 Social Support Facility (URCS)……..….4 Other _____.....6		A8. Facility Authority <*circle one*>: Public Facility (government)……..1 Non-Profit / NGO Facility……2 Private For-Profit Facility……3 Other_____6	

A9. [*START INTERVIEW*] I will read a list of services that might be offered at this facility. Please say "yes" if a patient can receive the service here or "no" if they cannot: *YES* *NO*

TB Symptom Screening……	1	0
TB Diagnostics (lab, x-ray, clinical)……	1	0
TB Inpatient Treatment……	1	0
TB Outpatient Treatment……	1	0
HIV Voluntary Counseling and Testing (VCT)……	1	0
IPT for the prevention of TB disease (isoniazid preventive therapy)..……...	1	0
CPT (Cotrimoxazole preventative therapy)……	1	0
ARV or ART (antiretroviral therapy) ……	1	0
Medication Assisted Therapy ……	1	0
Psychological Counseling……	1	0

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

	A10.1 Intensive	A10.2 Continuation
Directly observed therapy at facility (Facility DOTS)……	1	1
Directly observed therapy at patient's home (Home DOTS)……	2	2

A. Facility Identification			
Strategies that promote self-management (for example, treatment literacy, support groups)……3			3
B. TB Services			
B1. Number of staff providing TB services: B1.1. Administrative B1.2. Nurses B1.3. Doctors			
B2. Number of beds available at this facility for inpatient TB treatment			
B3. Number of beds available at this facility for inpatient TB treatment for TB/HIV coinfected patients			
B4. Number of TB patients who started Outpatient Continuation Treatment at this facility during the following time periods: B4.1. In the past 7 days B4.2. In the past 30 days B4.3. Between January – May 2014 B4.4. Between January – December 2014 B4.5. Between January – May 2015			

B5. For patients receiving TB Continuation Treatment, how frequently is drug therapy routinely observed? Record typical frequency for those served in facilities and those served at home.

B5.1 *AT FACILITY*:	B5.2 *AT HOME*:
Daily……1	Daily……1
Weekly……2	Weekly……2
Twice Monthly……3	Twice Monthly……3
Once Monthly……4	Once Monthly……4
Less than once a month…..5	Less than once a month…..5
Not provided……6	Not provided……6
Don't know……8	Don't know……8

C. Referrals			
The next questions refer to social support services provided currently, provided in 2014 and in 2015. For each question, consider current and previous services and referrals.	(a) Currently	(b) During Jan-May 2014	(c) During Jan-May 2015
C1. Does this facility refer patients for social support during outpatient care? *<skip to section D if no social support referrals>* *Yes……..1* *No……..2* *Don't know……..9*			
C2. What organization [provides/provided] social support? *<note service provider code:* *URCS (funded by USAID)……..……..1* *URCS (funded by Global Fund)……..2* *PLH (funded by Global Fund)……..3* *Government……..……..4* *Other……6*			
C3. *<IF UA GOVERNMENT PROVIDES SOCIAL SUPPORT>:* Is <u>funding</u> for social support services provided by: *Local Government …….1* *National Government…..2* *Other <record name>…..6*			
C4. Is patient information about social support services received included in your patient record at this facility or by the social support agency? *This facility……..1* *Social support agency…..2* *Copies kept by both……...3*			

Next, I will read a list of social support services often provided by external organizations, for each service offered during different periods, please state the frequency per month of services provided, 0=Not Offered, 9=Don't Know.	(a) Currently offered		(b) Offered Jan-May 2014		(c) Offered Jan-May 2015	
	URCS (USAID grant)	PLH (GF grant)	URCS (USAID grant)	URCS (GF grant)	URCS (USAID grant)	PLH (GF grant)
C5. Home Visits: *<list frequency code:* *Not offered ……..0* *Twice Monthly……3* *Daily……..1* *Once Monthly……4* *Weekly……2* Other *<record>……6*						
C5.1. Phone calls reminders: *<list frequency code:* *Not offered ……..0* *Twice Monthly……3* *Daily……..1* *Once Monthly……4* *Weekly……2* Other *<record>……6*						
C5.2. Text messages reminders: *<list frequency code:* *Not offered ……..0* *Twice Monthly……3* *Daily……..1* *Once Monthly……4* *Weekly……2* Other *<record>……6*						
C6. Food Packages *<Average per patient >*						
C7. Clothing or Hygiene Kits *< Average per patient >*						
C8. Transportation Vouchers *< Average per patient >*						
C9. Counseling and/or assistance with social benefits *< Average per patient >*						
C10. Cash upon completion *<UAH amount per patient >*						
C11. Other _____						

