## COMMUNITY BASED TREATMENT OF TUBERCULOSIS IN RURAL MOZAMBIQUE

by

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#### Abstract

**Background**: Tuberculosis (TB) is a contagious disease commonly occurring in the lungs and is spread through the air usually by coughing. This infectious disease is particularly dangerous for individuals with compromised immune systems, like those with HIV/AIDS. Treatment for pulmonary TB infections is a regimen of multiple antibiotics lasting for at least six months.

**Objectives**: Despite complete coverage of treatment costs for TB patients by the Ministry of Health in Mozambique, incidence of the disease remains a high 174 cases per 100,000. The objective of this project is to evaluate World Relief's (WR) community based TB directly observed therapy short-course (DOTS) treatment program.

**Methods**: Sixty-four TB treatment program volunteers within the three highest populated districts of the province of Gaza were interviewed and data were collected to identify accurate numbers of current community based DOTS patients per district. The central hospital in each district was also visited to directly acquire patient data and interview TB nurses.

**Results**: Currently a total of 153 TB patients are receiving community-based treatment in the three districts visited. On average, each village has one community based DOTS volunteer, and each volunteer oversees the treatment of up to three patients at a time. These volunteers

reported positive community reception to TB prevention education yet felt inadequate with the community based DOTS system of treatment as a whole.

**Conclusions**: Based on the data collected and interviews completed, the community based DOTS program was effective in raising community awareness of TB prevention, as well as educating about TB as an infectious disease and TB treatment. The evaluation also concluded that the program lacked proper training and education maintenance for the volunteers in rural villages.

**Implications for global health**: Much potential exists for the community based DOTS program to successfully reduce TB incidence in Mozambique, particularly if WR is able to implement the necessary changes and improvements in volunteer training to its program in order to maximize its effectiveness in the community. The health problem of TB is of considerable public health significance because of the highly contagious nature of the bacteria. Without substantial steps taken to decrease the number of cases particularly in populations of greater susceptibility, the disease will only spread and mortality will increase. A successful decrease in incidence of TB infections in Mozambique would lead to a longer average life span and increased health in the population overall.

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## PREFACE

The first time I set foot in Mozambique I only stayed for ten days. When I left, I wished I could have stayed longer—it is difficult to get to know people in such a short period of time, and with language differences. But I am incredibly grateful to have been blessed with multiple opportunities to return and spend longer periods of time in Mozambique. My experiences with the people there certainly changed my life, and I am hopeful that my evaluative public health work might change a life or two in return.

This thesis expresses the lessons learned from a professional internship, but also those learned from personal experiences and interactions with individuals who became dear friends. The best gift I have taken away from this experience is all I have learned about tuberculosis, public health evaluation, and the love of people.

I am grateful to my family and friends, and especially to my fiancé Logan, for all your support throughout my pursuit of a Master's of Public Health degree. To Dr. Pieter Ernst, Dr. Adolfo Cambule, Nameixia, Arlindo Machava, Sybil Baloyi, and every one at World Relief Chokwé who welcomed me—it was my pleasure to work alongside you. And to my God, who works out the details and makes all of my adventures possible. I am so grateful.

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#### **1.0 INTRODUCTION**

The developing world, largely sub-Saharan Africa, Southeast Asia, and the Western Pacific, is impacted by the burden of tuberculosis (TB). In 2010 the countries in these regions of the globe made up 85% of all active TB disease in the world (World Health Sciences, 2010). Because of its highly contagious nature and the difficulty to treat it, TB poses a serious threat to communities in which cases emerge. In 2009, global prevalence of TB infections was 164 per 100,000 population (World Health Organization [WHO], 2010). Comparatively, in the United States, where the disease is well controlled, prevalence in 2009 was 3.9 per 100,000 population (MMWR, 2011). In more developing areas of the world, TB is more prevalent and treatment is not as easy to obtain.

An infection of pulmonary TB is treated over a course of six months with multidrug chemotherapy, as described in the background chapter. Compliance to this strict and lengthy process often becomes a problem for patients, particularly those with existing issues in their access to consistent and effective medical care. Currently the most common treatment policy for TB is a design called Directly Observed Therapy, Short-course (DOTS) where health care providers *directly observe* patients taking their anti-TB medications and keep a detailed record of their treatment. This is effective because it guarantees that TB patients take accurate doses of anti-TB medications, which will cure the infected person. Community-based DOTS is also a system where the patients are observed as they take their medication; however, instead of a

doctor or trained health professional observing the patient's treatment, a local community lay health worker or family member supervises and keeps record of the treatment.

