2016

Analyzing Tuberculosis Diagnosis and Treatment in Kasungu, Malawi

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May 6, 2016

A thesis submitted to the faculty of the Environmental Studies Program in partial fulfillment of the graduation requirements for the Degree of Bachelor of Arts with honors in Environmental Studies

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ABSTRACT

Despite Tuberculosis (TB) being a highly curable disease, it continues to result in over 5% of deaths in the Sub-Saharan African country of Malawi. Coupled with HIV, the disease remains one of the leading causes of death in Malawi. In the summer of 2015, I joined a research team from Partners in Hope to conduct a survey evaluating the health centers that provide TB care in the Kasungu region of Malawi. After visiting 23 health centers, the results of the 47-question survey were compiled and analyzed to provide information on the capabilities and practices at each health center. The results of the survey revealed several factors that may result in an under-diagnosis of TB in Kasungu. Complications arising from dual infection of HIV and TB render the standard microscope diagnosis method less accurate, and patients are not being referred to the district hospital to receive a proper diagnosis by over 90% of health centers. The quality of record keeping was found to be insufficient at over 40% of health centers, which limited this study's ability to track patients from one site to another. The sputum collection system using satellite collection sites, which is designed to decrease the burden of travel on patients needing TB diagnosis services, is almost completely defunct. Health center staff, who are themselves overworked, identified lack of transportation as a major barrier for patients to receive care for TB. In order to diagnose a higher percentage of TB cases in Kasungu, health center staff needs to be provided with more information to follow referral procedures and keep patient records with more accuracy. Subsidized transportation would additionally reduce the burden of travel on patients and allow for more diagnoses to be made. TB record-keeping supplies, in short supply at most of the health clinics, should be delivered along with the readily available TB medications.

ACKNOWLEDGEMENTS

I would like to thank Dr. Alan Schooley for giving me the opportunity to join the Partners in Hope Research Team. I would also like to thank John Hamilton for all of his logistical support for my time in Malawi and for providing housing on the weekends. This project was conducted under the leadership of Dr. Schooley and led in the field by Khumbo Phiri, Jimmy Chitsulo, Temwa Multiso and Lumbani "The Transporter" Ndhlovu. I thank them for allowing me to join them for the month of June, cooking, driving and translating for me in addition to teaching me so many aspects of Malawian life.

I would also like to thank Professor Gail Carlson for being my faculty sponsor and offering countless revisions to this paper as well as guiding me through the entire process. Additionally, I would like to thank Manny Gimond for offering GIS guidance in producing the maps. I would also like to thank Professor Philip Nyhus and Professor William McDowell for being my readers. Dr. Risa Hoffman provided me with a very helpful revision and clarified some of the more tedious medical terms. Finally, I would like to thank my parents for offering the financial support necessary to make the trip to Malawi and for piquing my interest in public health.

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INTRODUCTION

Tuberculosis (TB) is one of the leading causes of global deaths despite being highly treatable. TB is a major burden in Sub-Saharan Africa, and the disease disproportionately impacts the poor in all countries. The current goal for combatting TB calls for a 95% reduction in TB deaths compared to 2015 and a 90% reduction in the TB incidence rate (WHA, 2014). For the current global strategy to succeed, in depth analyses of TB care in rural and hard-hit areas will be essential to understanding the barriers to preventing TB deaths. In this study, specific capabilities of TB health centers in Malawi are mapped, measured via a survey, and analyzed to reveal the factors that stand in the way of an effective TB response.

Tuberculosis is a disease caused by the bacterium *Mycobacterium tuberculosis* that primarily infects the lungs. An airborne communicable disease spread through coughing, sneezing or spit, TB is both curable and preventable (WHO, 2015). TB exists in both active and dormant (latent) forms. Once active, symptoms include cough, chest pain, weakness, weight-loss, fever and night-sweats. Without proper treatment, 45% of people with TB on average and nearly all HIV-positive people with TB will die (WHO, 2015). To test for TB, a microscopic examination of sputum ('smear') can identify the acid-fast bacilli (AFB) that signify infection with TB (Behr et al., 1999). Patients with tuberculosis with sputum smears negative for acid-fast bacilli are less infectious than those with positive smears, but both theoretical and empirical evidence suggest that they can still transmit TB (Behr et al., 1999).

Global Incidence of TB

The year 2015 marked the final year of the Millennium Development Goals (MDGs) and their target to reverse the spread of TB. It additionally marked 20 years since the WHO established a global TB monitoring system (WHO Global TB Report, 2015). TB incidence globally has fallen by an average of 1.5% per year since 2000 and currently stands 18% below the rate in 2000 (WHO Global TB Report*,* 2015). While these numbers remain encouraging, 1.5 million people still died from TB in 2014 despite TB being a highly curable disease (WHO Global TB Report, 2015). Additionally, 9.6 million people are estimated to have fallen ill with TB in 2014, of which 6 million were reported to the WHO. These calculations suggest that an estimated 3.6 million (37%) people with TB did not receive treatment in 2014 (WHO Global TB Report, 2015). According to the WHO 2015 Global TB Report, 8.6 million people develop TB yet fewer than 6 million cases are reported and treated (WHO, 2015). Case detection of TB is still quite below the UN Sustainable Development Goal to End TB by 2030 target of 70%. Clearly, identifying cases of TB is the first step in treatment and without a high detection rate, the burden of TB will continue. While progress has been made, eradicating TB globally will rely upon improvement in case detection and treatment in the countries where the burden has been the most significant.

Several international bodies have set goals and targets in order to stimulate global action in reducing the incidence of TB and increasing cure rates. In 2000, the United Nations General Assembly accepted the targets outlined in the Millennium Declaration and recommended that the WHO call for 70% TB case detection and 85% cure rates (WHO, 2009). The *Global Plan to Stop TB* 2006-2015 outlined several key goals to be met by 2015. The plan failed to reach 85% of HIV patients tested for TB and enrolled into Directly Observed Therapy programs (DOT) but succeeded in reducing mortality rates down to 50% (WHO/WHA, 2014). In 2015 the World Health Assembly accepted the World Health Organization's *Global strategy and targets for tuberculosis prevention, care and control after 2015.* With an ultimate goal of ending the global TB epidemic, the framework calls for a 95% reduction in TB deaths compared to 2015 and a 90% reduction in the TB incidence rate (WHA, 2014).

Dual Burden of HIV & TB

The rapid growth of tuberculosis (TB) in Sub-Saharan Africa has been inextricably linked with the HIV epidemic (Fielder, 2009; Chaisson, 2010; Tweya et al., 2013). The dual infection of HIV and TB presents numerous diagnostic and treatment issues. In 2014, 54% of TB patients in Malawi were HIV-positive (WHO, 2016). According to the WHO, the risk of developing TB is up to 31 times higher in HIV-positive people than those without the HIV infection (WHO, 2015). The interaction between TB and HIV can promote the prevalence of TB in two ways. First, if a population has high rates of latent TB, infection by HIV increases the reactivation of TB 100 fold in the individual (Chaisson et. al, 2010; Tweya et al., 2013). Second, people with HIV-induced immunosuppression are at an exceptionally high vulnerability to active TB (Lawn et al., 2006; Chaisson et. al, 2010; Kanyere et. al, 2005). In addition to being more susceptible to TB, HIV-positive individuals who acquire TB see faster rates of clinical decline due to the dual infection (Idemayor, 2007). In 2014, of the 9.6 million new reported cases of TB globally, 1.2 million were among those who were already HIV-positive (WHO, 2015). HIV prevalence among TB patients remains quite high in Sub-Saharan Africa overall (Van Lettow et al., 2015).

In response to the frequency of dual HIV and TB infection, the WHO has developed guidelines to facilitate the simultaneous care of both diseases (WHO, 2009). The number of TB cases can be reduced when additional strategies are developed to control both diseases concurrently (Kanyere et al., 2005). Integrating care for both diseases is a priority of the overall treatment plan in resource-limited countries. A study done at the Martin Preuss Centre in Malawi examining how well care for both diseases was integrated found that HIV testing for TB patients was done at a high rate, and the TB treatment rates for HIV-positive and negative patients were similar (Phiri et al., 2011). Overall, the approach to the dual epidemic has been successful in Malawi with 93% of TB patients currently knowing their HIV status (WHO, 2016).

Multiple studies reaffirm the statistic that one in four HIV infected patients in the world die from TB (Fielder, 2009). A study conducted by Coleblunders & Bastian (2010) found that countries with large numbers of people affected by both HIV and TB have experienced a disproportionate increase in smear-negative forms of TB. Smear-negative TB cases are those that show clinical and radiological evidence of pulmonary TB but repeatedly negative sputum investigations (Coleblunders & Bastian, 2010). They also found that HIV-positive patients with smear-negative pulmonary TB to be more immunocompromised, have more adverse drug reactions, and suffer higher mortality rates on treatment for TB (Coleblunders & Bastian, 2010). Diagnosis of sputum-negative TB cannot be done with high accuracy through standard sputum microscopy (Siddiqi et al., 2003). A similar study conducted in the Lilongwe district hospital in Malawi in 2001, that found the rise of HIV was associated with an increase in smear negative cases of TB (Hargreaves et al., 2001). However until recently, treatment protocol for management of smear negative TB was still based on this disease for an HIV negative population (Coleblunders & Bastian, 2010). This has resulted in the updated National TB Guidelines now requiring all HIV-positive patients to be tested for TB.

