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Strengthening TUBERCULOSIS CONTROL IN UKRAINE

Impact Evaluation Baseline Survey,

Ukraine 2014

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Strengthening Tuberculosis Control in Ukraine

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Contributors

The impact evaluation of the Strengthening Tuberculosis Control in Ukraine (STbCU) is being conducted by MEASURE Evaluation Project for the USAID mission in Ukraine. The principal investigators for the overall evaluation are Martha Priedeman Skiles (University of North Carolina at Chapel Hill [UNC]) and Stephanie Mullen (John Snow Inc [JSI]). The Ukraine-based research partner IFAK implemented the data collection and assisted with qualitative data analyses. Data analysis and report writing were supported by Futures Group, IFAK, JSI, and UNC. Many individuals and organizations made important contributions to this baseline report and are listed below by institutional affiliation and alphabetical order within institution:

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ACRONYMS

AIDS	acquired immune deficiency syndrome
AR Crimea	Autonomous Republic of Crimea
ART	antiretroviral treatment
ARV	antiretroviral drugs
CPT	Co-trimoxazole preventive therapy
CT	computer tomography
DOTS	directly observed treatment, short course
ELISA	enzyme-linked immunosorbent assay
GBTI	Global Tuberculosis Institute, New Jersey Medical School
HIV	human immunodeficiency virus
HR	high risk
ID	infectious disease
IDU	injecting drug use
IE	impact evaluation
IPT	isoniazid preventive therapy
LR	low risk
MDR-TB	multi-drug resistant tuberculosis
MOH	Ukraine Ministry of Health
MRI	magnetic resonance imaging
NGO	nongovernmental organization
PCR	polymerase chain reaction
PHC	primary health care
PLWH	people living with HIV/AIDS
PMDT	programmatic management of drug-resistant tuberculosis
RR-TB	Rifampicin-resistant tuberculosis
STbCU	Strengthening Tuberculosis Control in Ukraine
STbCU-IE	Strengthening Tuberculosis Control in Ukraine Impact Evaluation
TB	tuberculosis
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNC-CH	University of North Carolina at Chapel Hill
URCS	Ukraine Red Cross Society
USAID	U.S. Agency for International Development
VCT	voluntary counseling and testing

WHO	World Health Organization
XDR-TB	extensively drug resistant tuberculosis

EXECUTIVE SUMMARY

Background

The Strengthening Tuberculosis Control in Ukraine (STbCU) project, awarded in April 2012 to Chemonics International in partnership with Project HOPE and the New Jersey Medical School Global Tuberculosis Institute, works to improve the health of Ukrainians by reducing the burden of tuberculosis (TB). The project focuses on strategic actions to strengthen systems for routine TB services, as well as address the challenges of diagnosis and treatment for multidrug-resistant TB (MDR-TB) and TB-HIV co-infection.

In 2014, the MEASURE Evaluation project, upon the request of the U.S. Agency for International Development (USAID) mission in Kiev, initiated an impact evaluation to study two STbCU programmatic priorities: 1) providing social support services to improve TB treatment adherence; and 2) improving integration of TB and HIV services to reduce mortality through early diagnosis and treatment for TB-HIV co-infected patients. To evaluate the impact of these program efforts, MEASURE Evaluation designed two independent but complementary studies: the Social Support study and the TB-HIV Integration study.

This report provides information on the study designs and findings at baseline from data collected in four STbCU target oblasts (Dnipropetrovsk, Kharkiv, Odessa, and Zaporizhzhya) and three comparison sites (Kiev City, Mykolaiv, and Zhytomyr).

Methods

Both studies employed a mixed-methods approach, with a quasi-experimental quantitative evaluation design complemented by qualitative descriptive work to inform the findings. Data collection included surveys of medical facilities, provider interviews, and patient chart abstractions. For the Social Support study, TB diagnosis and treatment data were abstracted from medical records for five cohorts of TB patients to provide data on patients at high risk for defaulting on TB treatment, including those who did and did not receive any social support, patients at low risk for defaulting, and patients seen during early 2011 and early 2012. Sampling for the Social Support study required a random selection of high-risk patients who received social support followed by a matching procedure to identify patients from the other four cohorts. Multivariate regression analyses produced estimates for the impact of the social support program on treatment default and death.

The TB-HIV Integration study abstracted data from TB intensive treatment facilities and AIDS centers for a sample of single- and co-infected patients served in 2012. Diagnosis and treatment cascades were produced for each service to describe services received and identify unexpected drops in patient services. Survival analyses were employed to estimate differences in time to specific events for each group, including time to testing, treatment, and mortality.

Social Support Findings

Facilities: Almost all facilities provided referrals to the Ukraine Red Cross Society (URCS) for social support programs in 2012 in all oblasts. Typical services offered by URCS included daily home directly observed treatment short-course (DOTS) and twice-monthly food packages. The majority of facilities in Dnipropetrovsk and Odessa required at least one risk factor for referral, while the majority of sites in Kharkiv did not have a minimum number of risk factors as part of their referral criteria. Severe TB drug shortages were a concern nationwide in 2011 and were reported by 20% of the facilities surveyed. Patients were most often told to buy their own TB medications to complete therapy in 2011.

Patient Balance and Targeting: The study cohorts were found to be demographically similar to each other. On average, 35% of the patients were female, over 70% were under 50 years of age, and the majority were unemployed and living in urban centers. Among high-risk (HR) patients, 70%-76% reported two or more risk factors for default, while among the low-risk (LR) cohorts, over 50% reported no risk factors. On average, the HR-intervention cohort reported fewer treatment interruptions and shorter interruptions, compared to the HR-comparison cohort from 2012. Comparing the HR-intervention and HR-comparison cohorts from 2012, we found that program selection on alcohol abuse, injection drug use (IDU), presence of co-morbidities, health care workers, contacts to cases, and migrants was similar across the two cohorts. However, HIV-positive patients, the homeless, and ex-prisoners were less likely to receive the social support program, while the unemployed, "other" risk factors, and being female were predictive of receiving social support.

Impact: TB treatment default and fatality rates were highest among the HR-comparison groups from 2011 and 2012, while the HR-intervention group reported the lowest default rates in 2012. Logistic regression results controlling for sex, age, residence, oblast, risk status, year, and program status, found that the social support program in 2012 had a protective effect on treatment default; those in the program were significantly less likely to default on TB treatment compared to HR patients

not receiving the social support. Moreover, a protective effect on death was suggested, although the number of deaths was small. Additional analyses controlling for the selection process by providers when assigning patients to receive social support will improve estimates at endline.

TB-HIV Integration Findings

Facilities: Differences in TB facilities and AIDS centers were found both by characteristics and practices. TB facilities were larger in general in the comparison oblasts compared to the intervention oblasts, while AIDS centers had substantially higher patient and provider populations in the intervention sites. Screening and rapid testing for TB and HIV were offered in the majority of TB facilities and AIDS centers; however diagnostic testing requiring more advanced training and/or equipment, such as sputum microscopy, Xpert, ELISA, PCR, and Western Blot, were not offered on-site. Off-site testing added time to the receipt of testing outcomes, potentially slowing down the initiation of antiretroviral therapy (ART) among the co-infected. AIDS centers did not provide inpatient TB treatment for the smear-positive TB patients, yet no formal referral protocols between facilities were in place to expedite the transfer of patients for treatment. Providers at AIDS centers suggested that having TB physicians on staff would be one of the most important steps for improving diagnosis, treatment, and data sharing; and having an infectious disease (ID) specialist on staff at TB facilities was believed to improve and simplify the data exchange process between sites.

TB Facility Patient Balance: The majority of TB patients were male, over half were under 49 years of age, over 70% were unemployed, and the majority resided in urban areas in both intervention and comparison oblasts. The male-to-female ratio was significantly higher in comparison oblasts, while the urban-to-rural ratio was significantly larger in intervention oblasts. Single-infected TB patients in intervention sites were significantly more likely to have been seen for a first diagnosis (76.8%) in treatment Category I (66.4%) compared to patients seen in comparison sites who had higher rates of chronic TB (6.8%) in treatment Category II (34.7%). Similarly, the co-infected patients seen in comparison sites appeared to exhibit more advanced disease and higher rates of extra-pulmonary disease (14.0%) than patients seen in the intervention oblasts. Injection drug use was reported higher among the co-infected in the comparison sites (27.3%) versus the intervention sites (13.5%).

TB Patient Outcomes: Over 90% of the general TB patients received HIV screening and testing. The majority (65%-85%) received HIV testing within one month of TB diagnosis, although time to testing in the intervention oblasts was significantly slower than for the comparison oblasts. Only 10% of the general sample was confirmed to be co-infected with HIV and only two-thirds of this group initiated ART. It is unclear to what extent the drop-off from diagnostic testing to confirmed cases indicates negative diagnostic test results versus failure to accurately record and treat newly-diagnosed co-infected patients. Among the co-infected patients, ART was associated with approximately a 75% reduction in the likelihood of dying. However initiation of ART was slow, with less than 25% of the co-infected covered within the recommended two to eight weeks. Overall, comparison oblasts outperformed intervention oblasts in uptake of antiretroviral drugs (ARV). The oblast where TB patients received services was predictive of HIV testing, ART initiation, and death among the co-infected at baseline and may in part reflect an imbalance of high-risk patients across oblasts.

AIDS Center Patient Balance: The majority of HIV/AIDS patients were male, more than 60% were under 49 years of age, and almost 60% resided in urban areas in both intervention and comparison oblasts. The male-to-female ratio was significantly higher in comparison oblasts, with almost twice as many men and women patients. Among the single-infected HIV patients, patients served in comparison sites reported more advanced disease, with 18.1% classified as Stage 4 compared to only 9.4% among the intervention sites. They also had lower CD4 counts with 39.8% reporting levels under 50 cells/mm3; yet ARV treatment was recorded for only 40.3% of these patients, compared to 51.7% of the HIV-only patients from the intervention sites. Among the co-infected patients, data on HIV status and treatment was missing in over half of the cases seen in the intervention sites, making an assessment of balance between the groups by disease and treatment status impossible.

HIV Patient Outcomes: Between 25% to 30% of the general HIV patients received TB diagnostic testing within one month in both intervention and comparison sites, but by six months, over 50% of patients in the intervention oblasts received testing, compared to fewer than 35% in comparison sites.

Among co-infected patients, TB treatment success rates were higher in the intervention oblasts yet higher rates of death and treatment interruption among patients in these same sites were recorded as well. ART initiation was significantly higher in the comparison oblasts, with patients 63% more likely to have started ART. Time to ART initiation was much shorter in the comparison sites also, which may account for the lower mortality rates seen in these sites. ART was significantly predictive of survival; patients on ARV treatment were approximately 85% less likely to die, compared to those patients not on ARVs. Controlling for ART removed any differential effect by intervention and comparison site and removed most of the observed differential effects seen by oblast.

Conclusion

This baseline work shows the positive role that social support services had on health outcomes for a majority of the individuals who received services in the oblasts studied, although some of the most at-risk groups were less likely to have accessed those services. Additional analyses to control for provider referrals will improve these estimates. The integration analyses support the recommendation for early ART initiation to reduce mortality. However, the absence of systematic record keeping to allow tracking of patients between services restricts the ability to draw conclusions for the combined population of co-infected persons regardless of service entry point. Endline data will help to determine whether the STbCU project activities effectively influenced the provision of integrated services to shorten the time between diagnoses and treatment.

CHAPTER 1. INTRODUCTION

1.1 Background

Ukraine is a World Health Organization (WHO) priority country in the European Region for tuberculosis (TB) control and is among the highest drug-resistant TB burden countries in the world. In 2013, TB incidence, prevalence and mortality rates were 96, 120, and 14 per 100,000 population respectively.[1] Fourteen percent of the newly detected TB cases and 32% of the previously-treated TB cases have Rifampicin-resistant tuberculosis (RR-TB) or multi-drug resistant tuberculosis (MDR-TB), raising the number of new MDR-TB patients in need of treatment every year in the country to over 9,000.[1] There are also documented cases of extremely drug-resistant tuberculosis (XDR-TB) but the rate is unknown.

The burden of co-infection with TB and human immunodeficiency virus (HIV) is high (16/100,000 population) in 2013 and is disproportionally concentrated among socially marginalized populations including injecting drug users (IDUs), sex workers, and prison populations.[2] According to the Joint United Nations Programme on HIV/AIDS (UNAIDS), annual HIV diagnoses have doubled since 2001, making Ukraine the leader in adult HIV prevalence for Europe and Central Asia.[3] TB-HIV co-infection can substantially influence mortality; approximately 40% of AIDS deaths in Ukraine are associated with TB. UNAIDS recommends immediate initiation of antiretroviral therapy (ART) for anyone co-infected. In Ukraine, an estimated 92% of the newly co-infected patients received ART in 2012, yet the mortality among the co-infected declined by less than 25% since 2004.[2]

In light of the epidemiologic landscape in Ukraine, USAID-supported projects have focused on expanding availability and improving quality of DOTS services for TB patients, while concurrently working at the policy level to create a service environment with fewer barriers to accessing high quality case detection and treatment. According to PATH, 50% of the population now has access to high quality TB care and case detection rates have increased to 73%, exceeding the minimum recommendations from WHO.[3] However, treatment success rates remain well below the 85% WHO recommendation and emerging MDR-TB and difficulty in treating TB/HIV co-infection have further complicated effective treatment. Evaluation 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.

1.2 Project Description

The Strengthening Tuberculosis Control in Ukraine (STbCU) project was awarded to Chemonics International in partnership with Project HOPE and the New Jersey Medical School Global Tuberculosis Institute (GBTI) in April 2012. This USAID-funded effort targets geographic priority areas in southeastern Ukraine (Figure 1)[4] to improve the health status of Ukrainians by reducing the burden of TB through specific quality assurance and system strengthening measures for routine TB services, MDR-TB, and TB-HIV co-infection.

STbCU Key Objectives:

1. Improve the quality and expand availability of the WHO-recommended directly observed treatment, short course, (DOTS)-based TB services.
2. Enhance the safety of the medical environment through improved infection control and monitoring.
3. Increase the capacity to implement programmatic management of drug-resistant tuberculosis (PMDT) programs for MDR-TB and XDR-TB control.
4. Improve access to TB/HIV co-infection diagnostic and treatment services.

Source: STbCU Results Framework, May 2012

[1] World Health Organization (WHO). Ukraine Tuberculosis Profile 2013. Available from: http://www.who.int/tb/country/data/profiles/en/index.html.

[2] Joint United Nations Programme on HIV/AIDS. Global Report: UNAIDS Report on the Global AIDS Epidemic 2013.

[3] Joint United Nations Programme on HIV/AIDS. Global Report: Eastern Europe and Central Asia Fact Sheet. 2010.

[4] At the time STbCU was awarded, 10 areas were targeted for TB control activities. In 2014, STbCU ceased all operations in AR Crimea and Sevastopol City, and activities were suspended in Donestsk and Luhansk.

Figure 1. USAID-supported TB intervention targets in Ukraine.

USAID Targets Areas Activities Suspended 2014

Two strategies are of specific interest to this impact evaluation: 1) providing social support services to improve patient adherence to TB treatment regimens; and 2) integrating TB and HIV services and referrals to improve the timely and appropriate diagnostics and treatment for co-infected patients.

Social Support Strategy

STbCU is working with the Ukraine Red Cross Society (URCS) to promote patient adherence to TB treatment. Defaulting on TB treatment can lead to higher treatment failure rates, development of drug-resistant TB, and mortality. In 2010 an estimated 7.6% of new smear-positive TB cases defaulted on treatment; in the USAID focus areas, default rates ranged from 6.1% to 12.7%.[5] URCS provides DOTS to a limited number of patients in their homes. Additionally, incentive packages are periodically provided and may include food, counseling, and/or vouchers for transportation or other necessities. Patients who are deemed to be at high-risk for treatment default are referred from the TB treatment cabinet to URCS for in-home follow-up. Additional support for a few select small pilot projects to improve adherence are planned in collaboration with local governments and community organizations.

TB/HIV Integration Strategy

In the project areas, an estimated 16.8% of newly diagnosed TB cases are co-infected with HIV and the mortality rate among the co-infected is approximately 7.7 %.[6] STbCU's objective is to improve access and use of timely diagnostics and treatment for co-infected patients in an effort to decrease mortality. The STbCU strategy is to improve access to TB-HIV co-infection services at the national level and in USAID-supported areas by: 1) identifying gaps in TB-HIV co-infection services and building capacity to address them; 2) ensuring HIV testing for TB patients and effective referral of those found to be HIV positive and; 3) providing TB screening of HIV patients and referral to TB services for suspected TB cases. Specific activities planned for the first year of the project included cross-training TB and infectious disease (ID) specialists on symptom screening, diagnostics, treatment and referral protocols for the co-infected; identifying the weaknesses in TB-HIV co-infection service provision through a gap analysis and identify activities and models to address these gaps; scaling up successful international and national models of integration. Over the life of the project, the project will work with the National TB and AIDS Centers, the State Service for HIV and Other Socially Dangerous Diseases, the Ukraine Ministry of Health (MOH), and local health administrations in each USAID-supported oblast to strengthen the policy framework for co-infection service delivery. By the end of the project, the goal is to have increased the proportion of newly diagnosed TB-HIV co-infected individuals who undergo diagnostic and counseling services for dual infection in USAID-supported areas.

[5] 2010 Ukraine Ministry of Health.

[6] PATH. Ukraine Tuberculosis Control Partnership Project: Final Report. 2012 May 15, 2012.

1.3 Impact Evaluation

Objectives: The Strengthening Tuberculosis Control in Ukraine Impact Evaluation (STbCU-IE) encompasses two STbCU programmatic priorities: 1) providing social support services to improve TB treatment adherence; and 2) improving integration of TB and HIV services to reduce mortality through early diagnosis and treatment for TB-HIV co-infected patients. To evaluate the impact of these program efforts, two independent but complementary studies were designed. Both studies use a mixed methods approach with a quasi-experimental quantitative evaluation design complemented by qualitative descriptive work to inform the findings. During 2014, data on testing, treatment, interventions, and outcomes were collected retrospectively to establish baseline indicators. Prospective data collection from patients in intervention and comparison sites in 2015-16 has been proposed for the endline survey.

Evaluation Questions: To evaluate the effect of social support programs on TB treatment adherence (henceforth the social support study) and the effect of integrating TB and HIV services to improve outcomes for the co-infected (henceforth TB-HIV integration study), a number of key evaluation questions have been chosen.

Social Support

1.1 Does participation in a social support program affect the likelihood of TB treatment default, treatment success, or treatment failure among high-risk 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 social support program are most important to those receiving the program? What works best for ensuring adherence?

TB-HIV Integration

2.1 What proportion of TB and HIV/AIDS patients complete each step in the cascade of services from screening to treatment per national protocol?
2.2 What facilitates or impedes timely access to 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, and 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 co-infected patients?

Study Sites: At the time of the study design, STbCU was targeting eight oblasts (AR Crimea, Dnipropetrovsk, Donestk, Kharkiv, Kherson, Luhansk, Odessa, and Zaporizhzhya) and two cities (Kiev and Sevastapol). For the impact evaluation (IE), oblasts were selected for inclusion based on the STbCU targeting and their epidemiologic profiles. However following the annexation of the Autonomous Republic of Crimea (AR Crimea) by Russia, STbCU pulled out of AR Crimea and the city of Sevastopol, hence the selection of study sites changed in February 2014. For the social support study, three oblasts with active STbCU programming were selected: Dnipropetrovsk, Kharkiv, and Odessa. For the integration study, AR Crimea, Odessa and Zaporizhzhya oblasts were selected as intervention sites and Kiev, Mykolaiv, and Zhytomyr oblasts were selected as comparison sites. AR Crimea was later replaced with Kharkiv as an intervention study site.

Timeline: The STbCU project was awarded in April 2012 and MEASURE Evaluation was engaged to design the impact evaluation in September 2012. An initial exploratory trip for the STbCU-IE planning was completed in October 2012, followed by an additional fact-finding trip in May 2013. The final protocol was approved in February 2014,[7] instruments field tested in March 2014, and data collection conducted June-September 2014.

[7] Difficulties in obtaining appropriate government approvals and travel restrictions due to civil unrest led to some delays in protocol approval and data collection.

CHAPTER 2. STUDY METHODS

The social support study and the TB-HIV integration study were both designed to measure program impact on select TB indicators using a mixed-method, quasi-experimental design. However, the study designs are quite different and warrant individual descriptions of the methods.

2.1. Social Support Study

Study Design

The study design covers a quantitative survey at baseline and endline, plus a qualitative component at endline. The quantitative survey addresses research question 1.1 (see above) with retrospective medical record data abstraction from two time periods, 2011 and 2012, and prospective data collection in 2015-2016, for a sample of TB patients stratified by risk of defaulting on TB treatment. A pre-post measurement with controls for selection bias will be used to assess the impact of the social support program on treatment adherence at endline. Additional facility-level data collected from TB facilities in these oblasts will inform our understanding of differences seen between oblasts. The qualitative component will answer questions 1.2 and 1.3 and includes patient and provider in-depth interviews at endline.

The social support 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 sampling design draws from 2011 (no intervention) and 2012 (intervention) time periods, and both high-risk and low-risk patients to allow for comparison to routine care for low-risk and high-risk patients (see box).

Social Support Program High-Risk Eligibility Criteria

Smear-negative, pulmonary TB patients with one of the following risk factors:

- HIV-positive
- alcoholic
- injecting drug user
- co-morbidity
- homeless
- unemployed
- ex-prisoner
- TB contact
- health care worker
- migrant
- refugee/Immigrant
- other

Sampling Design and Implementation

Oblasts: Given the natural break in social support services and the availability of retrospective medical records, we decided to select three oblasts from the USAID-supported areas to study over time. The oblasts were purposively chosen to reflect oblasts with high treatment default rates and an adequate case load to study over time; Dnipropetrovsk, Kharkiv, and Odessa met these criteria (Table 2.1). Funding for URCS to offer social support services resumed in Dnipropetrovsk and Kharkiv in June 2011; Odessa received funding starting in January 2012.

Table 2.1. TB case counts and treatment default rates in USAID focus areas, Ukraine 2010 and 2012

USAID Focus Areas	TB Cases, 2010	Default Rate, 2010	TB Cases, 2012
Crimea	722	7.3	1497
Dnipropetrovsk	1077	12.4	3082
Donetsk	1619	6.1	3148
Kharkiv	738	11.1	1359
Kherson	455	10.1	1167
Kiev City	502	12.7	1168
Luhansk	784	7.0	1795
Odessa	789	9.4	2235
Sevastopol City	112	12.5	236
Zaporizhzhya	541	7.8	1243

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, they are 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 URCS for social support. To better understand the referral and treatment process 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. Additionally, the three URCS oblast offices that provided the social support program were surveyed.

Individuals: At baseline, individual medical data were collected for five patient cohorts: high-risk (HR) patients receiving social support in January-May 2012; HR patients not enrolled in the social support program in January-May 2012; low-risk (LR) patients not enrolled in the social support program in January-May 2012; HR patients not enrolled in the social support program in January-May 2011; and LR patients not enrolled in the social support program in January-May 2011. Patients served in 2011, regardless of their perceived risk for treatment default, were not exposed to the social support program. Hence they provide baseline data on the rates for treatment default by patient characteristics in 2011. By 2012, each study oblast was referring select patients for the social support program, providing intervention outcome data. The endline data collection will provide risk cohorts from a third point in time to measure changes in targeting and outcomes for the social support work.

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 (2,225 total TB continuation treatment patients), selected by oblast proportionate to size of their TB population. Selection of the study sample was based on program data from URCS. A complete listing of patients served by URCS in each of the study oblasts in 2012 was provided. A random sample of HR-Intervention patients were first selected from each oblast from the list of patients served by URCS in January-May 2012. 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 2012; one LR-Comparison patient from 2012; one HR-Comparison patient from 2011; and one LR-Comparison patient from 2011. 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.

Data Collection and Instruments

Data collection was lead by our partner, IFAK, in collaboration with the lead TB specialist in each oblast. In Kharkiv and Dnipropetrovsk oblasts, IFAK trained a team of TB specialists on the survey instrument and the sampling protocol. The lead oblast TB specialist requested all needed charts (TB-01, TB-01-1, TB-03) from the raions and then selected the matched cases for the social support study. After matches were selected the team completed the survey instrument using data abstracted from the official client records (form TB-01, TB-01-1 and medical record).

In Odessa oblast the procedure was slightly different. The lead oblast TB specialist first sent an official letter of support to all raions. The local raion TB specialists completed a training conducted by IFAK on the sampling protocol and chart abstraction. The raion TB specialists selected cases and completed the survey instrument using data abstracted from the official client record (forms TB-01, TB-01-1). Several raions were visited by IFAK team to coordinate the process of data collection and quality comparison. Other raions sent copies of TB-01, TB-01-1 directly to IFAK to verify abstraction.

The individual patient instrument collected basic socio-demographic characteristics; TB diagnosis, treatment, and outcomes; potential risk factors for defaulting or failing treatment; and participation in a social support program. The survey tool was developed based on the standard TB forms used in Ukraine (TB-01, TB-03). The tool was field tested in Kiev oblast in March 2014.

The facility 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 in the facility survey instrument included basic facility characteristics such as size and staffing; services provided, referrals provided, criteria for social support referrals, and information on TB drug shortages in 2011 and 2012. The facility survey tool was developed by the study team and field tested in Kiev oblast in March 2014.

Data Entry, Processing and Analysis

Completed facility and individual surveys were returned to 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 University of North Carolina at Chapel Hill (UNC-CH) for analysis using Stata v12 (College Station, TX). Analysis included descriptive analyses and multivariate logistic regression modeling examining TB treatment default and outcomes by intervention and risk status.

2.2. TB-HIV Integration Study

Study Design

The integration study design covers a quantitative survey at baseline and endline in intervention and comparison oblasts, plus qualitative interviews with medical providers at baseline and patients at endline. The quantitative survey addresses research questions 2.1-2.3 with retrospective medical record data abstraction from calendar year 2012, and prospective data collection in 2015-16 for a sample of newly diagnosed TB, HIV and TB-HIV co-infected patients. Patient treatment cascades were created to illustrate the series of testing and services recommended for new patients. Survival analysis methods are used to assess time to treatment for the co-infected and all-cause mortality among the co-infected in 2012 and at endline. Additional facility-level data collected from TB dispensaries and AIDS centers in intervention and comparison oblasts will inform our understanding of differences seen between oblasts. Provider interviews offer insight into the existing policies and practices vis-à-vis identifying and treating individuals co-infected with TB and HIV.

Sampling Design and Implementation

Oblasts: The oblasts were purposively chosen: three intervention oblasts from USAID-supported areas; and three comparison oblasts from outside the USAID focus areas. At the time of the evaluation site selection, STbCU's planned integration activities included cross-training of TB and HIV providers, system improvements in testing and referrals, plus a few select annual grants to provide support to co-infected patients needing services at multiple facilities. Because the training and system work was for the entire USAID-supported areas and the small grants were annual and not yet awarded, we focused our study site selection on factors external to STbCU. The intervention oblasts, Kharkiv, Odessa, and Zaporizhzhya, were selected based on TB and HIV case counts and co-infection rates. The comparison oblasts, Kiev, Mykolaiv, and Zhytomyr, were loosely matched to intervention oblasts on TB and HIV disease rates, population density, and socio-economic status (Table 2.2). Individual case matching between intervention and comparison patients was not possible at baseline due to the limited socio-demographic patient data available in the medical records; however, at endline prospective patient enrollment may allow additional data collection for a refined match between intervention and comparison cohorts to control for selection bias.

Facilities: For patients co-infected with TB and HIV, timely diagnosis and treatment of both diseases is critical to survival. This means the period of most interest to this study is the period immediately following TB diagnosis and intensive treatment initiation for TB patients or the period immediately following HIV diagnosis and patient registration. In each oblast only a few TB Dispensaries or outpatient TB facilities (range 1-7) offer intensive treatment and only one or two AIDS Centers and Primary Health Care facilities provide HIV care. The TB and HIV facilities were selected for a facility survey. Respondents included facility administrators/directors or lead TB physicians.

Providers: To understand and document routine processes for screening, testing, referral and treatment among TB and HIV patients in STbCU intervention and comparison oblasts, in-depth interviews were conducted with a sample of TB specialists from TB dispensaries and ID specialists at AIDS centers. Providers selected for interviews were the primary decision makers regarding the diagnosis, treatment, and referral of patients at their respective facilities.

Individuals: At baseline, individual medical record data were collected for two patient cohorts from each oblast: 1) TB patients starting TB intensive treatment during calendar year 2012; and 2) HIV patients newly registered during calendar year 2012. Each cohort (TB and HIV) was sampled independently, with no means of de-duplicating patients who were served by both types of facilities. Hence, the samples were collected and analyzed separately based on patient point of service.

Target sample size calculations were powered on the expected change in probability of testing TB patients for HIV and testing HIV patients for TB from baseline (2012) to endline (2016). Additional oversampling of co-infected patients at both TB and HIV facilities was done to provide power for the analysis of ART initiation and all-cause mortality among the co-infected. In total, the target sample was 2,500 patients: 1,448 from TB Dispensaries and 1,052 from HIV/AIDS centers.

For the TB patient sampling, the oblast TB specialist requested the TB registries from each facility providing intensive treatment in 2012. From these registries, the first random sample (S1) of patients was selected from all new TB patients without replacement, proportionate to size of the oblast (not the facility). A second sample (S2) was then selected from the remaining identified co-infected.

Table 2.2. Population, economic, and disease data by oblast, Ukraine 2011

Oblasts	Population Density (Pop. per KM2)	Level of socio-economic development[1] (Percent)	New TB Cases, 2011	TB Rate, 2011 (Cases per 100,000 pop.)	New HIV Cases, 2011	HIV Rate, 2011 (Cases per 100,000 pop.)	TB-HIV Co-infection Rate, 2011 (Cases per 100,000 pop.)
AR Crimea	34.8	3.9	1491	76.3	1,077	54.9	3.3
Dnipropetrovsk	31.7	8.1	3179	95.4	3,447	103.3	5.1
Donetsk	36.5	11.4	3231	73.1	3,994	90.0	4.4
Kharkiv	46.3	6.6	1492	54.5	565	20.5	0.7
Kherson	10.7	1.9	1070	98.5	716	65.8	2.5
Luhansk	16.3	5.2	1828	79.9	715	31.2	1.5
Odessa	30.3	4.9	2087	87.8	2,080	87.1	5.5
Zaporizhzhya	28.7	4.4	1185	65.8	523	29.0	1.7
Cherkasy	13.8	2.5	733	57.2	494	38.4	1.3
Chernihiv	9.3	2.0	722	66.3	481	43.8	2.9
Chernivtsi	31.1	1.4	440	48.8	106	11.7	0.2
Ivano-Frankivsk	16.1	2.1	905	65.7	142	10.3	0.2
Khmelnytsk	12.7	2.3	694	52.4	279	21.0	0.9
Kirovograd	9.6	2.1	795	79.2	358	35.4	1.3
Kiev	61.3	3.6	964	56.3	831	48.8	1.2
Lviv	33.6	5.0	1630	64.5	493	19.4	0.6
Mykolaiv	20.4	2.3	1056	89.3	1,132	95.6	5.1
Poltava	10.4	3.4	817	55.2	464	31.2	1.2
Rivne	12.4	2.1	720	62.5	246	21.3	0.1
Sumy	11.4	2.4	663	57.2	202	17.4	0.4
Ternopil	15.8	1.7	585	54.1	149	13.7	0.3
Vinnytsya	13.9	2.6	895	54.8	372	22.7	0.6
Volyn	10.5	1.8	537	51.9	280	27.0	0.4
Zakarpat	9.1	1.9	711	57.1	63	5.1	0.2
Zhytomyr	9.1	2.2	920	71.9	458	35.8	1.7

[1] The level of socio-economic development of the region was calculated using the following set of parameters: the number of unemployed (ILO methodology) and registered unemployed persons, the number of employed population, disposable income, payable for payroll, investment in fixed assets, etc. (State Statistics Committee of Ukraine, 2008-2009). The value of this indicator by oblast (%) is the proportion of area in relation to this indicator for Ukraine, whose value is taken as 100%.

For the HIV patient sampling, the central oblast AIDS center stored all of the new HIV registration cards and kept a registration journal. From the 2012 registration journal, the first random sample (S1) was drawn without replacement. Identification of co-infected patients was more challenging as that information was not always known at time of initial patient registration. Instead of relying exclusively on the HIV registration cards, the ID specialists in each oblast reviewed patient records to provide a list of all co-infected patients in the oblast. From this list the S2 over-sample of co-infected patients was drawn.

Data Collection and Instruments

Data collection was led by our partner, IFAK, in collaboration with the lead TB specialist and ID specialist in each oblast. The local staff provided de-identified client lists from each oblast and service facility registry. IFAK used these client lists to select the study sample randomly, following the sampling protocol described above. IFAK then trained lead TB and ID specialists on the two survey instruments and these specialists completed the tools using data abstracted from the official client records (form TB-01, TB-03, HIV control card, HIV medical record). The individual patient instrument collected basic socio-demographic characteristics; TB diagnosis, treatment, and outcomes; potential risk factors for defaulting or failing TB treatment; participation in a social support program; HIV diagnosis, treatment, and status.

The facility surveys were completed by IFAK with the assistance of the facility director or administrator most knowledgeable about the TB and HIV policies and activities at the facility. Data collected in the facility survey instrument included basic facility characteristics such as size and staffing; services and referrals provided; policies for screening, testing and treatment of co-infected patients; and information on TB and HIV drug shortages in 2012 (see appendix).

In-depth qualitative interviews were completed with a sample of TB and ID specialists in the six study oblasts. The interviews covered testing, treatment and referral protocols and practices commonly used at each facility. The provider interviews were conducted by different data collection firms during different periods. STbCU conducted provider interviews for a gap analysis of TB and HIV services in the same intervention oblasts.[8] The MEAUSRE Evaluation study team extracted data from eight interviews covering seven facilities that were relevant to this study. These data was shared between studies to avoid over-burdening staff at these facilities. IFAK then conducted 10 additional interviews in the comparison oblasts in June-September 2014 using the tools developed by STbCU. In total, 17 provider interviews were completed. Interviews lasted typically 30-60 minutes and were conducted in Ukrainian or Russian.

Data Entry, Processing and Analysis

Completed facility surveys and individual record abstractions were returned to IFAK's main office in Kiev for processing, which included 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 Microsoft Excel files were forwarded to UNC-CH for analysis using Stata v12 (College Station, TX). Analysis included descriptive analyses and survival analyses.

Provider interviews were recorded and transcribed in Ukrainian/Russian, with translation into English for analysis. Content analysis was completed by IFAK and Futures Group to identify common themes and differences across oblasts and facilities. A table of these questions and themes was constructed and used to draw out useful findings.

Review

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

[8] Mangura B, Ahamed N, Roman N, Lezhentsev K. TB/HIV co-infection services gap analysis. Chemonics International and Global Tuberculosis Institute at State University of New Jersey (GTBI). Kiev, 2014.

CHAPTER 3. SOCIAL SUPPORT STUDY FINDINGS

3.1. TB Outpatient Facilities and Services

Key Findings: TB Facilities and URCS

- The number of TB patients served by TB facilities was similar in 2011 and 2012; however the percent of facilities providing referrals for social support increased from 23% in 2011 to 94% in 2012 due to changes in funding.
- URCS was the sole provider of social support in Kharkiv and Odessa and the primary provider in Dnipropetrovsk. Additional services were provided by the government and the network for PLWH in Dnipropetrovsk.
- The majority of facilities, 84%, reported that the decision-maker for social support referrals was most often the raion or city TB physician.
- Over 70% of facilities in Dnipropetrovsk and Odessa required at least one risk factor for referral to social support; no minimum number of risk factors was required in over 60% of facilities in Kharkiv.
- The most commonly cited eligibility criterion for social support was HIV-positive status (82%) followed by alcoholism (70%).
- Social support provided by URCS included daily home DOTS and twice monthly food packages, except in Odessa where food packages were thrice monthly.
- 20% of the facilities reported TB drug shortages lasting more than 30 days in 2011, dropping to only 6% in 2012. During shortages in 2011, patients were most often told to buy their own medications; in 2012 patients were waitlisted for treatment during times of shortage.

Facility Surveys

To learn more about how social support works in relation to TB services, we conducted surveys with 50 TB facilities in three oblasts, as well as with one URCS social support office in each oblast (Table 3.1). The information provided in this section focuses primarily on data from the TB facilities, with supplemental information to summarize the key functions of URCS.

Table 3.1. TB facilities and URCS offices surveyed by oblast, Ukraine 2014

	TB Facility Services by Oblast		URCS Services by Oblast	
Oblast	Number	(Percent)	Number	(Percent)
Dnipropetrovsk	18	(36.0)	1	(33.3)
Kharkiv	15	(30.0)	1	(33.3)
Odessa	17	(34.0)	1	(33.3)
Total facilities	50	(100.0)	3	(100.0)

Facility Characteristics

All TB facilities surveyed were either TB cabinets within a polyclinic or TB dispensaries/hospitals, though a majority of facilities in all three regions were TB cabinets (Table 3.2). A wide range of services can be offered at TB facilities, including diagnostics, treatment, prevention, and counseling. Nearly all facilities provided TB diagnostic testing and TB outpatient treatment. Far fewer facilities provided TB inpatient treatment (20% overall), particularly in Kharkiv and Odessa where only one or two facilities provided such treatment. In Dnipropetrovsk, about 40% of facilities provided inpatient treatment.

HIV voluntary counseling and testing (VCT) was provided in all facilities in Dnipropetrovsk and Odessa and in two-thirds of the facilities in Kharkiv. Services for patients with HIV were also provided in many of the TB facilities, with all facilities in Kharkiv and Odessa and 83% of facilities in Dnipropetrovsk providing Isoniazid preventive therapy (IPT). HIV treatment options vary in the three regions. In Dnipropetrovsk, Co-trimoxazole preventive therapy (CPT) and ART are offered at 78% and 56% of their facilities; in Odessa, 60% of facilities provided CPT and less than 20% provided ART; whereas, in Kharkiv just two or three facilities offered CPT or ART. IDU substitution therapy and psychological counseling was not provided in the majority of facilities.

Table 3.2. TB facilities surveyed by type, services offered, and oblast, Ukraine 2014

Facility Characteristics	Dnipropetrovsk		Kharkiv		Odessa		Total	
	Number	(Percent)	Number	(Percent)	Number	(Percent)	Number	(Percent)
Facility Type								
TB cabinet within a polyclinic	12	(66.7)	11	(73.3)	13	(76.5)	36	(72.0)
TB dispensary/hospital	6	(33.3)	4	(26.7)	4	(23.5)	14	(28.0)
Services Offered								
TB diagnostic testing	18	(100.0)	14	(93.3)	17	(100.0)	49	(98.0)
TB inpatient treatment	7	(38.9)	2	(13.3)	1	(5.9)	10	(20.0)
TB outpatient treatment	18	(100.0)	15	(100.0)	17	(100.0)	50	(100.0)
HIV voluntary counseling and testing	18	(100.0)	10	(66.7)	17	(100.0)	45	(90.0)
Isoniazid preventive therapy (IPT)	15	(83.3)	15	(100.0)	17	(100.0)	47	(94.0)
Cotrimoxazole preventive therapy (CPT)	14	(77.8)	2	(13.3)	10	(58.8)	26	(52.0)
Antiretroviral therapy (ART)	10	(55.6)	3	(20.0)	3	(17.7)	16	(32.0)
Injecting drug user (IDU) substitution therapy	4	(22.2)	2	(13.3)	2	(11.8)	8	(16.0)
Psychological counseling	6	(33.3)	2	(13.3)	4	(23.5)	12	(24.0)
Total facilities	18	(100)	15	(100)	17	(100)	50	(100)

Information regarding staffing, number of beds for inpatient treatment, and number of new outpatient TB patients provides an understanding of the size and complexity of the surveyed TB facilities (Table 3.3). Nursing staff represents the largest number of staff at TB facilities, across all three regions, followed by doctors and administrative staff. Odessa facilities had fewer staff overall with a median of two administrative staff and nurses and one physician. In all regions, the number of staff varied widely, likely due to the catchment population size and proportion of part-time staff.

Ten of the 50 TB facilities provided inpatient treatment. Dnipropetrovsk region had the most number of beds for TB patients and TB-HIV co-infected patients. Overall, the range of the number beds varied considerably by facility with as few as 15 TB patient and four TB-HIV co-infected patient beds, and as many as 500 of each.

Nearly all of the surveyed facilities provided outpatient services to TB patients in the January-May 2012 and January-May 2011 time periods. The median number of new patients was similar across the time periods. The number of new TB outpatients was highest in Odessa, followed by Dnipropetrovsk and Kharkiv, where the median number was eight new patients in the January-May 2012 time period. As with staffing and number of beds, the number of new TB outpatients varied widely by facility.