C12. Now, consider factors that might make one eligible for social support. I will read a list of criteria that some programs use to identify those at high-risk for treatment default. For each criterion, note if it was or is used to determine someone's eligibility for social support currently, in Jan-May 2014, in Jan-May 2015 or not used. 1=Used, 0=Not used, 9=Don't Know	(a) Is this criteria currently used		(b) Was criteria used in 2014		(c) Was criteria used in 2015	
	URCS (USAID grant)	PLH (GF grant)	URCS (USAID grant)	URCS (GF grant)	URCS (USAID grant)	PLH (GF grant)
a. HIV-positive patient						
b. Alcoholic						
c. Injecting drug user						
d. Contact with a case						
e. Comorbidity: _____						
f. Homeless						
g. Unemployed						
h. Health Care Worker						
i. Migrant						
j. Refugee / Immigrant						
k. Ex-prisoner						
l. Low income: less than _____ Hrv/Month						
m. Other _____						
C13. What is the minimum number of criteria a client needs to meet to be given a referral? *<record number>*						
C14. Is there a specific criterion that must be met to receive a referral? If yes, which criterion? *<note the letter from above corresponding to the criterion >*						
C15. From the list above, which are the 3 most important criteria used for a patient's referral?						

<note the letter from above corresponding to the criterion>			

C16. What factors are considered or procedures followed when deciding whether a patient should be referred for social support services? How patients are selected in the social support program? Please explain.

URCS (USAID grant) _____

PLH (Global Fund grant) _____

C17. Who makes the decision regarding social support referrals for this facility? *(CIRCLE ALL THAT APPLY)*

Oblast TB Doctor 1
Rayon TB Doctor 2
City TB Doctor 3
TB Cabinet Nurse 4
URCS.....5
Other (specify)_____6

C18. Please describe the selection process for the URCS social support program funded by USAID in detail. If only one patient can be selected to the program out of five eligible patients, what are the key considerations that influence the selection?

_____

C19. Please describe interactions and communication between the URCS and TB services in the process of patient selection in the Social Support program:

a) Establishing the number of patients supported by the URCS for a facility
b) Interaction between TB services and Red Cross Society in case of emergence of a new patient who may qualify for the program (Who is informed about a new patient? How? Who calls whom? etc.)
c) Making a final decision on the participation of the patient in the program (who? when?)
d) Who informs patients that they can take part in the Social Support program (who? When? Where?)

_____

D. Drug Shortages

D1. Did this facility experience any drug shortages lasting more than 30 days in 2014 or 2015? This includes a situation where the number of patients eligible for treatment exceeds the drug supply.

	2014	2015

	Yes	No	Don't know	Was not offered	Yes	No	Don't know	Was not offered
D1.1 TB continuation treatment	1	0	9	8	1	0	9	8
D1.2 Medication assisted therapy	1	0	9	8	1	0	9	8
D1.3 ART	1	0	9	8	1	0	9	8
< if yes to any of the above, then complete drug shortage table> <if no "0" then END SURVEY>								

D2. IF this facility experienced TB drug supply shortages that lasted longer than 30 days in 2014 and/or 2015, then please check the months with shortages and complete the table.

YEAR: 2014	**Months suffering from shortages**													**Consequence of Drug Shortage**	
Drug shortage >30 days	J	F	M	A	M	J	J	A	S	O	N	D		<*Code*>	Other: describe
TB Drug 1 _____															
TB Drug 2 _____															
TB Drug 3 _____															
TB Drug 4 _____															
TB Drug 5 _____															
TB Drug 6 _____															
YEAR: 2015	**Months suffering from shortages**													**Consequence of Drug Shortage**	
Drug shortage >30 days	J	F	M	A	M	J	J	A	S	O	N	D		<*Code*>	Other: describe
TB Drug 1 _____															
TB Drug 2 _____															
TB Drug 3 _____															

TB Drug 4 _____ __															
TB Drug 5 _____ __															
TB Drug 6 _____ __															

Coding for Consequence of shortage:

Waitlisted patient……1

Switched treatment drugs ……..2

Stopped treatment……3

Referred patient to another facility ……4

Purchased out of pocket ……5

Other…… ……..6

D3. IF this facility experienced Medication Assisted Therapy supply shortages that lasted longer than 30 days in 2014 and/or 2015, check the months with shortages and complete table.