Challenges in TB Surveillance, Diagnostics, Treatment in Sub-Saharan Africa

The dual threat of HIV and TB is but one of the many challenges that face health care systems in resource poor Sub-Saharan Africa. As health care systems tackle the arduous challenge of combatting both epidemics simultaneously, several trends have emerged highlighting the past and current shortcomings of diagnosing and treating TB in Sub-Saharan Africa. As of 2000, "over half of all smear-positive TB cases were living in 49 countries that detected less than 40% of cases" (Dye et al., 2005). Focusing on these countries with low levels of case detection will be vital to achieving the WHO sponsored TB goals moving forward. A majority of the burden falls onto the diagnosis process as once TB is found, treatment success rates have been high. Globally, treatment success rates have been maintained at 85% or more since 2007 (WHO, 2014).

HIV-positive status & sputum smear negativity

The standard examination for TB in resource-limited settings is the microscopy of sputum samples testing for the presence of acid-fast bacilli (Behr et al., 1999; Fielder, 2009). A major complication in the diagnosis of TB among such a highly co-infected HIV-positive population is that HIV-positive patients commonly present with smear negative TB (Boniface et al., 2011; Fielder, 2009). Older studies show 33% to 50% of pulmonary TB cases in HIV-positive patients are smear negative (Elliot et al., 1993). Recent studies have shown that the majority of HIV-positive patients will be infected with smear negative TB currently defined as, "symptomatic illness in a patient with at least two sputum smear examinations negative for acid-fast bacilli (AFB) on different occasions in whom pulmonary tuberculosis is later confirmed by culture, biopsy, or other investigations"(Siddiqi et al., 2003). A study conducted in a South African ART clinic on HIV-positive patients recently found that despite having the highest quality microscopes, 87% of the culture proven pulmonary TB cases were smear negative, demonstrating the diagnostic difficulties of smear negative TB. Patients cannot be diagnosed by sputum smear through a microscope yet remain highly infectious (Behr et al., 1999; Edwards et al., 2009). In Kenya, standard microscopes resulted in 64% of culture confirmed TB cases testing smear negative in HIV-positive patients (Kivihya-Ndugga et al., 2009). The majority of clinical studies show that HIV-positive patients have a higher rate of smear negative TB than patients without HIV (Coleblunders et al., 2000).

Research on diagnosing HIV-positive patients with the standard sputum microscopy has led to the use of “Xpert MTB/RIF” (Xpert) as a more accurate diagnostic tool for TB. The Xpert is a fully automated nucleic acid amplification test (NAAT) that can diagnose TB in HIV-positive patients with higher accuracy than standard microscopy (Boehme et al., 2011). While the exact accuracy of the test varies by country, it has been successful enough for the WHO to endorse its implementation in countries with high TB incidence as of 2010 (WHO, 2010). Currently, the Malawian National TB Guidelines call for HIV-positive TB suspects to be referred to a facility with Xpert diagnostic capabilities (MTBG, 2014). Despite the efficacy of the Xpert, cost and practical barriers to implementation such as electricity and trained personnel has hindered widespread use (Hoffman, 2016). While expensive to implement, early results from a study conducted in nine countries resulted in the authors concluding, “benefits of improved diagnostics for TB and drug-resistant TB provide ample justification for long term support from donors” for the higher cost of machinery (Creswell et al., 2014).

TB Diagnosis

The standard microscopy test requires the collection of sputum samples from TB suspects. This approach has limited effectiveness because of the burden of travel for patients, as defined by the distance, cost and frequency of trips for patients to reach health centers. To help minimize the burden of travel, health centers set up sputum collection sites located in villages around the health center. Sputum refers to mucus collected from the lungs and differs from saliva (WHO, 2013). The system was designed to allow those with TB symptoms to submit sputum samples at designated areas regularly visited by the local health surveillance assistant (HSA) and transported to the health center for microscopy. The patient is then typically notified by phone with the results of the test.

The effectiveness of sputum collection systems has been an understudied component of Malawian TB care. The speed with which the sputum is delivered and submitted for testing is integral to an accurate diagnosis, as increased time in storage can lead to a false negative diagnosis (Banda et al., 2000). The WHO guidelines call for a sputum sample to be tested within two weeks of being submitted in order to avoid a false negative (WHO, 2013).

Although some research has found that sputum can still test positive up to 8 weeks after being submitted if properly refrigerated and that 50% of positive samples could be tested accurately even after 4 weeks without refrigeration (Banda et al., 2000). However these numbers highlight the importance of timely processing and refrigeration of sputum sample transport.

In the late 1990s, the National TB Program (NTP) instituted a bus collection service to transport sputum samples from rural areas to diagnostic centers. However, upon review, the system failed to deliver the samples within the adequate timeframe (Harries et al., 2004). A quality control study done in the central region of Ntcheu, Malawi found a successful sputum collection system in place. They found greater than 90% of samples collected from 817 patients reached their destination health centers within 7 days (Mundy et al., 2002), although all of the samples that did not make it to the health centers before 18 days all were from rural areas and none tested smear positive (Mundy et al., 2002*)*.

Diagnosing TB in children

In 2014, an estimated 140,000 children died from TB globally, (WHO Global TB Report, 2015). Diagnosis and treatment of TB is further complicated in children (Lawn et al., 2006), as the standard microscopy test often produces false negatives for children (Nicol et al., 2011; WHO, 2013). This is due in part to the difficulty in obtaining sputum samples from young children (Zar et al., 2005). In order to obtain a sputum sample, a deep cough must be repeated. It has been notoriously difficult to obtain sputum from children, as they must cough the sputum up themselves (Zar et al., 2005). Children with TB primarily present with a smear negative form of the disease (WHO, 2013) In 2001, a study conducted in Blantyre, Malawi found that 39% of children could not be diagnosed from sputum samples. Instead, the diagnosis was based on history of contact, clinical features and a single chest x-ray (Kiwanuka et al., 2001). A study conducted on the peri-urban community in the Western Cape, South Africa, investigated the epidemiological changes of TB cases from 1996-2004. They found the 10-49 year old age group to have the highest increase in rates of TB (Lawn et al., 2006).

Cost to the poor

The complexity in diagnosing and treating TB places an economic strain on already impoverished populations in resource-limited countries such as Malawi (Simwaka et al., 2007). Malawi ranks as the country with the lowest Gross National Income (GNI) per capita at $250 USD (World Bank, 2014). Malawi also ranked last in Gross Domestic Product (GDP) per capita at $255 USD (World Bank*,* 2014). With the majority of Malawians dependent upon daily work in urban areas or tending agricultural fields, taking a day off work to visit a health center comes at a substantial economic cost to the individual (Simwaka et al.*,* 2007). While TB drugs and treatment are free to patients, the cost of travel to clinics and lost income from missing work are important barriers to TB diagnoses and treatment. These direct and indirect costs are considered notable barriers to treatment (Simwaka et al*.,* 2007*).* For poor Malawians, the cost of accessing TB care can be up to 248% of their monthly income (Simwaka, 2012). With private health care providers being geographically and economically out of reach for the majority of Malawians, the burden of providing care will remain on the public health system (Simwaka, 2012*).*

Several research studies have identified other factors that present challenges for TB diagnosis and treatment. Distance from urban centers was the largest determinate for lack of TB knowledge and delayed treatment, with those living closer to large cities having higher TB knowledge regardless of education level (Ngwale, 2001; Kanyere et al., 2005). Overall distance and lack of transportation have been found to play the largest role in patient's delay for TB treatment (Kanyere et al., 2005). Patients living more than 10km from a diagnostic center in Malawi were found to have longer delays in treatment, a finding in line with a previous study done in Malawi in the late 1990s that found rural patients at higher risk of spreading TB (Salaniponi et al., 2000; Makwakwa et al., 2014).

The basis of the health center delay in patients visiting rural health centers without TB diagnostic capabilities results from the patient being referred further from home (Makwakwa et al., 2014). A study completed in 2014 found health centers in Malawi responsible for 70% of total delay between onset of symptoms and completion of TB therapy (Makwakwa et al., 2014). This finding carries significant weight, as delays in the diagnosis and treatment of pulmonary TB have been linked to an increased risk of infectivity and poor treatment outcomes (Makwakwa et al., 2014). The median health center delay in Malawi was found to be 59 days for new cases, well beyond the recommended WHO two-week period (Makwakwa et al., 2014). Health center delay refers to the time period between the first patient visit and start of antibiotic therapy for patients. In another study from Malawi, lack of knowledge about TB and HIV stigma associated with the poorest citizens played a role in delayed treatment, as patients associated TB with HIV and feared finding out they were HIV-positive (Kanyere et al., 2005; Simwaka et al., 2012).

TB Treatment

The National Tuberculosis Program in Malawi has implemented the WHO recommended Directly Observed Treatment Short Course (DOTS) strategy since the early 1980's. The strategy contains five main components spanning technical, logistical, operational and political fields. The first element is political commitment with increased and sustained financing. The second element calls for case detection through quality assured bacteriology. This includes use of a sputum microscopy and a pledge towards a strengthened laboratory network. The next element is standardized treatment with supervision and patient support. The WHO justifies the need for directly observing treatment as up to a third of patients do not take medication as prescribed and another third make errors in self-medication (WHO, 1990). An effective drug supply and management system is the fourth element of DOTS and specifies that TB drugs should always be free to patients. The final element is a monitoring and evaluation system with impact measurement. This calls for standardized recording of individual patient data and treatment outcomes to be complied into quarterly treatment outcomes for cohorts of patients (WHO, 1990).