Table 3.3. Number of TB staff, inpatient beds and outpatient patients in surveyed facilities by oblast, Ukraine 2014

	Dnipropetrovsk		Kharkiv		Odessa		Total	
	Median	(Range)	Median	(Range)	Median	(Range)	Median	(Range)
Staffing for TB services	(n=18)		(n=15)		(n=17)		(n=50)	
Administrative	2	(1-9)	2	(1-3)	2	(1-4)	2	(1-9)
Nurses	3	(1-95)	3	(1-82)	2	(1-23)	3	(1-95)
Doctors	2	(0-59)	2	(0-63)	1	(0-15)	2	(0-63)
Beds for inpatient treatment	(n=7)		(n=2)		(n=1)		(n=10)	
TB patients	115	(30-500)	70	(40-100)	15	NA	100	(15-500)
TB-HIV coinfected patients	80	(4-500)	15	(10-20)	15	NA	32.5	(4-500)
New outpatient TB patients	(n=17)		(n=14)		(n=16)		(n=47)	
January-May 2012	27	(12-229)	8	(2-204)	34	(2-109)	24	(2-229)
January-May 2011	26	(6-185)	6	(0-215)	33	(1-103)	22	(0-215)

TB Treatment Strategies

DOTS provision varied depending upon TB treatment phase and in some cases, region (Table 3.4). During TB intensive treatment, all facilities except for one in Odessa provided DOTS at the facility. During TB continuation treatment, a majority of facilities could provide DOTS at the facility or at home, although the standard practice varied by region. All but two facilities in Dnipropetrovsk provided DOTS at the facility; in Kharkiv, two-thirds of facilities provided DOTS at the facility, the remainder at home; and in Odessa all but two facilities provided DOTS at home.

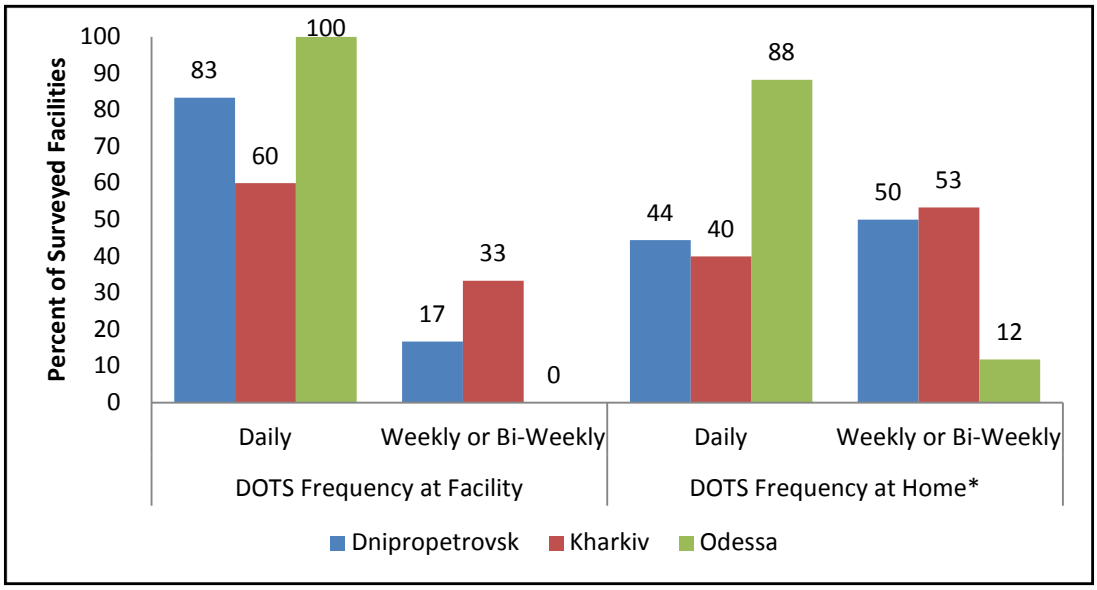
Table 3.4. TB treatment adherence strategy in surveyed facilities by oblast, Ukraine 2014

	Dnipropetrovsk		Kharkiv		Odessa		Total	
Adherence Strategies	Number	(Percent)	Number	(Percent)	Number	(Percent)	Number	(Percent)
TB intensive treatment*								
DOTS at facility	18	(100.0)	14	(100.0)	16	(94.1)	48	(98.0)
DOTS at home	0	(0.0)	0	(0.0)	1	(5.9)	1	(2.0)
TB continuation treatment								
DOTS at facility	16	(88.9)	10	(66.7)	2	(11.8)	28	(56.0)
DOTS at home	2	(11.1)	5	(33.3)	15	(88.2)	22	(44.0)
Total facilities	18	(100.0)	15	(100.0)	17	(100.0)	50	(100.0)

* Limited missing values not shown

Frequency of TB continuation treatment differed by location of DOTS treatment and in some cases by region (Figure 3.1). For patients receiving continuation treatment in the facility, the majority of treatment was provided daily (82%). This varied by region with 100% of facilities in Odessa providing DOTS daily compared to 83% in Dnipropetrovsk and 60% in Kharkiv where the remaining facilities provided DOTS in the facility on a weekly or bi-weekly basis. For patients receiving continuation treatment in the home nearly all facilities in Odessa provided it daily, compared to Dnipropetrovsk and Kharkiv where about half of facilities provided it daily and the other half, weekly.

Figure 3.1. Frequency of directly observed treatment by location and oblast, Ukraine 2014.



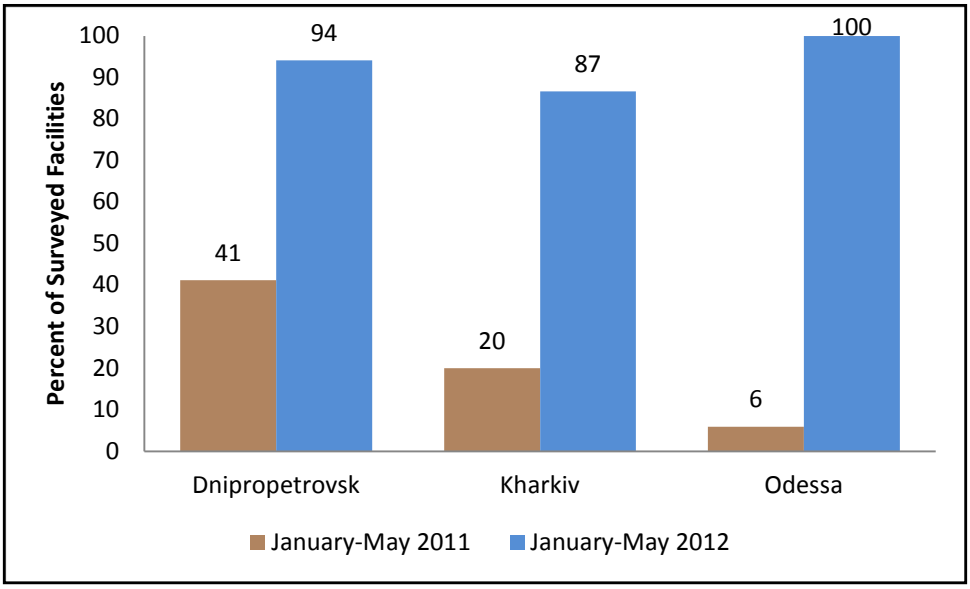
*Limited missing values not shown

Social Support Services

The percent of facilities providing social support referrals changed considerably from 2011 (23%) to 2012 (94%) as expected due to changes in funding between these periods (Figure 3.1).

URCS was the only national provider of social support services in Kharkiv and Odessa in 2011 and 2012, and the primary provider in Dnipropetrovsk (see box). However in Dnipropetrovsk, the Ukrainian government and the network of people living with HIV (PLWH) provided social support services as well.

Figure 3.2. Percent of surveyed facilities referring patients to social support programs for continuation treatment, Ukraine 2011 and 2012.



Facilities reported that the decision about whether or not a client receives a referral for social support primarily lies with the raion (64%) or city TB physician (20%) (Table 3.5). In Dnipropetrovsk and Kharkiv, some facilities reported other sources of referrals such as the deputy TB doctor, patient's TB physician, a special commission, or "head" doctor. Very few facilities reported that the oblast TB physician made the decision, confirming the assumption that the decision to refer for social support was made after a client has been discharged from inpatient treatment.

For facilities providing referrals, requirements for social support eligibility varied widely. In Dnipropetrovsk and Odessa, over 70% of facilities required a minimum of one risk factor to consider someone as eligible for a referral (Figure 3.3). In 2012, two criteria were required by 18.8% and 5.9% of facilities respectively. In contrast, Kharkiv had no minimum number of risk factors in over 60% of their facilities and no facilities required two or more factors.

Ukrainian Red Cross Society Social Support Model Program

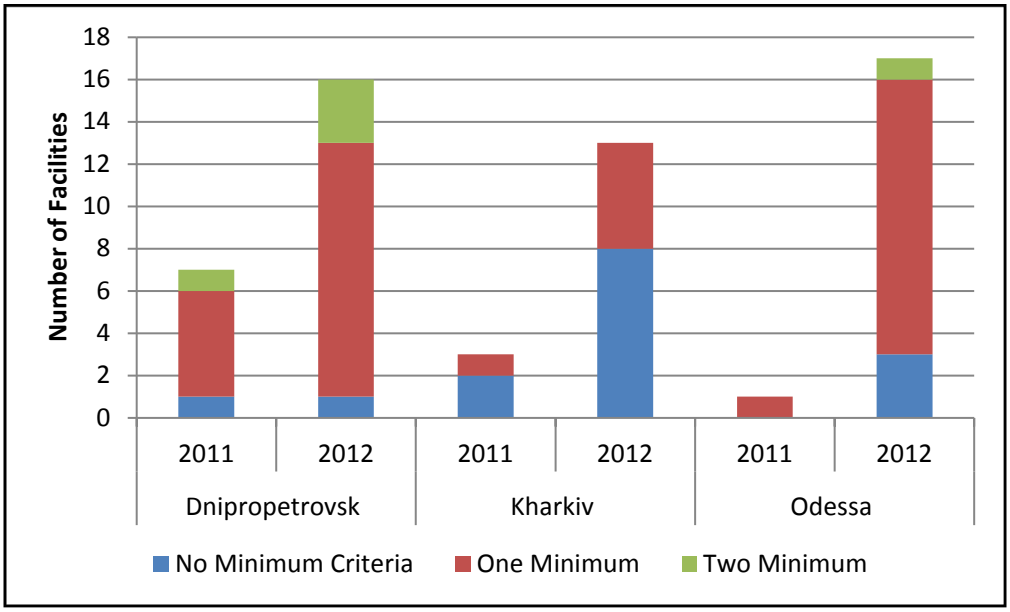
URCS provides support for various activities nationwide in 27 oblasts and 667 raions. Support for TB and HIV clients are just some of the services social support nurses on staff provide when donor funding is available from agencies such as Global Fund to Fight AIDS, Tuberculosis and Malaria and USAID. In the three study oblasts, URCS is the primary provider of social support services which includes home daily DOTS support, food packages, and psychological counseling. URCS has both administrative and nursing staff, with approximately three administrative staff and between 47 to 93 social support nurses depending on the facility.
Source: Meeting with URCS Program Office, 2013.

Table 3.5. Primary decision maker for social support program referrals in surveyed facilities by oblast, Ukraine, 2014

	Dnipropetrovsk		Kharkiv		Odessa		Total	
Referral Source*	Number	(Percent)	Number	(Percent)	Number	(Percent)	Number	(Percent)
Oblast TB physician	1	(5.6)	2	(13.3)	0	(0.0)	3	(6.0)
Raion TB physician	8	(44.4)	12	(80.0)	12	(70.6)	32	(64.0)
City TB physician	5	(27.8)	2	(13.3)	5	(29.4)	12	(24.0)
TB cabinet nurse	1	(5.6)	0	(0.0)	3	(17.6)	4	(8.0)
Other	6	(33.3)	2	(13.3)	0	(0.0)	8	(16.0)
Total facilities	18		15		17		50	

*Not mutually exclusive, facility may report more than one source

Figure 3.3. Minimum number of risk factors required to be eligible for referral to a social support program among facilities providing referrals, by oblast and year, Ukraine, 2011 and 2012.



The eligibility criteria used to refer for social support were fairly similar across the two time periods (Table 3.6). The most commonly cited risk factor for both time periods included HIV-positive status (around 82% of facilities) and alcoholism (around 70%), though there were five facilities that did not use HIV status as a criterion. Half of the facilities reported using other risk factor criteria such as an injecting drug user, homeless person or ex-prisoner, and anecdotally many facilities noted their preference for referring patients who consistently demonstrated commitment to treatment. Across both time periods, eligibility for social support was rarely based on identification as a health care worker, refugee, or migrant. The proportion of facilities using unemployment, low income, contact with a case, and co-morbidity increased substantially from 2011 to 2012.

Table 3.6. Risk factors used and not used by surveyed facilities to determine eligibility for social support program referrals by time period, Ukraine, 2011 and 2012

	Factor Used for Referrals				Factor not used in either time period	
	Jan-May 2011		Jan-May 2012			
Risk Factors	Number	(Percent)	Number	(Percent)	Number	(Percent)
HIV-positive	9	(81.8)	38	(82.6)	5	(10.9)
Alcoholic	8	(72.7)	32	(69.6)	10	(21.7)
Injection drug user	6	(54.5)	26	(56.5)	15	(32.6)
Co-morbidity	4	(36.4)	27	(58.7)	17	(37.0)
Homeless	7	(63.6)	26	(56.5)	15	(32.6)
Unemployed	5	(45.5)	34	(73.9)	10	(21.7)
Contact with case	3	(27.3)	22	(47.8)	20	(43.5)
Ex-prisoner	5	(45.5)	24	(52.2)	15	(32.6)
Health care worker	2	(18.2)	12	(26.1)	30	(65.2)
Migrant	3	(27.3)	13	(28.3)	26	(56.5)
Refugee/immigrant	3	(27.3)	11	(23.9)	28	(60.9)
Low income	4	(36.4)	25	(54.3)	17	(37.0)
Total facilities	11	(100.0)	46	(100.0)	46	(100.0)

Social support services typically included daily DOTS provision at home, counseling, and food packages. For facilities offering social support, home visits were primarily conducted on a daily basis (Table 3.7). Across the regions, food packages were primarily offered to clients twice per month, though in Odessa seven facilities provided food packages three times per month. Other types of social support such as clothing or hygiene kits, transportation vouchers, and counseling were not provided or were only provided upon request.

Table 3.7. Social support services offered according to referral facilities in 2011 and 2012, Ukraine, 2011 and 2012

	Jan-May 2011		Jan-May 2012	
Patient Incentives	Number	(Percent)	Number	(Percent)
Home visits				
Daily	7	(63.6)	40	(87.0)
Weekly	0	(0.0)	1	(2.2)
Twice Monthly	1	(9.1)	2	(4.3)
Not offered	3	(27.3)	2	(4.3)
Missing	0	(0.0)	1	(2.2)
Food packages				
1 per month	4	(36.4)	7	(15.2)
2 per month	5	(45.5)	31	(67.4)
3 per month	0	(0.0)	7	(15.2)
Not offered	2	(18.2)	1	(2.2)
Total facilities	11	(100)	46	(100)

TB Drug Supply Shortages

Among the 50 facilities surveyed, one-fifth experienced drug shortages lasting longer than 30 days during 2011 and 6% reported prolonged shortages in 2012 (Figure 3.4). In 2011, five facilities each in Dnipropetrovsk and Odessa experienced drug shortages compared to no facilities in Kharkiv (Table 3.8). Of the 10 facilities with reported drug shortages in 2011, approximately half of them reported shortages of four or more drugs. The most commonly reported drug shortages in 2011 were for Pyranzinamide, Isoniazid, Rifampicin, Ethambutol, and Rifapex (data not shown). In 2012, three facilities reported shortages of Rifampicin.

In nearly all cases of drug shortages in 2011, facilities reported that patients had to obtain their own medication. For the shortages in 2012, facilities either waitlisted patients or patients had to get their own medications.

Figure 3.4. Percent of facilities that reported a TB drug supply shortage lasting longer than 30 days in 2011 and 2012.

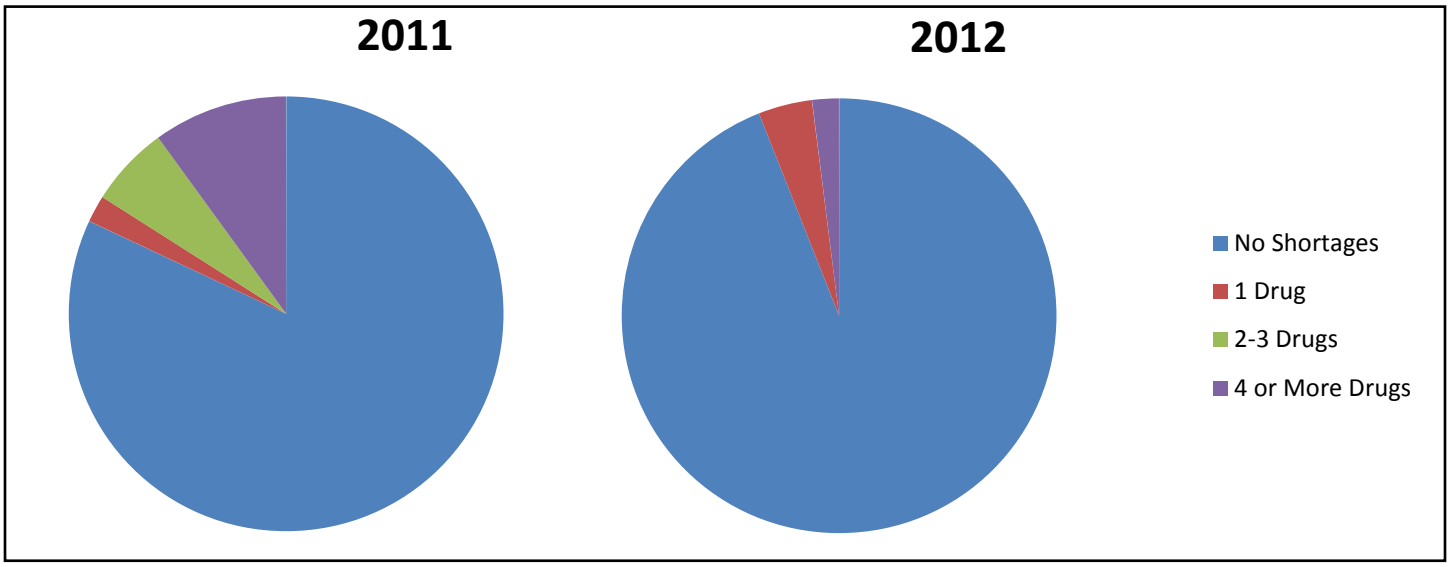


Table 3.8. Reported TB drug supply shortages lasting longer than 30 days, by facility and oblast, Ukraine, 2011 and 2012

	Dnipropetrovsk				Kharkiv				Odessa			
	2011		2012		2011		2012		2011		2012	
Drug Shortages	No.	(Percent)	No.	(Percent)	No.	(Percent)	No.	(Percent)	No.	(Percent)	No.	(Percent)
No shortages	13	(72.2)	16	(88.9)	15	(100.0)	14	(93.3)	12	(70.6)	17	(100.0)
1 drug	0	(0.0)	1	(5.6)	0	(0.0)	1	(6.7)	1	(5.9)	0	(0.0)
2-3 drugs	3	(16.7)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
4 or more drugs	2	(11.1)	1	(5.6)	0	(0.0)	0	(0.0)	3	(17.6)	0	(0.0)
Number unknown	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(5.9)	0	(0.0)
Total facilities	18	(100.0)	18	(100.0)	15	(100.0)	15	(100.0)	17	(100.0)	17	(100.0)

Key Findings: TB Patients

- Similar demographic profiles were seen in each study cohort; approximately two-thirds of patients were male, three-quarters were under fifty years of age, and over 80% lived in urban areas.
- Among the high-risk cohorts, 64% to 73% reported two or three risk factors for treatment default, while 4% to 6% reported four or more risk factors.
- During TB continuation treatment, HR-Intervention 72.8% reported no treatment interruptions compared to 55.9 percent among the HR-comparison cohort in 2012.
- The HR-Intervention group on average reported shorter treatment interruptions, although in all risk cohorts almost one-fifth of the patients reported a treatment interruption lasting longer than four weeks.
- Comparing HR-intervention and HR-comparison cohorts in 2012 we found that HIV-positive patients, homeless, and ex-prisoners were less likely to receive the social support while the unemployed and "other" were more likely to receive the intervention. Potential selection bias introduced by provider referral differences will need to be controlled for at endline.
- The social support appears to have a protective affect on treatment default. An average TB patient (male, 42 years old, living in urban area) had a 1.9% probability of defaulting on treatment if in the HR-Intervention group compared to an 11.2% and 12.9% probability of default among the HR-Comparison group from 2012 and 2011 respectively.
- The social support appears to have a protective affect on death however the number of cases is small. In Odessa the HR-intervention group had a 10 percentage point lower probability of dying compared to the 2012 HR-comparison group.

Response Rates

Overall response rates for the chart abstraction across all oblasts and risk cohorts was 85.0% (Table 3.9). The highest abstraction rates were reported for the 2012 HR-intervention cohort, as expected given the detailed patient participation list provided by URCS. Matching on risk status and year at the facility-level proved more difficult particularly in 2012 and at smaller facilities. In 2012, the majority of patients received social support services, and in smaller facilities everyone was referred for social support, making it difficult to identify any HR or LR patients who did not receive social support. Also, a greater number of TB patients in 2012 were not referred for continuation treatment at all due to diagnosis with MDR-TB or death during intensive treatment phase.

Table 3.9. TB patients response rates by risk cohort and intervention group per oblast, Ukraine, 2011 and 2012

	2012			2011			Total		
Oblast and Risk Group	Sample	Abstracted	Rate	Sample	Abstracted	Rate	Sample	Abstracted	Rate
Dnipropetrovsk Oblast									
High-risk intervention	230	223	97.0	NA	NA	NA	230	223	97.0
High-risk non-intervention	230	178	77.4	230	178	77.4	460	356	77.4
Low-risk non-intervention	230	158	68.7	230	190	82.6	460	348	75.7
Sub-total	690	559	81.0	460	368	80.0	1150	927	80.6
Kharkiv Oblast									
High-risk intervention	100	100	100.0	NA	NA	NA	100	100	100.0
High-risk non-intervention	100	97	97.0	100	90	90.0	200	187	93.5
Low-risk non-intervention	100	87	87.0	100	89	89.0	200	176	88.0
Sub-total	300	284	94.7	200	179	89.5	500	463	92.6
Odessa Oblast									
High-risk intervention	115	111	96.5	NA	NA	NA	115	111	96.5
High-risk non-intervention	115	90	78.3	115	122	106.1	230	212	92.2
Low-risk non-intervention	115	86	74.8	115	93	80.9	230	179	77.8
Sub-total	345	287	83.2	230	215	93.5	575	502	87.3
Total patients	1335	1130	84.6	890	762	85.6	2225	1892	85.0

Table 3.10. Background characteristics of TB patients by risk cohort and year. Ukraine, 2011 and 2012

Background characteristics	High-Risk Patients						Low-Risk Patients				Total	
	Intervention 2012		Comparison 2012		Comparison 2011		Comparison 2012		Comparison 2011			
	Number	(Percent)	Number	(Percent)	Number	(Percent)	Number	(Percent)	Number	(Percent)	Number	(Percent)
Sex												
Female	170	(39.1)	117	(32.1)	132	(33.8)	109	(32.9)	145	(39.0)	673	(35.6)
Male	264	(60.9)	248	(67.9)	258	(66.2)	222	(67.1)	227	(61.0)	1219	(64.4)
Age												
18-29 years	105	(24.1)	48	(13.2)	61	(15.6)	87	(26.3)	104	(28.0)	405	(21.4)
30-39 years	114	(26.3)	117	(32.1)	128	(32.8)	104	(31.4)	85	(22.8)	548	(29.0)
40-49 years	106	(24.5)	103	(28.2)	106	(27.2)	64	(19.3)	67	(18.0)	446	(23.6)
50-59 years	64	(14.8)	62	(17.0)	69	(17.7)	54	(16.3)	70	(18.8)	319	(16.9)
60-69 years	27	(6.2)	26	(7.1)	16	(4.1)	16	(4.8)	31	(8.3)	116	(6.1)
70 and older	18	(4.2)	9	(2.5)	10	(2.6)	6	(1.8)	14	(3.8)	57	(3.0)
Employment												
Employed	55	(12.7)	73	(20.0)	49	(12.6)	107	(32.3)	106	(28.5)	390	(20.6)
Unemployed	303	(69.8)	229	(62.7)	283	(72.6)	178	(53.8)	203	(54.6)	1196	(63.2)
Retired/disabled	68	(15.6)	54	(14.8)	53	(13.6)	21	(6.3)	42	(11.3)	238	(12.6)
Student/housewife/other	8	(1.9)	6	(1.6)	2	(0.5)	21	(6.3)	17	(4.6)	54	(2.9)
Missing	0	(0.0)	3	(0.8)	3	(0.8)	4	(1.2)	4	(1.1)	14	(0.7)
Residence												
Rural	64	(14.8)	56	(15.3)	77	(19.7)	55	(16.6)	68	(18.3)	320	(16.9)
Urban	370	(85.2)	308	(84.4)	313	(80.3)	276	(83.4)	303	(81.5)	1570	(83.0)
Missing	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	1	(0.3)	2	(0.1)
Oblast												
Dnipropetrovsk	224	(51.7)	178	(48.8)	178	(45.6)	158	(47.7)	190	(51.1)	928	(49.1)
Kharkiv	112	(25.9)	90	(24.7)	122	(31.3)	86	(26.0)	93	(25.0)	503	(26.6)
Odessa	98	(22.5)	97	(26.6)	90	(23.1)	87	(26.3)	89	(23.9)	461	(24.3)
Total patients	434	(100.0)	365	(100.0)	390	(100.0)	331	(100.0)	372	(100.0)	1892	(100.0)

Study Population

The study populations shared similar demographic profiles across risk cohorts and years (Table 3.10). Approximately two-thirds of the patients were male in every risk group, three-quarters were under fifty years of age, and over 80% lived in urban areas. Fewer HR patients reported being employed, which is not surprising given that unemployment is one of the risk factors used to identify patients at higher risk for treatment default.

Among the HR cohorts, 64% to 73% reported two or three factors, putting them at risk for treatment default; while 4% to 6% reported four or more factors (Table 3.11). The most common risk factor reported was unemployment, followed by alcoholism, having disease co-morbidity, or being HIV-positive. Over half of the LR patients reported no risk factors for treatment default, and among those who reported one risk factor, unemployment was by far the most frequently cited risk. Notably, the proportion of patients who reported injection drug use as a risk factor in their records was very small, ranging from 5% to 12% among the HR cohort. Upon discussion with facility staff, we concluded that information on IDU status and treatment is not routinely recorded in the TB records nor shared across cabinets due to concerns of confidentiality. Hence the provider may be unaware of the patient's status unless volunteered by the patient.

Table 3.11. TB Patient risk profile by sampled risk cohort and year. Ukraine, 2011 and 2012

Risk Profile	High-Risk Patients						Low-Risk Patients				Total Patients	
	Intervention 2012		Comparison 2012		Comparison 2011		Comparison 2012		Comparison 2011			
	Number	(Percent)	Number	(Percent)	Number	(Percent)	Number	(Percent)	Number	(Percent)	Number	(Percent)
Risk factor*												
HIV-positive	89	(20.4)	154	(42.2)	137	(35.1)	0	(0.0)	0	(0.0)	380	(20.1)
Alcoholic	187	(43.1)	126	(34.5)	160	(41.0)	2	(0.6)	6	(1.6)	481	(25.4)
Injection drug user	20	(4.6)	29	(7.9)	46	(11.8)	0	(0.0)	0	(0.0)	95	(5.0)
Co-morbidity	150	(34.6)	127	(34.8)	122	(31.3)	10	(3.0)	10	(2.7)	419	(22.2)
Homeless	7	(1.6)	19	(5.2)	13	(3.3)	0	(0.0)	0	(0.0)	39	(2.1)
Unemployed	274	(63.0)	181	(49.6)	232	(59.5)	145	(43.8)	143	(38.4)	975	(51.5)
Contact to case	26	(6.0)	24	(6.6)	26	(6.7)	1	(0.3)	2	(0.5)	79	(4.2)
Ex-prisoner	7	(1.6)	20	(5.5)	15	(3.8)	0	(0.0)	2	(0.5)	44	(2.3)
Health care worker	7	(1.6)	12	(3.3)	7	(1.8)	0	(0.0)	1	(0.3)	27	(1.4)
Migrant	5	(1.1)	2	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	7	(0.4)
Refugee/immigrant	2	(0.5)	0	(0.0)	5	(1.3)	1	(0.3)	0	(0.0)	8	(0.4)
Other	79	(18.3)	37	(10.1)	43	(11.0)	0	(0.0)	1	(0.3)	160	(8.5)
Number of risk factors												
No risk factors	1	(0.2)	0	(0.0)	5	(1.3)	173	(52.3)	212	(57.0)	391	(20.7)
1	118	(27.1)	109	(29.9)	87	(22.3)	157	(47.4)	155	(41.7)	626	(33.1)
2-3	296	(68.3)	234	(64.1)	284	(72.8)	1	(0.3)	5	(1.3)	820	(43.4)
4 or more	19	(4.4)	22	(6.0)	14	(3.6)	0	(0.0)	0	(0.0)	55	(2.9)
Total patients	434	(100.0)	365	(100.0)	390	(100.0)	331	(100.0)	372	(100.0)	1892	(100.0)

*Multiple responses possible, may not sum to 100%

TB Status and Treatment

Overall, 81.3% of the TB patients were seen for first diagnoses, although among the HR cohorts a few more were re-initiating treatment after earlier failure or relapse compared to the LR cohorts (Table 3.12). Over 90% of all cases were pulmonary TB and most cases fit a Category I classification (65.0%).

As anticipated, intensive treatment lasted on average two or three months, with little variation seen across risk groups (Table 3.13). The one exception being that over one-quarter of the LR patients completed intensive treatment in less than two months time. A larger spread in treatment times was seen during continuation therapy with fewer completing in under two months time and more continuing over six months. During continuation treatment, HR-intervention patients reported fewer interruptions with 72.8% of the cohort reporting no treatment interruptions compared to 55.9% of the HR-comparison group from 2012. All cohorts reported a substantial proportion of patients with one to three interruptions during continuation treatment, ranging from 21.9% among the HR-Intervention group to 32.8% among the HR-Comparison group from 2011. Among those with interrupted care, the HR-Intervention group reported shorter interruptions with 52.8% reporting less than a one week interruption. In all other risk cohorts, almost one-fifth reported an interruption lasting more than four weeks.

TB treatment outcomes for the LR-comparison cohorts are very similar in 2011 and 2012, with 84.9% and 90.6% reporting treatment success respectively, and fewer than 5% defaulting on treatment (Table 3.13). Similar success is seen in the HR-intervention group with even lower default rates in 2012 (1.9%). However, in both 2012 and 2011 the HR-comparison cohort reported lower success (70.1% and 72.3% respectively) and over twice the default rates, 11.0% and 13.1%, respectively.

Table 3.12. TB patient's disease status by risk cohort and year. Ukraine, 2011 and 2012

	High-Risk Patients						Low-Risk Patients				Total	
	Intervention 2012		Comparison 2012		Comparison 2011		Comparison 2012		Comparison 2011			
Disease Status	No.	(Percent)	No.	(Percent)	No.	(Percent)	No.	(Percent)	No.	(Percent)	No.	(Percent)
TB classification												
First diagnosis	330	(76.0)	287	(78.6)	314	(80.5)	278	(84.0)	330	(88.7)	1539	(81.3)
Re-initiation*	50	(11.6)	27	(7.4)	39	(10.0)	13	(3.9)	19	(5.1)	148	(7.8)
Relapse	50	(11.5)	50	(13.7)	37	(9.5)	38	(11.5)	23	(6.2)	198	(10.5)
Referral	4	(0.9)	1	(0.3)	0	(0.0)	2	(0.6)	0	(0.0)	7	(0.4)
TB clinical form												
Pulmonary	409	(94.2)	339	(92.9)	354	(90.8)	313	(94.6)	347	(93.3)	1762	(93.1)
Extra-pulmonary	25	(5.8)	26	(7.1)	35	(9.0)	18	(5.4)	25	(6.7)	129	(6.8)
TB treatment category												
Category I	269	(61.9)	252	(69.0)	261	(66.9)	212	(64.0)	235	(63.2)	1229	(65.0)
Category II	95	(21.9)	78	(21.4)	77	(19.7)	52	(15.7)	42	(11.3)	344	(18.2)
Category III	66	(15.3)	35	(9.6)	51	(13.1)	67	(20.2)	95	(25.5)	314	(16.6)
Other	3	(0.7)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.2)
Total patients	434	(100.0)	365	(100.0)	390	(100.0)	331	(100.0)	372	(100.0)	1892	(100.0)

* Includes re-initiated treatment and treatment failure

Table 3.13. TB patient treatment duration and outcome by risk cohort and year. Ukraine, 2011 and 2012

Treatment and Outcome	High-Risk Patients						Low-Risk Patients				Total	
	Intervention 2012		Comparison 2012		Comparison 2011		Comparison 2012		Comparison 2011			
	No.	(Percent)	No.	(Percent)	No.	(Percent)	No.	(Percent)	No.	(Percent)	No.	(Percent)
Intensive treatment duration												
< 2 months	68	(15.7)	61	(16.8)	56	(14.4)	86	(26.1)	98	(26.3)	370	(19.5)
2-3 months	297	(68.5)	249	(68.1)	287	(73.6)	207	(62.7)	235	(63.1)	1275	(67.4)
4-5 months	59	(13.6)	52	(14.2)	45	(11.6)	35	(10.6)	5	(9.4)	226	(11.9)
≥ 6 months	10	(2.3)	2	(0.5)	1	(0.3)	2	(0.6)	3	(0.8)	18	(0.9)
Missing	0	(0.0)	1	(0.3)	1	(0.3)	0	(0.0)	1	(0.3)	3	(0.2)
Continuation treatment duration												
< 2 months	9	(2.1)	58	(15.9)	54	(13.9)	24	(7.3)	19	(5.1)	164	(8.7)
2-3 months	116	(26.8)	91	(25.0)	76	(19.5)	103	(31.2)	109	(29.4)	496	(26.2)
4-5 months	222	(51.1)	163	(44.6)	160	(41.0)	155	(46.7)	167	(44.9)	866	(45.8)
6-8 months	69	(15.9)	38	(10.4)	72	(18.4)	40	(12.0)	69	(18.4)	287	(15.2)
≥ 9 months	17	(3.9)	12	(3.2)	22	(5.6)	7	(2.1)	7	(1.9)	64	(3.4)
Missing	1	(0.2)	3	(0.8)	6	(1.5)	2	(0.6)	1	(0.3)	13	(0.7)
Number of interruptions during continuation treatment												
None	316	(72.8)	204	(55.9)	160	(41.1)	201	(60.7)	205	(55.1)	1086	(57.4)
1	51	(11.8)	49	(13.4)	51	(13.1)	44	(13.2)	47	(12.6)	242	(12.8)
2-3	44	(10.1)	58	(15.9)	77	(19.7)	43	(12.9)	56	(15.0)	278	(14.7)
4 or more	21	(4.8)	33	(8.9)	71	(18.2)	24	(7.2)	29	(7.7)	177	(9.3)
Missing	2	(0.5)	21	(5.8)	31	(8.0)	19	(5.8)	35	(9.5)	109	(5.8)
Duration of longest interruption during continuation treatment among those with any interruptions	(n=117)		(n=161)		(n=230)		(n=130)		(n=167)		(n=804)	
< 1 week	62	(52.8)	59	(36.5)	86	(37.4)	69	(53.0)	61	(36.6)	337	(41.9)
1-2 weeks	40	(34.3)	52	(32.2)	73	(31.7)	30	(22.9)	46	(27.2)	240	(29.9)
3-4 weeks	9	(7.8)	16	(9.8)	20	(8.7)	7	(5.4)	14	(8.3)	66	(8.2)
≥ 5 weeks	6	(5.1)	34	(21.1)	51	(22.2)	24	(18.6)	46	(27.7)	162	(20.1)
TB treatment outcome												
Success*	383	(88.2)	256	(70.1)	282	(72.3)	281	(84.9)	337	(90.6)	1539	(81.3)
Died	8	(1.9)	27	(7.4)	17	(4.4)	6	(1.8)	1	(0.3)	59	(3.1)
Treatment failed	33	(7.6)	38	(10.4)	36	(9.2)	26	(7.9)	14	(3.8)	147	(7.8)
Treatment interrupted (Default)	8	(1.9)	40	(11.0)	51	(13.1)	15	(4.5)	15	(4.0)	129	(6.8)
Transferred	2	(0.5)	4	(1.1)	4	(1.0)	2	(0.6)	5	(1.3)	17	(0.9)
Missing	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.1)
Total patients	434	(100.0)	365	(100.0)	390	(100.0)	331	(100.0)	372	(100.0)	1892	(100.0)

Note: Table excludes 7 presumed cases when the TB diagnosis was canceled.

* Includes those cured and those who completed treatment

Social Support Program Targeting

The intent of the social support program by 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 2012, the program was serving patients in all three oblasts; however, the demand for the social support services often exceeded the capacity to provide care to all high-risk patients. URCS, along with the funders and government, established the risk criteria for social support referrals, which, according to the facility surveys, were applied with some variability by facility (Table 3.6). In the majority of facilities, the lead TB physician was the decision-maker for referrals to URCS.

From the evaluation standpoint, it is important to understand the application of the criteria to the referrals received by URCS, particularly when some but not all HR patients in 2012 were referred. Looking only at the HR 2012 patients, we first tested whether any risk factors were predictive of receipt of social support among the HR compared to no social support received. For many risk factors (alcoholism, IDUs, presence of co-morbidities, 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 2012 were comparable across these risk categories. Among the remaining risk factors, HIV-positive patients, homeless, and ex-prisoners were less likely to receive the intervention, while the unemployed and "other" risk factors were predictive of receiving the intervention. The homeless and ex-prisoner populations were very small in our sample, less than 50 cases each; additionally we know from facility surveys that these two risk factors were not always prioritized. HIV co-infection however was cited by 82.6% of the facilities as an important referral consideration in 2012 and 20% of the total sample reported co-infection. One possible reason for the lower referrals among HIV-positive patients was the higher proportion (15%) of these cases that had extra-pulmonary TB compared to less than 5% of the TB-only patients. URCS does not provide social support services to patients with extra-pulmonary TB.

To understand the magnitude of the differences between intervention and comparison HR cohorts in 2012, we estimated the predicted probability of receiving the social support intervention by these select risk factors (Table 3.14). If the two cohorts were similar, we would expect the predicted probability of each risk factor to be around 50% — meaning half of the population with a specific risk factor received the treatment and half did not. As shown in Table 3.14, we find that for an average TB patient (male, 42 years of age, living in an urban environment), the probability of receiving the social support if he was HIV-positive was 23.7% overall, ranging from 12.4% in Kharkiv to 26.9% in Odessa. A similar pattern is seen for those who were homeless or ex-prisoners, with lower representation in Kharkiv and higher yet still unequal representation in Dnipropetrovsk and Odessa. HR patients who were unemployed had a higher probability of receiving the social support (65.5%) and "other" risk factors were predictive of intervention, particularly in Odessa and Dnipropetrovsk. "Other" likely includes patients with lower income, a risk factor cited by 54% of the facilities (Table 3.6) but not captured explicitly as a risk factor in the screening tool used by facilities in 2012.

Finally, we looked at the predicted probability of receiving the intervention for females compared to males. Given the current distribution of risk factors, residence and age in the dataset, if we base a prediction on all females or all males, we find that females have a 61.0% probability of being in the HR-Intervention sample compared to only 52.7% probability for the males. This difference was statistically significant (data not shown).

The application of risk factor criteria based both on facility surveys and patient records, suggests that a certain degree of latitude is afforded to clinicians when making their referral recommendations. Understanding and controlling for this selection process in the analysis will be a key element in the endline survey work.