YEAR: 2014	**Months suffering from shortages**												**Consequence of Drug Shortage**	
Drug shortage >30 days	J	F	M	A	M	J	J	A	S	O	N	D	<*Code*>	Other: describe
Substitution Drug 1														
Substitution Drug 2														
Substitution Drug 3														
YEAR: 2015	**Months suffering from shortages**												**Consequence of Drug Shortage**	
Drug shortage >30 days	J	F	M	A	M	J	J	A	S	O	N	D	<*Code*>	Other: describe
Substitution Drug 1														
Substitution Drug 2														
Substitution Drug 3														

Coding for Consequence of shortage:

Waitlisted patient……1
Switched treatment drugs ……..2
Stopped treatment……3
Referred patient to another facility ……4
Purchased out of pocket ……5
Other……..6

D4. IF this facility experienced ARV drug supply shortages that lasted longer than 30 days in 2014 and/or 2015 or if a lack of ARV drugs limited the initiation of therapy during 2014, then check the months with shortages and complete the table.

YEAR: 2014	**Months suffering from limitations**												**Consequence of Drug Limitation**	
Drug limitations	J	F	M	A	M	J	J	A	S	O	N	D	<Code>	Other: describe
ARV Drug 1														
ARV Drug 2														
ARV Drug 3														
ARV Drug 4														
ARV Drug 5														
YEAR: 2015	**Months suffering from limitations**												**Consequence of Drug Limitation**	
Drug limitations	J	F	M	A	M	J	J	A	S	O	N	D	<Code>	Other: describe
ARV Drug 1														
ARV Drug 2														
ARV Drug 3														
ARV Drug 4														
ARV Drug 5														

Coding for Consequence of limitations:

Waitlisted patient……1

Switched treatment drugs ……..2

Stopped treatment……3

Referred patient to another facility ……4

Purchased out of pocket ……5

Other…… ……..6

Ukrainian Red Cross (URCS) FACILITY SURVEY

URCS Social Support Services

E. URCS Office			
A1. Today's Date: (DD-MM-YY)	A2. Oblast	A3. Rayon	A4 Data Collector ID:
☐☐ - ☐☐ - ☐☐	☐☐	☐☐	☐☐☐

A5. [*START INTERVIEW*] I will read a list of services that might be offered by the URCS. Please say "yes" if a patient can receive the service here or "no" if they cannot:

	YES	*NO*
TB Outpatient Treatment	1	0
IPT for the prevention of TB disease (isoniazid-preventive therapy)	1	0
CPT (Cotrimoxazole preventative therapy)	1	0
ARV or ART (antiretroviral therapy)	1	0
Psychological Counseling	1	0

A6. Next I will list TB treatment adherence support strategies, identify the one that best describes your strategy for Intensive and Continuation TB therapy?

	A6.1 Intensive	A6.2 Continuation
Directly observed therapy at facility (Facility DOTS)	1	1
Directly observed therapy at patient's home (Home DOTS)	2	2
Strategies that promote self-management (for example, treatment literacy, support groups)	3	3

F. TB Services in Oblast

B1. Number of staff providing TB services: B1.1. Administrative	☐☐
B1.2. Doctors	☐☐
B1.3. Nurses	☐☐

B2. For patients receiving TB Continuation Treatment, how frequently is drug therapy routinely observed? Record typical frequency for those served in facilities and those served at home.

B2.1 *AT FACILITY*:	B2.2 *AT HOME*:
Daily……..……1	Daily……..……1
Weekly……2	Weekly……2
Twice Monthly……..……3	Twice Monthly……..……3
Once Monthly……4	Once Monthly……4
Less than once a month…..5	Less than once a month…..5
Not provided……0	Not provided……..0
Don't know……..……8	Don't know……..……8

G. Social Support Services

I will read a list of social support services sometimes provided to improve outpatient TB treatment. For each service offered during different periods, please state the frequency per month of services provided, 0=Not Offered, 9=Don't Know.	(a) Currently offered	(b) Offered Jan-May 2014		(c) Offered Jan-May 2015
	URCS (USAID grant)	URCS (USAID grant)	URCS (GF grant)	URCS (USAID grant)
C1. Home Visits: *<list frequency code:* *Not offered ……..0* *Twice Monthly……3* *Daily……..1* *Once Monthly……4* *Weekly……2* Other *<record>……6*				
C2.1. Phone calls reminders: *<list frequency code:* *Not offered ……..0* *Twice Monthly……3* *Daily……..1* *Once Monthly……4* *Weekly……2* Other *<record>……6*				
C2.2. Text messages reminders: *<list frequency code:* *Not offered ……..0* *Twice Monthly……3* *Daily……..1* *Once Monthly……4*				