The DOTS strategy has been implemented in the Malawian TB control program since 1984 (Harries et al., 2001). Countries that employ the DOTS strategy have had good data on case finding, high rates of sputum positive pulmonary TB and better cure rates than programs that do not utilize DOTS (Harries et al., 2001). While overburdened by the onset of the HIV epidemic, a declining economy and generally poor health indicators, Malawi has seen the DOTS program as the best option for the control of TB (Harries et al., 2001; WHO, 2013).

Despite some tangible successes of the DOTs program, some research suggests it may not be fully attributable to direct observation. A randomized controlled trial in South Africa comparing the treatment rates of directly-observed to self-supervised patients found that the self-supervised patients had a slightly higher treatment success rate of 60% than the directly-observed patients at 54% (Zwarenstein et al., 1998). The researchers behind this study highlight the costs that would be saved without direct observation and called requiring patients to be observed taking their pills "alienating and authoritarian"(Zwarenstein et al., 1998*)*. Removing the "directly-observed" portion of treatment would free time for health service assistants (HSA) that could be redirected to other patients and save money by reducing transportation costs. In line with these findings, a study from Pakistan compared treatment outcomes of sputum positive patients who were health center-observed, family-observed and self-observed during their TB treatment. They found similar cure rates among each group, again challenging the effectiveness of health center directly observed treatment (Walley et al., 2001). In a comprehensive look at all of the studies done on the effectiveness of directly observed treatment (n=111), researchers concluded that the directly observed component of DOTS should not be given the marquee designation of the program (Volmink et al., 2000). Instead, they call for the WHO to redefine the factors that make up a successful DOTS TB treatment strategy as including an actively managed program of tuberculosis control, with a mixture of inputs to improve overall adherence (Volmink et al., 2000*)*.

Adherence to medication

If patients are able to overcome the socio-economic and health systems hurdles to receive an accurate TB diagnosis, the course of treatment remains far from convenient. Currently, the standard TB treatment regimens are a combination of the isoniazid, rifampicin, pyrazinamide and ethambutol antibiotics (Chirwa et al., 2013; WHO, 2014). Those who had taken medication in accordance with the prescribed schedule saw cure rates of 95% however, cure rates decrease in accordance with the number of treatment days missed (Chirwa et al., 2013*)*. A study in Malawi found that missing 15-29 days of treatment resulted in the cure rate falling to 42%, demonstrating that treatment of TB requires a high degree of compliance to medication to facilitate cure (Chirwa et al., 2013).

Achieving the goals set by the Post 2015 Global TB Strategy Framework of a 75% reduction in TB deaths and a 50% reduction in incidence rate by 2025 will require improvements at every stage of the TB diagnostic and treatment process. Research has focused on improving the effectiveness and efficiency of TB care in resource-limited settings. In a study on the effectiveness of current estimations used for TB incidence and prevalence, several recommendations were made to improve the current surveillance methods. It called for: monitoring the performance of health facilities including: whether all facilities report, how many cases reported, their catchment areas, and the variation from year to year and from one facility to another (Dye et al., 2003). Another study highlighted the importance of specifically targeting the areas with the highest risk of TB, including families of patients with HIV or TB (Chaisson et al., 2010). The WHO highlights the importance of improvements to current quality of data collection at all levels of care (WHO/WHA, 2014). An overview study done on the Malawian healthcare system found weak monitoring and evaluation, poor data management and inconsistent reporting to be a major challenge in providing care (Chitsulo et al., 2014)

Malawian Healthcare System

TB remains a major public health issue in Malawi, one of the poorest countries in the world. The Malawian healthcare system operates within the broader context of severe underdevelopment. As of 2013, HIV was responsible for 25.2% of deaths in Malawi while TB accounted for 5% of total deaths (IHME, 2013). HIV/AIDS remains the leading cause of death in Malawi while TB ranks fourth (IHME, 2013). The WHO estimates that only 78% of total TB cases are currently diagnosed in Malawi (USAID, 2015). The number of TB cases in Malawi increased steadily from 1995 until 2003, when it reached its peak of 28,000 cases (USAID, 2015). In 2013 alone, 20,335 new and relapse cases and 1,400 deaths were reported in Malawi (USAID, 2015). The Malawian healthcare system operates

The healthcare system in Malawi is broken up into a four-tiered network consisting of community, primary, secondary and tertiary care levels (Zere et al., 2007). Primary health care consists of health care centers located throughout the country providing a broad variety of services and are primarily staffed by health service assistants (HSAs) and nurses. The services offered by primary health care centers include the Malawi Essential Health Package (EHP): reproductive health, HIV treatment, TB treatment, diarrheal disease treatment, malnutrition care and care of common injuries (Chitsulo et al., 2014). Of the 900 primary health care facilities, 493 are government operated. Secondary level care is provided through district hospitals, non-profit mission hospitals operating under the Christian Hospitals

Association of Malawi (CHAM) and for-profit hospitals in the private sector. Secondary level care includes the EHP in addition to additional diagnostic services and limited specialized care (Chitsulo et al., 2014*).* Tertiary care is completed by centralized level hospitals that have the ability to provide advanced specialized care, research and teaching services. Currently, Malawi has only 6 "central" hospitals and a doctor to patient ratio of 1:50,000 (Chitsulo et al., 2014*)*. Most central hospitals are lacking qualified specialists and advanced diagnostics and care offered in these settings is often only marginally better than that offered at the district level (Hoffman, 2016). TB care is offered as a branch of care at all levels of care.

TB care is handled at all four levels of care in Malawi and can be further broken down by the specific TB services offered. Some health centers offer a combination of diagnostic, initiation and continuation services. Diagnostic services are offered by health centers with staff trained in proper sputum collection and testing, usually through microscopy (AFB smear). Initiation services include being able to start a patient on their course of drug treatment after diagnosis. Finally, continuation services stock patient's treatment drugs and hold the requisite supply of refills (Hoffman, 2016). For example, if a patient had TB symptoms and visited the nearest health center, a continuation site, they would be referred to a site with diagnostic services. Once they had been diagnosed and initiated into treatment, they could continue their course of therapy through the continuation site located closest to their home.

Partners in Hope

Partners in Hope is a non-profit hospital that provides care in Lilongwe, Malawi. In the summer of 2015, Partners in Hope Hospital conducted an evaluation of the TB health services in the Kasungu region of Malawi. Funded by USAID and in partnership with UCLA, Partners in Hope's (PIH) EQUIP-Malawi project provides "training, mentoring and facility development at over 70 hospitals and clinics in Malawi's Central and Northern Region" (PIH, 2016). Recognizing that HIV/AIDS does not occur in a vacuum, PIH expanded its work to broader health systems strengthening, including the Kasungu TB service evaluation. The project surveyed each health center to characterize level of staffing, adherence to TB guidelines, and to identify major issues from each site to characterize patterns in difficulty accessing TB care.

METHODS

Survey

This research draws upon data collected over the course of the summer of 2015 by a research team from Partners in Hope including Khumbo Phiri, Jimmy Chitsulo, Temwanani Mulitswo, Lumbani Ndhlovu and Andy Currier. This district was chosen as Partners in Hope already works in Kasungu with HIV care, and because nearly all of its TB facilities could be surveyed over the course of a month. The research team visited two or three health clinics per day over a month period in the district of Kasungu. Usually, the research team visited each site accompanied by the district TB officer from Kasungu District Hospital (KDH). The Chronic Cough Register, TB Register and Referral sheets were photographed at each site, with the initial goal of tracking patients referred from one facility to another.

A 47-question survey was developed by Dr. Alan Schooley at Partners in Hope (Appendix 1) and administered to each health center's TB focal person. The TB focal person is the member of each health center that has been trained in TB diagnosis and treatment guidelines and oversees all TB care at the site. The questions addressed basic information about staffing, adherence to guidelines, diagnostic information and primary issues facing the health centers and patients. It was made clear that the answers given would not be used to "grade" the performance of the staff and would not be followed by any form of financial compensation. The purpose of the survey questions was clearly stated as to gain a better understanding of the issues constraining effective TB care in Kasungu and to compile the first data on the successes and failures of the referral network. The preliminary findings of the survey were compiled into a short appendix in a yearly report from Partners in Hope to the United States Agency for International Development (USAID). The research presented here expands on this preliminary analysis to identify patterns and constraints to effective TB care in the district.

GIS Methods

I used ARC GIS (ESRI 10.3) to create maps of the spatial distribution of health centers, population and HIV estimates per health center and the referral path within the district from health centers. Data containing the administrative boundaries for each catchment area in Kasungu was obtained from DIVA-GIS. The catchment areas are not clearly delineated boundaries and were approximated using a mid-level Malawian administrative boundary similar to a county. Data on GPS coordinates for each health clinic were provided by the U.S. President's Emergency Plan for Aids Relief (PEPFAR). Arrows showing pathways of patient referrals were generated from information acquired in the survey. The transportation costs associated with patient referrals were identified on the survey. The cost to reach another health center was broken into three categories and displayed by colored arrows.

HIV prevalence rates and estimates of total population for each catchment area were provided by PEPFAR and used to calculate total number of HIV cases in each catchment area. A color scale was then applied to demonstrate the catchment areas with the highest number of people living with HIV. TB prevalence data for each catchment area is not available, but as the majority of TB patients are also HIV-positive, this comparative distribution of HIV cases may approximate the distribution of TB in Kasungu.