Table 3.14. Predicted probability of receiving social support by risk factor and oblast among the high-risk cohorts in 2012 , n=797

	All Oblasts			Dnipropetrovsk			Kharkiv			Odessa		
Risk Factor	Predicted Prob-ability	(SE)	Confidence Interval	Predicted Prob-ability	(SE)	Confidence Interval	Predicted Prob-ability	(SE)	Confidence Interval	Predicted Prob-ability	(SE)	Confidence Interval
HIV-positive	0.237***	0.040	(0.157, 0.316)	0.257***	0.046	(0.167, 0.347)	0.124***	0.035	(0.056, 0.192)	0.269***	0.050	(0.270, 0.368)
Homeless	0.239**	0.089	(0.065, 0.412)	0.311**	0.109	(0.098, 0.524)	0.156*	0.068	(0.023, 0.289)	0.325**	0.118	(0.093, 0.556)
Ex-prisoner	0.219*	0.089	(0.049, 0.393)	0.277*	0.109	(0.064, 0.490)	0.135*	0.067	(0.005, 0.266)	0.290*	0.114	(0.067, 0.513)
Unemployed	0.655***	0.049	(0.559, 0.751)	0.694***	0.049	(0.598, 0.789)	0.481***	0.076	(0.331, 0.630)	0.707***	0.055	(0.599, 0.815)
Other	0.601***	0.056	(0.490, 0.712)	0.776***	0.061	(0.656, 0.896)	0.586***	0.057	(0.474, 0.698)	0.787***	0.062	(0.666, 0.908)

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

Social Support Program Results

To evaluate the results of the social support program we looked at two outcomes, TB treatment default and mortality. We ran logistic regressions using the three cohorts, 2012 HR-Intervention, 2012 HR-Comparison, and 2011 HR-Comparison, and also stratified by oblast to identify any oblast-specific differences. Predicted probabilities were calculated to understand the magnitude and direction of the effect of the social support program.

Table 3.15 presents the predicted probability of defaulting on TB treatment for an average 42 year old male living in an urban area from each of the cohorts. For the combined oblast results, we find that an average male in the HR-Intervention group had a 1.9% probability of defaulting on treatment compared to an 11.2% probability of default for the average HR-comparison patient in 2012 and 12.9% probability for the 2011 HR cohort. By oblast we see in general that the HR comparison groups from both years had similar probabilities of defaulting on treatment and the probabilities were substantially higher than the intervention group. Odessa had the highest defaults while Kharkiv had much lower probabilities, even among the HR who received no treatment.

Improved treatment adherence should lead to reduced mortality among those who complete treatment successfully. We next looked at mortality by risk cohort and oblast (Table 3.16). The highest predicted probability of death was in Odessa among the HR-Comparison group from 2012 at 13.8%. The HR-Intervention group from Odessa had a 10 percentage point lower probability of dying compared to the 2012 HR-comparison group, a substantial improvement that aligns with the 13 percentage point difference in treatment default for this same group (Tables 3.16 and 3.15). However, drawing definitive conclusions is difficult given the small number of deaths in these three cohorts (n=52).

Limitations

For an impact evaluation of a program offered selectively to some eligible patients and not to others, the primary challenge to producing unbiased impact estimates is the problem of selection bias. In the case of the social support program, specific referral criteria were proposed by the government and the URCS; however, the final decision for referral was made by the raion or city TB physician. What factors may have influenced the physicians' decisions are unknown and may be subject to recall bias. Anecdotally, we heard from some providers that there was a preference for providing the referral as a reward to those who already demonstrated treatment compliance. Analysis of program targeting, however, largely supported the use of the established risk criteria for URCS referrals. By abstracting records from the same facilities over time (with and without the program), we have a dataset that will support additional analyses to control for facility-level fixed effects such as social support referral practices. Controlling as possible for facility differences will improve estimates of the effect of social support services on treatment adherence. Furthermore, prospective data collection at endline will allow for improved tracking and control for different referral practices.

Table 3.15. Predicted probability of treatment default by intervention and oblast, n=1189

Oblast	High-Risk Intervention 2012			High-Risk Comparison 2012			High-Risk Comparison 2011		
	Predicted Probability	(SE)	Confidence Interval	Predicted Probability	(SE)	Confidence Interval	Predicted Probability	(SE)	Confidence Interval
All Oblasts	0.019**	0.007	(0.005, 0.032)	0.112***	0.197	(0.073, 0.150)	0.129***	0.019	(0.091, 0.166)
Dnipropetrovsk	0.019*	0.007	(0.005, 0.033)	0.117***	0.023	(0.072, 0.162)	0.130***	0.023	(0.086, 0.175)
Kharkiv	0.010*	0.004	(0.002, 0.018)	0.065**	0.019	(0.028, 0.102)	0.073**	0.019	(0.035, 0.110)
Odessa	0.027*	0.012	(0.004, 0.050)	0.160***	0.038	(0.086, 0.234)	0.177***	0.037	(0.104, 0.250)

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

Table 3.16. Predicted probability of dying by intervention group and oblast in 2012, n=1189

Oblast	High-Risk Intervention 2012			High-Risk Comparison 2012			High-Risk Comparison 2011		
	Predicted Probability	(SE)	Confidence Interval	Predicted Probability	(SE)	Confidence Interval	Predicted Probability	(SE)	Confidence Interval
All Oblasts	0.019**	0.007	(0.004, 0.033)	0.075***	0.016	(0.044, 0.105)	0.045***	0.011	(0.022, 0.067)
Dnipropetrovsk	0.016*	0.007	(0.002, 0.030)	0.067***	0.017	(0.034, 0.100)	0.037**	0.011	(0.016, 0.058)
Kharkiv	0.007	0.004	(-0.000, 0.014)	0.030*	0.014	(0.002, 0.058)	0.016*	0.008	(0.001, 0.031)
Odessa	0.035**	0.013	(0.010, 0.061)	0.138***	0.034	(0.072, 0.204)	0.079**	0.023	(0.034, 0.123)

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

CHAPTER 4. TB-HIV INTEGRATION STUDY: TB FACILITY AND PATIENT FINDINGS

To understand and document routine processes for screening, testing, referral and treatment among TB and HIV patients in STbCU intervention and comparison oblasts, information was collected through facility surveys, provider interviews, and patient chart abstractions from TB and HIV facilities. Below, findings from the TB facilities, providers and patients are presented first, followed by findings from the HIV facilities, providers and patients in Chapter 5.

4.1. TB Facilities and Services

Key Findings: TB Facilities

- TB facilities in comparison oblasts were larger on average than intervention facilities. No distinction between TB and TB-HIV co-infected patient beds was made routinely in most facilities in either intervention or comparison oblasts.
- Testing for pulmonary TB was routinely available in all sites; however, diagnosis of extra-pulmonary TB is much more difficult and was not always available on-site.
- Inpatient intensive TB treatment was available for smear-positive TB and co-infected patients in all sites, and a mix of inpatient and outpatient continuation treatment was available for all patients.
- All facilities offered VCT for HIV; however one-third of the sites did not offer any rapid testing. Other diagnostic testing (ELISA, PCR, Western Blot) required drawing samples and sending out to off-site lab for testing.
- Interviewees cited the new ART recommendations for the co-infected and all comparison and 83% of the intervention sites reported routinely providing ART according to the two-to-eight week guideline.
- Providers stated that efforts to protect HIV patients from TB exposure were insufficient.
- Fewer than half of the facilities provided drug substitution therapy for TB-IDU patients.
- No formal protocols dictating referral practices for HIV patients to TB services exist. Facilities rely on relationships between providers to track referrals between services or rely on patients to follow-up on referrals on their own.
- Following TB intensive treatment, HIV services were notified of pending discharge and need for ongoing care for co-infected patients in intervention oblasts. Comparison oblasts more commonly provided all the necessary TB treatment information to the patient and relied on the patient to seek additional HIV care.
- Only one facility reported a shortage of one TB drug lasting more than 30 days in 2012. No facilities reported ARV or substitution therapy drug shortages, although two facilities and additional providers reported HIV rapid test kit shortages.

Facility Surveys and Provider Interviews

We administered 18 surveys across six oblasts (three intervention and three comparison oblasts) (Table 4.1). Facility surveys were administered in 18 TB dispensaries where patients received intensive TB treatment at the raion and oblast level. From these TB facilities, a sample of lead TB physicians was selected to complete an in-depth interview; 10 TB providers in total were interviewed.

Facility Capacity and Services

All but one facility provided inpatient TB intensive treatment. The median number of beds used for inpatient treatment and for TB or co-infected patients was the same in both intervention (115 beds) and comparison sites (207), suggesting that no distinction was made between beds for TB patients and co-infected patients (Table 4.2). The number of beds varied extensively by facility, with some facilities having 20 beds and others nearly 600.

Table 4.1. TB facility surveys and TB provider interviews at baseline by oblast, Ukraine 2014

	Facility Surveys	Provider Interviews
Intervention sites		
Kharkiv Oblast	7	2
Odessa Oblast	2	1
Zaporizhzhya Oblast	3	1
Sub-total: intervention	12	4
Comparison sites		
Kiev Oblast	3	3
Mykolayiv Oblast	2	2
Zhytomyr Oblast	1	1
Sub-total: comparison	6	6
Total	18	10

The median number of new patients (TB patients, HIV/AIDS patients, and co-infected patients) in 2012 was higher at comparison than intervention facilities, likely due to larger facilities and populations in those areas. The number of new patients varied considerably with some facilities having no new HIV or co-infected patients and others serving up to 1,800. The majority of new patients were TB patients and comparison facilities had a median number of new patients three times that of intervention facilities. The number of new co-infected patients was a fraction of the total number of new patients. Numbers varied widely by facility for all types of patients.

Table 4.2. TB facility capacity and staffing by intervention status, Ukraine, 2014

	Intervention		Comparison	
	Median	(Range)	Median	(Range)
Beds for inpatient treatment				
TB patients	115	(30-510)	208	(30-595)
TB-HIV coinfected patients	115	(20-510)	208	(30-595)
New patients, 2012				
TB patients	206	(42-1,398)	665	(33-1,832)
HIV/AIDS patients	7	(0-138)	25	(4-203)
TB-HIV coinfected patients	16	(0-401)	108	(11 - 631)
Staffing for TB services				
Administrative	2	(1-4)	2	(1 - 4)
Nurses	56	(6-198)	79	(13 - 168)
Doctors	15	(2-63)	14	(4 - 50)
Number of TB facilities	12		6	

Staffing in TB Facilities

Medical personnel at TB dispensaries is regulated by relevant national protocols and orders approved by the MOH.[9] Typically, TB dispensary staff include administrative personnel, TB specialists, nurses, and laboratory assistants. Staffing of intervention and comparison TB facilities was fairly similar, with a median of 14 to 15 doctors and two administrative staff providing TB services (Table 4.2). The median number of nurses was about 30% higher in comparison sites (79) than intervention sites (56). The range for the number of nurses and doctors varied widely from six to 198 nurses and two to 63 doctors per TB facility.

[9] № 276, National Protocol on TB/HIV Co-infection, and №1091 "Unified clinical protocol for primary, secondary (specialized) and tertiary (highly specialized) medical care Tuberculosis" issued on December 21, 2012.

According to the facility surveys, most (14 facilities) had TB specialists on staff, three facilities contracted with TB specialists on a consultancy basis, and 1 facility had missing data. While almost no staff were dedicated exclusively to HIV services, 10 of the 17 TB facilities had ID specialists on staff. The remaining facilities had ID specialists who served as regularly scheduled consultants. When ID specialists were not on staff, the frequency of their visits was not regulated, though most facilities reported that an ID specialist was available in urgent cases.

During the in-depth provider interviews, interviewees described different continuing education opportunities (conferences, trainings, and workshops) for TB and HIV infection topics that are available to medical personnel from the TB dispensaries. Both in comparison and intervention oblasts, the majority of respondents reported attending trainings on such topics as providing HIV tests and HIV counseling. Training on identifying risk factors for HIV was conducted in three of the four TB facilities in intervention oblasts and half of the facilities (three out of six) in comparison oblasts. Training on recording and reporting on HIV was held for a majority facilities in comparison oblasts (five of six), but at only one intervention facility.

All interviewees mentioned the importance of such educational programs in terms of increasing the effectiveness of the treatment and diagnostics of TB-HIV. Experts mentioned the following topics for further education activities: 1) diagnosis and treatment of opportunistic infections; and 2) innovative methods of diagnosis and treatment of TB-HIV co-infection.

Record Keeping

Interviewees provided information on record keeping in TB facilities, which was uniform across sites. All MOH-approved forms related to the treatment of TB and TB-HIV are kept in TB dispensaries, including:[10]

- Patient's medical record. The record contains all necessary information about the diagnosis and treatment of TB and HIV. HIV status is coded.
- TB-01 form. This form provides information on diagnostics and treatment of TB (e.g., dates of analysis, medicines administration, number of doses received).
- TB 01-1 form. This form contains the information about risk factors, VCT performance date, HIV testing, ART and CPT prescription.
- TB-03. This form captures patient registration such as general information about the patient, registration date, and patient's HIV status.
- TB-09 form (discharge card). The TB-09 form is given to the patient upon the patient's discharge from the TB dispensary inpatient department. This form includes information on received TB treatment, results of the analysis, etc.

Interviewees also mentioned forms related to TB-HIV co-infection:

- Primary HIV patient's registration form (№ 030-5/0). This form is sent to the AIDS Center for patient registration in cases when HIV is diagnosed within a TB facility.
- HIV test registry
- Pre-testing (VCT) and post-testing consulting registry.
- ART prescription registry

In general, TB specialists are responsible for keeping medical records, while ID specialists are responsible for record keeping related to the treatment and diagnosis of HIV infection. Keeping of all other documentation (registry logs) is performed primarily by nurses.

TB Diagnostics

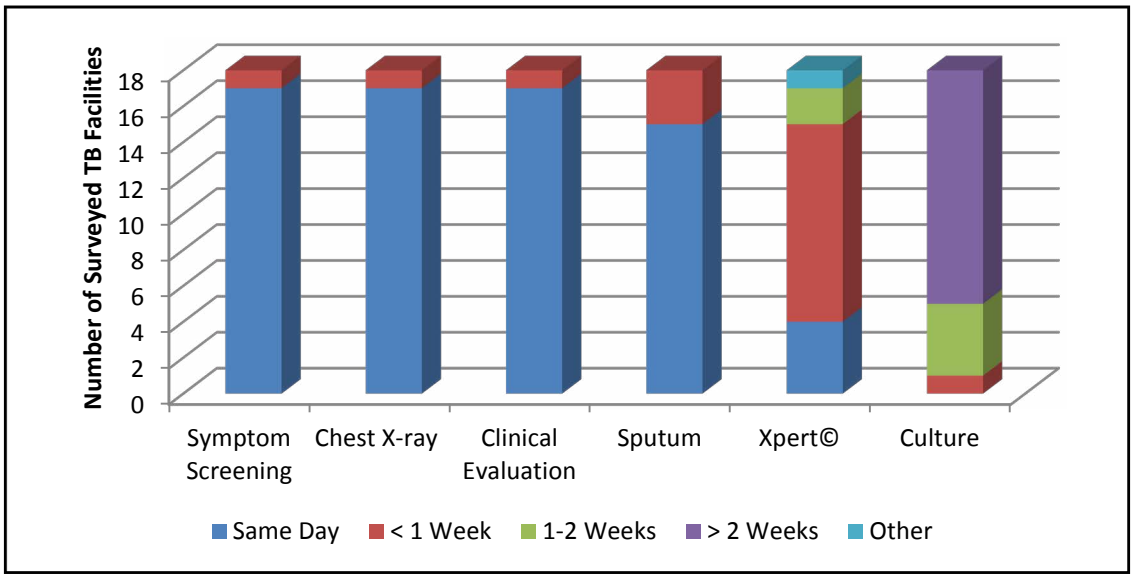
Diagnosis of TB patients involves TB symptom screening, laboratory testing, x-rays and clinical evaluation. Nearly all 18 TB facilities reported having these TB diagnostics at their facility, with the exception of Xpert testing. Xpert and other tests using nucleic acid amplification technology, provide advanced testing for multi-drug-resistant tuberculosis (MDR-TB) and more sensitive testing for TB-HIV co-infected patients. In 2013, WHO recommended Xpert rapid testing for initial diagnostics in high endemic MDR-TB areas and among populations suspected of TB-HIV co-infection.[11] In two-thirds of the facilities surveyed, specimens for Xpert were collected at the facility and sent to an off-site laboratory for analysis, or patients were referred elsewhere for testing.

The average amount of time from testing to receiving diagnostic results differed depending on the type of test (Figure 4.1). Results of TB symptom screening, chest x-rays, clinical evaluations, and sputum microscopy were routine diagnostics typically received the same day of the test. Xpert and TB cultures take longer. In most cases, Xpert results were returned in less than a week while TB cultures typically take more than two weeks.

[10] Since the provider interview tool does not include a straight question about existing forms of documentation, this list is based on information mentioned by the TB doctors within the interview as well as on TB doctors' evaluation of compliance with all national protocols approved by the Ministry of Health of Ukraine.

[11] WHO Recommendations: Tuberculosis Diagnostics Xpert MTB/RIF Test. World Health Organization: Feb 2013.

Figure 4.1. Time between TB testing and receipt of results, Ukraine, 2014.



Ability to diagnose extra-pulmonary TB was reported as a challenge by providers in both control and intervention regions because TB facilities are not fully equipped with the necessary equipment (CT, MRT) and/or specialists required to diagnose extra-pulmonary TB. When additional diagnostic procedures are required, it involves additional costs to the patient (service fee, transportation, etc.). At times, nongovernmental organizations (NGOs) provide support for such additional diagnostic testing. Several interviewees shared their challenges in diagnosing extra-pulmonary TB:

> ***"It is a very difficult group of patients. I try to offer them additional diagnostics: CT (we've got plenty of CT units in the city, if a patient can pay for it the other way, we try to involve NGOs). Surgeons conduct histological studies in polyclinics, but these studies are not always of high quality."***

> ***"We try to make examinations if there is such possibility. When other assistance or further examination needed, we refer patients to regional TB dispensary. We do not perform ultrasound investigation as there is no specialist. We perform computerized tomography if there is the suspicion of cerebral or abdominal cavity infection."***

TB Treatment

Seventeen of 18 TB facilities provided both inpatient and outpatient TB treatment and all facilities provided DOTS at the facility (Table 4.3). For smear-positive TB patients, all 18 TB facilities provided inpatient TB intensive therapy. For smear-negative TB patients both TB intensive therapy and continuation therapy through a mix of inpatient, outpatient, and both inpatient/outpatient are offered in all facilities.

For smear-positive co-infected HIV patients, all TB facilities provided inpatient TB intensive therapy. For smear-negative co-infected HIV patients, all TB facilities provided TB intensive therapy through inpatient (five), outpatient (four), or both inpatient and outpatient services (nine). All but one of the TB facilities provided TB continuation therapy, some inpatient and some outpatient care.

Slightly less than half of the TB facilities also provided inpatient IDU drug substitution therapy for TB-IDU patients.

Table 4.3. Treatment offered by facilities and by intervention status, Ukraine, 2014

Services Offered	Intervention		Comparison		Total	
	Number	Percent	Number	Percent	Number	Percent
TB inpatient treatment	11	(91.7)	6	(100.0)	17	(94.4)
TB outpatient treatment	11	(91.7)	6	(100.0)	17	(94.4)
DOTS at facility	12	(100.0)	6	(100.0)	18	(100.0)
IDU drug substitution therapy	6	(50.0)	2	(20.0)	8	(44.4)
Number of TB facilities	12	(100.0)	6	(100.0)	18	(100.0)

Referrals from AIDS Centers

Interviewees reported that AIDS centers refer HIV patients primarily to the oblast TB dispensaries for diagnosis confirmation and further treatment. Rarely are referrals provided to raion-level facilities, though one provider noted that a patient is referred from the AIDS center to the raion TB specialist, who in turn refers the patient to the TB dispensary.

Formal protocols used to guide HIV patient referrals to TB facilities do not exist. According to provider interviewees, the referral procedure depends on established collaboration and interpersonal relationships between TB and HIV facilities or specialists. Referrals are often provided by telephone, but the process differs depending on the type of case. Some of the ways in which referrals were described include:

- Referral without medical personnel supervision. In these cases, the AIDS center ID specialist provides a patient with the necessary documentation for the patient to take to the TB dispensary by himself. This practice is common for both comparison and intervention oblasts.
- Referral with medical or social personnel supervision. This less common mechanism is used for patients in critical condition or with unique circumstances (e.g., risk factors, distance to facility) that would require facility transport.

In cases when the patient is referred without medical supervision, the patient should have a completed MOH referral form, with a short anamnesis, complaint description, TB diagnostics results (which usually include a chest x-ray) and recommendations for treatment of HIV. Some interviewees noted that these referral forms are not always completely filled in by AIDS center staff.

In general, interviewees reported that the referral system lacks a standardized system for tracking patient referrals which can lead to loss to follow-up, as described by one interviewee:

> ***"This mechanism does not exist. Patient takes the appointment card and only he makes a decision to visit TB doctor or not. If he did not visit us, we know nothing about him."***

Interviewees described different strategies for ensuring that referred patients arrive at the TB facility, including:

- the ID specialist who refers the patient will follow-up on the referral;
- HIV and TB service specialists will compare and reconcile referral logs (those referred and those arriving); and
- the TB facility will inform the AIDS center ID specialist by phone if a patient has not arrived (in cases where the ID has informed the TB facility they are referring a patient).

Interviewees from raion-level facilities reported that they typically do not provide TB diagnostic services as patients arrive with a TB diagnosis.

HIV Diagnostics in TB Facilities

The primary document that is used as a guideline for HIV diagnostics algorithm in TB facilities is a protocol approved by the MOH.[12] In some facilities, interviewees mentioned that local protocols exist with adaptations to the MOH protocol.

[12] National clinical protocol on medical care to the patients with co-infection TB/HIV, approved by the Ministry of Health of Ukraine order N 276 of 28 May 2008. ART ID specialists also refer to this protocol: National clinical protocol on ART for adults and adolescents, approved by the Ministry of Health order N 551.

Interviewees provided in-depth information regarding HIV diagnosis in TB facilities. The process works similarly in both intervention and comparison regions and generally includes the following steps:

1. Voluntary counseling and testing. All newly registered patients receive VCT, typically by the TB specialist, and either HIV testing or referral for testing. In some facilities other staff such as the psychologist, ID specialist, or senior nurse fill this role.
2. HIV testing procedure. HIV testing is provided only with the written consent of the patient. The most common methods of diagnosing HIV infection, both for intervention and comparison oblasts, are described next.

Rapid test. All able in facilities, some respondents from both control and intervention regions mentioned that the supply of HIV test kits is often unsustainable. Rapid tests are provided by health departments and NGOs. In one region, interviewees pointed out that they are not allowed to buy rapid test kits themselves even if they have funds to do so.

> ***"Now we have them [rapid test kits], but they will be finished soon. In 2012, it was a shortage for a 2.5–3-month period. The rapid tests are not provided to the tuberculosis dispensaries by the state program, and we cannot buy them for some reason too, even using local budget funds."***

In cases when the rapid test supply is insufficient, facilities prioritize clients such as pregnant women, newly diagnosed TB patients, or patients with critical health status.

Enzyme-linked immunosorbent assay (ELISA). In the case of two positive rapid tests, further verification by ELISA is mandatory. ELISA is also conducted when there is one positive and one negative rapid test result. In case of negative results, ELISA usually is not conducted. This process is at times lengthy and may put patients in danger, as described by an interviewee in one of the comparison facilities.

> *"[The] Procedure depends on the case – it might be a rapid test or ELISA. Usually, we use rapid tests in case of first diagnosed TB cases, in order to understand the full diagnosis of the patient and assign the proper treatment in a short period. The rapid-tests system includes two tests, after first rapid test we do a second test and then record the result. However, still after two positive rapid tests we should conduct an ELISA test. For patient's registration as HIV positive in AIDS center, we should apply two ELISA tests. Often, it takes about month and in some cases it might be fatal. This procedure is described in Clinical protocol for HIV testing and should be followed in all regions in Ukraine."*

Polymerase Chain Reaction (PCR) and Western Blot. These tests were conducted less frequently at the time of baseline. One interviewee noted that there have been recent changes in the protocol for offering PCR, so that test is now more common. In the past, PCR was offered in the case of high risk of MDR-TB and for children.

The ID specialist is usually the first person who receives and interprets the HIV test results. Test results are also provided to the attending TB specialist, psychologist, and nurses who keep HIV patients' logs. In one of the comparison TB dispensaries, the nurses also must be notified about the positive HIV status of the patient, in order to avoid contact with blood of HIV-infected patients.

3. Post-test counseling. After receiving test results, patients are provided with post-test counseling. Who provides post-test counseling depends on staffing but it may be conducted by the attending doctor, ID specialist or psychologist. In the case of an HIV-negative result, the patient is advised about safety precautions to prevent HIV infection and provided with information about the necessity of re-testing.

In the case of an HIV-positive result, the ID specialist conducts an additional patient examination and prescribes further treatment. HIV-positive patients are advised to notify their sex partners about their HIV status and inform them about the need to be tested for HIV. Also in the case of a positive result, a registration card (form № 502-1/0) and other reporting documents, approved by MOH Ukraine Order are completed. The registration card for an HIV patient is sent to the AIDS Center for patient registration.

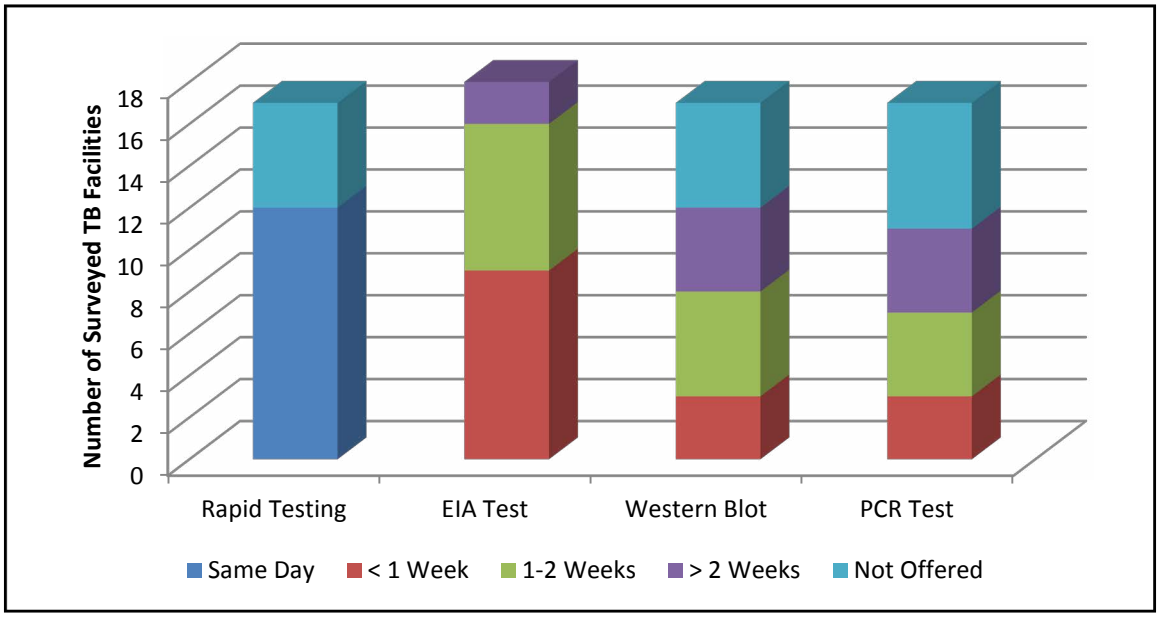
TB facilities were surveyed to document the HIV diagnostics available. All 18 TB facilities reported offering VCT (Table 4.4). Two-thirds of those facilities reported conducting rapid tests at the facility, the other one-third (all intervention sites) did not offer the rapid test at all (Figure 4.2). For the remaining HIV diagnostics (ELISA, Western Blot, PCR), none of the TB facilities offered the tests on site. Samples were either collected at the facility and sent to the AIDS center or patients were referred to an HIV facility for the test. ELISA was collected at all 18 facilities, Western Blot and PCR at 12 of the 18 facilities.

Table 4.4. HIV diagnostic services offered by TB facility and intervention status, Ukraine, 2014

	Intervention Oblasts				Comparison Oblasts			
Diagnostic Services	Avail-able at facility	Specimen collected and sent out	Patient referred	Not provided	Avail-able at facility	Specimen collected and sent out	Patient referred	Not provided
HIV counseling	12	0	0	0	6	0	0	0
Rapid testing	6	0	0	5	6	0	0	0
EISA test	0	12	0	0	0	5	1	0
Western Blot	0	7	2	3	0	3	0	3
PCR Test	0	5	3	3	0	1	2	3
Number of TB facilities	12	12	12	12	6	6	6	6

The amount of time it takes for TB facilities to receive HIV test results varied depending on the type of test (Figure 4.2). All rapid tests yielded results on the same day. ELISA test results were typically returned in less than two weeks, though two facilities did not receive results until after a two week period. Receipt of test results for Western Blot and PCR varied considerably across facilities.

Figure 4.2. Time between HIV testing and receipt of results, Ukraine, 2014.



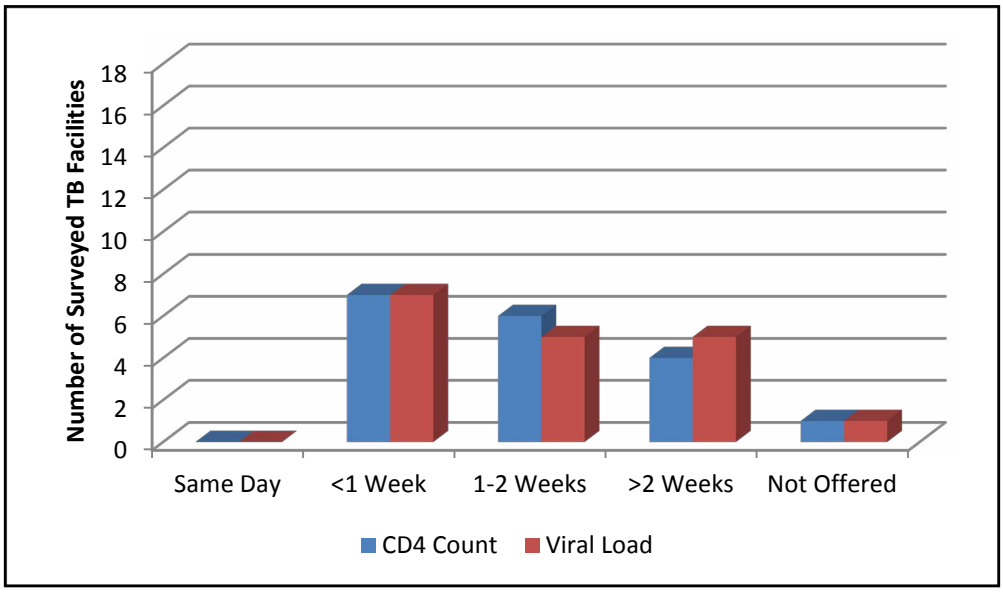
HIV Treatment in TB Facilities

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

In TB facilities, the procedure for HIV treatment is regulated by national protocols. Once a patient is confirmed HIV positive, blood samples need to be tested to determine CD4 count and viral load, markers that dictate treatment regimen. A majority of facilities (approximately 80%) collect blood samples and send them to the AIDS center laboratory for testing; a few facilities refer patients for the blood draw as well. One TB facility does not offer either specimen collection or referral. One of the provider interviewees noted it was not possible to collect samples because of a shortage of vacuum containers for blood sample storage. In this case, patients were referred to the Center of Immunocorrection or AIDS centers.

The amount of time it took to receive CD4 count and viral load results varied from less than one week to more than two weeks and depended on the established protocol between facilities (Figure 4.3).

Figure 4.3. Time between blood draw and receiving results, Ukraine, 2014.



According to interviewees, treatment decisions are made by an ID specialist, in some cases in collaboration with the TB specialist according to Protocol #551, the national clinical protocol on ART for adults and adolescents.[13] Interviewees report that there is no regulated period for ART initiation and that it depends on certain indicators such as general clinical findings, pregnancy, TB status and treatment adherence, and the symptoms of immunodeficiency (CD4 analysis results). Individual respondents referred to recent changes in the national protocol, according to which all co-infected patients are eligible for ART treatment regardless of CD4 and viral load analysis, and in the absence of contraindications. The ART initiation date is recorded in both TB and AIDS center registries. Both in control and intervention regions it was mentioned that ART is usually initiated after the beginning of the intensive phase of TB treatment and through completion.

> ***"Previously ART assignment during the intensive stage of treatment of TB was not mandatory. Now they recommend assigning ART in three weeks after the intensive phase beginning and the patients with multi-drug resistant stage — to assign immediately."***

> ***"According to the new procedure the ART is prescribed to the all patients with the CD4 index lesser than 350 cells. The patients ill of active TB are prescribed to ART regardless of the analysis result (CD4 index or viral load)."***

[13] Desk review of national guidelines and policy recommendations available in English at: http://www.euro.who.int/__data/assets/pdf_file/0004/194071/Evaluation-report-on-HIV-AIDS-treatment-and-care.pdf

In the 18 TB facilities surveyed, ART treatment for co-infected patients was provided to co-infected patients in all comparison facilities (n=6) and in 10 of the 12 (83.3%) intervention facilities.

> *"According to the Order No. 551, all patients with TB/HIV are subject to ART, within two-eight weeks of TB intensive treatment. Our ART-site is launched since January, and during the first month, I try [to] refer patients for ART depending on their acceptability of anti-phthisic agents and their degree of immunosuppression. I try to treat them for two to four weeks, but there are patients who have chemoresistance, and I have to prolong the procedure up to two months."*

Preventive Measures for HIV Patients in TB Dispensaries

Preventive measures taken vary depending on the type of client. For example, therapies such as CPT are offered for patients with HIV who may/may not have TB while IPT is offered for patients with HIV only. For co-infected patients, 16 of the 18 facilities provided inpatient CPT therapy; all comparison sites and 10 of the 12 intervention sites (data not shown). Few TB facilities have HIV positive only patients, but there were three facilities reporting provision of IPT, all in intervention sites.

Preventive measures also included facility procedures such as patient flow. Provider interviewees reported that efforts to protect HIV patients from exposure to TB and other opportunistic infections were insufficient at TB facilities. Primary suggestions for protecting HIV patients include: availability of separate treatment departments for patients with bacillary/ non-bacillary forms of TB and co-infected patients (different wards); and offering different days for visits and separate waiting areas for HIV patients.

The most commonly-used protective measures described in both comparison and intervention oblasts were:

- use of respirators, mask regime
- ventilation, ultraviolet germicidal irradiation
- separation of patient flow (different cabinets for consultations of patients with bacillary TB and HIV patients (HIV patients are accepted out of the queue)
- separate wards for patients with bacillary and non-bacillary forms of tuberculosis

In terms of prophylaxis, all but one intervention facility reported availability of following services:

- CPT medications are mainly provided by AIDS Center, also by NGOs
- palliative therapy and pain relief
- alcohol/drug addiction counseling
- psychiatric care
- consultations on HIV risk issues
- annual HIV testing for facility staff (optional)

IPT is not provided by inpatient departments of TB dispensaries as patients with active TB are not eligible for IPT. This service is offered at HIV services, as well as at TB cabinets.

Drug and Equipment Shortages

Few drug shortages were reported in TB facilities in 2012. Of 18 facilities, just one comparison facility reported a TB drug shortage lasting more than 30 days. In this instance, they switched treatment drugs. No TB facilities reported any shortages of ARVs or IDU drug substitution medications lasting more than 30 days in 2012. Two facilities reported shortages of rapid test kits. As mentioned previously, some of the individuals interviewed reported challenges with maintaining a supply of rapid test kits.

Factors Influencing HIV Diagnostics and Treatment of HIV-Infected Patients in TB Dispensaries

Interviewees reported the existing conditions for the provision of services for diagnosis and treatment of HIV infection in TB facilities as satisfactory. However, there are still challenges that may delay or prevent diagnosis of HIV patients at TB facilities, including:

- patient refusal of HIV testing
- patients engaging in high risk behavior: alcohol and/or narcotics consumption and other risk factors
- lack of necessary equipment and materials for the diagnosis of HIV (unsustainable supply of HIV rapid tests, lack

of laboratory tests for immunological analysis on site, and lack of vacuum containers for sending samples to AIDS center)
- lack of experts on TB facility staff who can provide complete and timely HIV diagnostics and treatment
- unfavorable conditions for patients in the hospital such as no individual departments for patients with bacillary and non-bacillary forms of TB and no individual rooms/departments for TB-HIV co-infected patients
- shortages of medicines necessary for prevention and treatment (excluding ARV)
- necessity of compliance with the law on combating HIV-related diseases and on legal and social protection of PLWH, which creates obstacles for exchanging information on HIV positive patients between AIDS centers and raion TB specialists (in addition, it was mentioned that the law on confidentiality complicates treatment of HIV patients in separate rooms/departments as it might reveal their HIV status)

Discharge Planning from TB Dispensaries

After the completion of the intensive treatment phase, a patient is discharged from the TB dispensary and referred for treatment continuation (follow-up phase) to a TB facility at the place of residence. Co-infected patients are also referred to AIDS centers to continue ART. The process of discharging HIV-related TB patients from inpatient care varies between comparison and intervention sites, as follows.

Discharge of the Patient with No HIV-Services Notification.

When discharged, the patient is referred to an ID specialist at the place of residence or upon request of the patient, to the Oblast AIDS center. The patient (and in some cases, the AIDS center) receives all necessary information about diagnostics and treatment performed at the TB dispensary (TB-09, X-ray plates, and recommended treatment) when discharged. Such discharge procedures imply that the patient is fully responsible for continuation of further treatment. This mechanism is more common in comparison regions, as it was only mentioned by one provider from an intervention facility.

Discharge of the Patient with Preliminary HIV-Services Notification

Notification of HIV-services about planned discharge of the patient from TB facilities is more common for intervention regions. In intervention regions, there are some differences to note. In Kharkiv and Zaporizhzhya, the HIV-facility is notified by phone. In Odessa, several days before discharge, patients on ART are referred to the AIDS center and receive a month supply of ARV drugs before being discharged from the TB dispensary. In comparison oblasts, informing the Oblast AIDS center regarding patient's discharge was mentioned only in Zhytomyr; however, respondents from secondary level facilities mentioned collaboration and preliminary notification of discharge to raion ID specialists.

Discharge of the Patient with Notification of TB-Service at the Place of Residence.

When a TB patient is discharged, the raion TB specialist is notified by telephone about the upcoming discharge. The raion TB specialist has to ensure further interaction of the patient with the ID specialist at the place of residence or has to refer the patient to the oblast AIDS center or raion ID specialist. This discharge procedure was mentioned both in intervention and comparison oblasts.

If TB treatment is interrupted, and the patient leaves the inpatient department at his/her discretion, the raion TB specialist at the place of residence is informed. The raion TB specialist ensures further search for the patient (sometimes in cooperation with an NGO). Also in some cases, TB dispensaries will inform the raion ID specialist (more standard for facilities that have ID specialist on staff). This practice was mentioned both in intervention and comparison oblasts.

Collaboration of TB Dispensaries with Social Services and Public Organizations

According to respondents, there is an interaction between TB dispensaries and social services or public organizations, on TB-HIV issues both in intervention and comparison oblasts. In particular, the following organizations were mentioned:

- Ukrainian Red Cross Society
- ICF International HIV/AIDS Alliance in Ukraine
- All-Ukrainian Charitable Organization Convictus Ukraine
- Ukrainian Network of PLWH
- Chas Zhyttya Plus
- Zhytomyr Regional Public Organization

Respondents of both intervention and comparison oblasts mentioned the following forms of interaction with social services/ public organizations on TB-HIV issues:

- financial support for expensive diagnostics (CT, MRI) and purchase of certain medicines (CPT, ART medicines, etc.)
- psychological support, accompaniment and counseling for the patients with diagnosed HIV status, as well as the patients

with the risk of treatment interruption
- providing rapid HIV tests for diagnostics
- providing patients with food kits
- providing assistance in finding patients who have defaulted from treatment
- providing informational support (provision of medical information brochures, posters, booklets on TB-HIV, drug addiction booklets)
- provision of syringes, condoms, and other supplies
- conducting trainings, and seminars for the personnel of TB dispensaries

Key Findings: TB Patients

- Statistically significant differences at baseline between intervention and comparison oblasts indicate the need to control for TB disease stage in endline analyses:
  - More TB-only patients in the intervention oblasts, compared to the comparison oblasts, were seen for their first diagnosis and were in Category I; while fewer were chronic TB or referral patients.
  - More co-infected patients in the intervention oblasts were seen for their first diagnosis, were in TB Category I, and had pulmonary-only disease. Fewer co-infected patients in the intervention oblasts reported IDU.
- HIV was diagnosed in 37.9% of the total TB patient sample before TB diagnosis and new testing was performed for 58.7% of newly-diagnosed TB patients; there were no significant differences in percent tested between intervention and comparison oblasts.
- ARV was initiated in 40% of all patients testing HIV-positive in the intervention oblasts and in 53% of patients testing HIV-positive in the comparison oblasts ($p<0.001$).
- TB treatment outcomes for the entire study cohort were similar in the intervention and comparison oblasts with roughly half of all cases recorded as a treatment success. Treatment failure and death rates were both around 18% overall.
- The cascade of services received by the sample SI patients found: over 95% underwent VCT, and of those, 97% underwent further HIV diagnostic testing. Only 10% were confirmed to have HIV, half of whom completed registration and two-thirds of whom began ART. It unclear to what extent the drop-off from diagnostic testing to confirmed cases indicates negative diagnostic test results versus failure to accurately record and treat newly-diagnosed co-infected patients. (Figure 4.4)
- Between 65-85% of TB patients (sample S1) were tested for HIV within one month of TB diagnosis, with significantly slower time to testing in intervention versus comparison oblasts ($p<0.001$).
- For co-infected patients, initiation of treatment with ARVs was slow with less than 25% covered within the first two months. Overall, comparison oblasts outperformed intervention sites in uptake of ARVs.
- ART was highly protective and associated with approximately a 75% reduction in the likelihood of death.
- IDU and co-infection with HIV increased the likelihood of death by 2.1 and 3.7 times, respectively. Despite higher rates of and more prompt HIV screening and ARV initiation in Mykolaiv, TB patients in this oblast experienced higher death rates, which may reflect a disproportionate share of high-risk patients in the oblast.
- Oblast where TB patients received services proved to be a significant predictor in models for HIV testing, ARV initiation and death among co-infected at baseline.