Weekly……2 Other <*record*>……6				
C3. Food Packages <*Average per patient* >				
C4. Clothing or Hygiene Kits < *Average per patient* >				
C5. Transportation Vouchers < *Average per patient* >				
C6. Counseling and/or assistance with social benefits < *Average per patient* >				
C7. Cash upon completion <*UAH amount per patient* >				
C8. Other _____				
C9. Is patient information about social support services received reported back to the TB facility or recorded in your patient records only? *Reported to TB Facility*……1 *Kept by URCS Only*……..2 *Recorded by both*……...3				

C10. Who makes the decision regarding social support referrals for this facility? *(CIRCLE ALL THAT APPLY)*

Oblast TB Doctor..... 1	Facility TB Doctor 5
Oblast TB Nurse 2	Facility TB Nurse 6
Rayon TB Doctor 3	URCS..... 7
Rayon TB Nurse 4	Other (specify)_____8

IF the URCS PARTICIPATES IN REFERRAL DECISION FOR SOCIAL SUPPORT THEN COMPLETE REST OF SECTION C, OTHERWISE SKIP TO SECTION D.

C11. Please describe the selection process for the URCS social support program funded by USAID in detail. If only one patient can be selected to the program out of five eligible patients, what are the key considerations that influence the selection?

_____

C12. Please describe interactions and communication between the URCS and TB services in the process of patient selection in the Social Support program:

a) Establishing the number of patients supported by the URCS for a facility

b) Interaction between TB services and Red Cross Society in case of emergence of a new patient who may qualify for the program (Who is informed about a new patient? How? Who calls whom? etc.)

c) Making a final decision on the participation of the patient in the program (who? when?)

d) Who informs patients that they can take part in the Social Support program (who? When? Where?)

_____

C13. Now, consider factors that might make one eligible for social support. I will read a list of criteria that some programs use to identify those at high-risk for treatment default. For each criterion, note if it was or is used to determine someone's eligibility for social support currently, in Jan-May 2014, in Jan-May 2015 or not used. 1=Used, 0=Not used, 9=Don't Know	(a) Is this criteria currently used	(b) Was criteria used in 2014		(c) Was criteria used in 2015
	URCS (USAID grant)	PLH (GF grant)	URCS (USAID grant)	URCS (GF grant)
n. HIV-positive patient				
o. Alcoholic				
p. Injecting drug user				
q. Contact with a case				
r. Comorbidity: _____				
s. Homeless				
t. Unemployed				
u. Health Care Worker				
v. Migrant				
w. Refugee / Immigrant				
x. Ex-prisoner				
y. Low income: less than _____ Hrv/Month				
z. Other _____				
C14. What is the minimum number of criteria a client needs to meet to be given a referral? *<record number>*				
C15. Is there a specific criterion that must be met to receive a referral? If yes, which criterion? *<note the letter from above corresponding to the criterion or write-in other criterion used>*				
C16. From the list above, which are the 3 most important criteria used for a patient's referral? *<note the letter from above corresponding to the criterion>*				

H. Drug Shortages								
D1. Did this facility experience any drug shortages lasting more than 30 days in 2014 or 2015?								
	2014				2015			
	Yes	No	Don't know	Was not offered	Yes	No	Don't know	Was not offered
D1.1 TB continuation treatment	1	0	9	8	1	0	9	8
< if yes to any of the above, then complete drug shortage table> <if no "0" then END SURVEY>								

D2. IF this facility experienced TB drug supply shortages that lasted longer than 30 days in 2014 and/or 2015, then please check the months with shortages and complete the table.

YEAR: 2014	**Months suffering from shortages**												**Consequence of Drug Shortage**	
Drug shortage >30 days	J	F	M	A	M	J	J	A	S	O	N	D	<Code>	Other: describe
TB Drug 1														
TB Drug 2														
TB Drug 3														
TB Drug 4														
TB Drug 5														
TB Drug 6														
YEAR: 2015	**Months suffering from shortages**												**Consequence of Drug Shortage**	
Drug shortage >30 days	J	F	M	A	M	J	J	A	S	O	N	D	<Code>	Other: describe
TB Drug 1														
TB Drug 2														
TB Drug 3														
TB Drug 4														
TB Drug 5														
TB Drug 6														

Coding for Consequence of shortage:

Waitlisted patient……1
Switched treatment drugs ……..2
Stopped treatment……..……3
Referred patient to another facility ……4
Purchased out of pocket ……..……5
Other……..6

TB Data Abstraction Form

PLEASE PAY ATTENTION TO THE FOLLOWING CODING:
SERVICE WAS NOT PROVIDED IS '0'
INFORMATION IS NOT AVAILABLE OR UNKNOWN IS '9'