RESULTS

We surveyed 23 health centers in Kasungu, a district within the central region of Malawi (Figure 1).

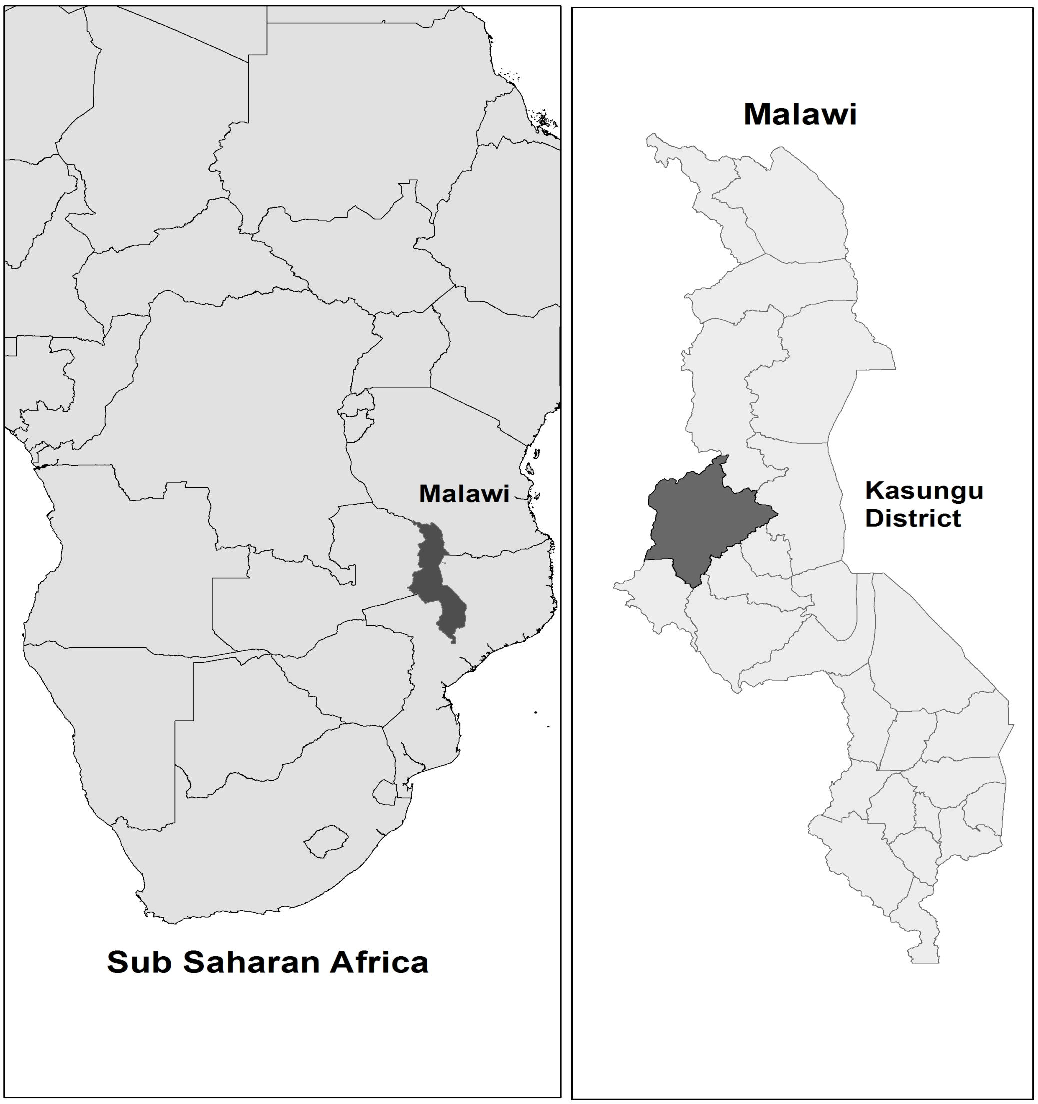

Figure 1. Kasungu region within Malawi and Sub Saharan Africa.

The population for each health center catchment area is displayed on Figure 2. The populations for catchment area were applied to the lowest administrative boundaries adjacent to the health centers, and in cases of overlap, combined. The services provided by each health center are additionally included and will be further explored in Figure 3.

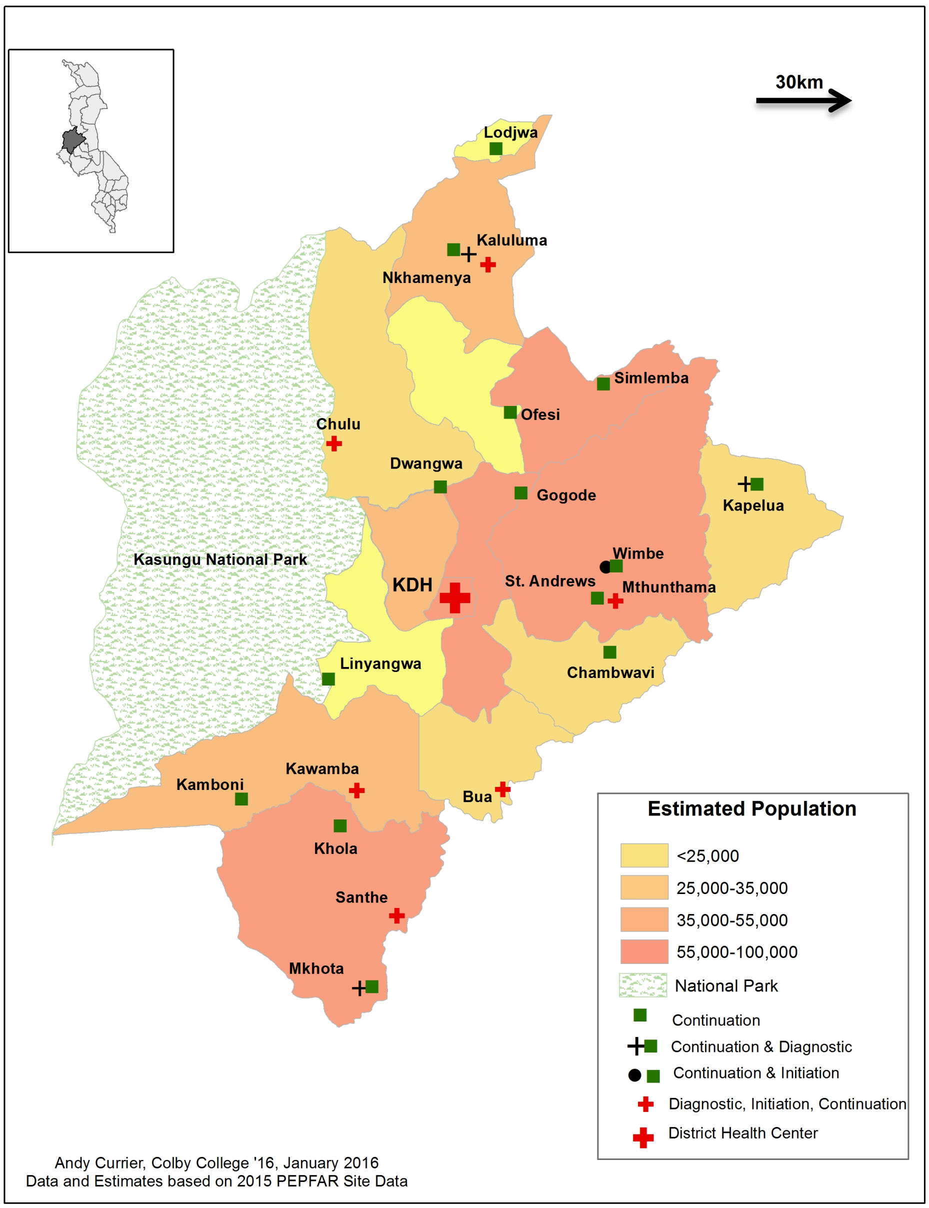

Figure 2. Population by health center catchment area and services offered by each health center.

The overview of the TB services offered by each health center is displayed in addition to the referral paths between health centers (Figure 3). A diagnostic has equipment and expertise to diagnose TB (typically microscopy for sputum AFB). An initiation site is able to start TB treatment based on expertise and drug supply. Finally, a continuation site is able to manage ongoing TB treatment based on resources, expertise and drug supply. The arrows reflect the flow of referrals between the health centers.