Individual Response Rates

Response rates for medical records abstraction for TB services were very high and in some cases exceeded targets (Table 4.6). The numbers of records abstracted were roughly even among the comparison oblasts, with slightly more from Mykolaiv (n = 270) and slightly fewer from Zhytomyr. Among intervention oblasts, more records were abstracted in Odessa (n = 314) and fewer in Zaporizhzhya (n=180). However, sampling was proportionate to size of TB caseloads in each oblast and analyses were weighted, such that the results are representative of the set of oblasts studied.

Table 4.6. TB patient response rates at baseline by oblast. Ukraine, 2012

Intervention Sites	TB Services		
	Sampled	Abstracted	Rate
Kharkiv Oblast	226	224	(99.1)
Odessa Oblast	317	314	(99.1)
Zaporizhzhya Oblast	181	180	(99.4)
Sub-total	724	718	(99.2)
Comparison Sites			
Kiev Oblast	238	237	(99.6)
Mykolaiv Oblast	260	270	(103.8)
Zhytomyr Oblast	226	202	(89.4)
Sub-total	724	709	(97.9)
Total TB Patients	1448	1427	(98.5)

TB Study Population

Table 4.7 presents the weighted background characteristics for the TB study population by intervention and comparison sites. Notable findings are that among TB patients, the ratio of males to females is between two and three to one; specifically in the comparison oblasts the ratio of males to females is significantly larger than that in the intervention group (chi-square test, $p<0.05$). The vast majority of TB patients are in the 30 to 49 age range, with no statistically significant differences between treatment and comparison groups by age. Unemployment rates exceed 70% among TB patients with no statistically significant differences between treatment and comparison groups. The urban to rural ratio is significantly larger in the intervention group compared to the comparison group ($p<0.001$).

TB Patient Status and Treatment

TB disease status for single infections and co-infected patients seen in TB facilities is presented in Table 4.8. For both intervention and comparison oblasts results are similar across disease classification categories. Roughly 60% to 75% of patients were diagnosed with TB for the first time. Co-infected patients in the comparison oblasts appear to exhibit more advanced disease (higher percentages of patients undergoing retreatment and with chronic, extra-pulmonary disease, and Category II treatment). Significantly, more IDUs were represented among the co-infected patients, especially in the comparison oblasts (27.3%). Among TB only patients and comparing intervention to comparison oblasts, significantly more patients in the intervention oblasts were first diagnosis while fewer were chronic TB or referral patients ($p<0.001$), and more were in TB treatment Category I ($p<0.01$). Similarly, among co-infected TB patients comparing intervention to comparison oblasts, significantly more patients in the intervention oblasts were first diagnosis, more had pulmonary TB ($p<0.05$) and fewer have extra-pulmonary disease ($p<0.05$), more were in treatment Category 1 ($p<0.001$), and fewer reported IDU ($p<0.001$).

HIV Services received by TB Patients

HIV testing and treatment services received by TB patients in intervention and comparison oblasts were abstracted where available. Between 35% and 40% of patients in both intervention and comparison groups had a diagnostic test for HIV prior to their intake into the TB services (Table 4.9). Between 56% and 62% received HIV testing at the time of TB treatment initiation. There were no statistically significant differences on these two measures by intervention versus comparison oblasts. It should be noted that these HIV identification categories are non-exclusive and that some patients may have been re-tested for HIV. ARV was initiated in 40% of patients testing HIV-positive in the intervention oblasts and in 53% of patients testing HIV-positive in the comparison oblasts. This difference was statistically significant ($p<0.001$).

Table 4.7. Background characteristics of TB patients at baseline by intervention group, Ukraine, 2012

Background characteristics	TB Patients			
	Intervention		Comparison	
	Number	(Percent)	Number	(Percent)
Sex				
Male	518	(66.8)	476	(73.1)
Female	258	(33.2)	175	(26.9)
Missing	0	(0.0)	0	(0.0)
Age				
18-29	157	(20.2)	111	(17.1)
30-39	308	(39.7)	259	(39.8)
40-49	193	(24.9)	167	(25.7)
50-59	74	(9.5)	76	(11.7)
60-69	27	(3.5)	25	(3.8)
70 and older	12	(1.5)	13	(2.0)
Missing	5	(0.6)	0	(0.0)
Employment				
Employed	91	(11.7)	88	(13.5)
Unemployed	576	(74.2)	468	(71.9)
Retired/person with disabilities	71	(9.1)	80	(12.3)
Student/housewife/other	22	(2.8)	15	(2.3)
Missing	16	(2.1)	0	(0.0)
Residence				
Urban	563	(72.6)	377	(57.9)
Rural	213	(27.4)	268	(41.2)
Missing	0	(0.0)	6	(0.9)
Oblast				
Kharkiv	131	(16.9)		
Odessa	490	(63.1)		
Zaporizhzhya	155	(20.0)		
Kiev			214	(32.9)
Mykolaiv			333	(51.2)
Zhytomyr			104	(16.0)
Total TB patients	776	(100.0)	651	(100.0)

Table 4.8. Disease status of TB patients at baseline by co-infection status and intervention group, Ukraine 2012

	Intervention Oblasts				Comparison Oblasts			
	TB Only		Co-Infected		TB Only		Co-Infected	
TB Status	Number	(Percent)	Number	(Percent)	Number	(Percent)	Number	(Percent)
TB classification								
First diagnosis	249	(76.8)	341	(75.4)	164	(65.3)	229	(57.3)
Re-treatment*	69	(21.2)	83	(18.3)	53	(21.1)	114	(28.5)
Chronic TB	0	(0.0)	0	(0.0)	17	(6.8)	35	(8.8)
Referral	6	(1.8)	28	(6.3)	17	(6.8)	22	(5.5)
TB clinical form								
Pulmonary	305	(94.1)	401	(88.7)	233	(92.8)	329	(82.3)
Extra-pulmonary	15	(4.6)	36	(8.0)	16	(6.4)	56	(14.0)
Both	4	(1.2)	15	(3.3)	2	(0.8)	1 5	(3.8)
TB treatment category								
Category I	215	(66.4)	317	(70.1)	138	(55.0)	219	(54.8)
Category II	69	(21.3)	109	(24.1)	87	(34.7)	166	(41.5)
Category III	39	(12.0)	25	(5.5)	25	(10.0)	12	(3.0)
Other/missing	0	(0.0)	1	(0.2)	1	(0.4)	3	(0.8)
IDU								
Yes	4	(1.2)	61	(13.5)	4	(1.6)	109	(27.3)
No	320	(98.8)	391	(86.5)	247	(98.4)	291	(72.8)
Total TB patients	324	(100.0)	452	(100.0)	251	(100.0)	400	(100.0)

*Includes: re-initiation, treatment failure, relapse

Table 4.9. Services received by TB patients at baseline, Ukraine 2012

	Intervention Oblasts		Comparison Oblasts		Total	
Testing and Treatment Services	Number	(Percent)	Number	(Percent)	Number	(Percent)
HIV identification*						
HIV diagnosis (pre-TB)	311	(40.1)	230	(35.3)	541	(37.9)
HIV testing	435	(56.1)	403	(61.9)	838	(58.7)
HIV care (among only HIV-positive patients)						
ARV initiation	177	(40.1)	221	(53.0)	398	(46.4)

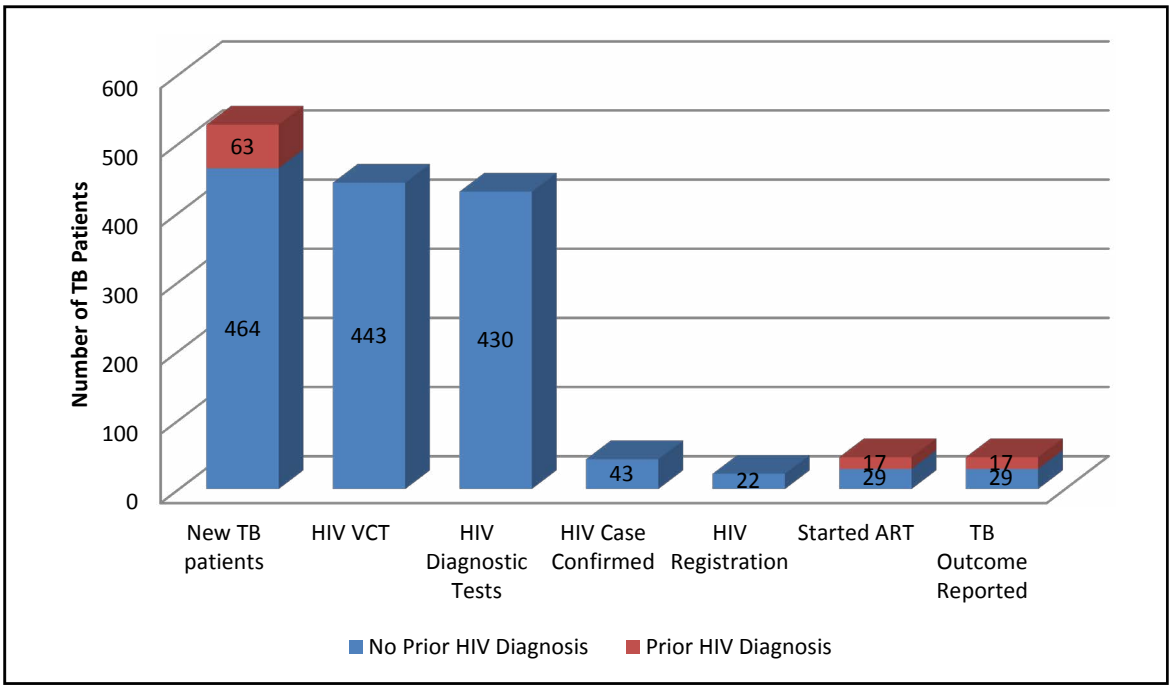
*Diagnosed prior to and/or tested at the time of TB treatment initiation; the two categories are not mutually exclusive

Service Cascade for TB Patients

A cascade or series of testing and treatment steps is required for TB-HIV co-infected patients to assure that they receive the full continuum of care for both diseases. Figure 4.4 shows the HIV testing and treatment cascade for newly-diagnosed TB patients. This includes the random sample from all TB patients (S1), and excludes the over-sampled co-infected cases as they by definition have received HIV testing. Only about 12% of the 527 newly-diagnosed TB patients had an HIV diagnosis prior to TB service intake, and only 25% of those patients began ART treatment/retreatment. Over 95% of newly diagnosed TB patients underwent VCT, and of those, 97% underwent further HIV diagnostic testing. Only 10% were confirmed to have HIV, half of which completed registration and two-thirds of which began ART. All of the newly-diagnosed TB patients who began ART had a TB outcome recorded.

It is not clear to what extent the drop-off from diagnostic testing to confirmed cases indicates negative diagnostic test results versus failure to accurately record and treat newly-diagnosed co-infected patients. Certainly some of both are represented among these drop-off cases.

Figure 4.4. HIV testing and treatment cascade for newly-diagnosed TB patients, (sample S1).



TB Treatment Outcomes

Among TB patients, treatment outcomes were recorded for all abstracted cases from 2012. This was expected given treatment on average lasts between two and 12 months and data were collected in 2014. Outcomes were similar in the intervention and comparison oblasts with roughly half of all cases recorded as a treatment success (Table 4.10). A slightly higher percentage of deaths in the comparison oblasts and slightly higher percentage of treatment failures in the intervention oblasts were noted. None of these differences were statistically significant. Treatment death rates and failure rates were both around 18% overall.

Table 4.10. TB treatment outcome among TB patients at baseline, Ukraine 2012

	Intervention Oblasts		Comparison Oblasts		Total	
TB Patient Records	Number	(Percent)	Number	(Percent)	Number	(Percent)
TB treatment outcome						
Treatment success*	396	(51.0)	324	(49.8)	720	(50.5)
Died	124	(16.0)	127	(19.5)	251	(17.6)
Treatment failed	147	(18.9)	105	(16.1)	252	(17.7)
Treatment interrupted	91	(11.7)	84	(12.9)	175	(12.3)
Case transferred	18	(2.3)	11	(1.7)	29	(2.0)
Total TB patients	776	(100.0)	651	(100.0)	1427	(100.0)

* Success included cured and completed

Survival Curves

A series of Kaplan-Meier survival curves were produced to examine the differences in time to seminal events for the patients seen in TB facilities (Figures 4.5-4.9). First we examined the time from TB diagnosis to time of HIV testing among sample S1 (i.e., TB patients randomly sampled from total 2012 TB population) (Figure 4.5). Next we focused on the co-infected population from both S1 and S2 samples, to estimate the time to ARV initiation and time to death among the co-infected (Figures 4.6-4.9). Note that the TB patient samples used in these analyses are weighted to be representative of case loads by oblast and co-infection status.

Between 65 and 85% of randomly sampled TB patients were tested for HIV within the first month of TB diagnosis, with a significant slowdown in testing thereafter in the intervention oblasts (p<0.001). For TB co-infected patients, large variation in ART initiation was seen by oblast. By approximately eight weeks following initiation of TB diagnosis and treatment, less than 25% of co-infected patients in any oblast received ARVs (Figure 4.6). In Mykolaiv, eventually over 85% of the co-infected started ART; however that coverage was not reached until a year had passed. When oblasts were grouped by intervention and comparison, a statistically significant difference in ART initiation is seen with comparison sites outperforming the intervention sites (p<0.001) (Figure 4.7).

Time to death in intervention and comparison oblasts were similar, although among all TB patients survival was slightly better in comparison oblasts versus intervention oblasts (data not shown). Among the co-infected, ART was highly protective as seen in Figure 4.8. However, even with ART approximately 20% of these patients from TB services died within one year. Among TB patients on ART, survival rates were not significantly different by sex (Figure 4.9).

Figure 4.5. Time to HIV testing for patients at TB Facilities, (sample S1).

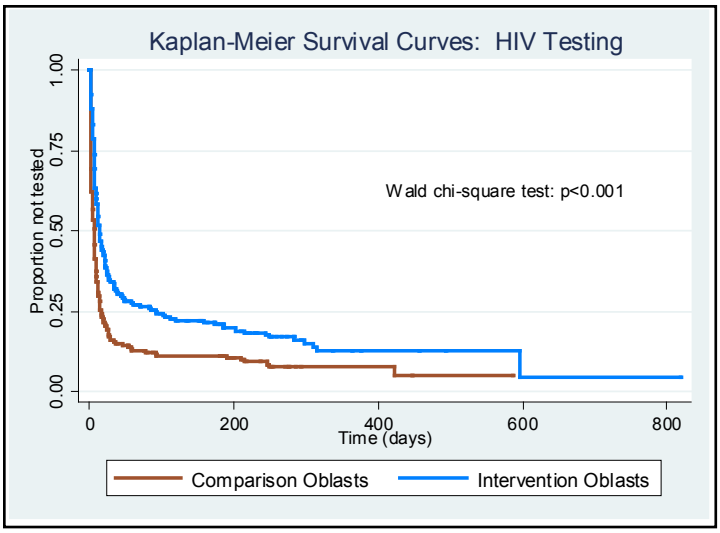


Figure 4.6. Time to ART initiation among co-infected patients at TB facilities, by oblast.

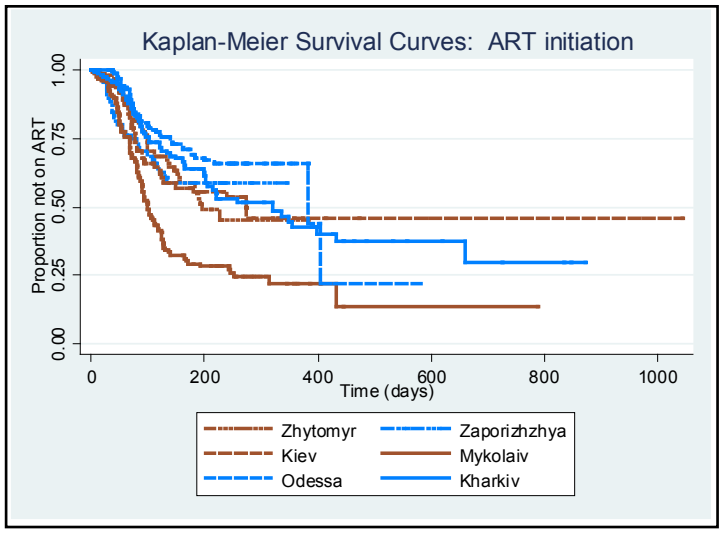


Figure 4.7. Time to ART initiation among co-infected patients at TB facilities, by intervention status.

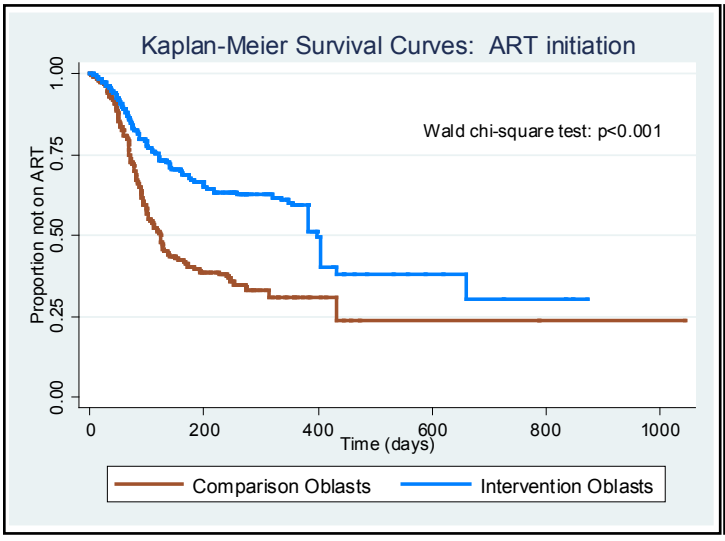


Figure 4.8. Time to death among co-infected patients at TB facilities, by ART status.

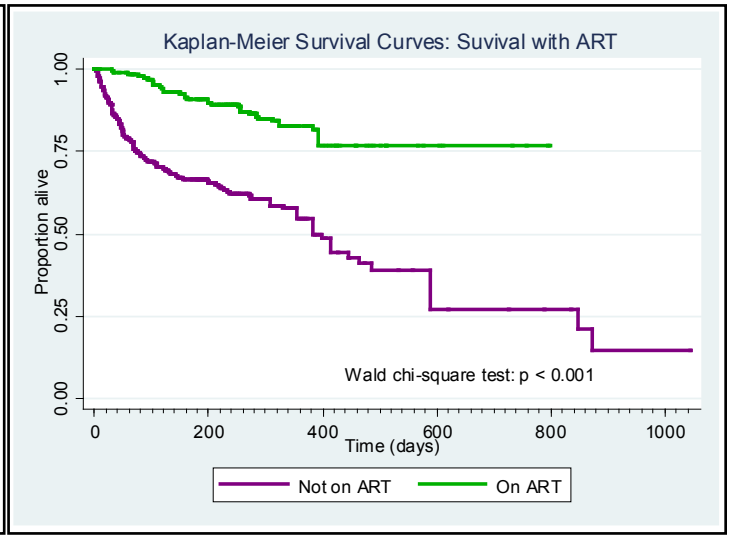
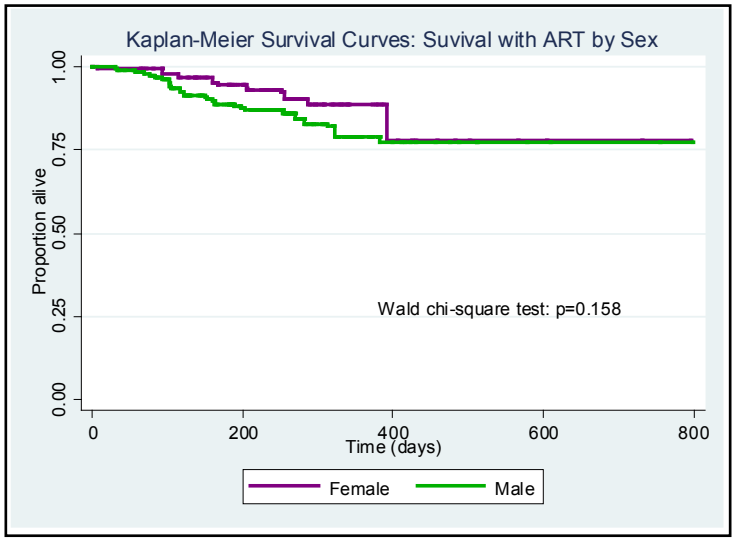


Figure 4.9. Time to death among co-infected on ART, by sex.



Survival Analysis

Cox proportional hazard models were used to examine the determinants of time to the different events of interest among our populations of TB patients. In particular, these models allowed us to examine the difference between intervention and comparison areas at baseline after controlling for other observed characteristics. As noted above, weighted data was used in the survival analyses.

Table 4.11 shows the Cox proportional hazard ratios for the outcome HIV testing among the random sample of all TB patients (S1). Model 1 indicates that, controlling for sex, age, employment and intravenous drug use, patients in the intervention group were 42% less likely to undergo HIV testing compared to those in the comparison group. Model 2 indicates that, controlling for the same variables, there were significant differences in rates of HIV testing among all oblasts compared to the referent oblast, Mykolaiv, a comparison site. These differences ranged from a 52% lower likelihood of testing in Odessa to over twice as likely to test in Zhytomyr; however, the majority of oblasts had significantly lower rates of testing compared to Mykolaiv, as suggested in Figure 4.6 above.

Table 4.12 shows the Cox proportional hazard model results for the outcome ARV initiation among co-infected patients seen in TB facilities. Similarly to Table 4.11, where one received services (intervention or comparison oblast) was the only predictor of ARV initiation, controlling for sex, age, employment and IDU (Model 1). Model 2 indicates that, controlling for the same variables, all oblasts had lower likelihood of ARV initiation compared to Mykolaiv, ranging from 67% less likely in Odessa to 49% less likely in Zhytomyr.

When looking at survival among all TB patients, Model 1 indicates that there was no difference in the likelihood of death by intervention versus comparison group, although several factors were associated with a significantly increased likelihood of death: unemployment, IDU, and co-infection with HIV (Table 4.13). The latter two factors increased the likelihood of death by 2.1 and 3.74 times, respectively. Model 2 shows similar findings regarding risk factors for increased likelihood of death. The results for oblasts indicate that compared to Mykolaiv and controlling for all other factors in the model, there was a reduced likelihood of death among patients in all other oblasts, though only in Kharkiv was this reduction statistically significant (a 46% reduction in likelihood of death compared to Mykolaiv, $p < 0.05$). The discrepancy between higher rates of testing and ARV initiation in Mykolaiv on the one hand, and higher death rates in Mykolaiv on the other hand may suggest that more severe patients were referred to Mykolaiv. Additional analyses to control for disease severity at endline may be warranted.

Table 4.11. Cox proportional hazard models predicting HIV testing, TB patients (S1 sample), Ukraine 2012

Variables	Model 1				Model 2		
	HR	(95% CI)	p-value		HR	(95% CI)	p-value
Intervention							
Yes	0.58***	(0.49-0.69)	0.000				
No	1						
Oblast							
Kharkiv					0.63**	(0.48-0.84)	0.002
Odessa					0.48***	(0.36-0.65)	0.000
Zaporizhzhya					0.61***	(0.47-0.80)	0.000
Kiev					0.64**	(0.48-0.85)	0.002
Zhytomyr					2.57***	(1.78-3.71)	0.000
Mykolaiv					1		
Sex							
Male	0.95	(0.79-1.14)	0.552		0.97	(0.80-1.17)	0.759
Female	1				1		
Age							
18-29					1		
30-39	0.95	(0.74-1.21)	0.665		0.94	(0.74-1.20)	0.623
40-49	1.00	(0.77-1.30)	0.984		1.02	(0.79-1.31)	0.901
50+	0.86	(0.66-1.13)	0.248		0.79	(0.61-1.03)	0.078
Employment							
Employed	1				1		
Unemployed	0.80	(0.63-1.00)	0.052		0.81	(0.64-1.03)	0.088
Retired/disabled	0.88	(0.63-1.23)	0.445		0.96	(0.68-1.35)	0.796
Student/other	0.87	(0.58-1.30)	0.490		0.84	(0.56-1.26)	0.392
Intravenous drug user							
Yes	0.53	(0.24-1.42)	0.104		0.46	(0.21-1.03)	0.058
No	1				1		
Number of TB patients	635				635		

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

Table 4.12. Cox proportional hazard models predicting ARV initiation, coinfected TB patients, Ukraine 2012

Variables	Model 1			Model 2		
	HR	(95% CI)	p-value	HR	(95% CI)	p-value
Intervention						
Yes	0.47***	(0.36-0.60)	0.000			
No	1					
Oblast						
Kharkiv				0.42***	(0.29-0.60)	0.000
Odessa				0.33***	(0.23-0.47)	0.000
Zaporizhzhya				0.49**	(0.31-0.77)	0.002
Kiev				0.50***	(0.35-0.72)	0.000
Zhytomyr				0.51***	(0.35-0.75)	0.001
Mykolaiv				1		
Sex						
Male	1.03	(0.79-1.35)	0.823	1.05	(0.80-1.37)	0.745
Female	1			1		
Age						
18-29	1			1		
30-39	0.92	(0.65-1.29)	0.619	0.87	(0.62-1.23)	0.440
40-49	0.95	(0.65-1.40)	0.798	0.86	(0.58-1.28)	0.464
50+	0.74	(0.44-1.27)	0.275	0.68	(0.40-1.16)	0.154
Employment						
Employed	1			1		
Unemployed	0.79	(0.58-1.10)	0.163	0.87	(0.61-1.24)	0.444
Retired/disabled	0.84	(0.46-1.55)	0.575	0.94	(0.51-1.75)	0.846
Student/other	0.69	(0.29-1.64)	0.399	0.70	(0.31-1.56)	0.383
Intravenous drug user						
Yes	0.90	(0.63-1.29)	0.567	0.88	(0.61-1.29)	0.523
No	1			1		
Number of co-infected TB patients	1,061			1,061		

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

Knowing the protective treatment effects of ART for those co-infected with HIV, we included ART as a time-varying covariate in Cox models predicting death among only the co-infected TB patients (Table 4.14). In Model 1 co-infected patients in the intervention group were 34% less likely to die when all other covariates including ART were controlled for. As in the previous table, IDU was associated with twice the likelihood of dying (in Models 1 and 2), while ARV use was highly protective, associated with approximately a 75% reduction in the likelihood of death in both models. In Model 2 controlling for all covariates and treating ARV use as a time-varying covariate, patients in all oblasts had a statistically significant reduction in the likelihood of death compared to the referent oblast (Mykolaiv). These reductions range from 60% in Kharkiv and Zhytomyr to 42% in Kiev.

Table 4.13. Cox proportional hazard models predicting death, all TB patients, Ukraine 2012

	Model 1			Model 2		
Variables	HR	(95% CI)	p-value	HR	(95% CI)	p-value
Intervention						
Yes	0.89	(0.66-1.18)	0.403			
No	1					
Oblast						
Kharkiv				0.54*	(0.33-0.89)	0.016
Odessa				0.87	(0.60-1.26)	0.453
Zaporizhzhya				0.73	(0.44-1.21)	0.220
Kiev				0.85	(0.55-1.29)	0.441
Zhytomyr				0.63	(0.38-1.03)	0.064
Mykolaiv				1		
Sex						
Male	1.04	(0.74-1.45)	0.842	1.03	(0.74-1.45)	0.851
Female	1			1		
Age						
18-29	1			1		
30-39	0.86	(0.56-1.32)	0.492	0.85	(0.55-1.32)	0.467
40-49	1.10	(0.70-1.74)	0.687	1.05	(0.66-1.69)	0.830
50+	1.67	(1.00-2.79)	0.051	1.64	(0.97-2.76)	0.064
Employment						
Employed	1			1		
Unemployed	1.76*	(1.07-2.91)	0.027	1.64	(0.98-2.74)	0.058
Retired/disabled	1.17	(0.58-2.40)	0.658	1.08	(0.52-2.22)	0.838
Student/other	1.19	(0.32-4.43)	0.798	1.08	(0.29-4.06)	0.913
Intravenous drug user						
Yes	2.09***	(1.46-3.01)	0.000	2.04***	(1.42-2.95)	0.000
No	1			1		
Coinfected						
Yes	3.74***	(2.56-5.45)	0.000	3.48***	(2.37-5.10)	0.000
No	1			1		
Number of TB patients	2520			2520		

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

Table 4.14. Cox proportional hazard models predicting death among co-infected TB patients, with ARV as time-varying covariate, Ukraine 2012

Variables	Model 1			Model 2		
	HR	(95% CI)	p-value	HR	(95% CI)	p-value
Intervention						
Yes	0.66*	(0.48-0.91)	0.011			
No	1					
Oblast						
Kharkiv				0.40**	(0.23-0.72)	0.002
Odessa				0.52**	(0.35-0.79)	0.002
Zaporizhzhya				0.53*	(0.30-0.94)	0.028
Kiev				0.58*	(0.36-0.93)	0.024
Zhytomyr				0.40**	(0.23-0.71)	0.002
Mykolaiv				1		
Sex						
Male	0.89	(0.61-1.31)	0.559	0.88	(0.59-1.29)	0.500
Female	1			1		
Age						
18-29	1			1		
30-39	0.83	(0.53-1.30)	0.414	0.79	(0.50-1.24)	0.301
40-49	1.17	(0.71-1.91)	0.538	1.05	(0.63-1.75)	0.849
50+	0.84	(0.41-1.73)	0.634	0.78	(0.37-1.62)	0.503
Employment						
Employed	1			1		
Unemployed	1.18	(0.72-1.94)	0.507	1.11	(0.66-1.86)	0.688
Retired/disabled	0.73	(0.30-1.79)	0.490	0.67	(0.27-1.67)	0.385
Student/other	1.03	(0.25-4.26)	0.971	0.93	(0.23-3.82)	0.919
Intravenous drug user						
Yes	2.00	(1.37-2.91)	0.000	1.95**	(1.31-2.89)	0.001
No	1			1		
On ARVs						
Yes	0.25	(0.18-0.37)	0.000	0.23***	(0.16-0.34)	0.000
No	1			1		
Number of co-infected TB patients	1455			1455		

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

Limitations

For the integration study, the intervention oblasts were already chosen by the STbCU program and these oblasts were targeted due to their disease epidemiology, population socio-economic characteristics, and health system needs. For the evaluation, a set of comparison oblasts were matched to intervention oblasts based on similar disease trends and population characteristics. When testing the balance of the dataset to see whether the patient populations selected for the intervention and comparison groups were comparable, we found some significant differences. Differences in TB and HIV disease status and ART initiation were found at baseline between intervention and comparison sites. Oblasts where patients received TB services were predictive of HIV testing, ART initiation, and death at baseline. These observable baseline differences in disease status and treatment options can be controlled for during endline analyses. The challenge will be controlling for any unobserved differences that may underlie the observable differences. At endline with prospective data collection, more detailed and complete data on disease status, treatment, referrals, and outcomes will be available as well as the opportunity to control for time-invariant unobserved facility fixed effects that may influence treatment and outcome.

CHAPTER 5. TB-HIV INTEGRATION STUDY: HIV FACILITY AND PATIENT FINDINGS

5.1. HIV Facilities and Services

Key Findings: AIDS Centers

- AIDS centers had approximately four times as many HIV/AIDS patients as TB-HIV co-infected patients. Larger patient loads were reported in the intervention oblasts and two to four times as many medical providers as well.
- Having TB specialists on staff at AIDS centers would be one of the most important steps for improving the system of diagnosis, treatment and data sharing. All of the faculties surveyed reported that TB specialists were consultants only. Similarly having an ID specialist at the TB facilities was believed to simplify the exchange of patient information.
- All nine AIDS centers offered VCT and the majority offered rapid testing and ELISA on-site. Most collect specimens for Western Blot and/or PCR testing off-site.
- All nine AIDS centers conducted TB symptom screening and two-thirds offered x-rays; however the majority of centers were not equipped for sputum microscopy, Xpert or culture analyses.
- No AIDS centers provided inpatient intensive TB treatment for smear-positive co-infected patients.
- Providers cited the government protocol for immediate ART initiation among the co-infected; the majority of providers noted starting ARVs within two weeks of TB treatment initiation.
- All centers provided CPT and the majority provided IPT; however in comparison oblasts some providers interviewed expressed doubts about the sustainability of the supply of CPTs and IPTs.
- None of the AIDS centers reported drug or equipment shortages in 2012.

Facility Surveys and Provider Interviews

Surveys and interviews were conducted at the oblast AIDS centers and/or city AIDS centers. We administered nine facility surveys; five in intervention oblasts and four in comparison oblasts (Table 5.1). A total of seven HIV provider interviews were completed in AIDS centers (three intervention and four control sites).

Table 5.1. AIDS centers facility surveys and provider interviews at baseline by oblast, Ukraine, 2014

Intervention Sites	Facility Surveys	Provider Interviews
Kharkiv Oblast	1	1
Odessa Oblast	2	1
Zaporizhzhya Oblast	2	1
Sub-total: intervention	5	3
Comparison cites		
Kiev Oblast	2	2
Mykolayiv Oblast	1	1
Zhytomyr Oblast	1	1
Sub-total: comparison	4	4
Total	9	7

AIDS Centers' Capacity and Services

None of the AIDS centers had beds for exclusive inpatient TB treatment and very few had beds for co-infected patients. While intervention sites had no beds for HIV/AIDS patients, there was a median of 14 beds for such patients in comparison sites (Table 5.2).

AIDS centers had approximately four times as many HIV/AIDS patients as co-infected patients. In both cases, the number of new patients varied extensively by facility.

Table 5.2. AIDS center staffing and capacity by intervention status, Ukraine, 2014

	Intervention		Comparison	
	Median	(Range)	Median	(Range)
Beds for inpatient treatment				
TB patients	0		0	
HIV/AIDS patients	0		14	(0-60)
TB-HIV coinfected patients	0	(0-50)	0	
New patients, 2012				
TB patients	0		0	
HIV/AIDS patients	591	(87-1,214)	427	(144-613)
TB-HIV coinfected patients	141	(42-556)	100	(61-143)
Staffing for HIV services				
Administrative	2	(2-8)	2	(1-4)
Nurses	19	(16-31)	8	(4-20)
Doctors	27	(8-32)	8	(6-11)
Staffing for TB services				
Administrative	0		1	(0-1)
Nurses	0		1	(0-11)
Doctors	0	(0-1)	1	(0-9)
Number of AIDS centers	5		4	

Staffing in AIDS Centers

Typically, AIDS center staff includes administrative personnel, ID specialists, psychologists, inpatient nurses and laboratory assistants. Staffing for HIV services differed between intervention and comparison sites, with the median number of nurses at intervention sites more than double the comparison sites and the median number of doctors almost four-fold that of comparison sites. Overall, there were very few staff for TB services at AIDS centers, with slightly more in the comparison oblasts (Table 5.2).

According to provider interviews, TB specialists were on staff at all oblast-level AIDS centers in intervention sites and at just one site in the comparison regions. In the facility surveys, all facilities reported that TB specialists were not on staff, but served as regularly scheduled consultants who visit once or twice a week, or upon request. At one of the facilities with an outpatient procedure of providing TB services for co-infected patients, all patients had access to a TB specialist in the outpatient TB department of that facility. In general, it was noted that having TB specialists on staff at the AIDS center would be one of the most important steps for improving the system of diagnosis, treatment, and data sharing on TB-HIV patients.

The scope of medical care for co-infected patients is regulated by state social standards and clinical protocols.[14] In certain facilities, respondents mentioned that there also exists a local protocol that was developed on the basis of the MOH protocol considering local specifics and facilities' structure.

Medical personnel in all AIDS centers reported occasional participation in different conferences, trainings and workshops on TB and HIV infection topics. All ID specialists reported completing training on TB diagnostics and screening; whereas training on identifying risk factors for TB and recording and reporting for TB were not as common. Interviewees emphasized the significance of providing more frequent continuing education opportunities related to TB-HIV, particularly given constant changes in the procedures.

Record Keeping

The procedure of record keeping is also described in clinical protocols and orders approved by the MOH. All AIDS centers maintained the official forms of documentation for the treatment of TB and TB-HIV. Additionally some facilities kept extra registries that were not available in other facilities.

Interviewees mentioned the following records/registries at their facilities:[15]

- medical record — contains all necessary information about HIV and TB diagnostics and treatment.
- log of HIV-infected patients (EPIDAIDS) — log contains information about the date of HIV status confirmation, date of prescription and ART administration, TB status of the patient); one interviewee reported that he/she does not have access to EPIDAIDS
- analysis registry
- primary patient's registration form (№ 030-5/o) which includes patient's information and analysis results
- control card of dispensary control over HIV-infected patient
- registries on ART, laboratory monitoring, and patient's referrals and others

The ID specialists maintain patients' records and information on TB which was added to the medical record by the TB specialist (when TB specialists are on staff). Currently no single unique registration number is used for co-infected patients — rather, patients have separate registration numbers at TB and AIDS centers.

HIV Diagnostics

As previously described, the process for HIV diagnostics begins with VCT, rapid tests, and ELISA test for confirmation, and other tests such as the Western Blot and PCR as needed. All nine of the AIDS centers provided HIV VCT counseling (Table 5.3). All of the intervention and three of the four comparison sites offered rapid testing at the AIDS center. Three of the five intervention AIDS centers offered ELISA at the facility; the other two centers collected the specimen and sent it out for analysis. All four comparison AIDS centers conducted the ELISA test on site.

Western Blot and PCR tests were also offered, but less frequently. About half of the AIDS Centers offered Western Blot at the center; the remaining centers collected specimens and sent them out for analysis. Two of the intervention centers offered the PCR test at the center, but most collected the specimen and sent for analysis or referred patients for testing if needed.

[14] Clinical protocol for antiretroviral therapy of HIV-infection for adults and adolescents, approved by MoH Ukraine Order 12.07.2010 № 551 on approval of clinical protocol for antiretroviral therapy of HIV-infection for adults and adolescents. Clinical protocol for diagnosis and treatment of opportunistic infections and general symptoms in adults and adolescents with HIV-infection approved by MoH Ukraine Order 13.04.2007 № 182 on approval of clinical protocols. Clinical protocol for provision of palliative care; symptomatic and pathogenic therapy for patients with HIV infection/AIDS, approved by MoH Ukraine Order 03.07.2007 № 368 on approval of clinical protocol for provision of palliative care; symptomatic and pathogenic therapy for patients with HIV-infection/AIDS.

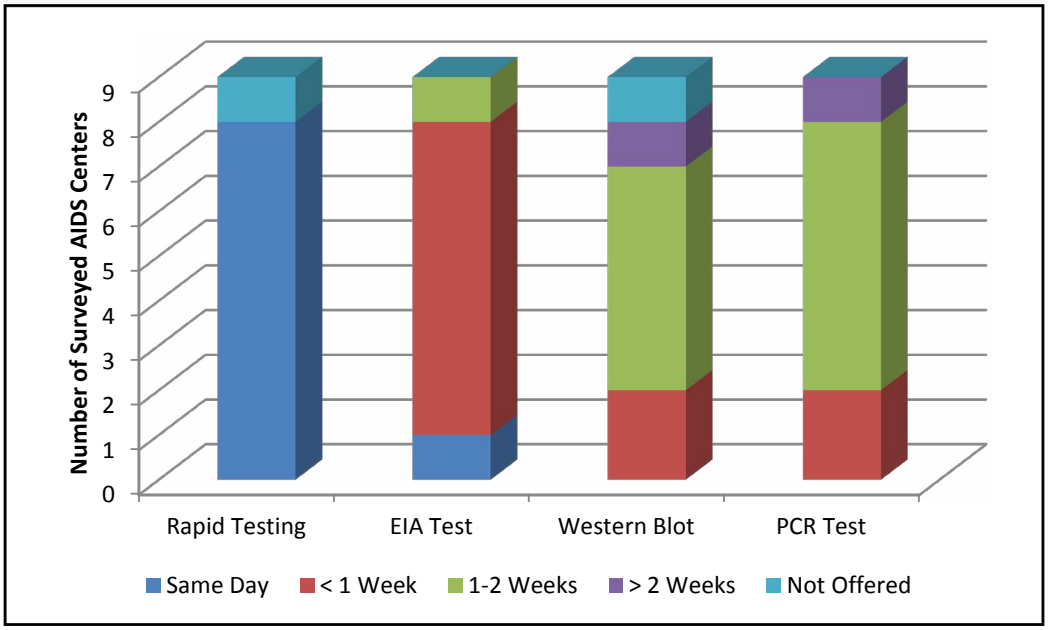
[15] Since the provider interview tool does not include a direct question about existing forms of documentation, this conclusion is based on information mentioned by the HIV doctors within the interview as well as on HIV doctors' evaluation of compliance with all national protocols approved by the Ministry of Health of Ukraine (order of MOH and state committee of statistics of Ukraine of 24.12.2004 № 640/663 on approval of forms of primary recording and reporting forms on HIV/AIDS and instructions for their completion).