Tuberculosis is currently a concern in many developing countries, like Mozambique, and a returning concern in more developed countries, like the United States (US). Individuals exposed to TB who have a weakened immune system, like those who are HIV positive or have AIDS, are at a greater risk of susceptibility to TB, a highly contagious bacterium, even for those with healthy immune systems. In developing nations, where rates of HIV and AIDS are significantly higher than in the more developed world, this means that rates of TB are also increased.

In the nation of Mozambique, in eastern sub-Saharan Africa, the method of communitybased DOTS for treating TB is very effective. Due to the rural nature of the majority of the country, a hospital-based system of treating TB is ineffective: rural community members have no source of transportation to get to the hospitals, which are located in sparse urban centers. This lack of transportation keeps individuals with TB from properly complying with the daily medications required to treat a TB infection. Non-compliance leads not only to the patient remaining ill, but also to the development of drug-resistant strains of TB that are far more difficult to treat and to an increase in transmission of the disease to the remaining population.

The target population of this research in community-based TB DOTS treatment is comprised of community members of all ages and gender identifications of rural villages in the southern Mozambican province of Gaza. Individuals in this area share a common susceptibility to both TB and HIV/AIDS due to a risk-exposing social structure and lifestyle risks. Structural risks in this society include a lack of organized health care and disease prevention at the village level. Based on the experiences of several Mozambican community members, men living in this area tend to work abroad in South Africa for months at a time while their families remain in Mozambique. As a result of encounters with HIV positive sex workers in South Africa, Mozambican men may contract HIV and subsequently transmit the virus to their wives and children when they return home (MacPhail et al., 2009). Lifestyle risks like these perhaps lead to more individuals living with HIV/AIDS, who subsequently have an increased susceptibility to contracting TB due to their compromised immune system.

The objective of this research was to investigate how to effectively increase positive outcomes of TB treatment as well as to assess areas needing improvement within the community based DOTS strategy and delivery in economically developing rural settings like Mozambique. This leads to the research question: is community based DOTS an effective method of treating TB patients in rural developing settings like Gaza, Mozambique?

This thesis first provides background information about TB and its impact in Mozambique. Following this it provides an overview of the current literature available regarding tuberculosis and treatment in the developing world. It introduces the methodology used to collect data to evaluate this treatment program and then the results. A discussion of these will follow.

#### 2.0 BACKGROUND

Tuberculosis, an infection caused by the bacteria Mycobacterium tuberculosis, occurs often in the lungs (pulmonary TB) but can also spread to infect other organs and systems in the body. The bacteria are highly contagious and difficult to treat. TB infections are typically treated with a combination of three drugs, isoniazid, pyrazinamide, and rifampin, administered over a period of six months (NIAID, 2007a). B ecause the infection is generally located in the lungs, the sputum and cough of an individual with an active TB infection often contain *M. tuberculosis* bacilli, which have infiltrated the airways of the infected individual. The bacilli released into the air during a cough are thus highly infectious. Usually those in close contact with the same air supply being breathed by the infected individual, such as those in shared residences, are at the highest risk for acquiring the infection (Virginia Department of Health, 2011). HIV positive individuals are also at a higher risk of susceptibility due to their already compromised immune system.

If the bacteria successfully bypass the body's primary immune system, they enter the new host and, following the path of inspiration, end up in the lungs where they stay and multiply. The host immune system, in an attempt to control an infection that it cannot kill, induces natural antimicrobial activities to control the infection, including sending white blood cell macrophages to latch onto the bacteria and essentially surround the bacteria so that they cannot spread further or reproduce. The macrophage-surrounded bacteria develop into small granulomas in the lungs. The macrophages create a toxic environment surrounding the bacteria; however, this can negatively impact the lungs if a granuloma ruptures and contaminates the lung tissue.

TB infected individuals are treated with multiple drugs that work together to destroy the bacteria. Combinations of drugs are used to treat TB, but the most common is a mixture of "first line" drugs that are most commonly and effectively used to treat and cure individuals with TB infections. Currently four medications are considered first line drugs: isoniazid, rifampin, and pyrazinamide (National Institute of Allergy and Infectious Diseases [NIAID], 2007a). Rifampin disables the *M. tuberculosis* by targeting the DNA transcription machinery, while isoniazid inhibits the synthesis of the pathogen's protective cell wall. Pyrazinamide is recently discovered to target ribosomes within the bacterial cell, thus restricting protein synthesis within *M. tuberculosis* and weakening the bacteria (Shi et al., 2011).