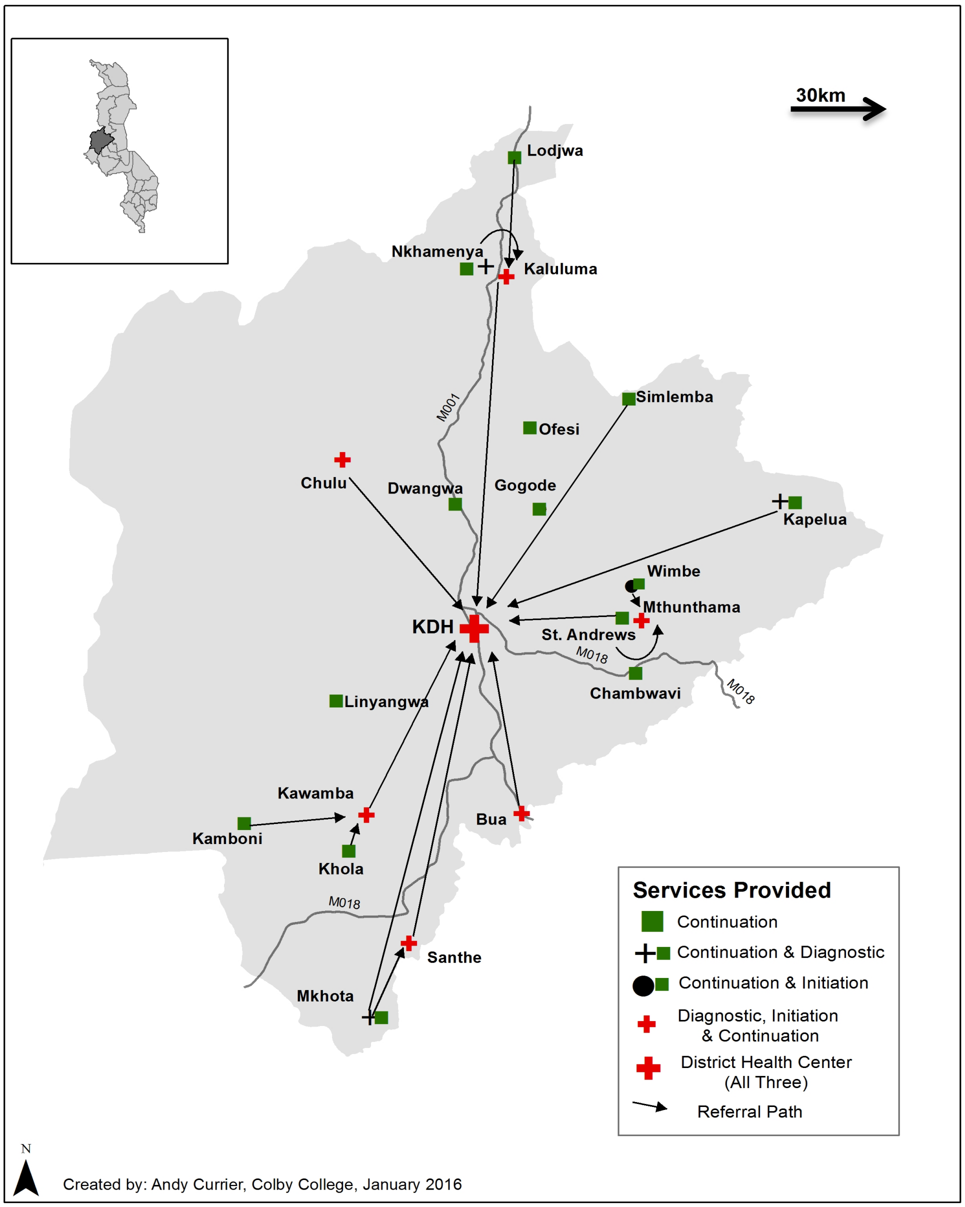

Figure 3. Overview of health centers in Kasungu with services offered and referral paths.

HIV prevalence rates previously collected PEPFAR site data for each health center catchment area with the populations of health center (Figure 2) are combined to estimate the number of people with HIV in each catchment area (Figure 4).

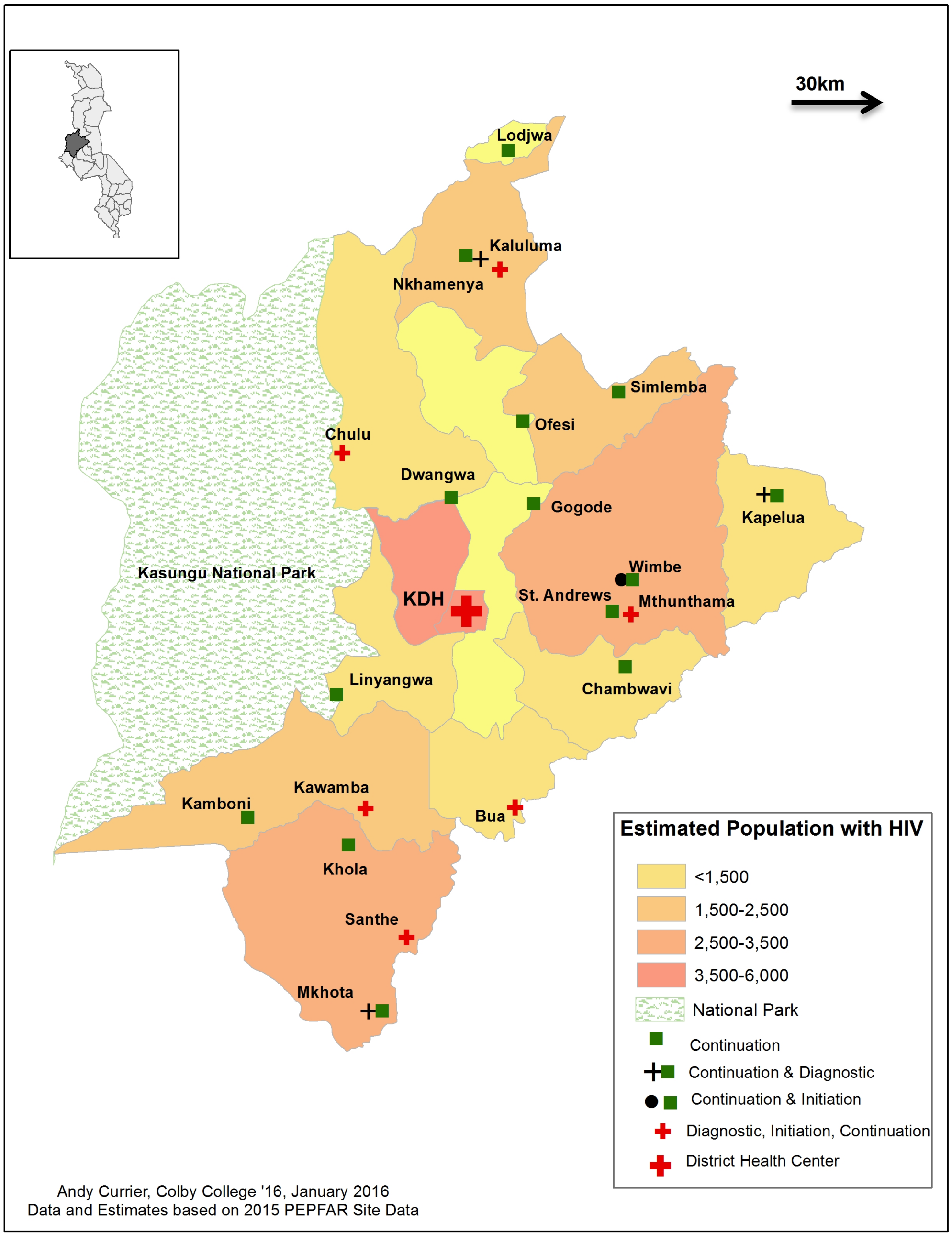

Figure 4. Estimated number of HIV-positive patients per health center catchment area in comparison to the distribution of health centers and the TB services they provide.

Survey results

We administered the survey to 23 health centers. All responses to the survey questions are summarized in Table 1. The survey responses from 23 health centers provided insights into TB diagnosis, treatment, referral patterns, patient constraints and record keeping. The total number of respondents varies by question, as some questions were only relevant to facilities that provided diagnostic care (n=10) and others applied to all of the health centers (n=23). A compilation of survey answers surrounding the capabilities of health centers reveal several trends in the diagnosis and treatment of TB in Kasungu (Table 1).

Diagnostic services refer to health center with staff trained in proper sputum collection and testing, usually through microscopy. Initiation sites begin patients on their treatment regime of drugs once diagnosed with TB. Finally, Continuation sites stock patient's treatment drugs and monitor consumption of the pills in line with the prescribed DOTS strategy. Sites that solely offered continuation services were the most common, with sites offering all three services the second most frequent with seven. Only four sites offered a dual combination of diagnostic, continuation and initiation services (Table 1).

The results from the survey offer the first comprehensive look at numbers and levels of staffing of TB health centers in Kasungu. HSA's and nurses can undergo TB therapy training to learn the national treatment protocols. Typically, each site has a "TB focal person" that oversees TB care in addition to performing their tasks as an HSA or nurse. Nine of the 23 sites had two staff members trained in TB therapy while seven sites had one trained staff member. Four sites did not have a current staff member trained in TB therapy. TB therapy refers to overall knowledge of the diagnosis and treatment process. The majority of sites rely upon a single HSA or nurse to provide TB care for the entire facility. Seven sites rely upon two HSAs while only one site had three staff members devoted to TB care (Table 1).

Table 1. Compilation of key survey results on questions surrounding health center capabilities.

SURVEY QUESTION	RESPONSES	
	Number	Percentage
What TB services does your health center provide? (n=23)		
All three	7	30%
Diagnostic, Continuation	3	13%
Initiation, Continuation	1	4%
Continuation	11	48%
No Services	1	4%
Number of staff trained in TB therapy at your site? (n=23)		
0	4	17%
1	7	30%
2	9	39%
3	3	13%
How many people provide TB care at your site? (n=23)		
1	15	65%
2	7	30%
3	1	4%
Has your site had a diagnostic supply stock out in the past year? (n=21)		
Yes	8	38%
No	13	62%
Has your site had a drug supply stock out in the past year? (n=10)		
Yes	2	20%
No	8	80%
Does your site have access to water and electricity? (n=23)		
Electricity/No water	2	8%
Water/ No electricity	4	17%
Both	10	43%
Neither	7	30%
For HIV+ patients not on ART who are diagnosed with TB, do you have a system in place to ensure they are started on ART as per the Malawi guidelines? (n=22)		
Yes	20	90%
No	2	10%
Are TB patients who are HIV+ able to receive treatment for both diseases during a single visit? (n=22)		
Yes	20	90%
No	2	10%

Responses to survey questions additionally highlighted strengths and weaknesses in treating TB once it had been diagnosed. Drug stock outs had not been an issue within the past year for 8 of the 10 health centers that distribute drugs (Table 1). Of the two health centers that reported drug stock outs within the prior 6 months, Mthunthama for 3 days and Simlemba for 1 week, neither noted drug stock outs as a recurring problem, as the follow up survey question asked. Diagnostic supply stock outs refer to a health center running out of items used to record patient information, including chronic cough registries, TB registries, patient referral cards and lab supplies used in the diagnostic process. These were a more frequent issue with nearly 40% of health centers identifying recurring stock outs (Table 1).