Table 5.3. HIV diagnostic and analytic services offered by AIDS Centers and intervention status. Ukraine, 2014

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

The time period between when the sample was taken and when the results were received, varied by test type (Figure 5.1). Rapid tests, when offered, produced results the same day. ELISA test results were typically returned within a week. The time period for receiving Western Blot test results varied, a couple of facilities received results in less than a week, most (n=5) received results within one or two weeks, and at one facility it took over two weeks to receive results. PCR test results were usually provided within one or two weeks.

Figure 5.1. Time between HIV testing and receipt of results. Ukraine, 2014.



HIV/AIDS Treatment

Interviewees indicated that ART prescription is determined according to Protocol #551, national clinical protocol on ART for adults and adolescents. Initiation of ART depends on certain indicators (CD4 analysis, general clinical findings.

Once there is a positive HIV test, blood analysis is conducted to determine CD4 counts and viral load. Five AIDS centers were able to conduct CD4 count and viral load analyses at the facility; the remaining four either collected the specimen and sent it out to a laboratory for analysis, or referred a patient for testing (Table 5.3). CD4 counts were usually provided within a week; viral load took longer, up to 1 to 2 weeks (Figure 5.2). Some facilities were able to provide results more quickly.

For co-infected patients, ART was prescribed during the intensive phase of TB treatment regardless of other test results (most commonly mentioned period is two weeks after initiation of TB treatment). The ART initiation date was recorded both in TB and AIDS center registries.

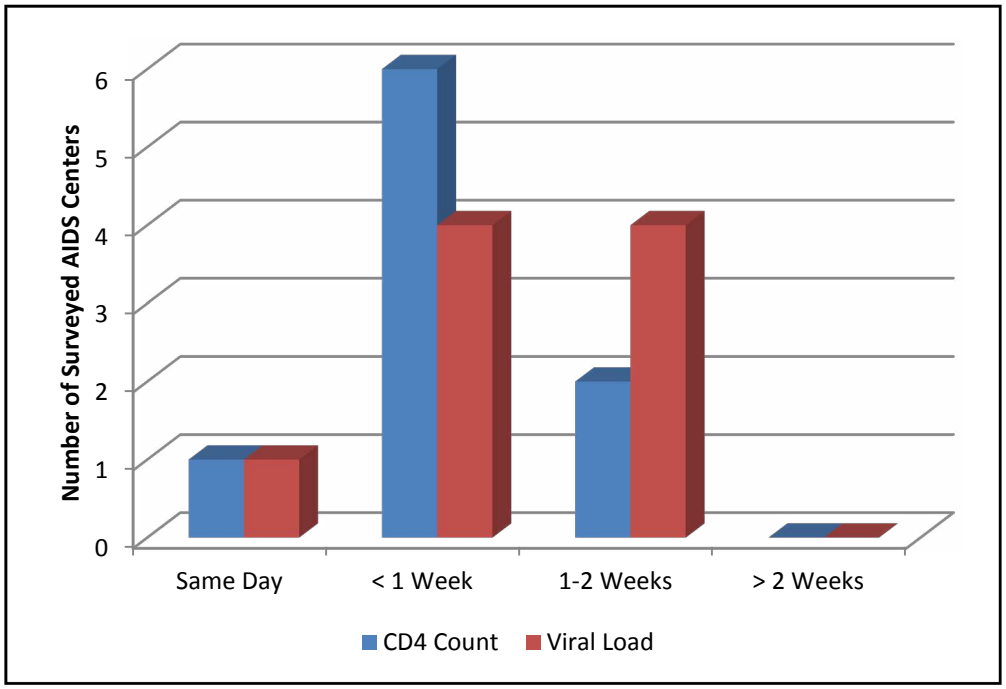
> ***"He would not be discharged until he shows that he has ARV for at least a month; that means that he has already visited the AIDS center. He comes to us to get acquainted, and if at the raion there is no site, we negotiate with patient, when he would come to us for ART. If there is a site, we provide him with ARV for a month and explain where in the future it might be received. In the TB hospital there also our doctors provide consultations, they know when the patients are discharged. And they explain patients where they should go."***

> ***"If HIV was diagnosed in other facility, they send us the registration form of the patient, a 501/2 form, and nothing more. They send us this form during the diagnosis process, and nothing after the discharge.***
>
> ***The patients, discharged from the TB facilities are informed, where they can apply to continue the ART."***

> *"According to the new protocols all the patients with the HIV-TB co-infection, irrespective of number of CD cells, get the ART upon their agreement. In 2012 it depended on CD4 analysis. According to the national standards the ART is appointed in 2-3 weeks after the start of intensive phase."*

For smear-positive co-infected patients, ART was provided in just three facilities. This is likely because the TB dispensaries provide inpatient care for all smear-positive patients during intensive treatment. For co-infected patients who are smear-negative, eight of the AIDS centers offered ART. For HIV positive patients with no TB diagnosis, all of the AIDS centers provided ART.

Figure 5.2. Time between blood draw and receipt of results, Ukraine, 2014.



Referrals from TB Facilities

Co-infected patients are discharged from TB hospitals and referred to Oblast AIDS centers for additional diagnoses and further HIV treatment after inpatient TB intensive phase treatment. Respondents in AIDS centers reported the same referral procedure (discharge of the patient with or without HIV-services notification) as described under the TB section of this report.

Interviewees from AIDS centers discussed how sharing information between TB and HIV services involves a reciprocal exchange of diagnostic results and primary registration forms for patients who were diagnosed with HIV in a TB dispensary, and in some cases the TB-09 form might be also sent directly to the AIDS center. Several interviewees shared how this information sharing might occur.

Interviewees also noted that the presence of an ID specialist at the TB facilities, either as a staff member or as a consultant from the AIDS center, simplifies the procedure of informational exchange between these two services.

The procedure for HIV diagnostics and treatment at the AIDS centers is also approved by the respective order of the MOH. Patients who were referred from a TB dispensary have access to all services provided by an AIDS center. However, after discharge from the TB facility, the patients arrive at an AIDS center with already diagnosed HIV, so additional HIV diagnostic testing is uncommon.

TB Diagnostics and Treatment at AIDS Centers

The primary document used as a guideline for TB diagnostics in AIDS facilities is a protocol, approved by the MOH.[16] TB diagnostics procedures in AIDS centers is standardized and includes the following steps: TB symptom screening (administering a standard questionnaire to patients on TB symptoms), clinical evaluation, x-rays (made during initial evaluation and annual follow-ups), and laboratory diagnostics.

All nine of the AIDS centers surveyed conducted TB symptom screening and clinical evaluation on site (Table 5.4). Two-thirds of the AIDS centers referred patients for chest x-rays. Laboratory diagnostics included TB sputum microscopy (which is the mandatory minimum diagnostic procedure for patients with suspected pulmonary TB), Xpert, and TB cultures. Two of the nine AIDS centers conducted the sputum microscopy on site; the remaining facilities either collected and sent specimens for analysis or referred for testing. Most of the AIDS centers collected samples for Xpert and TB cultures and sent them out for analysis; however, interview respondents did not commonly mention using Xpert.

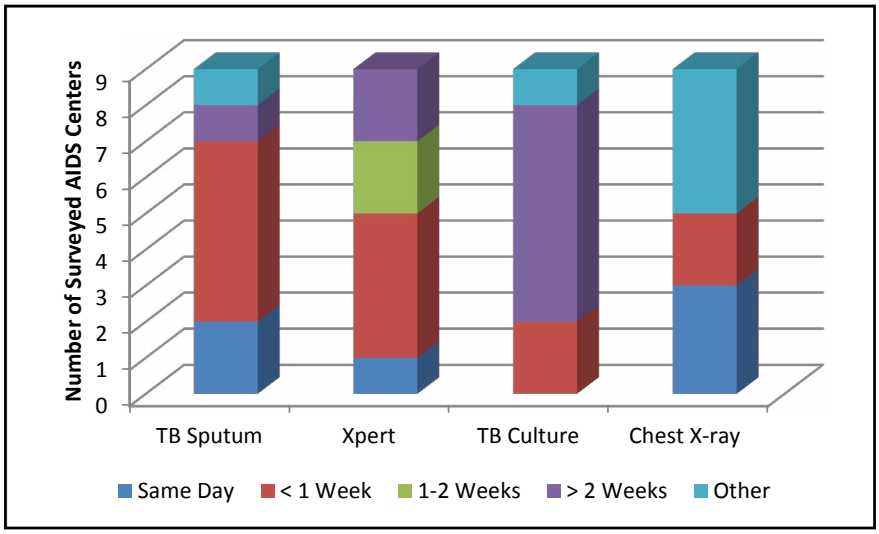
Table 5.4. TB diagnostic services offered by AIDS centers and intervention status, Ukraine, 2014

	Intervention				Comparison			
Diagnostics	Available at facility	Specimen collected and sent out	Patient Referred	Not provided	Available at facility	Specimen collected and sent out	Patient Referred	Not provided
TB symptom screening	5	0	0	0	4	0	0	0
TB sputum microscopy	1	2	1	1	1	2	1	0
Xpert (or other NAAT)	0	4	1	0	0	3	1	0
TB culture	0	2	2	1	0	3	1	0
Chest X-ray	1	0	4	0	2	0	2	0
Clinical evaluation	5	0	0	0	4	0	0	0
Other diagnostics	1	0	0	0	1	0	0	0
Number of AIDS centers	5				4			

[16] Clinical protocol for provision of medical care for patients with co-infection of TB and HIV infection" approved by MoH Ukraine Order 28.05.2008 № 276 on approval of clinical protocol for provision of medical care for patients with Co-infection of TB and HIV.

The time between testing and receiving results varied by type of TB test (Figure 5.3). TB symptom screening and clinical evaluation results were provided on the same day. Chest x-ray results were available on the same day as the x-ray was taken in three facilities (presumably where x-rays were available on site). For several facilities, the timing of x-ray results depends on when the patient brings the x-rays from the x-ray site. All but one AIDS Center provided TB sputum results in less than a week, though in one facility it took more than 2 weeks. Facilities varied in the length of time to receive Xpert results though the majority received results within a week. TB culture results overall took the greatest length of time to receive, in most cases it took more than two weeks.

Figure 5.3. Time between TB diagnostic test and receiving results. Ukraine, 2014.



Interviewees provided more information regarding TB diagnostics at AIDS centers. The majority of interviewees reported that x-ray diagnostics were available on site — this is different from the situation in the surveyed facilities. Interviewees noted that a lack of x-ray equipment in AIDS centers prevents timely TB diagnosis. As evidenced in the facility survey findings, AIDS centers in both intervention and comparison oblasts do not have the necessary equipment for laboratory diagnostics, requiring samples to be drawn at AIDS centers and sent to the oblast TB dispensary for analysis. Periodic logistical problems (transport and fuel availability) also hindered timely receipt of the laboratory results. When results were received, the ID or TB specialist (if available on site) notified the patient of the results.

Interviewees also discussed their experiences with extra-pulmonary TB. When suspected, patients are referred for an additional examination (MRI, CT, ultrasound investigation, histological examination etc.). Considering that AIDS centers in the study sites do not have specialists for extra-pulmonary TB diagnostics or necessary diagnostic equipment, patients were referred to other facilities such as the Oblast TB dispensaries, F.G. Yanovsky Institute of Phthisiology and Pulmonology in Kiev or to primary health care facilities depending on the type of diagnostics needed.

TB Treatment at AIDS Centers

No AIDS centers provided inpatient intensive TB treatment for co-infected patients and only two provided TB outpatient treatment and DOTS (Table 5.5). Psychological counseling was provided at all of the AIDS centers. For IDU patients with HIV or TB-HIV co-infected, only two AIDS centers offered substitution therapy (data not shown).

Interviewees provided more information on TB treatment procedures at AIDS centers. If TB diagnosis was confirmed, depending on the type of TB, patients were referred for further TB treatment to the following institutions: treatment for patients with the active form or smear-positive TB was provided in an inpatient department of a TB dispensary; and treatment for patients with an inactive form or smear-negative TB was typically provided in outpatient departments of TB services (TB cabinets) in the raion of residence. In intervention oblasts, respondents reported the possibility of treatment of non-active and extra-pulmonary TB directly at the Oblast AIDS center.

Table 5.5. TB treatment offered at AIDS Centers by intervention status, Ukarine, 2014

	Intervention	Comparison	Total
Services Offered	Number	Number	Number
TB inpatient treatment	0	0	0
TB outpatient treatment	1	1	2
DOTS at facility	1	1	2
DOTS at home	0	0	0
Self-management	1	1	2
Number of AIDS centers	5	4	9

Preventive Measures in AIDS Centers

Provider interviewees described the follow drug treatments available in AIDS centers:

- Isoniazid preventive therapy. IPT is prescribed to patients under certain indications described in the clinical protocol (absence of active TB; contact with TB patient; CD4 analysis results). Regular access to IPT medications was reported in a majority of interviewed AIDS Centers; two providers in control oblasts reported periodic problems with IPT procurement—when there are shortages of IPT, patients buy medication at their own cost.
- Co-trimoxazole preventive therapy. CPT is prescribed to patients with an indication for drug administration. Two providers in the control regions mentioned problems with the CPT procurement.

Facility surveys provided additional information on the availability of CPT and IPT in AIDS centers. All of the AIDS centers provided CPT and eight of the nine provided IPT; however, when these treatments are provided depends upon patient status. For co-infected patients who are smear-positive, four facilities offer CPT; for smear-negative co-infected patients, eight of the nine facilities offered CPT. For HIV patients with no TB diagnosis, CPT and IPT are offered in all facilities except one.

Interviewees at AIDS centers reported that procedures to prevent TB exposure and other opportunistic infections to HIV patients are for the most part, effective. However, in comparison oblasts, respondents reported that the supply of CPT and IPT is not sustainable.

Additional preventive measures put in place at AIDS centers include:

- mask regime
- TB screening, cough monitoring
- different days of consultations for patients referred from TB dispensaries
- separate entrance to TB specialists' cabinet
- annual HIV and TB diagnostics for medical personnel

Interviewees also pointed out the importance of conducting staff awareness sessions on HIV/TB preventive compliance as a way to improve preventive services.

Drug and Equipment Shortages

None of the nine facilities that were administered a survey reported shortages in 2012.

Key Findings: HIV Patients

- Among HIV-only patients there was evidence of later stage HIV disease, lower CD4 counts, more instances of multiple visits in the past year, and fewer patients receiving ARV treatment in the comparison oblasts versus intervention oblasts.
- TB diagnostic testing rates among all newly registered HIV patients were 76% and 68%, respectively in intervention and comparison oblasts ($p<0.01$).
- Among co-infected patients, intensive TB treatment was completed by a significantly larger proportion of patients in the intervention oblasts (70%) versus the comparison oblasts (52%) ($p<0.001$). Continuation treatment was completed by just over a third of patients in both intervention and comparison oblasts.
- ARV was initiated among a significantly larger proportion of patients in the comparison oblasts (67%) versus that in the intervention oblasts (48%) ($p<0.001$).
- The cascade of services received by the sample SI patients found that among patients with no prior TB diagnosis registered at an AIDS Center: 82% were screened for TB and 70% of those screened underwent further diagnostic testing. Only 18% of the latter were confirmed to have TB, 86% (48 of 56) of whom started TB treatment. Of these patients, 77% (37 of 48) also started ART. It is unclear to what extent the drop-off from diagnostic testing to confirmed cases reflects negative test results versus failure to accurately record and treat newly-diagnosed co-infected patients. (Figure 5.4)
- Among co-infected patients seen at AIDS Centers, 32.9% reported TB treatment success. The distribution of treatment outcomes differed by sites, with more patients in the intervention oblasts experiencing death and treatment interruptions ($p<0.001$).
- Between 25% and 30% of HIV patients (sample S1) received TB diagnostic testing within one month, with comparable rates between intervention and comparison oblasts. By six months, over 50% of the patients in intervention oblasts received testing while under 35% received it in comparison sites ($p<0.001$).
- Among the co-infected, time to initiate ARVs was faster overall in comparison versus intervention sites and relative to TB facilities. However a substantial proportion of co-infected patients had delayed or no ART. Patients in the intervention group were twice as likely to be tested for TB compared to the comparison group, controlling for sex, age, and employment.
- Patients in the intervention group were 37% less likely to begin ART compared to those in the comparison group and persons aged 40 to 49 were 67% more likely to begin ART compared to those aged 18-29.
- ARVs were extremely protective; patients on ARV treatment were 85% less likely to die compared to those not on treatment ($p<0.001$).
- Controlling for ART removed most of the observed differential effects seen by oblast in predicting death among the co-infected.

Individual Response Rates

Response rates for medical records abstraction for HIV services were very high and in some cases exceeded targets (Table 5.6). For HIV services, a much larger number of records (between three and four times as many) was abstracted from Odessa (n = 347) compared to the other two intervention oblasts, and similarly among the comparison sites a much larger number of records (1.4 to 2.3 times as many) was abstracted from Mykolaiv (n=241) compared to the other two comparison oblasts. Sampling was proportionate to HIV caseload by oblast reported in 2011. Sampling weights based on actual 2012 case counts were applied to assure that the analytic dataset was representative of the set of oblasts studied.

Table 5.6. HIV patient response rates at baseline by oblast, Ukraine, 2012

	HIV Services		
Intervention Sites	Sampled	Abstracted	Rate
Intervention sites			
Kharkiv Oblast	95	110	(115.8)
Odessa Oblast	343	347	(101.2)
Zaporizhzhya Oblast	88	88	(100.0)
Sub-total	526	545	(103.6)
Comparison sites			
Kiev Oblast	180	174	(96.7)
Mykolaiv Oblast	245	241	(98.4)
Zhytomyr Oblast	101	104	(103.0)
Sub-total	526	519	(98.7)
Total HIV patients	1052	1064	(101.1)

HIV Study Population

Table 5.7 gives the weighted background characteristics for the HIV patients by intervention and comparison sites, enabling us to identify any critical differences between our study populations at baseline. The sex ratio is roughly equal to one within the HIV intervention group; however the ratio of males to females in the comparison group is significantly higher than that in the intervention group (chi-square test, $p<0.001$). The vast majority of patients across treatment categories are in the 30 to 49 age range, and there are no statistically significant differences in age between treatment and comparison groups. Unemployment rates exceed 60% among HIV patients in the intervention group, but more than half of the employment data is missing for the HIV comparison patients, making it difficult to draw any conclusions regarding differences in employment status by treatment assignment. The urban and rural residence for HIV intervention and comparison sites are very similar with approximately 60% urban, 40% rural.

HIV Patient Status and Treatment

Table 5.8 shows disease status for intervention and comparison groups of HIV-only patients and those who are co-infected with TB. In the intervention group it should be noted that over 50% of co-infected patients have missing data on numbers of visits, clinical stage, CD4 count and IDU status at the most recent visit, so it is difficult to interpret the findings regarding HIV disease status for these patients. Nevertheless, among these co-infected patients there is an indication of more advanced disease by clinical stage, 38% are Stage 4, and only 4% have CD4 counts ≥ 350 cells/mm,[3] compared to a more even distribution of most HIV only patients across Stages 1 to 3 and over 40% with ≥ 350 cells/mm.[3]

In the comparison oblasts more advanced disease among HIV patients co-infected with TB is more apparent across all HIV status indicators. The percentages of IDUs are no higher, in either intervention or comparison groups, among HIV patients co-infected with TB compared to those only infected with HIV. Among HIV-only patients and comparing intervention to comparison oblasts, there are significant differences across clinical stage categories ($p<0.01$), although 15% of the data is missing for patients in the intervention oblasts. There is evidence of later stage HIV disease and lower cell counts among patients in the comparison oblasts versus the intervention oblasts among the HIV only patients. More patients in the intervention oblasts have a record of ARV treatment ($p<0.01$). Comparing co-infected patients in the intervention versus comparison oblasts, more patients in the comparison oblasts appear to report multiple visits in the past year, although 52% of the data is missing in the intervention group. Similarly, it is difficult to interpret the comparisons regarding clinical stage, CD4 counts, ARV treatment, and IDU given that 52% of the data on all of these measures is missing among co-infected patients in the intervention oblasts.

Table 5.7. Background characteristics of HIV patients at baseline by intervention group, Ukraine, 2012

Background Characteristics	HIV Patients			
	Intervention		Comparison	
	Number	(Percent)	Number	(Percent)
Sex				
Male	343	(50.7)	246	(63.6)
Female	315	(46.5)	141	(36.4)
Missing	19	(2.8)	0	(0.0)
Age				
18-29	139	(20.5)	82	(21.2)
30-39	291	(43.0)	176	(45.5)
40-49	184	(27.2)	97	(25.1)
50-59	53	(7.8)	30	(7.8)
60-69	10	(1.5)	2	(0.5)
70 and older	0	(0.0)	0	(0.0)
Missing	0	(0.0)	0	(0.0)
Employment				
Employed	122	(18.0)	71	(18.3)
Unemployed	413	(61.0)	86	(22.2)
Retired/Person with Disabilities	14	(2.1)	12	(3.1)
Student/Housewife/Other	63	(9.3)	2	(0.5)
Missing	65	(9.6)	216	(55.8)
Residence				
Urban	400	(59.1)	226	(58.4)
Rural	266	(39.3)	160	(41.3)
Missing	11	(1.6)	1	(0.3)
Oblast				
Kharkiv	74	(10.9)		
Odessa	513	(75.8)		
Zaporizhzhya	90	(13.3)		
Kiev			143	(37.0)
Mykolaiv			171	(44.2)
Zhytomyr			73	(18.9)
Total HIV patients	677	(100.0)	387	(100.0)

Table 5.8. Disease status of HIV patients at baseline, by co-infection status and intervention group. Ukraine 2012

	Intervention Oblasts				Comparison Oblasts			
	HIV Only		Co-Infected		HIV Only		Co-Infected	
HIV Status	Number	(Percent)	Number	(Percent)	Number	(Percent)	Number	(Percent)
Number of visits in past 12 months								
1	156	(47.4)	101	(29.0)	103	(46.6)	56	(33.7)
2	72	(21.9)	36	(10.3)	48	(21.7)	33	(19.9)
3	32	(9.7)	15	(4.3)	30	(13.6)	31	(18.7)
4 or more	25	(7.6)	14	(4.0)	23	(10.4)	37	(22.3)
Missing	44	(13.4)	182	(52.3)	17	(7.7)	9	(5.4)
HIV clinical stage (most recent visit)								
Stage 1	104	(31.6)	0	(0.0)	85	(38.5)	3	(1.8)
Stage 2	67	(20.4)	5	(1.4)	33	(14.9)	3	(1.8)
Stage 3	77	(23.4)	27	(7.8)	43	(19.5)	41	(24.7)
Stage 4	31	(9.4)	132	(37.9)	40	(18.1)	110	(66.3)
Missing	50	(15.2)	184	(52.9)	20	(9.0)	9	(5.4)
CD4 count (most recent visit)								
< 50 cells/mm3	73	(22.2)	58	(16.7)	88	(39.8)	72	(43.4)
50-349 cells/mm3	71	(21.6)	93	(26.7)	39	(17.6)	68	(41.0)
≥ 350 cells/mm3	142	(43.2)	15	(4.3)	77	(34.8)	17	(10.2)
Missing	43	(13.1)	182	(52.3)	17	(7.7)	9	(5.4)
ARV treatment								
Yes, known treatment	170	(51.7)	166	(47.7)	89	(40.3)	111	(66.9)
No record of treatment	159	(48.3)	182	(52.3)	132	(59.7)	55	(33.1)
IDU								
Yes*	20	(6.1)	11	(3.2)	18	(8.1)	18	(10.8)
No	263	(79.9)	154	(44.3)	179	(81.0)	135	(81.3)
Missing	46	(14.0)	183	(52.6)	24	(10.9)	13	(7.8)
Total HIV patients	329	(100.0)	348	(100.0)	221	(100.0)	166	(100.0)

* Includes current IDUs and those on substitution therapy

TB Services Received by HIV Patients

Services received by HIV patients by intervention versus comparison oblasts are presented in Table 5.9. TB symptom screening rates were high in both groups, between 85% and 90%, and TB diagnostic testing rates were 76% and 68%, respectively, in the intervention and comparison oblasts. Differences by intervention versus comparison oblasts on both of these identification measures were statistically significant ($p<0.01$). Among patients identified as TB-positive, intensive treatment was completed by 70% of patients in the intervention oblasts and 52% of patients in the comparison oblasts ($p<0.001$). Continuation treatment was completed by 34% of patients in the intervention oblasts and 36% of patients in the comparison oblasts. ARV was initiated among 67% or patients in the comparison oblasts and 48% of patients in the intervention oblasts ($p<0.001$).

Table 5.9. Services received by HIV patients at baseline, Ukraine, 2012

Testing and Treatment Services	Intervention Oblasts		Comparison Oblasts		Total	
	Number	(Percent)	Number	(Percent)	Number	(Percent)
TB identification	**667**		**387**		**1064**	
TB symptom screening	572	(84.5)	349	(90.2)	921	(86.6)
TB diagnostic testing	515	(76.1)	264	(68.2)	779	(73.2)
TB care (among TB-positive patients)	**348**		**166**		**514**	
Intensive treatment completed	241	(69.3)	87	(52.4)	328	(63.8)
Continuation treatment completed	118	(33.9)	60	(36.1)	178	(34.6)
ARV initiation	166	(47.7)	111	(66.9)	277	(53.9)

Note: Substantial number of HIV patient records were missing data on completion status for TB testing and treatment. For purposes of analysis we considered missing to be "no."

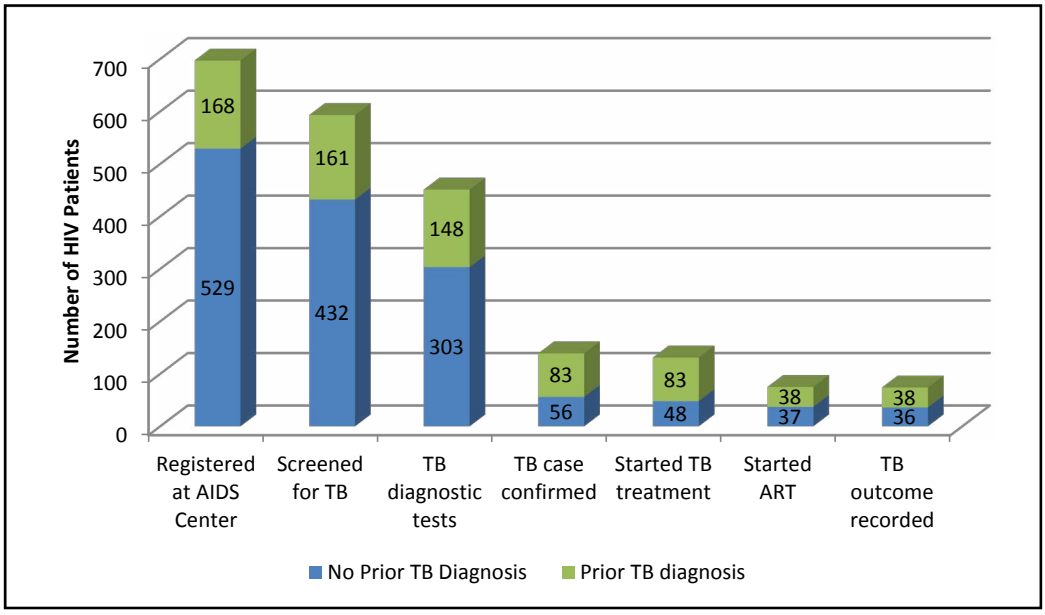
Service Cascade for HIV Patients

Similar to Figure 4.4 above, Figure 5.4 shows the TB testing and treatment cascade for the newly-diagnosed HIV patients at AIDS centers, combined for intervention and comparison oblasts. Note, the cascade is limited to our first sample (S1) selected randomly from all HIV patients; excluding the oversample of co-infected patients. Nearly 25% of the newly-diagnosed HIV patients had a prior TB diagnosis, yet most of these patients were nevertheless screened for TB and underwent TB diagnostic testing. Just over half of these patients were confirmed TB cases requiring intensive treatment. This discrepancy between expected and confirmed among those who entered the HIV facility with a prior TB diagnosis may in part be due to the patient having a prior diagnosis but already completing TB intensive and/or continuation treatment. Eighty-three newly confirmed and untreated cases began TB treatment and 46% (n=38) started ART; all reported a TB outcome.

Among patients with no prior TB diagnosis registered at an AIDS center (n=529), 82% were screened for TB and 70% of these underwent further diagnostic testing. Only 18% of those undergoing diagnostic testing were confirmed to have TB, 86% (48 of 56) of whom started TB treatment. Of these patients starting TB treatment, 77% (37 of 48) also started ART and all had a TB outcome recorded.

It is not clear to what extent the drop-off from diagnostic testing to confirmed cases indicates negative diagnostic test results versus failure to accurately record and treat newly-diagnosed co-infected patients. Certainly some of both are represented among these drop-off cases. Some of the following tables and graphs should shed some light on these questions.

Figure 5.4. TB testing and TB-HIV treatment cascade for HIV patients, sample S1, Ukraine 2012.



TB Treatment Outcomes

Among the co-infected patients seen at AIDS centers, treatment success rates were low in both intervention and comparison groups, 33% and 32%, respectively (Table 5.10). The proportion of patients dying was different by treatment group, with 24% of HIV patients dying in the intervention oblasts and 18% in the comparison oblasts. Overall, 17% of patients experienced treatment interruptions. The differences in treatment outcomes by intervention and comparison oblasts were statistically significant, with intervention oblast patients experiencing more deaths and treatment interruptions ($p<0.001$).

Table 5.10. TB treatment outcome among HIV patients co-infected at baseline, Ukraine, 2012

	Intervention Oblasts		Comparison Oblasts		Total	
TB Treatment Outcome	Number	Percent	Number	Percent	Number	Percent
Treatment success*	116	(33.3)	53	(31.9)	169	(32.9)
Treatment failed	30	(8.6)	11	(6.6)	41	(8.0)
Treatment interrupted	62	(17.8)	23	(13.9)	85	(16.5)
Died	83	(23.9)	30	(18.1)	113	(22.0)
Case transferred	2	(0.6)	10	(6.0)	12	(2.3)
Unknown/missing	55	(15.8)	39	(23.5)	94	(18.3)
Total co-infected HIV patients	348		166		514	

* Success included cured and completed

Survival Curves

A series of Kaplan-Meier survival curves were produced to examine the differences in time to seminal events for the patients seen in AIDS centers (Figures 5.5-5.9). Looking first at TB testing among HIV patients from sample S1, approximately 25% to 30% of HIV patients received TB diagnostic testing within one month, with comparable rates between intervention and comparison oblasts (Figure 5.5). By six months, over 50% of the patients in intervention oblasts received testing while under 35% received it in comparison sites ($p<0.001$).

For HIV co-infected patients, some variation in ART initiation was seen across oblasts (Figure 5.6). Mykolaiv and Zaporizhzhya provided better ART coverage with over 50% of patients initiating ARVs within eight weeks of co-infection diagnosis. While this is faster relative to the other oblasts and in comparison to initiation at the TB facilities; still a substantial proportion

of co-infected patients missed the optimal window for starting on ART. Uptake was much slower in Kharkiv, Odessa and Zhytomyr where less than 10% of the co-infected patients received ART by eight weeks. Collapsing by intervention and comparison oblasts, the survival curve for the comparison sites performed better ($p<0.001$) (Figure 5.7).

Time to death in intervention and comparison oblasts were similar, although among all HIV patients survival was slightly better in comparison oblasts versus intervention oblasts (data not shown). Among co-infected AIDS center patients, ART was highly protective ($p<0.001$) (Figure 5.8). Looking at HIV patients on ART by sex, significantly fewer males survived during the study period compared to females, however, the numbers of events (deaths) observed here were very small, (18 total deaths) (Figure 5.9).

Survival Analysis

Similar to the TB patient analysis, Cox proportional hazard models were used to examine the determinants of time to the different events of interest among our intervention and comparison populations of HIV patients, controlling for other observed characteristics. Table 5.11 shows two models predicting TB testing among HIV patients from sample S1. Patients in the intervention group were twice as likely to be tested for TB compared to the comparison group, controlling for sex, age, and employment, as seen in Model 1. Patients aged 30 to 49 were more likely to be tested compared to those aged 18 to 29, and these results are statistically significant. Model 2 disaggregates by oblast to see whether oblast-level differences are driving the baseline difference between intervention and comparison groups. Patients in Kiev are 95% less likely to be tested for TB compared to the referent oblast, Mykolaiv ($p < 0.001$); both of these oblasts are in the comparison group.

Figure 5.5. Time to TB testing for patients at AIDS centers, (sample S1).

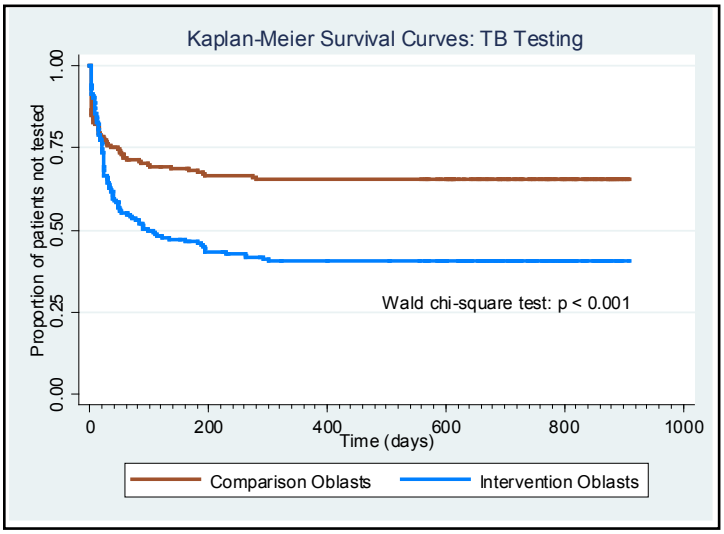


Figure 5.6. Time to ART initiation among co-infected patients at AIDS centers, by oblast.

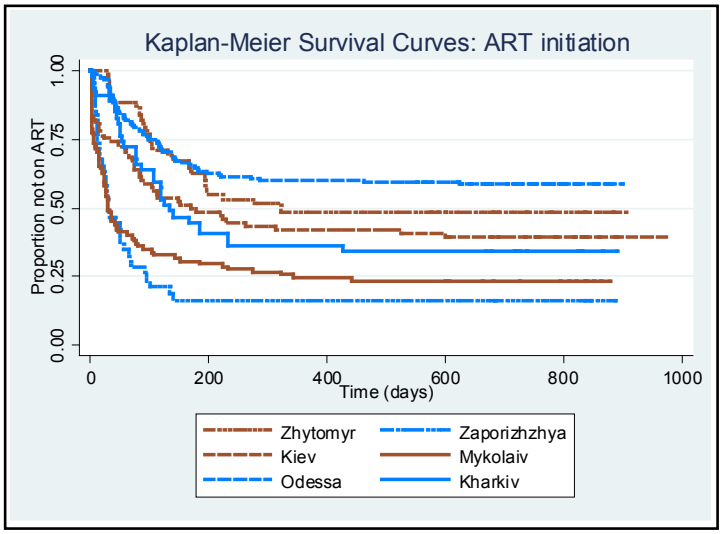


Figure 5.7. Time to ART initiation among co-infected patients at AIDS centers, by intervention status.

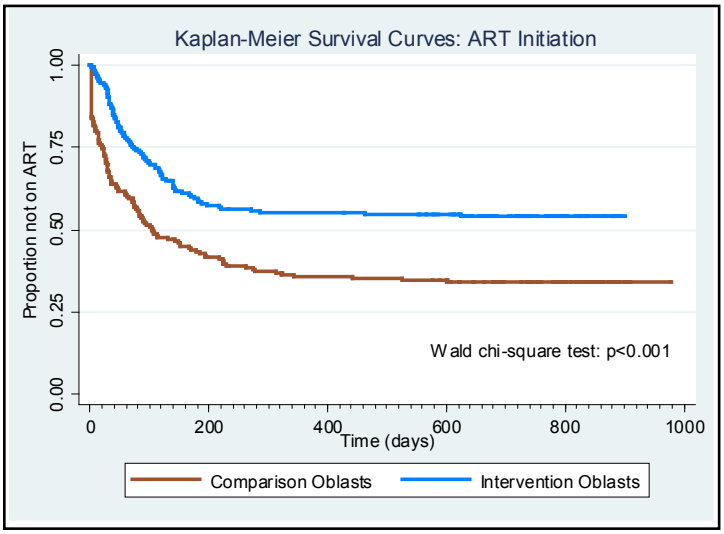


Figure 5.8. Time to death among co-infected, by ART status.

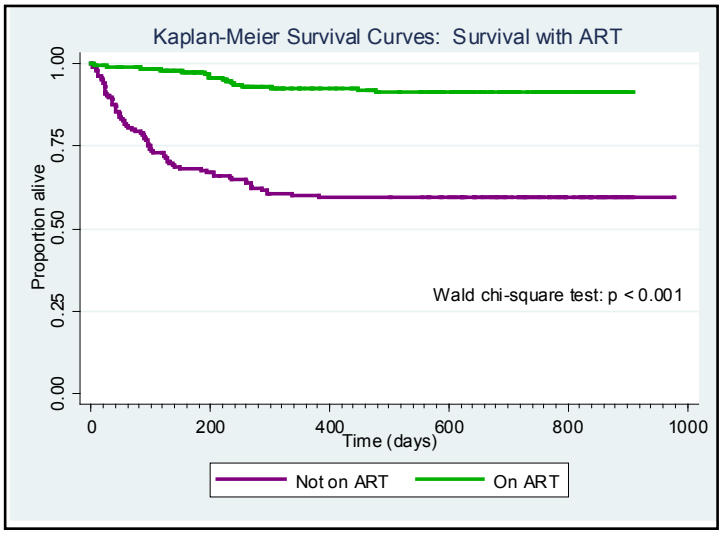


Figure 5.9. Time to death among co-infected on ART, by sex.

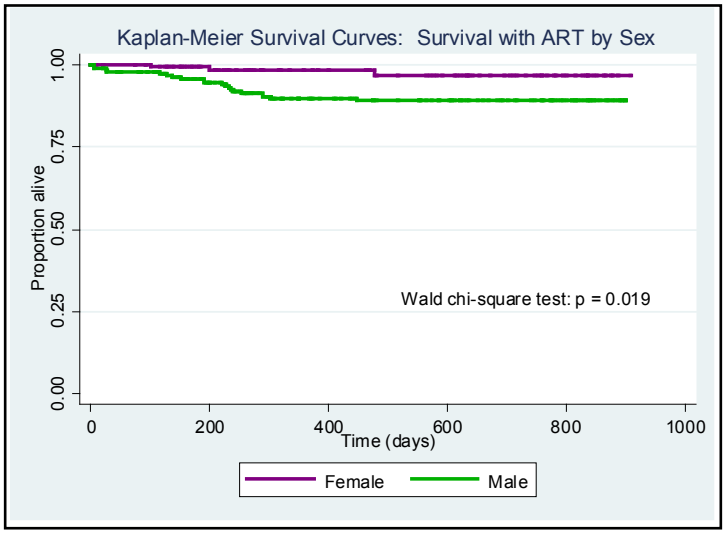


Table 5.11. Cox proportional hazard models predicting TB testing among HIV patients (S1 sample), Ukraine 2012

	Model 1			Model 2		
Variable	HR	95% CI	p-value	HR	95% CI	p-value
Intervention group						
Yes	2.04***	(1.49-2.78)	0.000			
No	1					
Oblast						
Kharkiv				0.55*	(0.32-0.97)	0.038
Odessa				0.47**	(0.28-0.78)	0.004
Zaporizhzhya				0.90	(0.48-1.69)	0.736
Kiev				0.05***	(0.02-0.12)	0.000
Zhytomyr				0.40**	(0.22-0.73)	0.003
Mykolaiv				1		
Sex						
Male	0.99	(0.74-1.33)	0.938	1.05	(0.77-1.43)	0.741
Female	1			1		
Age						
18-29	1			1		
30-39	1.59*	(1.07-2.37)	0.022	1.55*	(1.04-2.30)	0.032
40-49	2.86***	(1.89-4.32)	0.000	2.56***	(1.67-3.92)	0.000
50+	2.02	(1.07-3.82)	0.030	1.50	(0.73-3.07)	0.270
Employment						
Employed	1			1		
Unemployed	0.74	(0.54-1.01)	0.055	0.97	(0.66-1.43)	0.887
Retired/disabled	1.61	(0.55-4.67)	0.382	1.25	(0.37-4.22)	0.715
Student/other	0.87	(0.53-1.44)	0.591	1.10	(0.62-1.94)	0.744
Total HIV patients	553			553		

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

Table 5.12 presents the Cox model results predicting ART initiation among co-infected HIV patients. Patients in the intervention group were 37% less likely to begin ART compared to those in the comparison group. Also, persons aged 40 to 49 were 67% more likely to begin ART compared to those aged 18-29. In model 2, patients in Odessa and Zhytomyr were 69% and 62% less likely to begin ART, respectively, and those in Kiev were 39% less likely to begin ART, compared to patients in Mykolaiv, controlling for the other factors in the model. A third model in which IDU was added as a control variable indicated that this variable was not predictive of ART initiation and caused the number of records to drop by half. Therefore results for this model are not reported.