Some *M. tuberculosis* strains are not affected by this combination of first line drugs so other medications must be combined to treat the infection. Multi drug-resistant (MDR) strains of *M. tuberculosis* are not affected by rifampin or isoniazid (NIAID, 2007b). In place of these medications, treatment providers can choose from a number of "second line" drugs that are more likely to be effective. Thioamides and cycloserine can effectively inhibit the synthesis of the bacterial cell wall, and PAS, fluoroquinolones, cyclic peptides, and aminoglycosides can do the same in the place of rifampin (NIAID, 2007b). Second line drugs in combination with first line pyrazinamide are more effective in curing cases of MDR TB (NIAID, 2007b).

In 2010, according to the WHO, the worldwide number of incident cases of TB was 8.8 million, which was a decrease from prior years, and which has been decreasing throughout the past five years (WHO, 2011). This is encouraging in the face of MDR TB and the challenges in treating all strains of TB bacteria. Although the incident number of cases has decreased from

2006, TB remains a threat to public health, particularly in the developing world, where HIV/AIDS remains a constant threat to health. Despite DOTS, Mozambique remains a highburden tuberculosis country, meaning that Mozambicans and citizens of other high-burden nations account for the majority of the total TB burden in the world (USAID, 2009). In 2007, over 92,000 new cases of TB in the world were estimated to have occurred in Mozambique, nearly half of which occurred in HIV positive individuals (USAID, 2009). The WHO incidence rate of TB in Mozambique in 2009 (MMWR, 2009) was 431 per 100,000; by comparison, in the US, it was 4.2 cases per 100,000 in the same year (CDC, 2012).

DOTS is highly effective in protecting against TB when used correctly. The communitybased DOTS strategy involves local healthcare providers being present for the distribution of anti-TB drugs and ensuring the compliance of their patients with each dose. Healthcare providers literally stand and watch their patients as they take their anti-TB drugs. Community based DOTS also requires government approval, cooperation, and funding (WHO, 2012). The strategy employs increased case detection with the use of surveillance and testing. The evaluation and monitoring of the program as it progresses is also a necessity for the success of community based DOTS (WHO, 2012). In Mozambique in 2009, TB treatment following the DOTS program saw an 83% success rate in cases (WHO, 2009).

## 2.1 REVIEW OF RELEVANT LITERATURE

This section will provide, first, a brief history of the DOTS method of treatment for TB, and then investigate the current effectiveness of community based DOTS as a t reatment for TB,

particularly in rural areas in the developing world. Finally, this section will discuss the future of TB and the DOTS method of treatment, based on current research.

According to the WHO (2006), the standard method of treatment for TB is DOTS, or directly observed therapy short course, a method that emerged in the early 1960s and that has been developed in the decades following (Bayer & Wilkinson, 1995). A n article about the history of treating TB with DOTS by Bayer and Wilkinson (1995) discusses the feasibility of the direct observation method of treatment. When it was originally developed, the general response to a method of treatment requiring daily observed treatment doses was that it was largely inconvenient and impractical (Bayer & Wilkinson, 1995). Initial studies using DOTS-like methods were in Madras, India, completed by Dr. W. Fox in 1958, and in Hong Kong, by Dr. A. S. Moodie in the early 1960s (Bayer & Wilkinson, 1995). Moodie's work emphasized the importance of prioritizing the care of the patient over health care provider convenience in the clinical setting (Bayer & Wilkinson, 1995). This work later led to approval of home care or community based care of TB patients (Bayer & Wilkinson, 1995).

There was, however, a gap in time before Fox and Moodie's approach to observed TB treatment research would surface again. In the late 1960s in the US, hospital researchers began to see the importance of increasing TB patient knowledge about their treatment and its protocol. "Supervised therapy" was suggested but not heeded by the majority of health care providers (Bayer & Wilkinson, 1995). In the 1970s, Dr. J.A. Sbarbaro began to argue for the "supervised therapy" method for TB patients (Sbarbaro, 1980). Sbarbaro published an analysis of the costs and benefits of the method, proving that it would be cost effective, but his audience was uninterested (Bayer & Wilkinson, 1995). In the early 1980s, the US Centers for Disease Control

and Prevention (CDC) began to support the "supervised therapy" method of treating TB but did not require it as a protocol for TB control in the US (Bayer & Wilkinson, 1995).

As cases of TB rose, particularly in New York in the 1990s, attention was finally paid to the method of treatment by direct observation (Bayer & Wilkinson, 1995). In 1993 the directly observed therapy method of treatment became the standard for TB treatment in the US by federal law for hospitals and treatment centers whose TB cure rates were below 90% (Bayer & Wilkinson, 1995). The WHO adapted the directly observed therapy method as its standard of TB care in the early 1990s after careful analysis of the several factors in the treatment process; WHO called the treatment process "DOTS" as it is known today (Sandoz, 2004).

Several studies investigate the use of community based DOTS and community involvement in TB treatment, particularly in rural developing settings. S ome of these are discussed below.