The availability of electricity and running water at each health center is a key indicator in health center capabilities overall. Ten sites had reliable access to both while six had neither. Four sites had water but not electricity while three had electricity and no running water. Of the ten sites without access to running water, five are solely continuation sites (Table 1). Three of the sites without water provide diagnosis, initiation and continuation services.

The survey highlighted most frequently identified factors that constrain TB treatment. Transportation, distance and fuel were given as primary constraints by 14 health centers. Transportation primarily concerns an inability to transport patients to referral sites and the limited ability to pick up sputum samples from collection points. A lack of trained staff was given as the second most frequent answer (9), with no site having more than three clinicians trained in TB care and the majority only having one (Table 1). Lack of district support in updating information on updates to National TB Guidelines was given by five health centers as a major issue. Finally, four sites gave lack of space in the health center devoted to TB care as a major issue. This primarily refers to adequate waiting space for patients and rooms to provide diagnosis and treatment.

The most common barriers for patients to accessing TB care, according to the health center staff were additionally revealed. The staff gave these answers freely and did not choose from a list of options. Of the 23 healthcare centers, 21 listed distance and cost of transportation as a primary barrier for patients to access care. The next most common answer was stigma of HIV. Healthcare workers noted that individuals sometimes fear that testing positive for TB will result in finding out they also have HIV. Four sites in total listed this stigma as a major barrier for patients.

Twenty sites (90%) followed the TB guidelines by starting HIV-positive patients on antiretroviral therapy (ART) and were able to offer treatment for both diseases during a single visit (Table 1).

Of the 10 sites with diagnostic capabilities, only Kasungu District Hospital (KDH) had access to the Xpert and an x-ray machine. The other nine diagnostic sites only carried a standard microscope. The lack of more Xpert machines means that all HIV-positive patients who test smear-negative must be referred to KDH to make a more accurate diagnosis.

The 2013 National TB Guidelines, composed by the WHO, stipulates that HIV-positive patients should be referred for GeneXpert even if their standard microscopy returns smear negative. This guideline stems from the aforementioned frequency of false negative microscopy sputum results from HIV-positive patients (Boniface et al., 2011; Fielder, 2009). One survey question asked the frequency that diagnostic centers followed the National TB Guidelines and referred HIV-positive patients who tested smear negative to the Kasungu District Hospital for Xpert testing. Of the ten diagnostic sites surveyed in Kasungu, only one (Chulu) follows the guideline and refers patients to KDH for Xpert. This result was obtained from the survey question, "Do you refer smear negative HIV-positive patients to KDH for Xpert as per the National TB Guidelines" (Appendix 1)? With the Kasungu District TB Officer present on the majority of the interviews, the TB focal person was hesitant to admit that they had not been following a guideline. Upon further questioning and observing records of referred patients, nine of the ten diagnostic sites admitted they had not been referring these cases.

The cost of travel for patients to travel from one health center to another is expressed in wages earned by days of work (Figure 5). To find this figure, the per capita Gross National Income was divided by 365. While it takes the average income per day of the entire country, it provides an accurate estimate of average daily wages in Malawi. The referrals primarily occur in cases when patients need additional diagnostic testing. This map only displays the cost of travel when a patient must travel from one health center to another and does not reflect the initial cost that must be paid to reach the first health center. With the average Malawian making $0.68 a day, transportation costs can greatly limit access to care (World Bank, 2015).

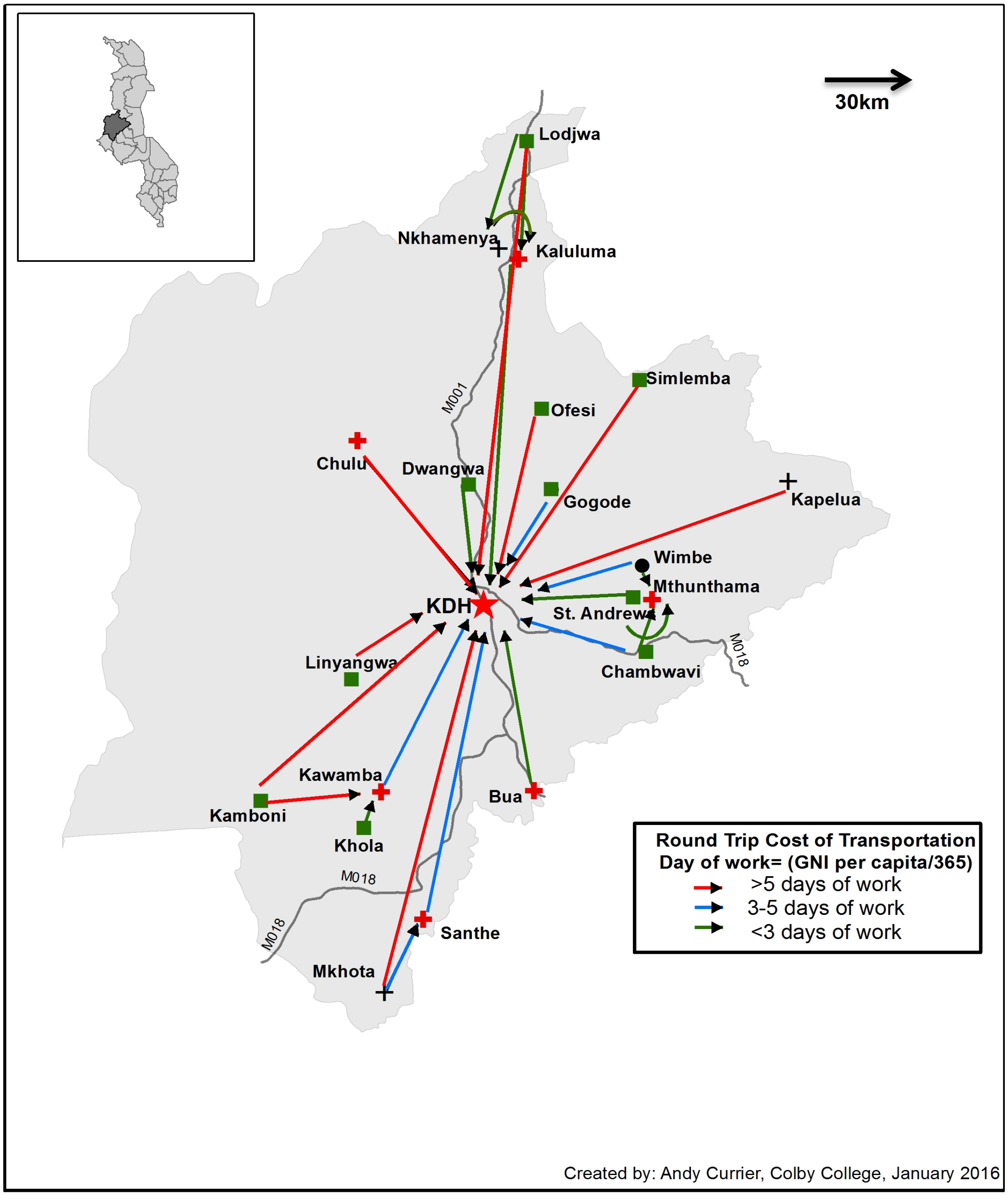

Figure 5. Cost of referral to travel between health centers expressed in days of work needed to pay for the trip.

The survey revealed an almost completely defunct sputum collection system in Kasungu. Sputum collection sites are located in villages and allow patients to submit sputum samples to a local Health Surveillance Assistant (HSA). The health center that manages the site is then responsible for collecting and testing the sample. This system has been designed to limit the burden of travel for patients. Combined, the 22 health centers collect sputum from 89 individual collection points. The health centers managed as few as one to as many as seven collection points, with a mean of 4.4 sites managed. If a patient tests positive, the health center contacts the local HSA who is then tasked with notifying the patient who can then travel to the health center to begin a course of treatment. The results of the survey revealed that of the 22 health centers that manage sputum collection sites, 14 are currently not actively collecting from the satellite sites. The five sites that collect samples monthly and quarterly do not do so in accordance to WHO guidelines for proper sputum management.

Table 2. Frequency of sputum collection by health centers.

Question: Frequency Sputum Collected (n=22)	**Weekly**	**Biweekly**	**Monthly**	**Quarterly**	**Not Active**
Number of Health Centers	1	2	3	2	14

Record Keeping

Members of the research team photographed the primary records at each health center. These included the chronic cough registry, TB register and referral log book. The amount of diligence in record keeping varied by site. In order to measure the overall accuracy of the records, a basic "sufficient" or "poor" classification was assigned to each site. Logbooks were given a score of sufficient if names had been logged in each quarter for the past year and if all of the available information (age, gender, sputum test results, HIV status and date) was included. Logbooks were insufficient if they not been recently updated or lacked significant amounts of the necessary information. Twelve of the sites (57%) had sufficiently kept record books. Nine sites (43%) had logbooks that had not been recently updated or that lacked significant amounts of patient information. These nine sites had only recorded the information of a handful of patients over the past year and had often missed vital information including if the patient had been referred and the updated diagnostic results.