Table 5.12. Cox proportional hazard models predicting ART initiation among co-infected HIV patients, Ukraine, 2012

Variable	Model 1			Model 2		
	HR	95% CI	p-value	HR	95% CI	p-value
Intervention group						
Yes	0.63*	(0.44-0.90)	0.010			
No	1					
Oblast						
Kharkiv				0.59*	(0.37-0.93)	0.024
Odessa				0.31***	(0.19-0.50)	0.000
Zaporizhzhya				1.29	(0.75-2.22)	0.356
Kiev				0.61*	(0.40-0.92)	0.020
Zhytomyr				0.38***	(0.24-0.60)	0.000
Mykolaiv				1		
Sex						
Male	0.83	(0.62-1.11)	0.202	0.88	(0.65-1.19)	0.398
Female	1			1		
Age						
18-29	1			1		
30-39	1.27	(0.79-2.04)	0.326	1.31	(0.83-2.06)	0.250
40-49	1.67*	(1.02-2.74)	0.042	1.61	(1.00-2.60)	0.050
50+	1.42	(0.77-2.61)	0.265	1.52	(0.84-2.77)	0.169
Employment						
Employed	1			1		
Unemployed	0.69	(0.48-1.00)	0.050	0.84	(0.57-1.24)	0.375
Retired/disabled	1.87	(0.97-3.57)	0.060	1.32	(0.75-2.34)	0.335
Student/other	1.19	(0.61-2.35)	0.605	1.76	(0.85-3.67)	0.130
Total co-infected HIV patients	794			794		
*p<0.05, **p<0.01, ***p<0.001						

Table 5.13 presents the Cox model results for survival among HIV patients co-infected with TB, using ARV as a time-varying covariate. Patients in Zaporizhzhya were over 3.5 times more likely to die compared to those in Mykolaiv, controlling for the other variables in Model 2. In both models the strongly protective effect of ARV therapy was evident. In models 1 and 2, patients on ARV treatment were about 85% less likely to die compared to those patients not on ARV treatment, controlling for all other covariates. As above, inclusion of IDU as a control causes a reduction in the number of records and does not add predictive value (data not shown).

Table 5.13. Cox proportional hazard models predicting death among co-infected HIV patients, with ARV as time-varying covariate, Ukraine 2012

	Model 1				Model 2		
Variable	HR	95% CI	p-value		HR	95% CI	p-value
Intervention Group							
Yes	1.00	(0.57-1.76)	0.986				
No	1						
Oblast							
Kharkiv					1.79	(0.70-4.54)	0.222
Odessa					1.12	(0.48-2.62)	0.795
Zaporizhzhya					3.56**	(1.42-8.95)	0.007
Kiev					1.64	(0.72-3.75)	0.241
Zhytomyr					0.91	(0.32-2.59)	0.857
Mykolaiv					1.00		
Sex							
Male	1.21	(0.73-1.99)	0.458		1.20	(0.72-2.01)	0.479
Female	1				1		
Age							
18-29	1				1		
30-39	2.17	(0.88-5.31)	0.091		2.08	(0.84-5.11)	0.111
40-49	1.53	(0.59-3.97)	0.379		1.51	(0.59-3.88)	0.394
50+	1.34	(0.44-4.05)	0.609		1.25	(0.42-3.76)	0.689
Employment							
Employed	1				1		
Unemployed	0.95	(0.52-1.73)	0.860		0.96	(0.52-1.80)	0.908
Retired/disabled	0.16	(0.02-1.29)	0.086		0.14	(0.02-1.11)	0.063
Student/other	0.23	(0.03-1.80)	0.161		0.25	(0.03-2.06)	0.199
On ARVs							
Yes	0.16***	(0.10-0.27)	0.000		0.14***	(0.08-0.23)	0.000
No	1				1		
N	980				980		

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

Limitations

Similarly to the TB integration study population, the HIV study population varied at baseline by intervention and comparison group both on disease status and treatment received. A similar approach at endline, controlling for facility fixed-effects, will be undertaken. Another limitation at baseline, particularly for the HIV patients, was the limited data available in the patient medical records. In 2012, the reporting forms did not track a unique patient identifier that linked to services received elsewhere, making it impossible to merge the TB and HIV patient datasets. Moreover, there was no place in the medical record to track information about referrals received and followed up on for TB services and no register that separately tracked co-infected patients. Based on the data received, it is likely that records were incomplete regarding TB services received. Endline prospective data collection will provide a much richer understanding of patients' movement between services and, will allow us to deduplicate records between the services in order to present a more comprehensive picture of the testing, referral, and treatment pathways for the co-infected populations.

CHAPTER 6. CONCLUSIONS

The baseline STbCU-IE survey collected comprehensive retrospective and current data about the oblast, facilities and patients who make up the intervention and comparison populations. The analyses carried out to date provide descriptions of these populations as well as results suggestive of the positive effects of social support on TB treatment adherence and solid baseline data on which to build future impact evaluation models once endline data collection is completed. Below is a brief summary of the two studies, including the study questions addressed and the next steps for analysis.

6.1 Social Support

The primary evaluation question for the social support study is whether or not the social support program improves TB continuation treatment adherence among patients at high-risk for default. To address this question we surveyed TB outpatient facilities to understand facility characteristics and practices. Additionally, we abstracted medical record data from patients served at these facilities, including those who received social support and those who did not. This data produced our baseline measures.

Almost all facilities provided referrals to social support programs in 2012 and URCS was the sole provider of these services in Kharkiv and Odessa, and the primary provider in Dnipropetrovsk. Typical services offered by URCS included daily home DOTS and twice-monthly food packages. Most often the person responsible for URCS referrals was the raion or city TB physician. The majority of facilities in Dnipropetrovsk and Odessa required at least one risk factor for referral, while the majority of sites in Kharkiv did not have a minimum number of risk factors as part of their referral criteria. Severe TB drug shortages were a concern nationwide in 2011 and reported by 20% of the facilities surveyed. Patients were most often told to buy their own TB medications to complete therapy in 2011 which may have influenced treatment adherence among the 2011 cohorts.

For the impact analyses, we examined similarities and differences in socio-demographics, disease status, treatment adherence, social support referrals, and treatment outcomes between the intervention and comparison cohorts. Next we tested whether the targeting of social support services followed the risk criteria established by URCS and the government, and whether the HR-intervention and HR-comparison groups were similar based on risk criteria. Last, we estimated the probability of treatment default and death among the HR-intervention and HR-comparison cohorts.

The study cohorts were found to be demographically similar to each other with a similar number of risk factors among the HR cohorts. On average the HR-intervention cohort reported fewer treatment interruptions and shorter interruptions compared to the HR-comparison cohort from 2012, although notably one-fifth of patients from each cohort reported an interruption lasting longer than four weeks. Comparing the HR-intervention and HR-comparison cohorts from 2012, we found that program selection on alcoholism, IDU, presence of co-morbidities, health care workers, contacts to cases, and migrants was similar across the two cohorts. However, HIV-positive patients, homeless, and ex-prisoners were less likely to receive the social support program, while the unemployed, "other" risk factors and being female were predictive of receiving social support. Impact analyses to date suggest that the social support program had a protective effect on treatment default, that is, those in the program were significantly less likely to default on TB treatment. Moreover, a protective effect on death was suggested, although the number of deaths was small. In both of these analyses, the impact may be overstated given that these analyses do not control for the selection process by providers when assigning patients to receive social support.

Additional analyses are recommended to control for facility-level fixed effects including social support referral practices that may introduce selection bias and drug shortages and response to these shortages that may have influenced treatment adherence and outcomes. Given the higher probability of social support for female patients, stratified analysis by gender and stratified sampling at endline may be warranted. Furthermore, prospective collection of additional socio-demographic variables and treatment experiences at endline will allow for more individual-level control variables in the analyses.

6.2 TB-HIV Integration

The primary evaluation question for the integration study is whether improvements in integration between TB and HIV/AIDS services result in a decline in all-cause mortality among the TB-HIV co-infected patients. Additional research questions looked at the proportion completing each step for the service cascade and the time to different outcomes including testing and treatment. To answer these questions we surveyed TB facilities providing intensive TB treatment, AIDS centers serving HIV/AIDS patients, and a selection of providers from both services in an effort to understand facility and provider characteristics and practices, particularly for identification and treatment of co-infected patients. Additionally we abstracted medical record data from patients served at these facilities, with samples targeting general TB patients, general HIV/AIDS patients, and co-infected patients.

Differences in TB facilities and AIDS centers were found both in facility characteristics and practices. TB facilities were larger in general in the comparison oblasts compared to the intervention oblasts, while AIDS centers had substantially higher patient and provider populations in the intervention sites. Screening and rapid testing for TB and HIV were offered in the majority of TB facilities and AIDS centers; however diagnostic testing requiring more advanced training and/or equipment, such as sputum microscopy, Xpert, ELISA, PCR, and Western Blot, were not offered on-site. Off-site testing invariably added some time to the receipt of testing outcomes, potentially slowing down the initiation of ART among the co-infected. Moreover, no AIDS center provided inpatient TB treatment for the smear-positive TB patients and no formal referral protocols between facilities were in place to expedite the transfer of patients for treatment. Rather, some facilities relied on personal relationships between different providers to facilitate the transfer of patients, while other sites left it up to the patients to seek the appropriate follow-up services. AIDS centers' providers suggested that having TB physicians on staff would be one of the most important steps for improving diagnosis, treatment and data sharing; and having an ID specialist on staff at TB facilities was believed to improve and simplify the data exchange process between sites.

For the baseline patient analyses, we examined similarities and differences in socio-demographics, disease status, testing, treatment and outcomes between the intervention and comparison cohorts. We produced service cascades to identify where patients might have dropped out of care. Finally, we produced survival curves and using Cox proportional hazards models, we estimated differences in time to specific events for the intervention and comparison cohorts seen in TB facilities and AIDS centers.

TB Facility Patients

Comparisons between the TB intervention population and the TB comparison population found some significant differences in disease status and ART initiation between the groups at baseline. However TB treatment outcomes for all cases served by a TB facility were similar, with roughly half of the cases recorded as a treatment success, and under 20% recorded as treatment failure or death.

For the general sample selected from all TB patients, over 90 percent received HIV screening and testing. The majority (65% to 85%) received HIV testing within one month of TB diagnosis, although time to testing in the intervention oblasts was significantly slower than for the comparison oblasts. Only 10% of the general sample was confirmed to be co-infected with HIV and only two-thirds of this group initiated ART. It is unclear to what extent the drop-off from diagnostic testing to confirmed cases indicates negative diagnostic test results versus failure to accurately record and treat newly-diagnosed co-infected patients. Tracking patients prospectively through the screening, testing, treatment process at endline will help to identify differences between record keeping and actual services received.

Among the co-infected patients, ART was associated with approximately a 75% reduction in the likelihood of dying. However initiation of ART was slow, with less than 25% of the co-infected covered within the recommended two to eight weeks. Overall, comparison oblasts outperformed intervention oblasts in uptake of ARVs. In fact, the oblast where TB patients received services was predictive of HIV testing, ART initiation and death among the co-infected at baseline. It is interesting to note that even with more timely HIV screening and ARV initiation in Mykolaiv, TB patients in this oblast experienced higher death rates. This may reflect a disproportionate share of high-risk patients in the oblast and suggests the need to control for TB and/or HIV disease stage at endline.

AIDS Center Patients

According to HIV disease and treatment status, HIV-only patients seen at the AIDS centers were different in intervention versus comparison oblasts, with those in the comparison oblasts worse off overall. Among the general HIV-patient population, TB screening and testing was not as pervasive as HIV testing in the TB facilities. Between 25% and 30% of HIV patients received TB diagnostic testing within one month in both intervention and comparison sites; but by six months, over 50 % of patients in the intervention oblasts received testing compared to fewer than 35% in comparison sites.

Among co-infected patients, TB treatment completion rates were higher in the intervention oblasts yet higher rates of death and treatment interruption among patients in these same sites were recorded as well. ART initiation was significantly higher in the comparison oblasts and time to ART initiation was much shorter in the comparison sites, which may account for the lower mortality rates seen in these comparison oblasts. Again, we found ART to be significantly predictive of survival and controlling for ART removed most of the observed differential effects seen by oblast.

At endline, prospective data collection will improve data validity, as historic record keeping of TB status and treatment in the HIV patient records was likely incomplete at baseline. Moreover, at endline it would be informative to track patients' movement between services and deduplicate records as possible between the services in order to present a more comprehensive picture of the testing, referral, and treatment pathways for the co-infected populations.

APPENDICES

Study Protocol

Impact Evaluation: Strengthening Tuberculosis Control In Ukraine

Study Instruments

TB Data Abstraction Form – Social Support Study

Social Support Facility Survey

Consent Form: URCS Survey

HIV Data Abstraction Form – Integration Study

TB Data Abstraction Form – Integration Study

Integration Facility Survey

Provider Consent Form: Provider Interviews

Questions For HIV Services/Physicians

BTM Draft List of Questions for Physicians in TB Service/Institutions In Ukraine

Patient Services and Data Sources

TB Medical Care In Ukraine: Services, Patients, and Data

HIV/AIDS Medical Care in Ukraine: Services, Patients, and Data

MEASURE Evaluation

Carolina Population Center in partnership with Futures Group International, ICF Macro, John Snow, Inc., Management Sciences for Health, and Tulane University

Impact Evaluation: Strengthening Tuberculosis Control in Ukraine

Revised: September 2014

Evaluation Purpose

USAID/Ukraine commissioned MEASURE Evaluation to conduct an impact evaluation of the newly awarded 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, national and international stakeholders. The project proposes 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), as well as prevention and treatment for the rapid growth of TB/HIV co-infection. The project began in March 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 social support services to improve treatment adherence among those at high-risk 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 co-infected. Ukraine is one of several countries struggling with high treatment default rates and rising co-infection rates, and USAID is one of many donors testing and investigating strategies to help combat these problems.

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 ranks second highest as a WHO priority country in the European Region for TB control. In 2010, TB incidence, prevalence and mortality rates were 101, 132 and 19 per 100,000 population respectively.(1) Ukraine is among the 27 highest drug-resistant TB burden countries in the world. Sixteen percent of the newly detected TB cases and 44% of the previously-treated TB cases have multi-drug resistant TB, raising the number of new MDR-TB patients in need of treatment every year in the country to almost 8,000.(1) There are also documented cases of extremely drug-resistant tuberculosis but the rate is unknown.

The burden of TB-HIV co-infection is high (11/100,000) and is disproportionally concentrated among socially marginalized populations including injecting drug users, sex workers, and prison populations. According to UNAIDS, annual HIV diagnoses have doubled since 2001, making Ukraine the leader in adult HIV prevalence for Europe and Central Asia.(2) TB-HIV co-infection can substantially influence mortality; approximately 40% of AIDS deaths in Ukraine are associated with TB. In the project areas, an estimated 16.8% of newly diagnosed TB cases are co-infected with HIV and the mortality rate among the co-infected is approximately 7.7 %.(3) UNAIDS recommends immediate initiation of antiretroviral therapy for anyone co-infected, yet in Ukraine, less than half of the co-infected received treatment in 2011.(4)

In light of the epidemiologic landscape in Ukraine, USAID-supported projects have focused on expanding availability and improving 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 and case detection rates have increased to 73%, exceeding the minimum recommendations from WHO.(3) However, treatment success rates remain well below the 85% WHO recommendation, with 64.3% treated successfully in 2010 in the 10 project areas. Emerging MDR-TB and difficulty in treating TB/HIV co-infection 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 5 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 co-infection services, and improve infection control practices to provide a safer medical environment for workers. STbCU will be working with: i) health facilities and laboratories to improve screening, diagnosis, and referrals for appropriate treatment as well as improving infection control for the protection of their workers; ii) social support agencies to improve treatment adherence particularly among marginalized populations; and iii) the health systems to improve training, reporting and procurement.

The interventions of particular interest to this evaluation include:

- Home-visiting program for TB patients vulnerable to treatment default, implemented by the Ukraine 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: 7 oblasts (Dnipropetrovsk, Donetsk, Kharkiv, Kherson, Luhansk, Odessa and Zaporizhya); 2 cities (Kyiv and Sevastopol); and 1 autonomous republic (Republic of Crimea) (Figure 1)[1]. Within these 10 areas, PATH selected facilities to pilot and scale-up their interventions from 2007-2012. STbCU will inherit these same areas for interventions in Years 1-2; Year 3 will see expansion to two new oblasts to be determined. An external evaluation will inform the selection of the expansion oblasts with high-medium TB burden.

[1] As of June 2014 when data collection began, the STbCU program was no longer working in Autonomous Republic of Crimea and Sevastopol. Donetsk and Luhansk were also removed from the list of potential oblasts for study selection per USAID/Kiev.

Figure 1. Ukraine map of USAID-supported TB intervention targets

Targeting

The selection criteria for the 10 target areas was based on TB and HIV disease burden, availability of DOTS services, geographic location, concentration of vulnerable populations, NGO's operating in areas already, and desire of local government officials to participate.(3) Within these 10 areas, the operating assumption is that every TB and HIV facility will receive some baseline project intervention including some training, supplies and mentoring. Additional interventions will be tested and rolled out over the life of the project with select services targeted by area. For example, URCS is already offered in each of the 10 areas but expanded social support services will initially target Kherson and Zaporizhska oblasts. For TB/HIV integration, providers from all 10 target areas will receive some common training on screening, referral, diagnosis, and treatment for co-infected patients. Additionally, 4 oblasts will receive additional small grants for special TB/HIV integrated care programs. These will be awarded annually to look at different integration models.

An additional layer of targeting will be used to select program participants for the URCS social support program to increase treatment adherence. The 10 key target high-risk groups for this intervention include: alcoholics, IDUs, TB contacts, homeless, migrants, refugees, ex-prisoners, unemployed, persons with co-morbidities, and other identified as high risk by the health care provider. Risk screening is completed by the health care provider at time of discharge from inpatient treatment or at the start of continuation therapy. Those considered at high risk for

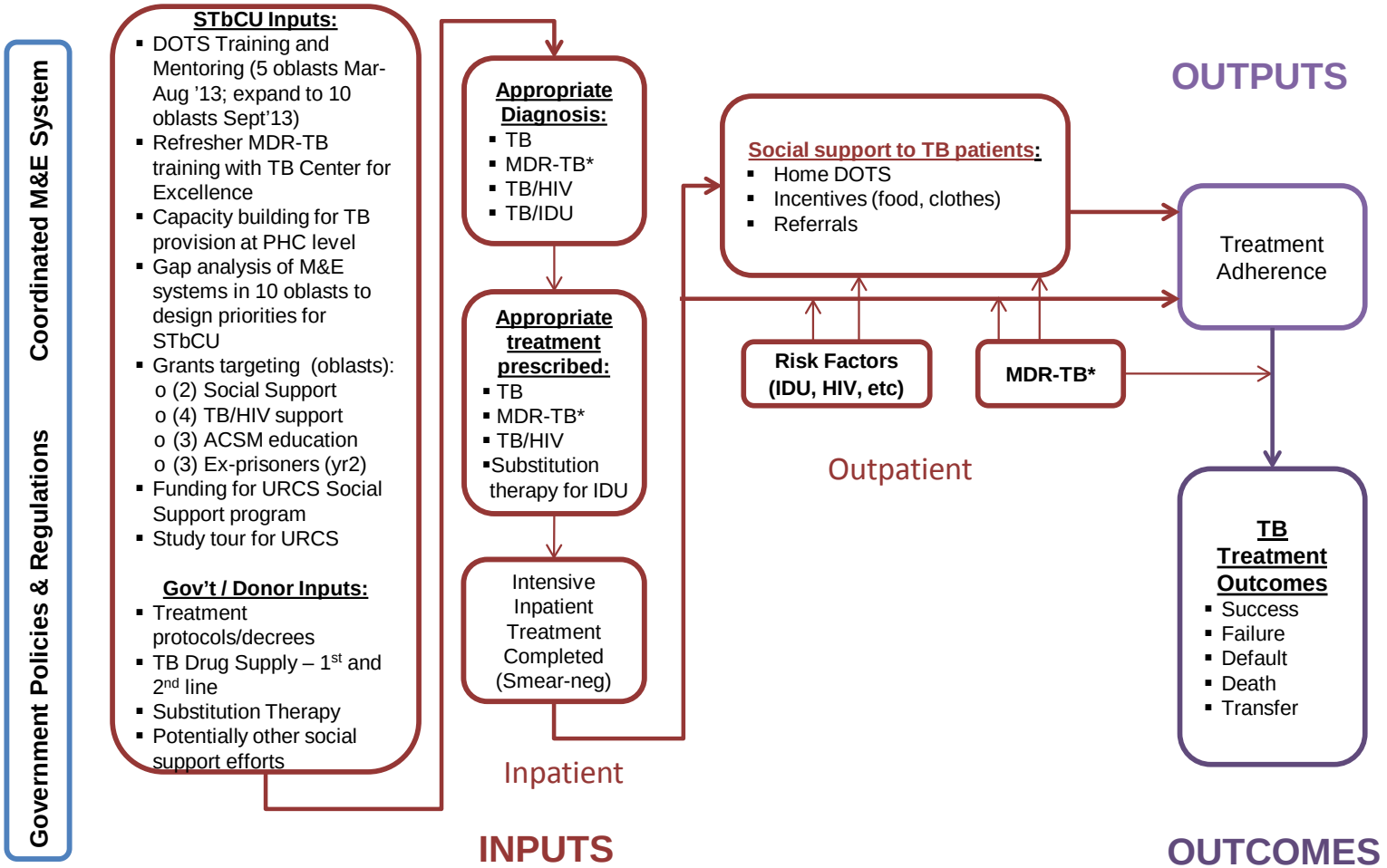
treatment default are eligible for social support provided by the outpatient facility responsible for their continued treatment. The underlying assumption is that refusal of social service support will be negligible.

Development Hypotheses

Figures 2 and 3 below illustrate the development hypotheses linking proposed interventions with anticipated outputs and outcomes. Figure 2 lists program inputs by STbCU, the government, and other donors that contribute to appropriate inpatient and outpatient treatment. The program input of primary interest is the outpatient URCS social support 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 high-risk 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 high-risk patients receiving social support compared to high-risk patients not receiving support. Secondary outcomes include treatment success versus treatment failure among those who adhere.

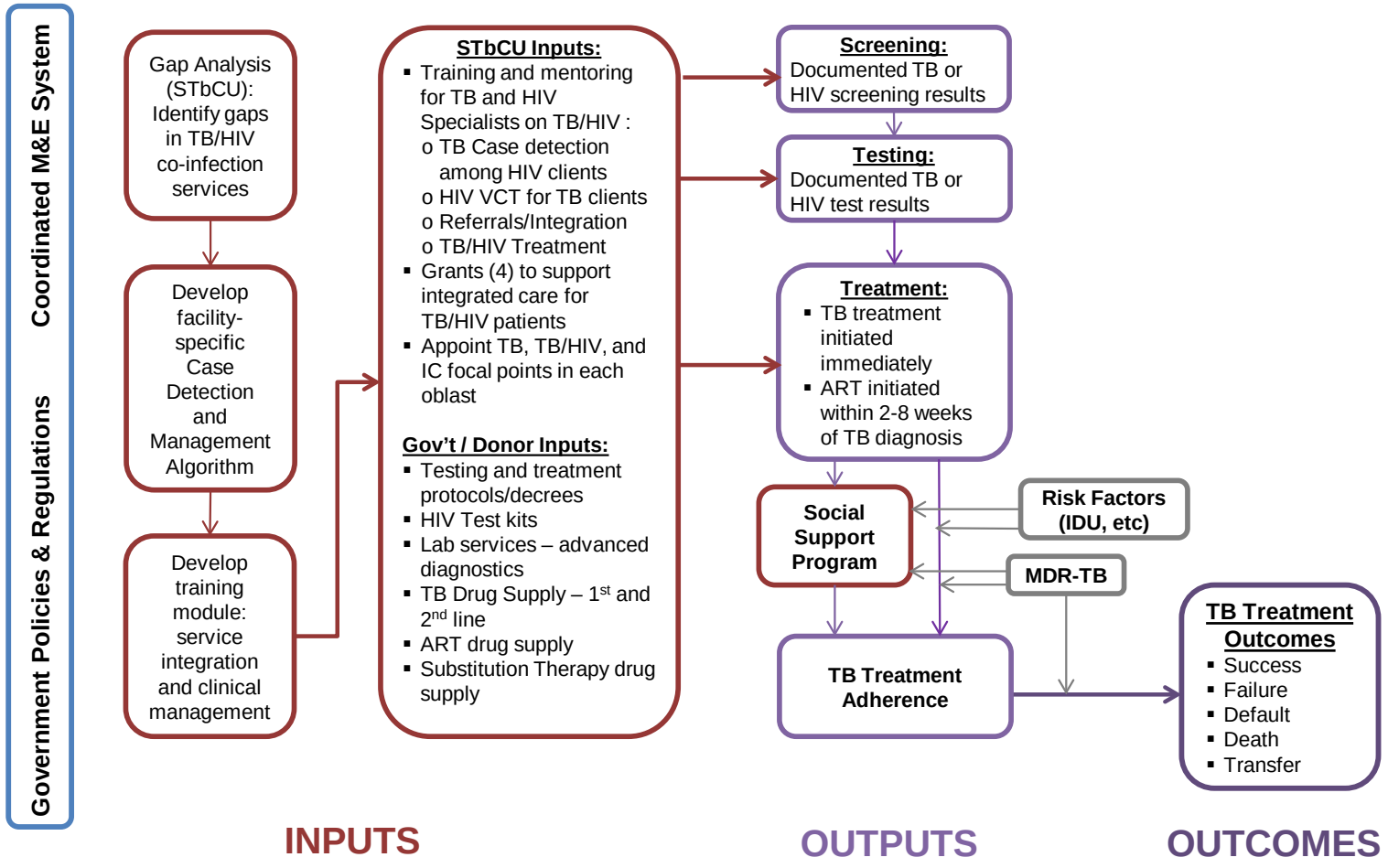
Figure 3 focuses on the collaboration between TB and HIV programs. Almost 17% of new TB cases are infected with HIV and 40% of the AIDS deaths are attributable to TB, yet the government services providing TB and HIV care remain vertical, with minimal collaboration across programs. STbCU, through policy 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 co-infected, antiretroviral therapy (ART) should be introduced during the primary 2-8 weeks of TB treatment in order to reduce mortality among the co-infected. The process outputs of interest include 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 2. 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 3. 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 social support; and ii) decline in mortality due to early diagnosis and early treatment among TB/HIV co-infected patients served by integrated programs. 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. During Phase 1, in 2014, data on testing, treatment, and outcome data will be collected retrospectively and analyzed to measure indicators at baseline. During Phase 2 in 2015-16, data from a prospective treatment cohort will be collected and analyzed to compare those participating and not participating in program interventions. To measure program impact, comparison groups will be identified to represent the counterfactual. For each priority area, evaluation questions, study design, and methods are detailed below.

Research Questions

Treatment Adherence

1.1 Does participation in a Social Support program affect the likelihood of TB treatment default, treatment success, or treatment failure among high-risk 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 Social Support program are most important to those receiving the program? What works best for ensuring adherence?

TB-HIV Integration

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 co-infected?

Quantitative Design

Research question 2.1 will be a descriptive quantitative analysis of proportion of TB and HIV/AIDS cases that complete the cascade of services per protocol. Questions 1.1, 2.3 and 2.4 will be evaluated quantitatively using survival analysis. In Phase 1, data will be abstracted from client records for a retrospective cohort to provide a baseline measure of key outcomes. In Phase 2, clients will be enrolled and tracked prospectively to provide a measure of the same key outcomes among those participating and not participating in the program interventions.

Counterfactual

For the impact evaluation, 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 social support and those who do not. Ideally one would measure two outcomes for each individual: the treatment outcome when the TB patient receives social support and the outcome when the same individual does not receive social support. As this scenario is impossible, the research 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 (Q1.1) is TB patients at high risk for treatment default during continuation treatment who receive social support services from URCS. The social support program was developed and piloted in 2010, a break in services occurred in 2011 for all sites, then activities resumed in 2012. A quasi-experimental design will sample from 2011 (no intervention) and 2012 (intervention) time periods, with both high-risk and low-risk patients sampled to allow for comparison to routine care for low-risk and high-risk patients. Five groups will be sampled: high-risk (HR) patients receiving the intervention in 2012 (the intervention group); high-risk (HR) patients not receiving the intervention in 2011; high-risk (HR) patients not receiving the intervention in 2012; low-risk (LR) patients not receiving the intervention in 2011; and low-risk (LR) patients not receiving the intervention in 2012. The inclusion of low-risk patients from both intervention and comparison periods will provide additional evidence of the adequacy of matching between these sites. For example, we hypothesize that low-risk patients in intervention and comparison periods will have similar treatment outcomes while the high-risk patients in both periods will have different outcomes based on the social support received. This scenario will strengthen confidence in the choice of comparison group.

The primary intervention population for the integrated TB/HIV services is co-infected patients receiving integrated TB/HIV services at a TB or HIV facility in the STbCU target areas. Sampling for the counterfactual will target oblasts not currently supported by USAID with similar HIV and

TB incidence rates and facilities providing TB and/or HIV testing and treatment services. For Phase 1 data collection will be retrospective for TB and HIV patients seen in 2012 in 3 intervention and 3 comparison oblasts. Intervention and comparison oblasts will be matched on TB and HIV epidemiology, plus similarities in health services and economy. Data for individual patient matching (propensity score matching techniques) are limited for the baseline data collection because of the limited socio-demographic data recorded in medical records. In Phase 2, patients will be enrolled prospectively with the opportunity to collect additional data that will prove useful for more refined matching.

Propensity score (PS) techniques provide one method of creating a counterfactual. The propensity score measures the probability of treatment assignment based on a set of observable variables or risk factors.(5) This method assumes that there are no unobservables confounding the relationship between the treatment and the outcome, rather confounding is assumed to be controlled by inclusion of the observable variables. To verify this assumption, the distribution of the covariates used to create the propensity score, conditional on the propensity score, should not vary statistically.(6) If variation in distribution is found, adjustments to the model are made.

Matching on propensity scores between participants in treatment and non-treatment groups allows one to narrow the comparison population to those who match best on observable characteristics; however, treatment cases without a good match in the comparison group will be dropped. An alternative is to use the scores to create a PS weight, the inverse probability of the PS for the treated and the inverse probability of (1-PS) for the non-treated. These weights are applied to all intervention/comparison patients in the full dataset for analysis. Additionally, using PS weights will allow estimation of the average treatment effect among the treated (ATT) and the average treatment effect among the untreated (ATU).(5, 7) Preliminary analysis of the data will determine which PS technique is the most appropriate to use.

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 lends itself to survival analysis. Basic survival analysis or time-to-event analysis includes censored data, cases for which data is incomplete or timing of an exit event is unknown.(8) 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 social support on duration of TB treatment, by type of exit event for different comparison groups.(8) 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: high-risk TB patients receiving social support in 2012; high-risk TB patients receiving routine care (no social support) in 2011 and 2012; and low-risk TB patients receiving routine care in 2011 and 2012.

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 and draw comparisons to the national diagnostic protocols (Q2.1). Next, discrete time hazard models will be run separately for each outcome in the service cascade and for intervention and comparison groups. These hazard models will be individually fit logit models with time included as a covariate, and will allow us to measure whether participants in the integration treatment groups received key services in a timelier manner compared to the comparison group (Q2.3). Among those co-infected who initiate TB treatment, a separate hazards model will model all-cause mortality events among the intervention and comparison groups (Q2.4).

Separate survival analyses will be completed for the Phase 1 and Phase 2 datasets. To compare outcome differences between the baseline and endline phases, interaction terms between the study phase and the intervention group, will be included to estimate the treatment effect above and beyond changes seen across time. Differential effects for men and women patients are not anticipated; hence sample size will not be powered on sex for Phase 1 data collection. Sex of study subject will be collected and stratified descriptive analyses will be conducted. If differential default patterns are noted for men and women in the baseline analysis, then sample size estimates for Phase 2 can be recalculated powered on sex.

Qualitative Design

Research questions 1.2, 1.3, and 2.2 will be qualitative, using patient and staff interviews supplemented with review of facility documentation and chart abstraction 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 effective for the intended audience. Patient interviewing will be completed in Phase 2 with the prospectively enrolled patient cohort.

To better understand the role of social support in treatment adherence, in-depth patient interviews will solicit information from high-risk patients regarding: i) primary barriers to treatment adherence; ii) aspects of the social support program which helped them stay on the treatment regimen; and iii) barriers that might be overcome if the social support program operated differently. Barriers to treatment adherence and the means of overcoming those barriers may differ by men and women. Interviewee sampling will be representative by sex.

For the TB/HIV integration interventions, the intent is to improve the timeliness of patient screening, testing and treatment initiation for those co-infected. Mapping the cascade of services will identify where patients are falling through the cracks. Patients who either drop out or have long delays along this continuum as well as some who successfully navigate these services will be interviewed further to understand the chain of events that either made it difficult or easy to access each service. Provider interviews will also add to our understanding of patient flow. For Q2.2, providers will be interviewed in both in Phase 1 and Phase 2. Again, sex of patient will be considered when selecting patient interviewees to provide insight into differences between men and women.

Evaluation Design Strengths and Limitations

The evaluation design draws on a mixed methods strategy to provide a comprehensive examination of two important strategies being implemented under the STbCU project. Survival analyses at baseline will quantify any pre-existing difference in outcomes across different risk groups. At end line, the survival analysis will produce estimates of the effect of the treatment among the treated at the endpoint, as well as survival curves for comparison across risk groups and time. Including multiple comparison groups over time will reinforce our ability to draw conclusions. The in-depth interviews of patients and providers will address research questions that explore why different interventions did or did not work.

There are a few potential limitations to note. The changing political climate in Ukraine has removed some of the USAID-target areas from consideration for this study, notably Autonomous Republic of Crimea, Sevastopol, Donetsk and Luhansk. Selection of sites has been adjusted accordingly. Another sampling concern is the loss of comparison areas if STbCU

expands beyond the original 10 target areas. For the Social Support study, this is not an issue because we only sampled from current STbCU target areas, and instead rely on retrospective data collection to create our intervention and comparison groups. By endline, it is expected that all of the Social Support study sites will be providing URCS social support. For the TB/HIV Integration study, this is a potential problem as STbCU may expand to the intervention areas. However, it is anticipated that either STbCU or another project will promote integration across Ukraine, so maintaining an intervention-free area is unrealistic. At this point, the best option is to collect the retrospective baseline data from designated intervention and comparison oblasts. For the prospective data collection in 2015/16, additional socio-demographic data will be collected from patients that might allow PSM to construct a valid counterfactual from any of the sites that do not implement direct integration work funded by USAID.

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 or on strategies that intervention and comparison sites might have employed to offset these shortages. Additional data will be collected on drug shortages and any major factors identified that could affect the outcomes of the analyses so that they can be controlled for in the analysis.

Finally, verification of treatment adherence will strengthen the plausibility of the findings. The protocol options for verification will depend on the intensity of the home-visiting program for the Phase 2 prospective study. If patients are visited weekly or monthly, then one option will be spot checking patient adherence with an unannounced home urine screen. If patients are visited daily, then confirmation of daily nurse visits through GPS phone tracking may be an option. Each of these verification activities carries budget and IRB/ethics implications.

Sampling

Social Support Study

The target population for the social support evaluation is TB outpatients. The sampling will be stratified at three levels, year, oblast, and risk group. For Phase 1 retrospective data collection will include patients initiating TB outpatient treatment between January-May 2011 and January-May 2012 in these oblasts. During Phase 2, TB patients will be enrolled consecutively until quotas are met. The selection of the non-intervention comparison patients will be driven by the HR intervention sample. For each HR intervention patient from 2012, a HR non-intervention patient and a LR non-intervention patient from 2012 will be selected based on date of treatment initiation, sex and age. Additionally a HR non-intervention and LR non-intervention patient from 2011 will also be selected from the same facility yet seen 1 year earlier when no URCS services were offered (Table 1).

Table 1. Sample Size Estimates for Social Support Study

	Dniprop	**Kharkiv**	**Odessa**	**Totals**
2012 HR Intervention (URCS)	230	100	115	445
2012 HR Non-Intervention	230	100	115	445
2012 LR Non-Intervention	230	100	115	445
2012 Sub-Total:	690	300	345	1335
2011 HR Non-Intervention	230	100	115	445
2011 LR Non-Intervention	230	100	115	445
2011 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 Default = 9%, LR Default=4%, Censoring=18%

Notes: Estimated with Stata SE 12, Stata Corp. (College Station, TX), *stpower logrank* command. Powered on assumption that primary effect will be due to intervention, hence comparison group will not see measurable change in rates.

TB/HIV Integration Study

The target populations for the integration study are TB patients, HIV patients, and co-infected TB/HIV patients seen in 6 oblasts during 2012 for Phase 1.

Two questions motivate the sampling for the integration study.

1. To measure the change in Testing from 2012 to 2016 between intervention and comparison populations seen at either TB or HIV/AIDS facilities.

2. To measure the change in Timing of ARV Initiation from 2012 to 2016 between intervention and comparison populations seen at either TB or HIV/AIDS facilities.

For question 1, Sample 1 (S1=1460) is selected from TB and HIV/AIDS facilities. For question 2, an additional oversample of co-infected patients (Sample 2 (S2=1040)) will be selected from TB and HIV/AIDS facilities. To calculate the sample sizes needed for S2, we assumed that 20% of TB+ clients are co-infected and 60% of HIV+ clients are co-infected; we also will supplement the S2 sample with the co-infected identified in S1. Phase 1 chart abstraction will cover a set 12 month period and Phase 2 subject enrollment will be prospective until quota is met. Time period for data collection is dependent on number of patients seen per facility. (Table 2)

Table 2. Sample Size Estimates for TB/HIV Integration Study

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

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

Sampling in Phase 2 for the qualitative study will target intervention sites only. Approximately 30 patients and 10 providers will be interviewed for the TB Adherence work (Q1.2, 1.3). These patients will be purposively selected from a mix of urban and rural treatment facilities, with attention to a balanced sample of men/women, and risk groups. For the TB/HIV integration, approximately 5-10 provider interviews and 10-20 patient interviews will be conducted. Selection for these will be purposive with attention to sex, age, and initial disease diagnosis.

Data Requirements, Collection and Security

Data required for the evaluation will be collected retrospectively in 2014 and prospectively in 2015-16 and include individual, program and facility data. The unit of analysis will be the individual for measurement of treatment adherence and treatment outcome. Data collection includes:

Individual Data: diagnosis and treatment, program participation (include participants, eligible not participating, eligible not offered), confounding health factors (IDU, alcohol use, smoking, HIV, diabetes), socio-demographics (age, gender, education, and employment). In Phase 1 data will be limited to what is available in the medical records; Phase 2 will expand to include patient survey data as well.

Program Data: frequency and intensity of program intervention (what was received, how often, by whom); start date of program and enrollment date for individuals (Phase 2 only).

Facility Data: implementation details of DOTS strategy, type of facility, availability of services (Tb, HIV, narcology, primary care, etc), referral mechanisms, stock-outs, other TB or HIV interventions (Phase 1 and 2).

Data Collection

Data sources and collection methods vary by phase and study design (Figure 4). For Phase 1, 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.

During Phase 2, patient medical record data will be abstracted and facility surveys will again collect information on services, volume, and externalities. In addition, as patients are enrolled prospectively into treatment, an intake survey of patient socio-demographics will be completed. Routine program monitoring data from the social support program will also supplement client and facility data. For the qualitative data collection, instruments will be developed to solicit information during one-on-one in-depth interviews with patients and providers. Interviews will be conducted throughout the Phase 2 study period to maximize potential of reaching patients as they complete treatment.