A. Facility Identification (WRITE NAME OF THE FACILITY) _____

A1. Today's Date: *(DD-MM-YY)*	A2. Data Collector ID:	A3. Facility name (**Intensive Phase**):
☐☐ - ☐☐ - ☐☐	☐☐☐	_____
A4. Oblast	A5. Rayon	A6. Facility name (**Follow-up Phase**):
☐☐	☐☐	_____

B. Patient Identification

B1. Patient Name	B2. Patient Record Number:	B3. Study Cohort:
Surname:_____	☐☐☐☐☐	**2014** / **2015**
First: _____		HR Interv…….1 / HR Non-Int….4
		HR Non-Int….2 / LR Non-Int…..5
		LR Non-Int…..3

B4. Date of Birth:	B5. Age (*years*)	B6. Sex:	B7. Residence:
☐☐ - ☐☐ - ☐☐	☐☐	Male……..…1	Urban……..1
	[if <18 years END SURVEY]	Female…….2	Rural……2

B8. Employment:

Employed……..…1
Unemployed……..2
Retired…….. ……..…3
Person with Disabilities……..4
Student…….……5
Housewife…..……...6
Other _____..7
Information not available……..……9

C. TB Case Initiation

C1. TB detected due to:

Own initiative……..1

Occupational screening……2

C2. Date of Emergence of first symptoms:

☐☐ – ☐☐ – ☐☐

C3. Date of First TB visit:

☐☐ – ☐☐ – ☐☐

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]

☐☐ – ☐☐ – ☐☐

D. TB Diagnosis

D1. Date of first microscopy *(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 ……1

Reinitiation following interruption ……..2

Treatment failure ……..……3

Relapse……4

Referred from: _____.....5

Other: _____.....6

D5. Diagnosis: Clinical form

D5.1 Lung……..1

D5.2 Extra-pulmonary……..…2

E. TB Treatment: Intensive Phase	
E1. Intensive Phase TB treatment was provided as: Inpatient……1 *or* Outpatient……2	
E2. Treatment Category: CATEGORY I……1 CATEGORY II……2 CATEGORY III……3 Other: _____..6	
E3. Intensive Treatment **Start** Date: ☐☐ – ☐☐ – ☐☐	E4. Intensive Treatment **End** Date: ☐☐ – ☐☐ – ☐☐
E5. Was direct observation of use of TB drugs recorded (regardless of whether it was observed at the facility or by relatives of the patient)? Yes……1 No……..0 *<skip to F1>*	
E5.1 Number of Planned Doses (doses planned to give)	☐☐☐
E5.2 Number of Doses Received (doses patient received)	☐☐☐
E5.3 Number of Interruptions (number of periods when no drugs received)	☐☐☐
E5.4 Duration of longest interruption (number of days)	☐☐☐

F. TB Treatment: Continuation / Follow-up Phase

F1.Follow-up Treatment **start** date: ☐☐ – ☐☐ – ☐☐

F2. Follow-up Treatment **end** date: ☐☐ – ☐☐ – ☐☐

F3. Was direct observation of use of TB drugs recorded (regardless of whether it was observed at the facility or by relatives of the patient)? Yes……1 No……..0 *<skip to G1>*

F3.1 Number of Planned Doses (doses planned) ☐☐☐

F3.2 Number of Doses Received (doses patient received) ☐☐☐

F3.3 Number of Interruptions (number of periods when no drugs received) ☐☐☐

F3.4 Duration of longest interruption (number of days) ☐☐☐

G. Treatment Outcome

G1. Outcome of treatment [*select one*]:

Cured……..……1

Treatment complete……..……2

Died from TB……..…3

Died (non-TB cause)……..……4

Treatment failed - smear/culture……5

Treatment failed – x-ray/clinical……6

Treatment failed – MDR-TB (transfer to Cat IV)……..……..7

Treatment Interrupted……..…8

TB diagnosis cancelled……9

Transferred: _____.....10

G2. Treatment Outcome Date (DD-MM-YY)

☐☐ – ☐☐ – ☐☐

G3. Notes [*include additional key information on diagnosis, treatment, or outcome*]

H. Factors that affect Course of Illness and Treatment

H1. Risk factors (*CIRCLE ALL THAT APPLY*):

H1.1 HIV positive……..1

H1.2 Alcoholic……2

H1.3 Injecting Drug User ……..3

H1.4 Contact with a case……..……...4

H1.5 Comorbidities ...……..……..…….5

H1.6 Homeless…….6

H1.7 Unemployed…….……..…….7

H1.8 Health Care Worker…….…..…..8

H1.9 Migrant…….9

H1.10 Refugee/Immigrant……..……10

H1.11 Ex-Prisoner……...……11

H1.12 Other_____ .12

H1.13 No known risk factors…… 13

→ 1.1.a Date of VCT

1.1.b Date of Testing

1.1.c Date of ART

1.1.d Date of CPT

→ **IF Comorbidities List**:

(DD - MM - YY)

		–			–
		–			–
		–			–
		–			–

_____

_____

_____

H2. Received Social Support during continuation treatment?