DISCUSSION

The results of the survey gave an overview of the TB patient referral network in Kasungu, Malawi, the capabilities of health centers, and the constraints to effective TB diagnosis and treatment.

Capabilities of Health Centers

Sites that only offered continuation TB services were the most frequent, as they require the least amount of diagnostic equipment and trained TB staff. These continuation sites allow patients to complete their regimen of medication and pick up their refills. In terms of diagnosis, the standard microscope remains the most common method of testing for AFB presence in sputum samples in Kasungu. This is due to its lower cost and complexity compared to chest x-rays and Xpert. In past surveys of Malawian TB care facilities, microscopes were nonfunctional around 22% of the time (Harries et al., 2001). Microscope functionality remained consistently strong in Kasungu, with none of the sites reporting their microscopes as broken (Appendix 1). While the Xpert provides a more accurate diagnosis, the high cost of the tool results in only the district hospital (KDH) currently utilizing the technology.

That only 17% of health centers have a staff member trained in TB therapy and 68% have only one staff member for TB care presents a number of problems. It is likely that the national TB guidelines are not explicitly followed, as health providers must be trained in order to understand and properly implement the guidelines (WHO, 2007). Lack of staff trained in TB therapy and lack of laboratory technicians have been noted as issues in Malawi (Harries et al., 2001) and may undermine TB care in Kasungu specifically.

The effects of lack of staffing include increased health center and patient delays (Kanyere et al., 2005). On particularly busy days, this results in long waits for individuals who have already travelled a long way to be tested for TB or receive treatment. If the staff responsible for TB care become sick or are unable to work, 15 sites are without anyone to provide TB care. TB staff shortages exist in the context of severe healthcare worker shortages in all Malawian health sectors. The limited number of staff providing TB care could play a role in the high level of health center delay for TB treatment found in a recent study from Malawi (Makwakwa et al., 2014).

Overall, TB and HIV care is synchronized in the district in order to reduce the strain on patients suffering from both diseases. Twenty sites either provide care for each disease five days a week or have synchronized the days of treatment for both diseases. The two sites that could not offer treatment for both HIV and TB during the same visit, Santhe and Linyangwa, have treatment days for each disease that do not overlap. ART drugs to treat HIV and the specifically trained staff provides counseling on Tuesday and Thursday and TB drugs are provided on Monday and Wednesday. This results in patients suffering from both diseases having to make an additional trip each week.

The availability of electricity and water plays a role in the services a health center can provide. In order for sputum smears to be prepared, a health center needs to have access to clean water. Of the ten sites without running water, four still provide diagnostic care through the use of a well, known locally as a borehole. While this can suffice for smear preparation, two of the sites noted that the borehole is not entirely functional. Among other things, electricity is used for the refrigeration of sputum samples. Eleven sites did not have reliable electricity, constraining their ability to store sputum samples (Creswell et al., 2014). Several sites relied upon coolers and solar panels to overcome the lack of electricity. For sites that only offer continuation services, electricity and running water are not necessary for administering the course of treatment. Chambwavi, a site with a microscope and staff trained in using it, is limited to only providing continuation services because they lack electricity. If Chambwavi had electricity, they could become a diagnostic site and avoid sending their sputum samples and patients to another site, saving time and resources.

Adherence to National TB Guidelines

Several survey questions sought to reveal areas where the everyday practices of TB health centers differed from the National TB Guidelines. The survey revealed a major discrepancy between the National TB Guidelines and practices for diagnostic clinics in Kasungu. The 2013 National TB Guidelines, composed by the WHO, stipulate that HIV-positive patients should be referred for Xpert even if their standard microscopy returns smear negative. This guideline stems from the aforementioned frequency of false negative microscopy sputum results from HIV-positive patients (Boniface et al., 2011; Fielder, 2010). An astounding 90% of clinics reported that they did not refer HIV-positive/ smear-negative patients for further testing using the Xpert at KDH. By not doing so, many of these health centers are more than likely misdiagnosing HIV patients as TB-free. Past studies have shown false negative sputum microscopy for HIV-positive patients at percentages between 33%-64% of cases (Fielder, 2010).

The WHO has designated two weeks as the longest time period that sputum samples can be analyzed accurately, yet many health centers in Kasungu fail to meet this time frame. Five of the 22 health centers that collect sputum samples from collection points do so only either monthly or quarterly. These five health centers manage 21 sputum collection sites in total. So, countless individuals who deposit sputum samples fail to receive an accurate diagnosis. In cases where sputum is collected in time, the health center makes a call to the HSA in charge of each collection site notifying him/her of the patients who tested positive and need to come in for initiation of treatment.

The 14 health centers that no longer actively run sputum collection sites had managed 48 collection points. It is unclear if individuals' still deposit sputum samples at these collection points. Over 50% of sputum collection points in Kasungu not currently active (Table 2), which may burden patients who make an additional trip to a health center to deposit sputum.

When functional, the system allows for convenient TB diagnosis for patients, who do not need to make the trip to the nearest health center, and reduces the burden on health center staff who can see fewer patients quarterly. Lack of money to operate the collection points and transport the samples has been cited as the underlying cause of the overall failure. For the sites that remain operational, infrequent collection results in questionable accuracy of the samples. This partial functionality is quite troubling as it could result in a patient submitting a sample and never being informed of their diagnostic outcome. The patient would rightfully assume that they were TB free and continue with daily life, possibly infecting more individuals in the community and increasing the risk of morbidity and mortality from undiagnosed TB. The sputum collection system is one of the least functional aspects of TB care in Malawi and should be high on the list of areas for improvement.

Health Center Supplies

One of the more positive findings of the survey was the infrequency of drug stock outs in an underfunded health care system. None of the sites identified recurring drug stock outs as a recurring issue (Table 1). This finding could very well reflect the attention paid by the international community to reducing the burden of TB in Sub-Saharan Africa. This focus appears to have materialized in the form of a constant supply of TB drugs. The constant supply of drugs found at even the most rural health centers demonstrates the steady supply and dissemination of TB antibiotics throughout Kasungu.

However, diagnostic supply stock outs were much more frequent and very likely play a role in the overall challenges with TB diagnosis, including poor keeping of patient referral records. Diagnostic supplies include the registries that patient information is kept in, referral cards recording that a patient has been sent to another facility and sputum containers to test for TB. The monitoring supply shortages could very well play a role in the high number of facilities that had insufficient records. These diagnostic supplies are much cheaper in comparison to the drugs that are successfully being passed along to even the most rural health centers. This could be an area that could be improved at little to no cost. The question remains if the true root of the record keeping and organizational issue lies in lack of supplies or general norms for overworked health center staff versus lack of training versus other, yet to be identified factors.

Constraints to TB Care

Transportation, distance and fuel were identified by HSAs as the major issues preventing their ability to provide TB care. This may stem from the variety of factors of TB care that rely upon transportation. The breakdown of the sputum collection system primarily occurs after the sample is given, as it never reaches the diagnostic center, as health centers lack access to a fueled automobile or motorbike to collect the samples. This places an increased burden of travel onto patients who must add an additional trip to the health center to deposit their sputum sample.

Distance and the cost of transport to the health center remains the primary barrier for patients to access care. A 91% of sites surveyed listed distance and transport cost as the primary barrier, in line with past research on constraints to TB care in Malawi (Salaniponi et al., 2000; Kanyere et al., 2005; Zere et al., 2007). The transportation issue is further complicated in the rainy season (November to April), when dirt roads become increasingly treacherous (Kaneyere et al., 2005; Appendix 1).

The main findings of this study lead to the conclusion that there is an under-diagnosis of TB in Kasungu. As data play a vital role in the allocation of funds, having TB statistics that do not reflect the reality of the current situation in Kasungu will hold several challenges for the future. The WHO sponsored Post- 2015 Global Plan to Stop TB seeks a 95% reduction in deaths from TB from 2015 levels. In order to attain these goals, resources will be allocated to areas based on current levels of TB. If the other districts in Malawi currently experience similar shortcomings to their diagnosis and treatment of TB, the entire countries TB figures could truly be significantly higher than currently recorded.

RECOMMENDATIONS

Taking steps to address the root causes driving under diagnosis of TB will allow the true impact of the disease to be measured. Accurately measuring the incidence and prevalence of TB in Kasungu can provide the WHO and Malawian government with the necessary data to properly combat the disease. Results of this study point to four main recommendations. These recommendations are all fairly low cost and would not require significantly higher levels of funding but could help to diagnose a higher proportion of TB cases.

First, in a resource-constrained setting, in order to increase the number of staff trained in TB care without hiring new HSA's, current health center staff could be cross-trained. Cross training more nurses and HSA's in TB care has been recommended to improve TB care in Malawi in the past, and would only require trainings led by the district TB health officer (Harries et al., 2001). Having more health center staff trained in TB would be a low cost method to improve overall knowledge of the TB guidelines and increase the number of HIV-positive patients referred for Xpert.