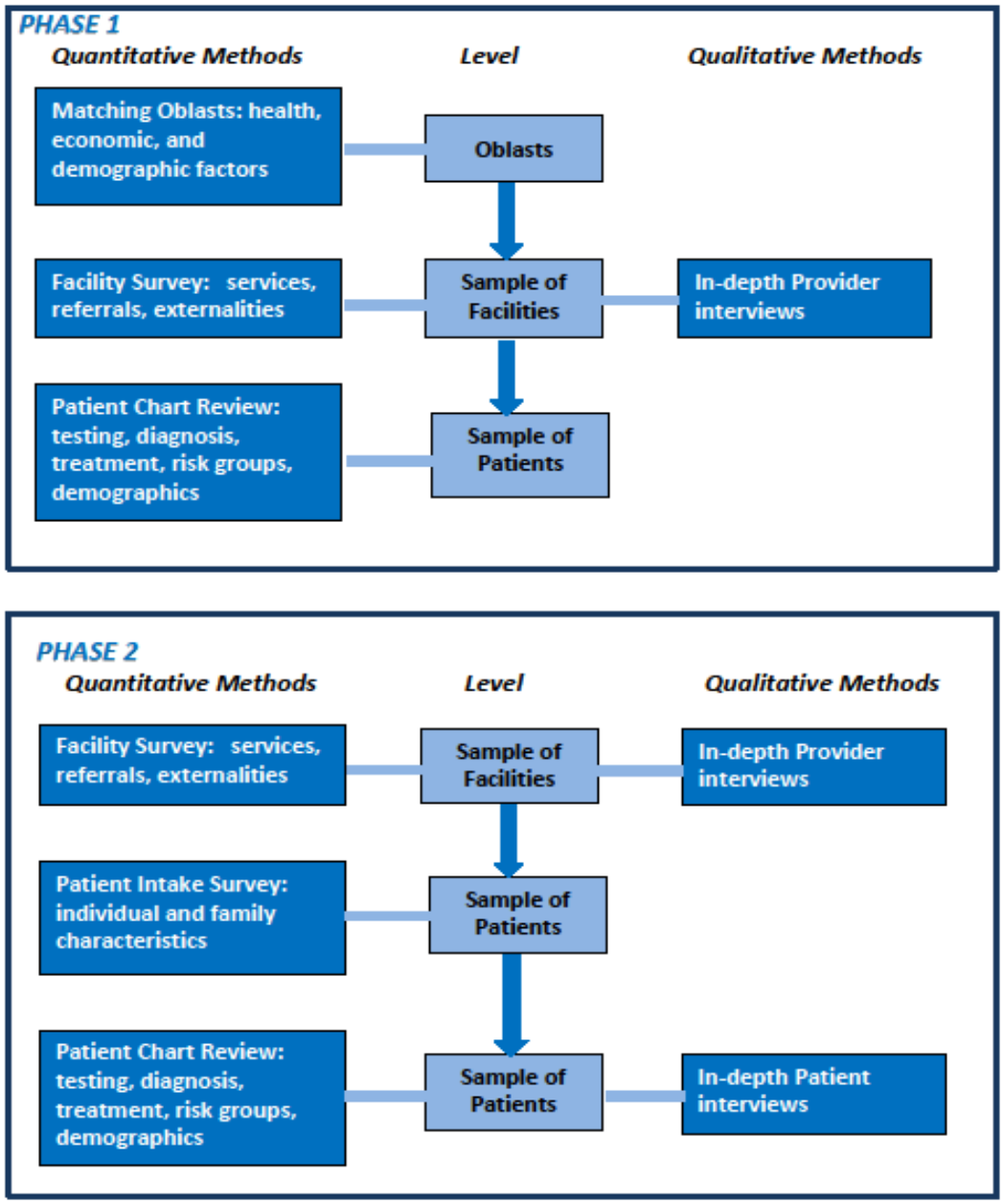


Figure 4. Data Collection Schema

Protection of Human Subjects

Human subjects review of the complete study protocol and data collection instruments from UNC-Chapel Hill Institutional Review Board and the most appropriate review board in the Ukraine will be obtained prior to data collection. For all interviews, written 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/or routine health information systems will be encrypted by data extractor and sent via secure data link to MEASURE Evaluation. Data collected via patient survey will be translated, encrypted and sent via secure data link to MEASURE Evaluation. All original data collection instruments and data will be sent to MEASURE Evaluation or destroyed by sub-contractor. The data subcontractor contract will specify data security requirements per the UNC data security policies and IRB requirements. A Memorandums of Understanding (MOU) between the subcontractor and MEASURE Evaluation project will detail the data sharing agreement between respective parties. Lastly, 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 Figure 4.

MEASURE Evaluation will submit the following deliverables to USAID:

1) Impact evaluation protocol for review and approval.
2) Final baseline report from Phase 1 study
3) Dissemination and data use workshop and report summarizing feedback and recommendations provided by workshop participants/stakeholders for Phase 1. [*Note: not in 2014, may be rescheduled for 2015*]
4) Final impact evaluation report with a synthesis of quantitative and qualitative findings. This report will follow the guidance specified in the USAID Evaluation Policy, *Appendix 1: Criteria to Ensure the Quality of the Evaluation Report*.(9)
5) Dissemination and data use workshop and report summarizing feedback and recommendations provided by workshop participants/stakeholders for Phase 2.

Following review and validation of the baseline report by all relevant stakeholders, MEASURE Evaluation will hold a workshop to disseminate and facilitate use of the baseline 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 involve sessions to solicit recommendations from stakeholders and potential steps for taking action in TB and TB/HIV policy and programming based on the evaluation. A similar workshop will be designed for dissemination of the final Phase 2 findings.

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 M&E, (3) quantitative and qualitative methodologies; and (3) data analysis and use. Key personnel for this SOW 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 reproductive health, HIV/AIDS, and tuberculosis programs. Her technical areas of expertise are monitoring and evaluation of health programs and building capacity of local organizations and individuals in the areas of tuberculosis, HIV/AIDS and reproductive health. She has provided technical assistance on monitoring and evaluation, data collection and analysis in the 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 monitoring and evaluation of HIV/AIDS and tuberculosis programs in collaboration with local training institutions with support from USAID, CDC, UNAIDS, and WHO. She has supervised a multi-country initiative to develop an M&E strategy for global tuberculosis programs with STOP TB partners in Southeast Asia, Latin America, Eastern Europe and Africa. Dr. Mullen has both quantitative and qualitative evaluation experience.

Martha Skiles, PhD., *Evaluation Specialist*
MEASURE Evaluation, Carolina Population Center, UNC

Martha Priedeman Skiles is a Postdoctoral Research Associate at the Carolina Population Center and has been working in international and domestic public health for the past 16 years. She has a PhD in Maternal and Child Health from the University of North Carolina at Chapel Hill and an MPH in Population and Family Health from the University of California at Los Angeles. Her primary research interests focus on impact evaluations for maternal and child health programs. This builds on previous work in program evaluation, surveillance and management in health system financing, immunizations, family planning, HIV/AIDS and STI prevention. Her current projects include an impact evaluation for an integrated agriculture

and nutrition project in Malawi, and linking contraceptive facility supply data with population-based outcome data in order to explore patterns of distribution and use, and determine the potential for predicting the contraceptive prevalence rate.

Nicole Judice, *Data Use Specialist*
MEASURE Evaluation, Futures Group International

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 areas such as policy, data use, strategic planning, M&E and strategic information (SI), individual and organizational capacity development, and costing. Currently, Ms. Judice is Data Demand and Use Specialist on MEASURE Evaluation and Senior Policy Advisor to the Health Policy Project Kenya country program. She recently led a team to conduct a HIV policy assessment in Ukraine, and has designed and conducted several studies in Ukraine and Russia, including a costing study of reproductive health interventions, study on the efficiency of use of health sector resources, tested approaches to preventing congenital syphilis, and conducted a situational analysis of the use of naltrexone to reduce opiate dependence. Ms. Judice is a proficient Russian speaker.

Siân Curtis, PhD., *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 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 (DHS) project. Dr. Curtis was awarded her PhD in Social Statistics and M.Sc. in Statistics with Applications in Medicine from the University of Southampton, U.K. Her research focuses on monitoring and evaluation 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 MCH 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. She is currently a member of the Board of the Routine Health Information Network (RHINO).

The Evaluation Team expects to contract local expertise for study coordination and data collection. Ideally we would like to identify a Ukrainian co-investigator or at minimum a consultant and/or a company with detailed knowledge of Ukraine's public health sector, TB and HIV/AIDS implementation, relevant governmental and non-governmental institutions and experience in conducting evaluations including data collection, cleaning, and analysis.

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. Ongoing dialogue is anticipated during the implementation of the study to ensure that USAID/Ukraine staff and fully informed throughout the process.

Implementing Partners such as the Ukraine Red Cross Society and Chemonics International will be consulted to inform the evaluation design in terms of how and where the social support and TB/HIV integration programs will be 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 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 co-infected patients through their routine data collection systems.

The evaluation, including data collection and analysis, will be conducted by MEASURE Evaluation staff and by a local consultant and/or organization who is not directly involved in the implementation of TB programs in Ukraine to minimize any biases.

Timeline

Figure 5 details the proposed timeline for study design, retrospective data collection, analysis, and report writing for Phase 1 findings. Figure 6 details the timeline required for prospective data collection in Phase 2. Per WHO TB cohort methodology, TB treatment outcomes for a

cohort are typically measured 12 months after enrollment and a 9-12 month enrollment period is anticipated to reach sample size estimates. For the qualitative study, the implementation time is approximately 9 months, depending on rate of subject enrollment. It is included in the calendar but note the timing of this activity is negotiable depending on when the stakeholders would like the information and depending on the schedule of the qualitative researchers.

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Figure 5. Activity Implementation Timeline for Phase 1

Tasks/Timeline	'12	2013												2014											
	Fall	Ja	Fe	Ma	Ap	Ma	Ju	Ju	Au	Se	Oc	No	De	Ja	Fe	Ma	Ap	Ma	Ju	Ju	Au	Se	Oc	No	De
Evaluation Planning																									
Literature Review																									
Trip: Protocol Development																									
Finalize research questions																									
Develop IE protocol/SOW: Indicators, design, comparison																									
Sub-contract local researchers																									
Trip: Finalize Study Design																									
Seek oblast/facility permission																									
IRB application UNC / Ukraine																									
Quantitative Evaluation																									
Define sampling plan for treatment / comparison																									
Evaluate facility data quality																									
Draft study instruments																									
Pretest instruments																									
Finalize instruments, consent, and data collection plan																									
Train data collectors, study coords																									
Trip: Train and Data Collection																									
Collect data – chart abstraction																									
Process and analyze data																									
Draft baseline report																									
Review by stakeholders and revise																									
Trip: Dissemination/Data Use Workshop																									

Figure 6. Activity Implementation Timeline for Phase 2

Tasks/Timeline	'14	2015												2016												2017							
	Fall	Ja	Fe	Ma	Ap	Ma	Ju	Ju	Au	Se	Oc	No	De	Ja	Fe	Ma	Ap	Ma	Ju	Ju	Au	Se	Oc	No	De	Ja	Fe	Ma	Ap	Ma	Ju	Ju	Au
Sub-contract local researchers																																	
IRB application UNC / Ukraine																																	
Quantitative Evaluation Plan																																	
Define sampling plan for treatment / comparisons																																	
Evaluate facility data quality																																	
Train data collectors and study coordinators																																	
Enroll subjects and complete enrollment survey																																	
Collect data – chart abstraction																																	
Process and analyze data																																	
Draft preliminary report																																	
Qualitative Study – timeline for qualitative study could shift per schedule of subcontractor or interest of stakeholders																																	
Define sampling plan																																	
Draft study instruments																																	
Pretest and finalize instruments																																	
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																																	
Revise and publish																																	
Trip: Dissemination/Data Use Workshop																																	

TB Data Abstraction Form – Social Support Study

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

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

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

B. Patient Identification

B1. Patient Name	B2. Patient Record Number:	B3. Study Cohort:
Surname:_____	☐☐☐☐☐	**2012** / **2011**
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:
☐☐ - ☐☐ - ☐☐	☐☐ *[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

C. TB Case Initiation

C1. TB detected due to:	C2. Date of Emergence of first symptoms:	C3. Date of First TB visit:
Own initiative……1 Occupational screening……2	☐☐ – ☐☐ – ☐☐	☐☐ – ☐☐ – ☐☐
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 smear *(DD-MM-YY)*	D2. Date of first culture *(DD-MM-YY)*	D3. Date of first x-ray *(DD-MM-YY)*

D4. Diagnosis: Type of case

First Diagnosis ……..1
Re-initiation following interruption……..2
Treatment failure ……..3
Relapse……4
Referred from: _____.....5
Other: _____.....6

D5. Diagnosis: Clinical form

D5.1 Lung……..1
D5.3 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 whether it was observed within 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	

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 whether it was observed within 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: Cured……1 Treatment complete……2 Died from TB……3 Died (non-TB cause)……4 Treatment failed - smear/culture……5 Treatment failed – xray/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 Injection Drug User ……..3
H1.4 Contact with a case……..4
H1.5 Co-morbidities ……..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

	(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 Co-Morbidities List**:

_____

_____

_____

H2. Received Social Support during continuation treatment?

Yes from 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>*

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

SOCIAL SUPPORT FACILITY SURVEY

CONSENT FORM: TB FACILITY SURVEY

Thank you for the opportunity to speak with you. My name is _____ from IFAK. We are conducting a study to learn about public health Tuberculosis services in Ukraine. We are working with the MEASURE Evaluation project, implemented by the University of North Carolina, and funded by United States Agency for International Development (USAID). We have received ethics approval to conduct this work from the F.H. Yanovskyi Institute of Phthisiology and Pulmonology under Academy of Medical Sciences of Ukraine

Your facility was selected to participate in this study. We will be asking you several questions about the types of services and procedures followed in your facility for TB patients. The survey will last approximately 20-30 minutes.

The information you provide us may be used by the USAID, the Ministry of Health, other organizations or researchers, for planning service improvements or further studies of services. Neither your name nor that of any other health worker respondents assisting us will be included in the dataset or in any report. The analysis will use only the aggregated data regarding all of the facilities of certain regions of Ukraine. We are asking for your help to ensure that the information we collect is accurate.

You may refuse to answer any question or choose to stop the interview at any time. However, we hope you will collaborate with the study.

Do you have any questions about the interview or what I have said?

Before we can continue I need to have your verbal consent:

- ☐ To participate in this interview; YES NO (circle answer)
- ☐ To participate in this interview; YES NO (circle answer)
  <ONLY if need to obtain information from a 2nd respondent>

Signature (of interviewer): _____

Facility: _____

Date: _____

If in the future you have any questions regarding the interview, or concerns or complaints we welcome you to contact < IFAK >, by calling [044 234 96 41] or email [info@ifak.com.ua]. We will leave one copy of this form for you so that you will have record of this contact information and about the study.

FACILITY SURVEY: TB Outpatient Services

A. Facility Identification			
A1. Today's Date: (DD-MM-YY) ☐☐ - ☐☐ - ☐☐	A2. Oblast ☐☐	A3. Raion ☐☐	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 People who Live with HIV (PLH) organization……5 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, xray, 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
IDU Substitution Drug 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
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 co-infected 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 2011	
B4.4. Between January – May 2012	
B4.5. Between January – December 2012	

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 2012 and in 2011. For each question, consider current and previous services and referrals.	(a) Currently	(b) During Jan-May 2012	(c) During Jan-May 2011	(d) None of these times
C1. Does this facility refer patients for social support during outpatient care: *<skip to section D if no social support referrals>*	1	1	1	1
C2. *W*hat organization [provides/provided] social support? *<note service provider code: URCS……..1* *PLH……..2* *UA Government……3* *Other <record name>….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 2012	(c) Offered Jan-May 2011	(d) None of these times
C5. Home Visits: *<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 2012, in Jan-May 2011 or not used.	(a) Is this criteria currently used	(b) Was criteria used in 2012	(c) Was criteria used in 2011	(d) Criteria not used
a. HIV-positive patient	1	1	1	1
b. Alcoholic	1	1	1	1
c. Injection drug user	1	1	1	1
d. Contact with a case	1	1	1	1
e. Co-morbidity: _____	1	1	1	1
f. Homeless	1	1	1	1
g. Unemployed	1	1	1	1
h. Health Care Worker	1	1	1	1
i. Migrant	1	1	1	1
j. Refugee / Immigrant	1	1	1	1
k. Ex-prisoner	1	1	1	1
l. Low income: less than _____ Hrv/Month	1	1	1	1
m. Other _____	1	1	1	1
C13. What is the minimum number of criteria a client needs to meet in order to be given a referral? <*record number*>				
C14. Is there a specific criterion that must be met in order 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. Are any other factors considered or procedures followed when deciding whether a patient should be referred for social support services? Please explain.

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

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

D. Drug Shortages

D1. Did this facility experience any drug shortages lasting more than 30 days in 2012 or 2011? This includes a situation where the number of patients eligible for treatment exceeds the drug supply.

<circle all that apply>	*2012*	*2011*	*Neither 2011/2012*
D1.1 TB continuation treatment……	1	2	0
D1.2 IDU substitution therapy ……	1	2	0
D1.3 Anti-retroviral therapy ……	1	2	0

< if yes to any of the above, then complete drug shortage table> <if no "0" then END SURVEY>

D2. IF this facility experienced <u>TB drug supply shortages</u> that lasted longer than 30 days in 2012 and/or 2011, then please check the months with shortages and complete the table.

YEAR: 2012 Drug shortage >30 days	**Months suffering from shortages**												**Consequence of Drug Shortage**	
	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 Other														
YEAR: 2011 Drug shortage >30 days	**Months suffering from shortages**												**Consequence of Drug Shortage**	
	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 Other														

Coding for Consequence of shortage:

Waitlisted patient……1
Switched treatment drugs ……2
Stopped treatment……3
Referred patient to another facility ……4
Other……5

D3. IF this facility experienced IDU Substitution Therapy supply shortages that lasted longer than 30 days in 2012 and/or 2011, check the months with shortages and complete table.

YEAR: 2012 **Drug shortage >30 days**	**Months suffering from shortages**												**Consequence of Drug Shortage**	
	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: 2011 **Drug shortage >30 days**	**Months suffering from shortages**												**Consequence of Drug Shortage**	
	J	F	M	A	M	J	J	A	S	O	N	D	<*Code*>	Other: describe
Substitution Drug 1														
Substitution Drug 2														
Substitution Drug 3														

D4. IF this facility experienced ARV drug supply shortages that lasted longer than 30 days in 2012 and/or 2011 or if a lack of ARV drugs limited the initiation of therapy during 2012, then check the months with shortages and complete the table.

YEAR: 2012 **Drug limitations**	**Months suffering from limitations**												**Consequence of Drug Limitation**	
	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: 2011 **Drug limitations**	**Months suffering from limitations**												**Consequence of Drug Limitation**	
	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
Other……5

CONSENT FORM: URCS SURVEY

Thank you for the opportunity to speak with you. My name is _____ from IFAK. We are conducting a study to learn about public health Tuberculosis services in Ukraine. We are working with the MEASURE Evaluation project, implemented by the University of North Carolina, and funded by United States Agency for International Development (USAID). We have received ethics approval to conduct this work from the F.H. Yanovskyi Institute of Phthisiology and Pulmonology under Academy of Medical Sciences of Ukraine

We will be asking you several questions about the types of services and procedures provided by your staff for TB patients. The survey will last approximately 20-30 minutes.

The information you provide us may be used by the USAID, the Ministry of Health, other organizations or researchers, for planning service improvements or further studies of services. Neither your name nor that of any other health worker respondents assisting us will be included in the dataset or in any report. The analysis will use only the aggregated data regarding all of the facilities of certain regions of Ukraine. We are asking for your help to ensure that the information we collect is accurate.

You may refuse to answer any question or choose to stop the interview at any time. However, we hope you will collaborate with the study.

Do you have any questions about the interview or what I have said?

Before we can continue I need to have your verbal consent:

- ☐ To participate in this interview; YES NO (circle answer)
- ☐ To participate in this interview; YES NO (circle answer)
  <ONLY if need to obtain information from a 2nd respondent>

Signature (of interviewer): _____

Facility: _____

Date: _____

If in the future you have any questions regarding the interview, or concerns or complaints we welcome you to contact < IFAK >, by calling [044 234 96 41] or email [info@ifak.com.ua]. We will leave one copy of this form for you so that you will have record of this contact information and about the study.

URCS Social Support Services

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

A5. [*START INTERVIEW*] I will read a list of services that might be offered by 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

B. TB Services in Oblast

B1. Number of staff providing TB services:	B1.1. Administrative	☐☐
	B1.2. 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……6	Not provided……6
Don't know……8	Don't know……8

C. 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 2012	(c) Offered Jan-May 2011	(d) None of these times
C1. Home Visits: *<list frequency code:* *Not offered ……0* *Twice Monthly……3* *Daily……1* *Once Monthly……4* *Weekly……2* Other *<record>……*6				
C2. Food Packages *<Average per patient >*				
C3. Clothing or Hygiene Kits *< Average per patient >*				
C4. Transportation Vouchers *< Average per patient >*				
C5. Counseling and/or assistance with social benefits *< Average per patient >*				
C6. Cash upon completion *<UAH amount per patient >*				
C7. Other _____				
C8. 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*				

C9. 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
Raion TB Doctor 3	URCS 7
Raion TB Nurse 4	Other (specify)_____8

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

C10. 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 2012, in Jan-May 2011 or not used.	(a) Is this criteria currently used	(b) Was criteria used in 2012	(c) Was criteria used in 2011	(d) Criteria not used
a. HIV-positive patient	1	1	1	1
b. Alcoholic	1	1	1	1
c. Injection drug user	1	1	1	1
d. Contact with a case	1	1	1	1
e. Co-morbidity: _____	1	1	1	1
f. Homeless	1	1	1	1
g. Unemployed	1	1	1	1
h. Health Care Worker	1	1	1	1
i. Migrant	1	1	1	1
j. Refugee / Immigrant	1	1	1	1
k. Ex-prisoner	1	1	1	1
l. Low income: less than _____ Hrv/Month	1	1	1	1
m. Other _____	1	1	1	1
C11. What is the minimum number of criteria a client needs to meet in order to be given a referral? <*record number*>				
C12. Is there a specific criterion that must be met in order to receive a referral? If yes, which criterion? <*note the letter from above corresponding to the criterion or write-in other criterion used*>				
C13. 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*>				
C14. Are any other factors considered or procedures followed when deciding whether a patient should be referred for social support services? Please explain.				

D. Drug Shortages

D1. Did this facility experience any drug shortages lasting more than 30 days in 2012 or 2011?

<circle all that apply>	*2012*	*2011*	*Neither 2011/2012*
D1.1 TB continuation treatment……	1	2	0

< if yes to any of the above, then complete drug shortage table> <if no "0" then END SURVEY>

D2. IF this facility experienced <u>TB drug supply shortages</u> that lasted longer than 30 days in 2012 and/or 2011, then please check the months with shortages and complete the table.

YEAR: 2012 **Drug shortage >30 days**	**Months suffering from shortages**												**Consequence of Drug Shortage**	
	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 Other														
YEAR: 2011 **Drug shortage >30 days**	**Months suffering from shortages**												**Consequence of Drug Shortage**	
	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 Other														

Coding for Consequence of shortage:

Waitlisted patient……1
Switched treatment drugs ……2
Stopped treatment……3
Referred patient to another facility ……4
Other……5

HIV DATA ABSTRACTION FORM – Integration Study

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

A. Facility Identification

A1. Today's Date: *(DD-MM-YY)*	A2. Data Collector ID:	A3. Rayon
☐☐ - ☐☐ - ☐☐	☐☐☐	☐☐
A4. Oblast ☐☐	A5. Facility Name: _____	

B. Patient Identification

B1. Patient's Code:

PLEASE, INSERT THREE FIRST LETTERS OF PATIENTS SURNAME, INITIALS AND DATE OF BIRTH

☐☐☐☐☐☐☐☐☐☐☐

B2. Sex:	B3. Date of Birth:	B4. Age (years)	B5. Residence:
Male……1 Female……2	☐☐ – ☐☐ – ☐☐ *DD - MM - YY*	☐☐ *<if <18 years END SURVEY>*	Urban……1 Rural……2

B6. Employment:

Employed……1	Retired……3	Housewife……6
Unemployed……2	Person with Disabilities…..4	Other _____7
	Student……5	Information not available……9

C. HIV Registration and Testing [HIV Control Card]

C1. HIV Registration Date	C2. HIV Date of Diagnosis	C3. Date of Most Recent Visit
☐☐ – ☐☐ – ☐☐	☐☐ – ☐☐ – ☐☐	☐☐ – ☐☐ – ☐☐

C4. Prescription ARV? (record first date)	C5. Patient Referred? Record Date of Referral
☐☐ – ☐☐ – ☐☐	☐☐ – ☐☐ – ☐☐ C5.1 Referral Facility:_____
C6. Patient stopped coming? Record Last Visit Date:	C7. Deceased? Record Date of Death:
☐☐ – ☐☐ – ☐☐	☐☐ – ☐☐ – ☐☐

D. Health Status and HIV Treatment [HIV Control Card]

REVIEW ALL PATIENT VISITS BETWEEN JANUARY AND DECEMBER 2012. STARTING IN **DECEMBER AND WORKING BACKWARDS**, COMPLETE TABLE INFORMATION FOR UP TO 4 VISITS DURING PERIOD. IF MORE THAN 4 VISITS, SELECT THOSE VISITS WITH DATA ON ARV OR OTHER HEALTH STATUS (TB, PREGNANT, IDU, ETC).

Visit Date	Clinical Stage	CD4 Count (absolute)	Viral Load (copies/ml)	ARV (Yes / No)	Pregnant (Yes / No)	Adherence (B, H) Reasons (1-11)	Functional Status (P, A, L)	IDU (C1-C5)	TB (T1-T7)	Viral Hepatitis (H1-H14)
D1. Visit Date ☐☐ – ☐☐ – ☐☐										
D2. Visit Date ☐☐ – ☐☐ – ☐☐										
D3. Visit Date ☐☐ ☐☐ – ☐☐										
D4. Visit Date ☐☐ – ☐☐ – ☐☐										

D5. Notes: include here if patient is receiving CPT or IPT treatment and date initiated

E. TB Screening and Referral [HIV Control Card, TB09, medical record]	
ASK ABOUT AVAILABILITY OF EACH SERVICE. IF OFFERED AND/OR PROVIDED, THEN RECORD THE DATE WHEN SERVICE INITIATED.	IF YES: Date Initiated (DD-MM-YY)
E1. Was patient <u>screened</u> for TB symptoms (e.g., asked about cough, fever, night sweats, weight loss) at this facility? Yes, screening provided……1 <*complete date*> No……0	☐☐ – ☐☐ – ☐☐
E2. Did patient undergo any additional TB diagnostic testing? Yes……1 No ……0 <*END SURVEY*> Don't know……9 <*END SURVEY*>	

EVALUATING A SUSPECT TB CASE MAY INCLUDE MULTIPLE TESTS TO ESTABLISH A DIAGNOSIS. FOR EACH OF THE FOLLOWING, NOTE IF THE TEST OR EXAM WAS PERFORMED AND THE DATE INITIATED.

TEST:	(a) Where evaluated	(b) Date of evaluation or referral
E2. Sputum microscopy	This facility……1 Referred to TB Facility……2 Previously at other facility ……3 Service was not provided……0	☐☐ – ☐☐ – ☐☐
E3. Culture	This facility……1 Referred to TB Facility……2 Previously at other facility ……3 Service was not provided……0	☐☐ – ☐☐ – ☐☐
E4. X-ray	This facility……1 Referred to TB Facility……2 Previously at other facility ……3 Service was not provided……0	☐☐ – ☐☐ – ☐☐
E5. Clinical Evaluation	This facility……1 Referred to TB Facility……2 Previously at other facility ……3 Service was not provided……0	☐☐ – ☐☐ – ☐☐
E6. Other _____	This facility……1 Referred to TB Facility……2 Previously at other facility ……3 Service was not provided……0	☐☐ – ☐☐ – ☐☐

E8. Diagnostic evaluation concluded patient is:
Confirmed TB Case……..1
TB ruled-out……..2 <*END SURVEY*>
TB status unknown……..9

IF TB DIAGNOSIS RULED-OUT ……..<END SURVEY >

IF TB CONFIRMED OR UNKNOWN: ……<GO TO F1>

F. Treatments [TB-09]

F1. Did patient start **Intensive** TB Treatment?
Yes, at this facility……..1 <*complete date*>
Yes, treated at other facility……2 <*complete date*>
Unknown, referred to other facility for treatment……3 <*complete date*>
No……..0 <*skip to F4*>
Don't know……..9 <*skip to F4*>

| | | – | | | – | | |

F2. Did patient finish **Intensive** TB Treatment?
Yes, at this facility……..1 <*complete date*>
Yes, finished at other facility……2 <*complete date*>
Unknown, referred to other facility for treatment……3
No……..0 <*skip to F4*>
Don't know……..9 <*skip to F4*>

| | | – | | | – | | |

IF IN QUESTION F1 CIRCLED OPTIONS 2 0R 3 THAN COMPLETE QUESTION F3.1

F3.1 Name of facility where patient was referred: _____

F4. Did patient start **anti-retroviral therapy** (ART)?
Yes, at this facility……..1 <*complete date*>
Yes, treated at other facility……2 <*complete date*>
Unknown, referred to other facility for treatment……3 <*complete date*>
No……..0 <*skip to F6*>
Don't know……..9 <*skip to F6*>

| | | – | | | – | | |

IF IN QUESTION F4 CIRCLED OPTIONS 2 0R 3 THAN COMPLETE QUESTION F 4.1

F4.1 Name of facility where patient was referred: _____

F5. Did patient start **Continuation (or Follow-up)** TB Treatment?
Yes, at this facility……..1 <*complete date*>
Yes, treated at other facility……2 <*complete date*>
Unknown, referred to other facility for treatment……3 <*complete date*>
No……..0 <*skip to F7*>
Don't know……..9 <*skip to F7*>

| | | – | | | – | | |

F6. Did patient finish **Continuation** TB Treatment?

Yes, at this facility……..1 <*complete date*>

Yes, finished at other facility……2 <*complete date*>

Unknown, referred to other facility for treatment……3 <*complete date*>

No……..0 <*skip to F9*>

Don't know……9 <*skip to F9*>

| | | – | | | – | | |

IF IN QUESTION F5 CIRCLED OPTIONS 2 0R 3 THAN COMPLETE QUESTION F 6.1

F6.1 Name of facility where patient was referred: _____

F7. Is patient an Injection Drug User?

Yes……..1

No……..0 <*skip to G*>

Don't know……9 <*skip to G*>

F8. Notes:

G. TB Treatment Outcome [TB09 or TB01]

G1. Outcome of TB Treatment: <*CIRCLE ONE*>

Cured……..1

Treatment complete……2

Died from TB……3

Died (non-TB cause)……4

Treatment failed - smear/culture……5

Treatment failed – xray/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*

END SURVEY

TB Data Abstraction Form – Integration Study

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

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

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

B. Patient Identification

B1. Patient Name Last (SURNAME):_____ First: _____			B2. Patient Record Number: ☐☐☐☐☐
B3. Date of Birth: ☐☐ - ☐☐ - ☐☐	B4. Age (*years*) ☐☐ *[if <18 years END SURVEY]*	B5. Sex: Male……..1 Female…….2	B6. Residence: Urban……..1 Rural……..2

B7. 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 smear *(DD-MM-YY)*	D2. Date of first culture *(DD-MM-YY)*	D3. Date of first x-ray *(DD-MM-YY)*
☐☐ – ☐☐ – ☐☐	☐☐ – ☐☐ – ☐☐	☐☐ – ☐☐ – ☐☐

D4. Diagnosis: Type of case

First Diagnosis ……1
Re-initiation following interruption……2
Treatment failure ……3
Relapse……4

Referred from: _____.....5

Other: _____.....6

D5. Diagnosis: Clinical form

Lung……1 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 whether it was observed within the facility or by relatives of the patient)? Yes……1 No……..0 *<skip to F1>*

E5.1 Number of Planned Doses (doses planned)	☐☐☐
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	☐☐☐

F. TB Treatment: Continuation / Follow-up Phase

F1. Did patient start Follow-up phase? Yes……1 No…….2 *<skip to G1>*

F1.Follow-up Treatment **start** date:	F2. Follow-up Treatment **end** date:

F3. Was direct observation of use of TB drugs recorded (regardless whether it was observed within 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	

G. Treatment Outcome

G1. Outcome of treatment: <*CIRCLE ONE*>

Cured……..1
Treatment complete……2
Died from TB……3
Died (non-TB cause)……4
Treatment failed - smear/culture……5
Treatment failed – xray/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. Factors (*CIRCLE ALL THAT APPLY*):

H1.1 HIV positive……..1
H1.2 Alcoholic……2
H1.3 Injection Drug User ……..3
H1.4 Contact with a case……...4
H1.5 Co-morbidities ……..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 (DD - MM - YY) | | – | | | – | | |
1.1.b Date of Testing | | – | | | – | | |
1.1.c Date of ART | | – | | | – | | |
1.1.d Date of CPT | | – | | | – | | |

→ **IF Co-Morbidities List**:

_____

_____

_____

H2. Referral for Social Support during continuation treatment? Yes……..1
No……..2
Don't Know……..9

I. HIV Screening, Testing, Referral and Treatment	
I1. Was patient diagnosed with HIV before TB diagnosis? Yes, HIV positive…….1 <*skip to I6*> No……..2 Don't know……9	
ASK ABOUT AVAILABILITY OF EACH SERVICE. IF OFFERED AND/OR PROVIDED, THEN RECORD THE DATE WHEN SERVICE INITIATED.	IF YES: Date Initiated (DD-MM-YY)
I2. Was HIV pre-test counseling provided? Yes, provided……..1 <*complete date*> No, not provided……..0	☐☐ – ☐☐ – ☐☐
I3. Were HIV diagnostic tests completed? Yes, tests provided……..1 <*complete date*> Yes, offered but not accepted……..2 <*complete date; skip to I5*> Referred to other facility for diagnostic test...3 <*complete date*> Not offered……..0 <*skip to I5*>	☐☐ – ☐☐ – ☐☐
I4. Diagnostic test confirms patient is: HIV-positive ……1 HIV-negative……..2 <*END SURVEY*> HIV status unknown……..9	

	IF YES: Keep date (DD-MM-YY)
I5. Was HIV Registration Card filled out for patient? Yes……1 <*complete date*> No……0 Don't know……9	__ – __ – __
I6. Did patient start **anti-retroviral therapy** (ART)? Yes, at this facility……1 <*complete date*> Yes, treated at other facility……2 <*complete date*> Unknown, referred to other facility for treatment……3 <*complete date*> No……0 <*end survey*> Don't know……9 <*end survey*>	__ – __ – __

IF IN QUESTION I6 CIRCLED OPTIONS 2 or 3 COMPLETE I6.1:

I6.1 Facility name where patient was referred: _____

NOTES:

END OF SURVEY

INTEGRATION FACILITY SURVEY

CONSENT FORM: TB AND HIV FACILITY SURVEY

Thank you for the opportunity to speak with you. My name is _____ from IFAK. We are conducting a study to learn about public health services in Ukraine. We are working with the MEASURE Evaluation project, implemented by the University of North Carolina, and funded by United States Agency for International Development (USAID). We have received ethics approval to conduct this work from the F.H. Yanovskyi Institute of Phthisiology and Pulmonology under Academy of Medical Sciences of Ukraine

Your facility was selected to participate in this study. We will be asking you several questions about the types of services and procedures followed in your facility for <TB or HIV> patients. The survey will last approximately 20-30 minutes.

The information you provide us may be used by the USAID, the Ministry of Health, other organizations or researchers, for planning service improvements or further studies of services. Neither your name nor that of any other health worker respondents assisting us will be included in the dataset or in any report. The analysis will use only the aggregated data regarding all of the facilities of certain regions of Ukraine. We are asking for your help to ensure that the information we collect is accurate.

You may refuse to answer any question or choose to stop the interview at any time. However, we hope you will collaborate with the study.

Do you have any questions about the interview or what I have said?

Before we can continue I need to have your verbal consent:

- ☐ To participate in this interview; YES NO (circle answer)
- ☐ To participate in this interview; YES NO (circle answer)
  <ONLY if need to obtain information from a 2nd respondent>

Signature (of interviewer): _____

Facility: _____

Date: _____

If in the future you have any questions regarding the interview, or concerns or complaints we welcome you to contact < IFAK >, by calling [044 234 96 41] or email [info@ifak.com.ua]. We will leave one copy of this form for you so that you will have record of this contact information and about the study.

FACILITY SURVEY: TB and/or HIV Services

A. Facility Identification			
A1. Today's Date: (DD-MM-YY) ☐☐ – ☐☐ – ☐☐	A2. Oblast ☐☐	A3. Raion ☐☐	A4 Data Collector ID: ☐☐☐
A5. Facility (where data collected): _____		A6. Facility ID Number: ☐☐☐☐☐☐	
A7. Facility type (circle one): HIV / AIDS Center……1 TB Dispensary……2 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, xray, 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
IDU Substitution Drug Therapy	1	0
Psychological Counseling	1	0

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

	10.1 TB Treatment	10.2 HIV/AIDS Treatment
Directly observed therapy (DOTS) at facility……1	1	
Directly observed therapy (DOTS) at patient's home ……2	2	
Strategies that promote self-management ……..3	3	

B. TB and HIV/AIDS Services			
How many staff at this facility provide TB and HIV/AIDS services? Consider administrative staff, nurses and doctors separately.	(a) TB Services	(b) HIV/AIDS Services	(c) Services for the Co-infected
B1.1. Administrative			
B1.2. Nurses			
B1.3. Doctor			
B2. How many beds are available for inpatient treatment for each service?			
During the following time periods, record the number of TB patients, Newly Registered HIV patients and those co-infected served at this facility	(a) TB Patients receiving Intensive Treatment	(b) Newly Registered HIV Patients	(c) TB-HIV Co-infected Patients
B3.1. In the past 30 days			
B3.2. Jan – Dec 2012			

For the following **TB screening and testing services**, identify availability and average time from testing to receiving results:	(a) Availability	(b) Average time from test to results received
B4. TB Symptom Screening – when patient is evaluated for cough, fever, night sweats, and weight loss, per protocol	Yes, at this facility……1 No, not at this facility……0	Same day……1 < 1 week……2 1-2 weeks……3 > 2 weeks……4
B5. TB sputum microscopy - sputum sample examined to determine smear-positive or smear-negative TB	Yes, at this facility……1 Specimen collected and sent to outside lab……2 Patient referred elsewhere……3	Same day……1 < 1 week……2 1-2 weeks……3 > 2 weeks……4
B6. *Xpert* (or other nucleic acid amplification test NAAT) – sputum sample analyzed with *Xpert* to identify TB and drug resistant TB	Yes, at this facility……1 Specimen collected and sent to outside lab……2 Patient referred elsewhere……3	Same day……1 < 1 week……2 1-2 weeks……3 > 2 weeks……4
B7. TB culture - sputum sample cultured to identify active TB	Yes, at this facility……1 Specimen collected and sent to outside lab……2 Patient referred elsewhere……3	Same day……1 < 1 week……2 1-2 weeks……3 > 2 weeks……4
B8. X-Ray – chest xray performed to identify TB pulmonary infection	Yes, at this facility……1 Specimen collected and sent to outside lab……2 Patient referred elsewhere……3	Same day……1 < 1 week……2 1-2 weeks……3 > 2 weeks……4
B9. Clinical Evaluation – physical examination to determine TB diagnosis	Yes, at this facility……1 Patient referred elsewhere……3	Same day……1 < 1 week……2 1-2 weeks……3 > 2 weeks……4
B10. Other TB Diagnostics: _____	Yes, at this facility……1 Specimen collected and sent to outside lab……2 Patient referred elsewhere……3	Same day……1 < 1 week……2 1-2 weeks……3 > 2 weeks……4

For the following **HIV screening and testing services**, identify availability and average time from testing to receiving results:	(a) Availability	(b) Average time from test to results received
B11. HIV Voluntary Counseling	Yes, at this facility……1 Patient referred elsewhere……3	Same day……1 < 1 week……2 1-2 weeks……3 > 2 weeks……4
B12. HIV Voluntary Testing with rapid HIV antibody test (*Rapid Test Kit*)	Yes, at this facility……1 Specimen collected and sent to outside lab……2 Patient referred elsewhere……3	Same day……1 < 1 week……2 1-2 weeks……3 > 2 weeks……4
B13. HIV Voluntary Testing with *Enzyme immunoassay (EIA)* test	Yes, at this facility……1 Specimen collected and sent to outside lab……2 Patient referred elsewhere……3	Same day……1 < 1 week……2 1-2 weeks……3 > 2 weeks……4
B14. HIV Voluntary Testing with *Western Blot* test	Yes, at this facility……1 Specimen collected and sent to outside lab……2 Patient referred elsewhere……3	Same day……1 < 1 week……2 1-2 weeks……3 > 2 weeks……4
B15. HIV Voluntary Testing with *PCR* (*Polymerase chain reaction)* test	Yes, at this facility……1 Specimen collected and sent to outside lab……2 Patient referred elsewhere……3	Same day……1 < 1 week……2 1-2 weeks……3 > 2 weeks……4
B16. CD4 Count	Yes, at this facility……1 Specimen collected and sent to outside lab……2 Patient referred elsewhere……3	Same day……1 < 1 week……2 1-2 weeks……3 > 2 weeks……4
B17. Viral Load	Yes, at this facility……1 Specimen collected and sent to outside lab……2 Patient referred elsewhere……3	Same day……1 < 1 week……2 1-2 weeks……3 > 2 weeks……4

For the following treatments, identify availability at facility by disease diagnosis:					
Diagnosis: ***Treatment:***	(a) Smear-Positive TB HIV-Negative	(b) Smear-Neg TB HIV-Negative	(c) Smear-Positive TB HIV-Positive	(d) Smear-Neg TB HIV-Positive	(e) No TB Diagnosed HIV-Positive
B18. Is **TB Intensive Treatment** offered to patients at this facility? Yes……1 *<complete table>* No……0 *<skip to B19>*	Inpatient……..1 Outpatient….2	Inpatient……..1 Outpatient….2	Inpatient……..1 Outpatient….2	Inpatient……..1 Outpatient….2	
B19. Is **TB Continuation Treatment** offered to patients at this facility? Yes……1 *<complete table>* No……0 *<skip to B20>*	Inpatient……..1 Outpatient….2	Inpatient……..1 Outpatient….2	Inpatient……..1 Outpatient….2	Inpatient……..1 Outpatient….2	
B20. Is **Antiretroviral Therapy** (ART/ARV) offered to patients at this facility? Yes……1 *<complete table>* No……0 *<skip to B21>*			Inpatient……..1 Outpatient….2	Inpatient……..1 Outpatient….2	Inpatient……..1 Outpatient….2
B21. Is **Isoniazid Prevention Therapy** (IPT) offered to patients at this facility? Yes……1 *<complete table>* No……0 *<skip to B22>*					Inpatient……..1 Outpatient….2
B22. Is **Co-trimoxazole Prevention Therapy** (CPT) offered to patients at this facility? Yes……1 *<complete table>* No……0 *<skip to B23>*			Inpatient……..1 Outpatient….2	Inpatient……..1 Outpatient….2	Inpatient……..1 Outpatient….2
B23. Is **IDU Drug Substitution Therapy** offered to patients at this facility? Yes……1 *<complete table>* No……0 *<skip to C1>*	Inpatient……..1 Outpatient….2	Inpatient……..1 Outpatient….2	Inpatient……..1 Outpatient….2	Inpatient……..1 Outpatient….2	Inpatient……..1 Outpatient….2

C. Drug Shortages

C1. Did this facility experience any drug shortages lasting more than 30 days in 2012? This includes a situation where the number of patients eligible for treatment exceeds the drug supply

	Yes	*No*	*Don't Know*
C1.1 TB Intensive Treatment……	1	0	8
C1.2 IDU Substitution therapy……	1	0	8
C1.3 Antiretroviral therapy……	1	0	8
C1.4 HIV Test Kits……	1	0	8

< if yes to any of the above, then complete drug shortage table> <if no "0" then END SURVEY>

C2. Complete if this facility experienced TB drug shortages that lasted longer than 30 days in 2012.