Yes from the URCS (*check B3 answer HR Interv 1*)……..1 *<CONSULT URCS TO COMPLETE SECTION I>*

Yes from other social support provider……..2 *SPECIFY*_____

<COMPLETE SECTION I IF DATA AVAILABLE IN RECORD>

No……..……..……3 *< END SURVEY>*

Don't Know.....*9 < END SURVEY>*

H. Factors that affect Course of Illness and Treatment	
H2.1. Please indicate the type of donor for Social Support.	
USAID	1
Global Fund	2
H2.2. Social Support start date: ☐☐ - ☐☐ - ☐☐	
H2.3. Social Support end date: ☐☐ - ☐☐ - ☐☐	

I. Social Support during Continuation Phase

FOR EACH SOCIAL SUPPORT SERVICE OR BENEFIT RECEIVED, RECORD THE NUMBER OF TIMES RECEIVED	NUMBER		NUMBER
I1. DOTS at Facility: I1.1 Planned		I1.2 Received	
I2. DOTS at Home: I2.1 Planned		I2.2 Received	
I3. Food Packages: I3.1 Planned		I3.2 Received	
I4. Clothing or Hygiene Kits			
I5. Psychological counseling			
I6. Assistance with social benefits (pension, disability benefits, housing, etc.)			
I7. Transportation Vouchers/reimbursement received			
I8. Cash / Debit Card once treatment completed *< UAH AMOUNT: _____>*			
I9. Other _____			

I10. Was there any interruption in social support during the treatment period? Yes……..1
No……..…2 *<skip to I11>*
Don't Know....9 *<skip to I11>*

I10.1 Reason for the interruption in support?_____

I11. Notes [*include additional key information about social support services*]

END OF SURVEY

Risk distribution Abstraction Form

PLEASE PAY ATTENTION TO THE FOLLOWING CODING:

INFORMATION IS NOT AVAILABLE OR UNKNOWN IS '9'

J. Facility Identification (WRITE NAME OF THE FACILITY) _____

A1. Today's Date: *(DD-MM-YY)*	A2. Data Collector ID:	A3. Facility name (**Intensive Phase**):
☐☐ - ☐☐ - ☐☐	☐☐☐	_____
A4. Oblast	A5. Region	A6. Facility name (**Follow-up Phase**):
☐☐	☐☐	_____

K. Patient Identification

B1. Patient Name	B2. Patient Record Number:
Surname:_____ First: _____	☐☐☐☐☐

B3. Cohort:

2011 Year.....1 2014 Year 3

2012 Year .....2 2015 Year 4

B4. Date of Birth:	B5. Age (*years*)	B6. Sex:	B7. Residence:
☐☐ - ☐☐ - ☐☐	☐☐ *[if <18 years* *END SURVEY]*	Male……..1 Female…….2	Urban……..1 Rural……2

B8. Employment:

Employed……..…1 Unemployed……..2 Retired…….. ……..…..3 Person with Disabilities…….4	Student…….……5 Housewife……...6 Other _____..7 Information not available……..……9

L. TB Case Initiation

C1. TB detected due to: Own initiative……..1 Occupational screening…….2	C2. Date of Emergence of first symptoms: ☐☐ – ☐☐ – ☐☐	C3. Date of First TB visit: ☐☐ – ☐☐ – ☐☐
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]* ☐☐ – ☐☐ – ☐☐

M. Treatment Outcome	
D1. Outcome of treatment: Cured……..…… ……..…1 Treatment complete……..……2 Died from TB……..…3 Died (non-TB cause)……..……4 Treatment failed - smear/culture……5 Treatment failed – x-ray/clinical……..…6 Treatment failed – MDR-TB (transfer to Cat IV)……..……..7 Treatment Interrupted……..…8 TB diagnosis cancelled……9 Transferred: _____.....10	D2. Treatment Outcome Date (DD-MM-YY) ☐☐ – ☐☐ – ☐☐
D3. Notes [*include additional key information on diagnosis, treatment or outcome*]	

N. Risk Factors that affect Course of Illness and Treatment

E1. Risk factors (*CIRCLE ALL THAT APPLY*):

E1.1 HIV positive……1

E1.2 Alcoholic……2

E1.3 Injecting Drug User ……..3

E1.4 Contact with a case……..……....4

E1.5 Comorbidities ....……..……..……..……5

E1.6 Homeless……..……6

E1.7 Unemployed……..……..……..……7

E1.8 Health Care Worker…..……..…..8

E1.9 Migrant……..……9

E1.10 Refugee/Immigrant……..……10

E1.11 Ex-Prisoner……...……11

E1.12 Other_____ .12

E1.13 No known risk factors…… 13

(DD - MM - YY)

→ 1.1.a Date of VCT

1.1.b Date of Testing

1.1.c Date of ART

1.1.d Date of CPT _____

→ **IF Comorbidities List**: _____

_____

E2. Received Social Support during continuation treatment?