Second, adding solar panels could expand access to electricity to every health center in Kasungu. Increasing access to electricity would allow for more reliable storage of sputum samples. Refrigerating sputum has been shown to increase the amount of time the sample can be accurately tested (Banda et al., 2000). Low cost installation of solar panels could provide electricity to the 11 sites in Kasungu currently lacking electricity.

Third, to revitalize the sputum collection system, a program to collect samples from collection points and transport them to health center could be implemented. The program would require paying individuals to facilitate the functionality of the system. With few options for formal employment in the current Malawian economy, offering even a limited amount of money to transfer the samples could revitalize the collection system. Paid collection systems have functioned and been highly effective in Malawi in the past (Mundy et al., 2002). To reduce the number of people who submit samples that are not tested in time, health centers should call and notify local HSA's by cell phone if the sample was not tested within the requisite timeframe just as they would for a sample that tested positive for TB. This would allow the individuals to resubmit another sample rather than assume they were TB free.

Fourth, “packs” of diagnostic and monitoring supplies (TB registries, TB cards, sputum containers, referral cards) could be included with drug deliveries to improve record keeping in the district overall. The success of stocking even the most rural of health centers with TB drugs demonstrates that having an equally high rate of diagnostic and monitoring supplies is attainable. Including these supplies with shipments of drugs would ensure all sites are always stocked and can keep records with more accuracy. Without constant supplies of the proper registries to record patient information, record keeping will remain a major issue with TB treatment in Kasungu. This study originally aimed to track patients from the health center they initially visited to the continuation or diagnostic site to which they were referred. However, with record keeping insufficient at such a high percentage of sites, the data was too incomplete to analyze. If record keeping improved, the actual number of patients referred could be analyzed to identify the most common paths of referral. Trainings on the importance of data collection could additionally improve the quality of patient records. These trainings could be included in the standard training to become trained in TB therapy.

With the maps of Kasungu now available, the district TB office and NGOs that provide assistance in Malawi can target their interventions at the health centers based on population and site capabilities. Allowing the HSA’s who work understaffed on the front lines on the fight against TB to voice their opinions on the major constraints to care will provide the Ministry of Health and NGO’s with an informed on the ground opinion to improve care. While the findings in Kasungu cannot be entirely applied to Malawi overall, they highlight certain aspects of TB care that should be explored in more detail for the other regions. Further research into the practices of health centers in other regions of the country with higher HIV prevalence rates could identify if the same issues in referral in Kasungu occur in other regions to determine the scope of under diagnosis throughout the country.

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APPENDICES

Appendix 1. Survey administered at each health center.

TB Site Assessment – District Name: ______________________________

"Please complete this questionnaire with the TB Officer at the site or the clinic staff who manages TB patients."

Site Information	
Site Name: MoH Site Code:	
Type of Site *(health centre, rural hospital, outreach clinic):*	
Site GPS Coordinates (Extract from MOH Spreadsheet):	
What is the name and position of the clinic staff answering these questions *(The respondent)*?	Name: ____ Position and Cadre: ________________________________ Phone number:
Approximately how many employed staff work at the site?	
How many staff member(s) are trained in TB Therapy? What are their cadres? (HSA, HTC	Number HSAs: __________/__________

counselors, nurse) How many of each provide TB care on a weekly basis?	Number HTCs: _________/_________ Number Clinicians: _________/_________ Number of Nurses: _________/_________ Volunteers/CHW: ________/__________
What type of TB services does your facility provide? (Diagnosis, Initiation, Continuation, no TB service at all)	☐ Diagnosis ☐ Initiation ☐ Continuation ☐ None ☐ Other: Describe: ___________________________________
If you are an initiation/diagnostic site, how many sites refer patients to you?	List Referring Sites:
If you are a diagnostic site, what are the types of tests you are using?	☐ Ultrasound ☐ Urine-LAM ☐ Culture

	☐ ove ☐ Chest X-ray: ☐ Microscopy: ☐ LED ☐ standard microscope ☐ Other:
If you are a diagnostic site and need additional testing not available at your site (i.e. GeneXpert, Chest X-ray) where do you send patients?	1) ______________/Distance: ________/est cost:________ 2) ______________/Distance: ________/est cost:________ 3) ______________/Distance: ________/est cost:________ 4) ______________/Distance: ________/est cost:________ 5) ______________/Distance: ________/est cost:________
Does your site record information on referrals and can you be sure that all referrals for additional testing are completed?	☐ Yes ☐ No If yes, please describe the process of documentation for referrals. If no, please describe the barriers that keep you from tracking patient referrals.
If you are a diagnostic site when was your last quality control for microscopy?	Date: Proportion of microscopists that Passed QC testing:______________

How many sputum collection sites does your site manage? Please list names of villages that have sputum collection sites:	Number of sites: ___________ Name of Villages:
How frequently are sputum collection sites visited?	☐ Daily ☐ Weekly ☐ Other
Who is responsible for collection sputum from collection sites?	Cadre:_____________________/Name:_____________________ Cadre:_____________________/Name:_____________________
What sputum collection site is farthest from your facility?	Name: ____________________/Distance:__________________
Is your site able to verify that all collection sites have been visited and any sputum samples collected and dropped off at the diagnostic site?	☐ Yes: ☐ No If yes, how?
How do you trace patients with positive sputum collected from sputum collection sites?	Describe:

Supply and Tools	
Do you use the following forms: (Tick all that apply)	☐ Tuberculosis Treatment Card ☐ Tuberculosis Identity Card ☐ TB Laboratory Request form ☐ TB Facility Register ☐ TB Health Centre Register ☐ TB Referral slip/Transfer Form ☐ Chronic Cough Registry ☐ TB Suspect Registry Other: ____________________
In the past six months did you experience any TB drug stock outs? ☐ Yes: ☐ No	If yes: Which TB drugs? 1)____________ 2)____________ 3)____________ Duration of stock out:________ Are drug stockouts a recurring problem? Y/N ☐ Yes ☐ No
In the past 6 months have you run out of any diagnostic or monitoring (registries, TB cards)	Supply types: 1) ________

TB supplies? Yes: ☐ No: ☐	2) ______________ 3) ______________ Duration of stock out: 1) ______________ 2) ______________ 3) ______________
How many weeks of drugs do you give to clients at the initiation visit? If you are a continuation site, how many weeks of TB medication are dispensed at follow-up visits?	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ Entire course of therapy
Does your site have electricity?	☐ Yes: ☐ No If yes, enter number of days in the most recent month the power has been out: __________
Does your site have water?	☐ Yes: ☐ No If yes, enter number of days in the most recent month the in which your site has been without water: __________

Diagnostic/Initiation: How do you track patient treatment outcomes? Prompt: What documentation do you use?	
For Continuation Sites: Do you always send back the master card to the referral or diagnosis center after a patient completes treatment?	☐ Yes: ☐ No
: For HIV+ patients not on ART who are diagnosed with TB, do you have a system in place to ensure they are started on ART as per the Malawi guidelines?	If yes, describe the process: If no, why?
Are TB patients who are HIV+ able to receive treatment for both diseases during a single visit?	☐ Yes: ☐ No If No, why?
Referral System – DIAGNOSTIC AND INITIATION SITES	
What tools do you use for documenting the outcomes of patients that are referred to you?	

How do you provide referring sites with information on the outcome of referred patients (No TB, Started therapy, smear neg/smear pos etc.)	
If you refer patients for TB continuation, do you receive any information about patient outcomes (completion of treatment, complication of treatment, death)	☐ Yes ☐ No Describe: Are there sites that are particularly bad at sending patient follow-up information? If so, list the sites and provide possible reasons.
How frequently do you assess patients as they continue treatment at your facility? If assessments are done, who does the assessment? [ ] Nurse [ ] Clinical Officer	Describe: ☐ Daily ☐ Biweekly ☐ Monthly ☐ Every two months (Bimonthly) ☐ Quarterly

[ ] Counselor [ ]HSA	☐ Never ☐ Other:____________________
For TB patients that complete their treatment at another site, do you see them during their therapy or at the completion of therapy?	☐ During their therapy. How often? ☐ At the end of their therapy ☐ Never
Referral System – CONTINUATION SITES	
Which diagnostic/initiation site do you refer your TB suspects? If more than one, list in order (most frequent to least frequent)	1___________/Distance: _______/est cost:_______ 2______________/Distance: _______/est cost:_______ 3______________/Distance: _______/est cost:_______ 4______________/Distance: _______/est cost:_______
Do you keep a register of patients referred for TB diagnostics or initiation of TB therapy?	☐ Yes ☐ No Describe documentation Who is responsible for updating the information? Cadre:_____________/Name:_________________ Cadre:_____________/Name:_________________ Does the facility update outcomes for TB suspects? ☐ Yes

	☐ No If no, why?
Does the site follow-up TB suspects at their homes? ☐ Yes ☐ No	If yes, who does the follow-up? Cadre:_____________/Name:___________________ Cadre:_____________/Name:___________________ How is the visit documented?
For patients that are referred back for continuation of TB treatment, how frequently are they seen	☐ Weekly ☐ Biweekly ☐ Monthly ☐ Every two months (bimonthly) ☐ Quarterly ☐ Never
Does your site notify the diagnostic or initiation site when the TB patient completes therapy or dies or defaults?	☐ Yes ☐ No If yes, how?
General Questions	
What is the most significant problem with TB care at your site? Examples: staffing, lack of supplies, lack of diagnostic	

equipment, lack of training, lack of district support, etc.	
What do you think is the most important barrier to accessing TB care for your patients?	