YEAR: 2012 Drug shortage >30 days	**Months suffering from shortages**												**Consequence of Shortage**	
	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 Other														

Coding for Consequence of shortage:

Waitlisted patient……1
Switched treatment drugs ……2
Stopped treatment……3
Referred patient to another facility ……4
Other……6

C3. Complete if this facility experienced IDU Substitution Therapy drug shortages that lasted longer than 30 days in 2012.

YEAR: 2012 Drug shortage >30 days	**Months suffering from shortages**												**Consequence of Shortage**	
	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
Other……6

C4. Complete if this facility experienced ARV drug shortages that lasted longer than 30 days in 2012 or if a lack of ARV drugs limited the initiation of therapy during 2012?

YEAR: 2012 Drug limitations	**Months suffering from shortages**												**Consequence of Shortage**	
	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														

Coding for Consequence of shortage:

Waitlisted patient……1
Switched treatment drugs ……2
Stopped treatment……3
Referred patient to another facility ……4
Other……6

C5. Complete if this facility experienced HIV Test Kit shortages that lasted longer than 30 days in 2012

YEAR: 2012 Drug shortage >30 days	**Months suffering from shortages**												**Consequence of Shortage**	
	J	F	M	A	M	J	J	A	S	O	N	D	<*Code*>	Other: describe
HIV Test Kits														

Coding for Consequence of shortage:

Waitlisted patient……1
Switched test ……2
Referred patient to another facility ……3
Other……6

Provider Consent Form: Provider Interviews

Thank you for the opportunity to speak with you. My name is _____ from IFAK. We are conducting a study to learn about public health services for [TB or HIV patients] in Ukraine. We are working with the MEASURE Evaluation project, implemented by the University of North Carolina, and funded by United States Agency for International Development (USAID).

Your facility was selected to participate in this study. We will be asking you several questions about the types of services, protocols and procedures followed in your facility for [TB or HIV/AIDS] patients served in this facility. We anticipate the interview will last approximately 30-60 minutes.

The information you provide us may be used by the USAID, the Ministry of Health, other organizations or researchers, for planning service improvements or further studies of services. Neither your name nor that of any other health worker respondents participating in this study will be included in the dataset or in any report. The analysis will use only the aggregated data regarding all of the facilities of certain regions of Ukraine. We are asking for your help to ensure that the information we collect is accurate.

You may refuse to answer any question or choose to stop the interview at any time. However, we hope you will collaborate with the study.

Do you have any questions about the interview or what I have said?

Before we can continue I need to have your verbal consent:

- ☐ To participate in this interview; YES NO (circle answer)
- ☐ To have the interview taped; YES NO (circle answer)

Signature (of interviewer): _____

Facility: _____

Date: _____

If in the future you have any questions regarding the interview, or concerns or complaints we welcome you to contact < IFAK >, by calling [########] or email [#########].We will leave one copy of this form for you so that you will have record of this contact information and about the study.

Questions for HIV services/physicians

1. DIAGNOSIS

TB Diagnosis in Patients in HIV Services

Question	
Is there an existing TB diagnostic algorithm for HIV patients? Is it documented? Who adopted it? Who uses it?	
After a patient is newly diagnosed with HIV, what are the next steps for TB screening?	
Who is referred for TB assessment? o All new patients? o Symptomatic new patients only?	
What risk factors, if any are considered when referring patients for TB assessment?	
How often are existing HIV positive patients screened or assessed for TB?	
Who makes the decision to refer for TB assessment?	
Is there a TB specialist available onsite at HIV institution? o Is he or she part of the AIDS Center staff? Consultant?	
What assessment for TB is performed? o Use of symptom questionnaire? o Laboratory assessment?	
Who performs this assessment?	
Where is this assessment performed?	
How and when does communication with TB specialist take place? (Does each infectionist have a way of contacting the TB doctor?)	

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Is there a specific person assigned as case manager for TB/HIV patients	
How are results received by HIV services?	
How long does it take to receive results of TB screening/referral? o Who receives this information? o Who provides this information to patients? o When and where does patient receive results? o Who else are TB test results provided to?	
In 2012, what percentage of HIV patients tested had TB disease?	
What happens next if a patient is found to have TB disease?	
What do you do when you suspect extrapulmonary TB in a person with HIV?	
How are children with HIV evaluated for TB?	
What counseling or services are offered to patients with TB/HIV?	
What screening is offered to sexual partners (HIV, TB?)	
What screening is offered to family and household contacts? Pediatric contacts?	
Where does patient receive TB services? Does patient receive a separate TB Service Registration number?	
If TB services are not provided at HIV facility, how far does patient need to travel for TB services?	
Which topics have infectionists at your facility been trained on?	
Identifying risk factors for TB?	
Screening and diagnosis of TB?	
Recording and reporting for TB?	
What are factors that delay or prevent diagnosis of TB in HIV patients?	
How could diagnosis of TB in patients at AIDS Centers be improved?	

HIV Diagnosis in Patients Referred from TB Branch

Question		
Which of the following do you provide to patients referred from TB service?		
HIV testing?		
Rapid test kit?		
CD4 count?		
Viral load?		
CBC?		
HIV counseling?		
Partner services?		
How many patients were referred to you by TB services in 2012? o What percentage of those who are referred report to HIV services? o What percentage are currently being treated for TB?		
How are patients from TB services referred to HIV clinic (phone call, email, patient arrives in person etc?		
When a patient is referred from TB services, what information do you receive? (chart, HIV results, TB treatment card, information etc?)		
Is there a mechanism for keeping track of who was referred by TB services and who reported to HIV facility?		
Are the existing TB forms used and adapted in treatment for HIV infected patients?		
Do HIV service forms include TB information?		
Are the TB HIV infected patients assigned a common number which can be traced in either TB HIV services to track progress?		
Is there a mechanism for following up those who did not report to HIV services?		
If TB patient is diagnosed with HIV, where is patient's HIV infection managed? • Where is their TB managed?		
How and when is information on patient shared back with referring TB specialist in TB services? (test results, CD 4 count etc)		
What are factors that delay or prevent diagnosis of HIV in patients in TB services?		
How could diagnosis of TB in patients with HIV be improved?		

2. TREATMENT

Question		
When a person in HIV services receives a TB diagnosis, what happens next?		
When a person with TB is diagnosed with HIV, what happens next?		
Who is eligible for ART? - by national treatment standards? - By WHO recommended HIV Clinical Staging? - In practice		
Which of the following treatment services are available at HIV facility?		
ART		
CPT		
IPT		
Treatment for TB disease?		
Palliative care?		
Is treatment provided by DOT? o For ART? o For TB meds?		
Who manages HIV infection (at TB hospital or AIDS center?) o Who orders CD4 etc? o Who decides to initiate ART?		
Who manages TB treatment?		
Where does patient receive HIV management service? o Where does patient go to get tests, see infectionist, o Where does patient receive ART? (with TB DOT)?		
Is there any cost for tests or treatment?		
Where does patient go for TB services?		
Does location for management and treatment depend on any factors? How sick patient is? If they are in TB hospital? If on ART or not? Anything else?		

When is ART generally initiated? o Where is the date recorded? o Is it in both TB & HIV registries?		
What ARV medications are available?		
Is there a National AIDS Programme recommended regimen ART regimen?		
Does the TB service registry have a reminder or cue for provider to remember the time to initiate anti-retroviral treatment?		
What ancillary medication for side effects is available?		
What percentage of TB patients with HIV began ART in 2012? • What percentage default from TB treatment? • From HIV treatment?		
What monitoring and recording is done?		
How is information shared between TB and HIV branches?		
Discharge Planning		
What happens when a co-infected patient is discharged from the TB facility after treatment completion? o How is HIV branch notified? o When are you notified? o How does patient access HIV management services? o What outreach is done to patient by HIV services?		
What happens when a co-infected patient leaves against advice from TB facility, or is expelled from facility? o How is HIV branch notified? o Is there a person who follows up on these patients? How? o How do these patients receive TB and HIV medications? o Is there continued coordination between HIV and TB branch about these patients? Case management team? o How is this group counted in the TB register? o In 2012, how many patients were expelled?		

o What are the reasons why patients are expelled from TB hospitals?	
What are factors that delay or prevent appropriate management of HIV in patients at TB hospital? (risk factors and gaps)	
What are factors that delay or prevent treatment of TB disease in patients from HIV branch?	
How could treatment of HIV in TB facilities be improved?	
How could treatment of TB disease in patients in HIV services be improved?	
How could provision of IPT in HIV services be improved?	

3. PREVENTION

Question		
Is IPT (Isoniazid prevention therapy) offered to people living with HIV? o By who and where? o Is drug supply available for IPT at HIV services?		
(In 2012, what percent of HIV positive patients who did not have TB received IPT?) What criteria were used to select patients for IPT? How often/frequently is the symptom screen conducted?		
Is CPT (Co-trimoxazole prevention treatment) offered to people living with HIV? o By who and where?		
(In 2012 what percent of patients with TB HIV received CPT?)		
What are factors that delay or prevent initiation of IPT in patients from HIV sector?		
What are factors that delay or prevent initiation of CPT in patients from HIV sector?		
How could the provision of TB preventive services to patients in HIV services be improved?		
How could the provision of HIV preventive services to patients in TB services be improved?		
What procedures are in place to protect HIV positive patients from exposure to infectious TB and other opportunistic infections among other patients? o Specific days to see only HIV positive patients (staggering, separate days, separate waiting areas)		

o Cough monitor, cough screening checklist? o Are there simple infection control plans available? Patient education cough etiquette, etc.		
Is there annual HIV testing for healthcare workers? • Are immediate services (rapid test kit, ART & follow up) available to healthcare workers who have accidental needle stick or splash injuries? • What are available? • Do health workers receive TB symptom screen?		

4. ADMINISTRATIVE/OVERARCHING

Question		
Is there an existing patient flow diagram for managing TB/HIV co-infected patients after diagnosis?		
Is there a set of nationally recommended indicators used for monitoring joint TB-HIV care?		
Do HIV registers reflect patients TB status? In 2012, what percent of patients had TB status recorded in HIV register?		
Does the patient card include both TB and HIV treatment information Is this information shared between services when new information is entered (i.e. lab results)? Does patient have a copy?		
Are patient registry numbers shared between two programs (TB registry and HIV registry)?		
Are there regular meetings between TB and HIV services, either general or specific to patient management? (case management team)?		
Is there a regular collaborative review of recorded data? • Number of patients seen from either system, referred, followed up etc? • Routine supervisory visits to examine registers look at referrals etc? By whom (TB or HIV supervisors)? • Are these visits generally supportive or punitive? • Is mentoring provided as part of this?		
Referral System • Overall, how do you think the current referral system is working?		

• What would you do to improve the referral system between TB and HIV services		
What training is provided for those at HIV services providing TB screening, diagnosis and treatment? • What additional training do you think is needed?		
Are there any laws or regulations that prevent you from providing appropriate TB/HIV diagnosis and treatment services?		
Do you currently coordinate or collaborate with any civil society, Non-Governmental Organizations (NGOs), or community organizations?		
What role do you think these organizations might have in providing TB/HIV prevention diagnosis and treatment services?		
Are there any laws or regulations that prevent you from providing appropriate TB/HIV diagnosis and treatment services?		

BTM Draft List of Questions for Physicians in TB Service/Institutions in Ukraine

1. DIAGNOSIS

HIV Diagnosis In Patients at TB Institutions

Question	
Is there an existing HIV diagnostic algorithm for TB patients and suspects? Is it documented? Who adopted it? Who uses it?	
When is HIV test given to TB suspect/patient?	
Who gets tested for HIV? Children? Is provider initiated testing and counseling utilized?	
In 2012, what percentage of those tested were HIV positive?	
What risk factors, if any are considered when providing test?	
Who orders the HIV test?	
Where is HIV test performed and by whom?	
Is rapid HIV test kit available onsite? What type of HIV test is used? How are HIV test supplies obtained?	
Is there an infectionist available onsite at TB institution? Is he or she part of the TB hospital staff? Consultant?	
How and when does communication with infectionist take place? (does each TB doctor have a way of contacting the infectionist?)	
Is there a specific person assigned as case manager for TB/HIV patients?	
How long does it take to receive results of HIV test? o Who receives HIV test result? o Who gives HIV test results to patients? o When and where does patient receive results? o Who else are HIV test results provided to?	

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o Are all results including indeterminate (or if not done) recorded and where?	
What happens after results are provided to patient? For HIV positive? For HIV negative?	
What counseling or services are offered to patient?	
What screening is offered to sexual partners (HIV, TB?)	
What screening is offered to family and household contacts? Pediatric contacts?	
Where does patient receive HIV services? Does patient receive a separate HIV Service Registration number?	
If HIV services not provided at TB facility, how far does patient need to travel for HIV services?	
Which topics have TB staff at your facility been trained on?	
Identifying risk factors for HIV	
Providing HIV tests	
HIV counseling	
Recording and reporting for HIV	
What are factors that delay or prevent diagnosis of HIV in patients at TB hospital?	
How could diagnosis of HIV in TB facilities be improved?	

TB Diagnosis In Patients Referred From HIV Branch

Question		
Which of the following do you provide to patients referred from to HIV service?		
Screening for disease in HIV infected persons		
Diagnosis of TB		
Treatment of TB disease		
DOT (directly observed therapy)		
IPT (TB prevention treatment) (In 2012, what percent of HIV positive patients who did not have TB received IPT?)		
CPT (Co-trimoxazole prevention treatment) (In 2012 what percent of patients with TB HIV received CPT?)		

How many patients were referred to you by HIV services in 2012? o What percentage of those who are referred report to TB services? o What percentage **are** on ART? o What percentage are **not** yet on ART		
What do you do when you suspect extrapulmonary TB in a person with HIV?		
How are children with HIV evaluated for TB?		
How are patients from HIV services referred to TB clinic (phone call, email, patient arrives in person etc?		
When a patient is referred from HIV services, what information do you receive? (chart, X-ray results etc?)		
Is there a mechanism for keeping track of who was referred by HIV services and who reported to TB facility?		
Is there a mechanism for following up those who did not report to TB services?		
If HIV patient is diagnosed with TB, where is patient's TB managed? • Where is their HIV infection managed?		
How and when is information on patient shared back with referring infectionist at HIV services? (x-ray smear results etc)		
What are factors that delay or prevent diagnosis of TB in patients in HIV branch? - What is average time for diagnostics of TB? - Who is "final" person to make TB diagnosis in HIV+?		
How could diagnosis TB in patients with HIV be improved?		

2. **TREATMENT**

Question		
When a person in TB facility is diagnosed with HIV (or arrives with pre-existing diagnosis of HIV), what happens next?		
Who is eligible for ARV? - by national treatment standards? - In reality?		
Which of the following services are available at TB facility?		
CD4 count		
Viral load		
CBC		

Counseling screening for STIs?		
ARV medications		
Who manages ART (at TB hospital or AIDS center?) o Who orders CD4 etc? o Who decides to initiate ART?		
When is ART generally initiated? o Where is the date recorded? o Is it in both registries?		
What ARV regimens are currently available in your facility (or can be ordered from the HIV Center?) • Are there effective ARV regimens for patients who require ARV/TB treatment • Also with ST?		
Does the TB service registry have a reminder or cue for provider to remember the time to initiate anti-retroviral treatment?		
Where does patient receive HIV management service? o Where does patient go to get tests, see infectionist, o Is there any cost for tests or treatment? o Where does patient receive ARV medication? (with TB DOT?)		
What percentage of TB patients with HIV begin ART? • What percentage default from TB treatment? • From HIV treatment?		
What monitoring and recording is done?		
How is information shared between TB and HIV branches?		
Discharge Planning		
What happens when a co-infected patient is discharged from the TB facility after treatment completion? o How is HIV branch notified? o How does patient access HIV infection management services? o What follow-up is done to see if patient reported to HIV services?		
What happens when a co-infected patient leaves against advice from TB facility, or is expelled from facility? o How is HIV branch notified? o Is there a person who follows up on these patients? How? o How do these patients receive TB and HIV		

medications? o Is there continued coordination between HIV and TB branch about these patients? Case management team? o How is this group counted in the TB register? o In 2012, how many patients were expelled? o What are the reasons why patients are expelled form TB hospitals?	
What are factors that delay or prevent appropriate management of HIV in patients at TB hospital? (risk factors and gaps)	
What are factors that delay or prevent treatment of TB disease in patients from HIV branch?	
How could treatment of HIV in TB facilities be improved?	
How could treatment of TB disease in patients in HIV services be improved?	
How could provision of IPT in HIV services be improved?	

3. PREVENTION

Question	
Is any counseling about HIV risk behaviors provided in TB facilities?	
Are all HIV + women attending TB services referred to HIV branch for services for prevention of vertical transmission?	
Is CPT offered to people living with HIV? o By who and where?	
Is IPT offered to people living with HIV? o By who and where	
What are factors that delay or prevent initiation of IPT in patients from HIV sector?	
What are factors that delay or prevent initiation of CPT in patients from HIV sector?	
How could the provision of TB preventive services to patients in HIV services be improved?	
How could the provision of HIV preventive services to patients in TB services be improved?	
What procedures are in place to protect HIV positive patients from exposure to infectious TB patients? o Specific days to see only HIV positive patients (staggering, separate days, separate waiting areas) o Cough monitor, cough screening checklist?	

Is there annual HIV testing for healthcare workers?	
Which of the following services are offered in TB facilities?	
Substitution treatment	
Palliative care and pain relief	
Alcohol/drug addiction counseling	
Psychiatric care	

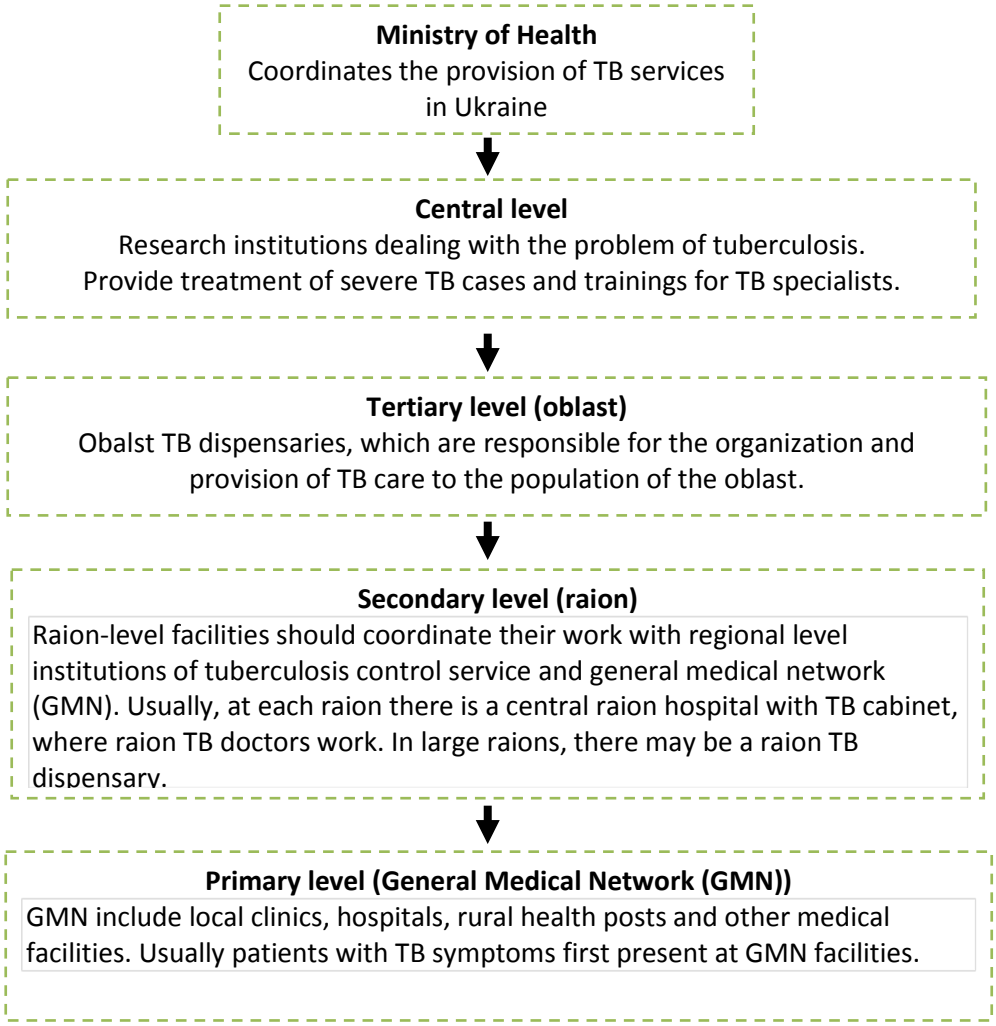
4. ADMINISTRATIVE/OVERARCHING

Question	
Is there an existing patient flow diagram for managing TB/HIV co-infected patients after diagnosis?	
Do TB registers reflect patients HIV status? In 2012, what percent of patients had HIV status recorded in TB register?	
Does the patient card include both TB and HIV treatment information Is this information shared between services when new information is entered (i.e. Lab results)? Does patient have a copy?	
Are patient registry numbers shared between two programs (TB registry and HIV registry)?	
Are there regular meetings between TB and HIV services, either general or specific to patient management? (case management team)?	
Is there a regular collaborative review of recorded data? • Number of patients seen from either system, referred, followed up etc? • Routine supervisory visits to examine registers look at referrals etc? By whom (TB or HIV supervisors)? • Are these visits generally supportive or punitive? • Is mentoring provided as part of this?	
Referral System • Overall, how do you think the current referral system is working? • What would you do to improve the referral system between TB and HIV services	
What training is provided for those at TB services providing HIV screening, diagnosis and treatment? • What additional training do you think is needed?	
Are there any laws or regulations that prevent you from providing appropriate TB/HIV diagnosis and treatment services?	

Do you currently coordinate or collaborate with any civil society, Non-Governmental Organizations (NGOs), or community organizations?	
How do you think these organizations could be involved in providing TB/HIV prevention, diagnosis and treatment services?	
Are there any laws or regulations that prevent you from providing appropriate TB/HIV diagnosis and treatment services?	

TB Medical Care in Ukraine: Services, Patients, and Data

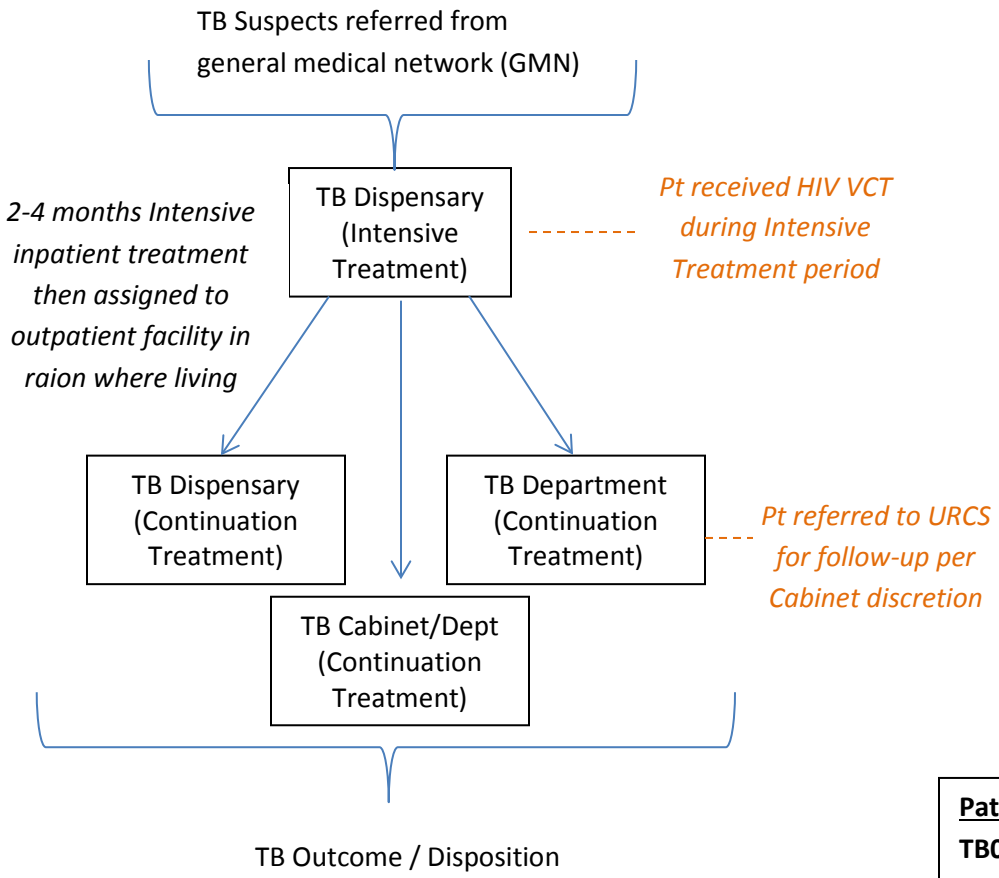
The TB Service of Ukraine consists of a network of specialized facilities located throughout the country. The Ministry of Health or local authorities (oblast level) oversee the other institutions of this network. The system of TB medical care in Ukraine includes central, oblast and primary health care facilities levels as follows.[1]



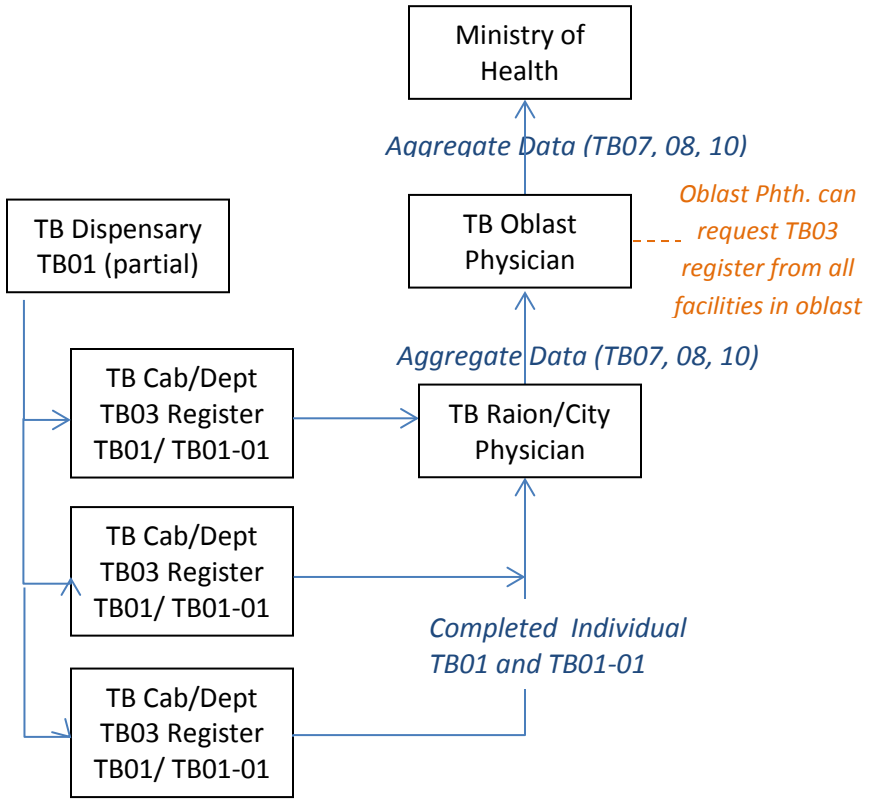
Data were collected from TB facilities at the secondary level (rayon) facilities and tertiary level facilities or Regional TB Dispensaries, which provide services to patients under referrals of district and municipal hospitals in the region.

[1] Analysis is based on the information available at: http://www.moz.gov.ua/

TB PATIENT FLOW



TB DATA FLOW



Patient Medical Records Sources:

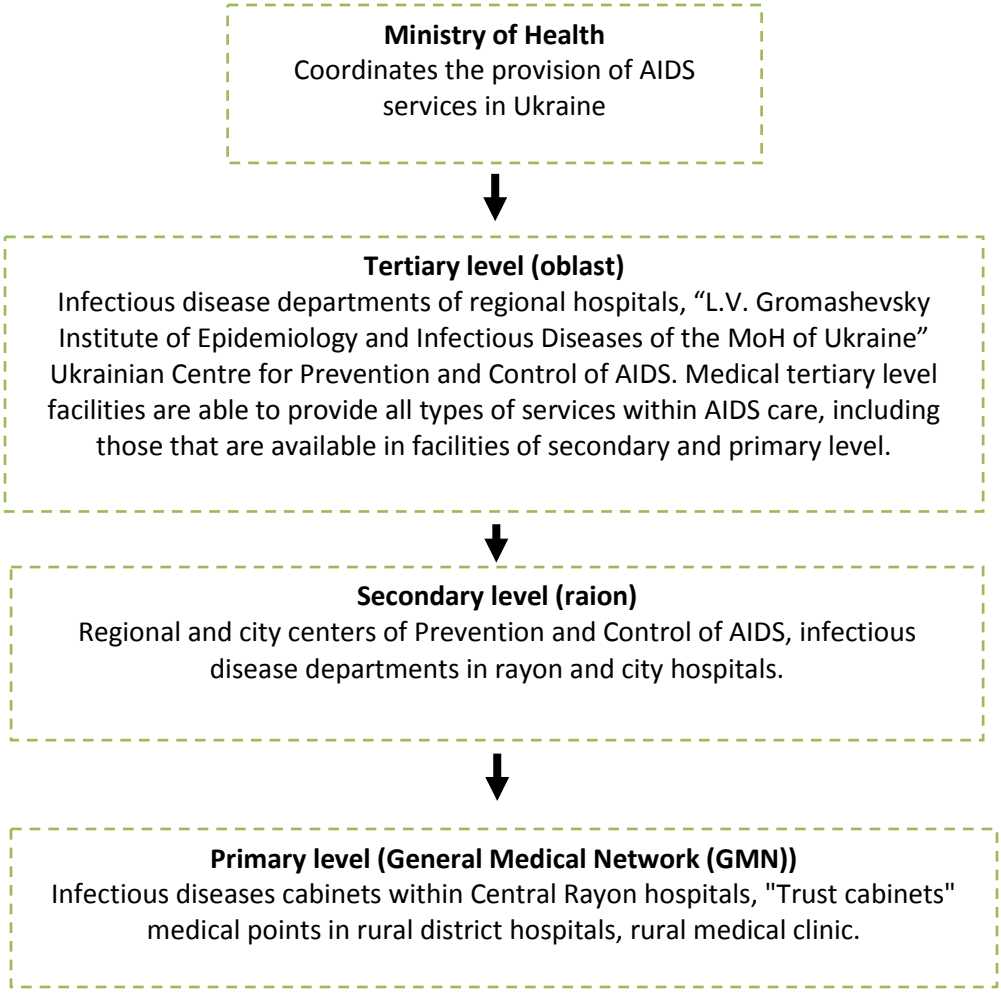
TB01: Primary tracking tool for patient diagnosis, treatment, and outcome.

TB01-01: Supplementary document to record high-risk factors that may influence treatment (e.g., alcoholic, HIV+, IDU, etc)

TB03: Registers used by TB Cabinet/Department to register patients and may contain treatment information from facility.

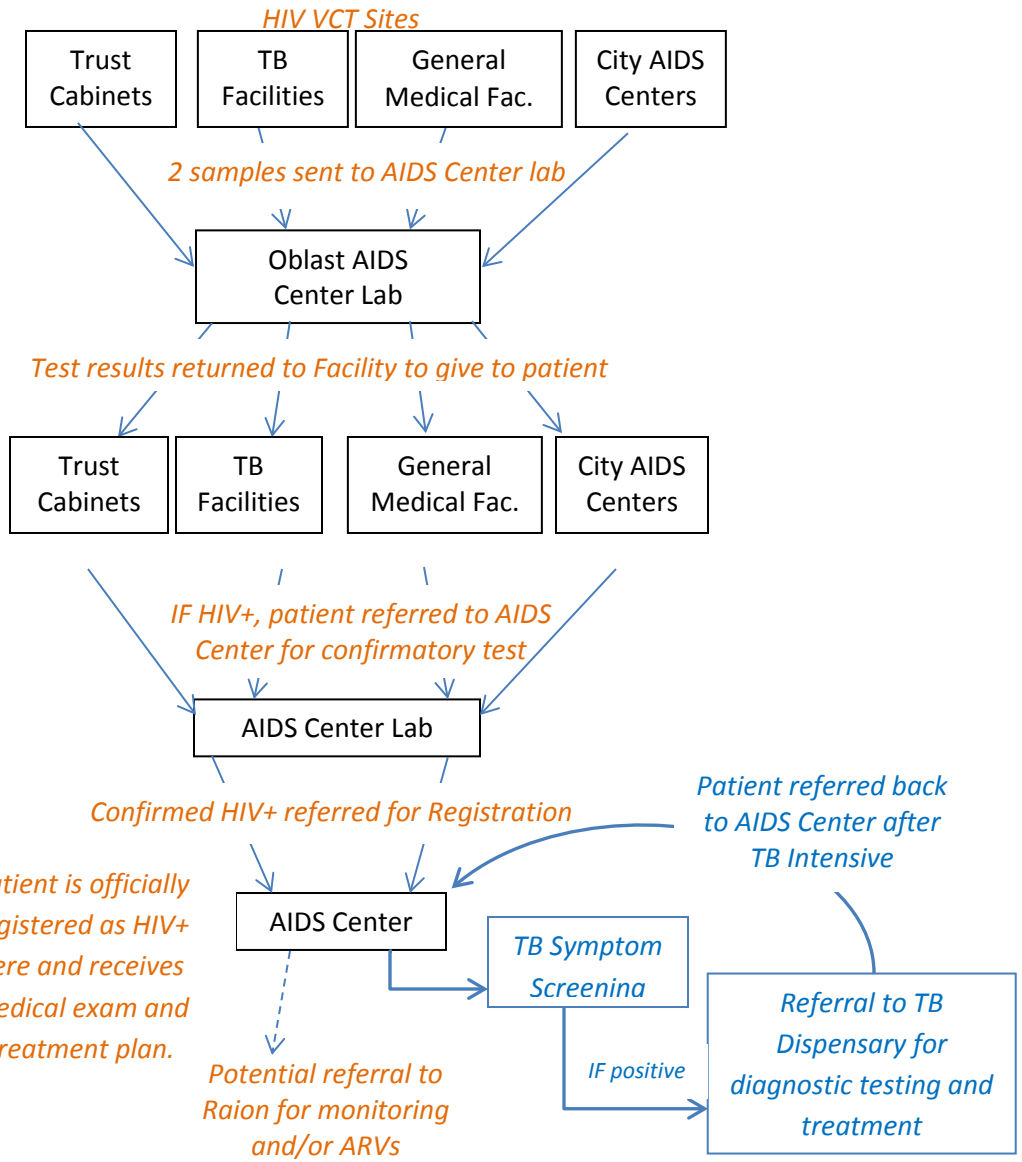
HIV/AIDS Medical Care in Ukraine: Services, Patients, and Data

AIDS medical care services in Ukraine includes primary, secondary and tertiary levels of specialized care facilities that report to the Ministry of Health. [1] Interviews and surveys were conducted with institutions at the secondary level such as regional AIDS centers and/or city AIDS centers.

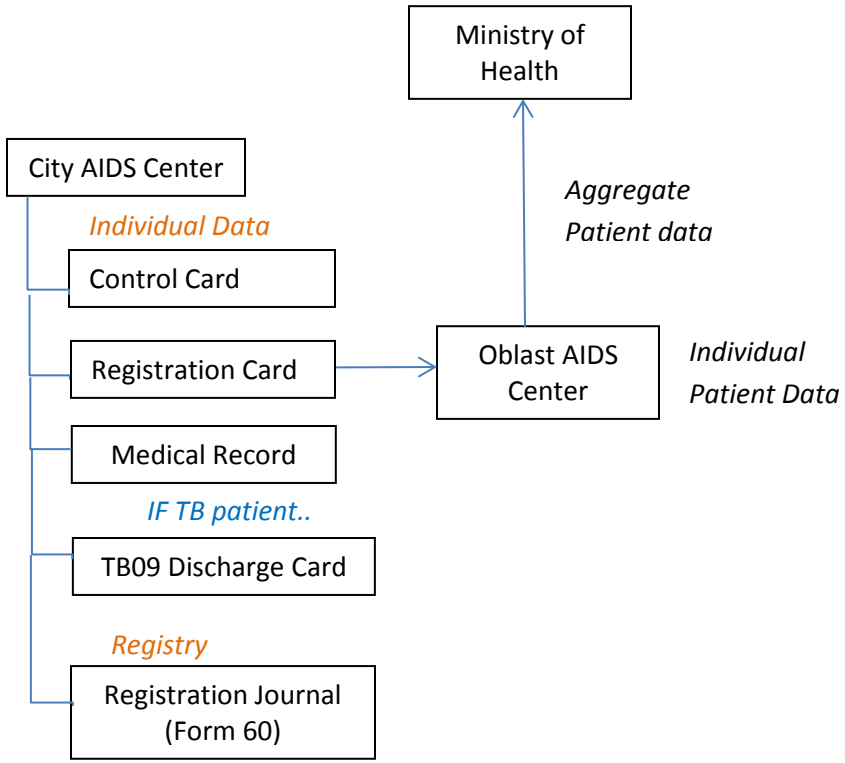


[1] Analysis is based on the information available at: http://www.moz.gov.ua/; http://www.aidsalliance.org.ua/

HIV TESTING AND PATIENT FLOW



HIV DATA FLOW



Patient Medical Records Sources:

Control Card: Documentation of new registration and initial medical exam.

Registration Card (N502-1): information on HIV testing, diagnosis, examination; includes TB diagnosis in past 12 months

HIV Medical Record (f-025u): Log of all care, testing, treatment, etc for patient

TB09 Discharge Card: TB diagnosis and treatment info including facilities; no treatment outcomes

Registration Journal (Form-60): registry of patients with infectious diseases (will only include TB if diagnosed before seen by AIDS Center and if reported by patient.

MEASURE Evaluation

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