Yes from the URCS……..……..1 *<CONSULT URCS TO COMPLETE SECTION F>*

Yes from other social support provider……..2 *SPECIFY*_____

<COMPLETE SECTION F IF DATA AVAILABLE IN RECORD>

No……..……..……3 *< END SURVEY>*

Don't Know.....9 *< END SURVEY>*

O. Social Support during Continuation Phase			
FOR EACH SOCIAL SUPPORT SERVICE OR BENEFIT RECEIVED, RECORD THE NUMBER OF TIMES RECEIVED	NUMBER		NUMBER
F1. DOTS at Facility: F1.1 Planned	☐☐☐	F1.2 Received	☐☐☐
F2. DOTS at Home: F2.1 Planned	☐☐☐	F2.2 Received	☐☐☐
F3. Food Packages: F3.1 Planned	☐☐☐	F3.2 Received	☐☐☐
F4. Clothing or Hygiene Kits			☐☐☐
F5. Psychological counseling			☐☐☐
F6. Assistance with social benefits (pension, disability benefits, housing, etc.)			☐☐☐
F7. Transportation Vouchers/reimbursement received			☐☐☐
F8. Cash / Debit Card once treatment completed *< UAH AMOUNT: _____>*			☐☐☐
F9. Other _____			☐☐☐
F10. Was there any interruption in social support during the treatment period? Yes……..1 No……..…2 *<Go to F11>* Don't Know....9 *< Go to F11>*			
F10.1 Reason for the interruption in support?_____			
F11. Notes [include additional key information about social support services] _____			
END OF SURVEY			

Interview guide for the in-depth interview with patients

Date of Interview: _____ **Start Time:** _____ AM PM

Name of Interviewer: _____

Sex: Female Male

Location: Rural Urban

City: _____

You are taking part in the URCS home visits program. Today, we would like to understand more about your experiences with this program.

1. Please describe how you were chosen to take part in the program.

1.a. How did you end up taking part in this program?

1.b. Who nominated you?

1.c. How did you learn about being selected? (*probe if not mentioned:* when?)

1.d. What factors influenced your selection for the program?

2. I would like to know more about the home visits

2.a. What happens during a typical visit?

-*probes:* Who? What? When?

2.b. Are these visits ever different? If so, please explain? (probes: who, what, when?)

3. Now I would like to hear more about your relationship with the person/s who visits you.

3.a. Please describe the relationship(s)?

3.b. Have you had the same person since you started? If Yes: How does this person make you feel? Does this person provide support for you? What kind of support is provided? How are you satisfied? Why/Why not?

3.c. If No to 3b: How many people visited you? How do you feel about receiving visits from different people? What do you like about it? What do you dislike about it?

4. We understand that everyone has different experiences with TB treatment. How easy/difficult is it for you to take your meds on time?

4.a. Do you have any challenges with taking your meds on time? Please explain.

4.b. Are there any times when it is more difficult for you to follow the regimen? If yes, please explain.

4.c. Are there times when it is easier to follow the regimen? Please explain.

Probes: What helps you to take your meds regularly? How are you able to follow the regimen? What are the most helpful things that help you to follow this regimen?

5. I would like to hear your opinions on the home visits program.

5.a. What is your opinion about the home visits program?

5.b. What do you like most about the program? What other things do you like?

5.c. What do you not like about the program? Please explain.

5.d. What is your opinion about the quality of services?

6. What aspects of the home visit program are the most important for helping you to take your meds on time?

7. How would you suggest changing the home visits so that they could support you more? How could home visits better help you and others like you to stay on the medication?

8. What other services do you receive from other organizations? How satisfied are you with the services you receive, their quality and frequency?

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

_____

_____

_____

_____

9. Do you have any questions for me?

Thank you very much for your time and for speaking with me about your experience with home visits program.

End Time: _____ AM PM

Interview guide for the in-depth interview with the URCS nurses

Date of Interview: _____ **Start Time:** _____ AM PM

Name of Interviewer: _____

Sex: Female Male

Location: Rural Urban

Organization: _____

Job title: _____

Length of time in current position:_____

City: _____

You are providing URCS home visits. Today, we would like to understand more about your experiences in providing these services.

1. First, I would like to learn about your responsibilities at the URCS.

1.a. What are your overall responsibilities at the URCS (all responsibilities, including home visits)

1.b. How long have you been working for the URCS?

Next I would like to hear about the home visits and your responsibilities related to home visits.

2. Please describe for me a typical home visit? (*after they describe a given step, use probes such as "what happens next?" or "what else do you do?")*

Probes: (if not described):

2.a. Who do you visit?

2.b. How much time do you spend with a patient during a typical visit?

2.c. What do you do during visits?

2.d. What else are you supposed to do for the patient as part of the home visits program? (Probe: are you supposed to accompany them to health facilities, do labs, anything else?)

3. Please tell me about your relationship with the patients?

4. How do you help patients to stay on treatment? (Probes: Type of support provided, referrals, ask if they bring food, clothes, listen, talk, accompany to health facility, etc.)

5. Please describe to me your patient workload.

Probe (if not described):

5.a. How many patients are you assigned to overall?

5.b. How many patients per week do you serve?

5.c. What is the average length of time that you serve a patient, in months?

5.d. How often do you visit a specific patient?

5.e. How long have you been doing this kind of work (i.e., work on home visits)?

6. Please describe how patients are selected in the program.

6.a. How do they end up taking part in this program? (*probe:* Who nominates them?)

6.b. How do they learn about being selected? (probe: when?)

6.c. What are the selection criteria? (*probe, if not addressed*: Why are these specific patients chosen over other high-risk patients?)

7. I would like to know your impression of the home visits.

7.a. What is your opinion about the home visits program?

7.b. What is the quality of the program?

7.c. What do you like most about the program? What else do you like about the program?

7.d. What do you not like about the program? Why?

7.e. What positive effects of the program, if any, have you seen? Please provide an example.

7.f. What negative effects of the program, if any, have you seen? Please provide an example.

8. What are some challenges that patients experience with following the TB treatment regimen? What makes it difficult for patients to adhere to the treatment? Why?

9. What aspects of the home visit are the most important for ensuring adherence?

10. Let's talk about supportive supervision at the URCS.

10.a. Do you receive supportive supervision? If so, what is your opinion of it?

10.b. Do you feel that you need further training to do your job well? If yes, what kind of training do you need?

11. Please describe to me any challenges you face that affect your ability to do your job well?

11.a. What aspects of the home visits program are most difficult?

11.b. What barriers exist for providing high quality services?

12. What helps you do your job well?

13. How could the program be improved so that you could better support patients to adhere to (i.e., taking the meds at the right times and staying on the meds over time) the medication?

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

_____

_____

_____

_____

15. 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

Interview guide for the in-depth interview with the STbCU and URCS project staff

Date of Interview: _____ **Start Time:** _____ AM PM

Name of Interviewer: _____

Sex: Male Female

Organization: _____

Job title: _____

Length of time in current position:_____

City: _____

You are working on the social support program. 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.

1.a. What are your overall responsibilities?

1.b. How long have you been working for this organization?

2. Please describe your responsibilities related to the social support program.

3. Please tell us what activities were planned in the social support program.

4. In your experience, how did the social support program 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 on the social support program? (Probes: Law/legislation, system constraints, providers, support from the project, lack of time, etc.)

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

4.d.ii. What barriers exist for providing high quality social support 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 adherence again, what would you do differently?

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

9. How could the social support 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 social support program.

End Time: _____ AM PM

MEASURE Evaluation
University of North Carolina at Chapel Hill
123 W. Franklin Street, Suite 330
Chapel Hill, NC 27516 USA
Phone: +1 919-445-9350 | measure@unc.edu
www.measureevaluation.org

This publication was produced with the support of the United States Agency for International Development (USAID) under the terms of MEASURE Evaluation cooperative agreement AID-OAA-L-14-00004. MEASURE Evaluation is implemented by the Carolina Population Center, University of North Carolina at Chapel Hill in partnership with ICF International; John Snow, Inc.; Management Sciences for Health; Palladium; and Tulane University. Views expressed are not necessarily those of USAID or the United States government. This report was prepared independently by Zulfiya Charyeva, MEASURE Evaluation/Palladium (team leader), Sian Curtis, MEASURE Evaluation/UNC, and Stephanie Mullen, MEASURE Evaluation/JSI. TRE-18-007

ISBN: 978-1-64232-004-6

USAID
FROM THE AMERICAN PEOPLE

PEPFAR

MEASURE
Evaluation