One article stresses the importance of community involvement in TB treatment and involves a randomized controlled trial in Swaziland, where direct observation was used to study the effectiveness of family caretakers of TB patients compared to the effectiveness of health workers in the community (Wright et al., 2004). Commenting on the necessity of community involvement, the authors suggest having a family or community member as the main caretaker for TB patients supplemented with weekly follow-up visits from trained health workers. There were no significant differences in the treatment results of community based DOTS compared to institutional DOTS, where patients receive daily treatment at a hospital or clinic, instead of in their homes. In discussion about the effectiveness of community based DOTS versus institutional DOTS, the authors recommend that the choice of therapy to be used should be based on what the patient prefers and to which he or she has better access (Wright et al., 2004).

Although they found no significant difference in outcomes of those treated by community or family members compared with those treated by health workers, the authors found a significant increase in treatment completion after the implementation of their study, compared to the completion rate before their study. They concluded that a community based TB treatment program does improve treatment completion and successful health outcomes of the treatment (Wright et al., 2004).

Another study researching the effectiveness of TB treatment success using community based DOTS compared with institutional DOTS is a randomized controlled trial completed in Pakistan. This study looked at the direct observation component of DOTS and which party held the responsibility of observing (Khan, Walley, Witter, Shah, & Javeed, 2005). Similar to the results found in the study completed in Swaziland, no s ignificant difference was found in treatment results when comparing family observation with health worker observation of patients' TB treatments (Khan et al., 2005). One interesting aspect of this study was that a control group, where patients administered and recorded their own medications without any observation, also saw no significant differences in treatment results (Khan et al., 2005). The authors thought that the similar rate of cures across each treatment method, including the control group, was likely due to lack of protocol followed in each method of treatment, calling into question the validity of the study's results altogether (Khan et al., 2005).

A study completed in Brazil by Prado, Wada, Guidoni, Golub, Dietze, and Maciel (2011) looks into the cost-effectiveness of treating TB with institutional DOTS compared with community based DOTS. The researchers asked 130 new TB patients to choose their preferred method of DOTS treatment and then followed the patients with intermittent interviews about costs directly from the treatment process (Prado et al., 2011). Among cured patients, community

based DOTS cost US\$398 for treatment per patient, compared to US\$548 for treatment using health workers (Prado et al., 2011). These differences in cost were largely due to transportation expenses incurred with institutional DOTS. Similar to the suggestions made by the authors of the study in Swaziland, these authors suggest that institutional DOTS should be used in conjunction with community based DOTS for more effective treatment, overall (Prado et al., 2011).

Another article investigating community based DOTS TB treatment looked into the use of paid lay workers compared to volunteer community workers (Kironde & Bajunirwe, 2002). This article focused on community based TB DOTS and gives a thorough background of why contacts in institutional DOTS does not occur often enough in the developing world to treat and cure TB successfully. While this article is informative about health care workers and volunteers, the study's research methods are not described for the reader. The social learning theory is explored as the authors investigate what would make the best care provider in a communitybased TB treatment program. They recognize that according to this theory, people are motivated by the consequences of what they do (Kironde & Bajunirwe, 2002). They speculate about whether monetary motivation or other incentives like reciprocity and improved community health would provide the best motivation for a community. The authors ultimately decided that paid workers bring about the best treatment results; however, how sustainable this decision is as well as where funding will come from are not discussed (Kironde & Bajunirwe, 2002).

Another study investigating TB treatment practices looks into patient non-compliance. This cross sectional study in urban Zambia by Kaona, Tuba, Siziya, and Sikaona (2004) investigates factors contributing to non-adherence to the strict TB treatment regimen. Researchers randomly selected 400 patients living in different areas of the city of Ndola, to

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complete household-based surveys including questions about demographic data, health seeking behavior, knowledge about TB and its prevention and treatment, as well as their own treatment practices (Kaona et al., 2004). The study results found that the main cause for non-compliance/non-adherence was that patients begin to feel physically well before the end of the treatment course. When they started to feel better they did not see the need to continue taking their medication. The second most important factor in non-compliance was patients not understanding the importance and necessity of treatment course completion.

The authors recognized the effectiveness of DOTS in successful TB treatment, but the authors failed to explain whether the DOTS method of treatment was worth continuing or how it could be improved, especially to combat the issues of non-compliance seen in Zambia during this study. The authors of this study did comment on community-based DOTS and suggested that the responsibility of DOTS within the home posed "serious challenges" to household members (Kaona et al., 2004). Contrary to the studies completed in Swaziland, Pakistan, and Brazil, these authors brought up more negative aspects of treating TB within the Zambian community (Kaona et al., 2004). These negative aspects include unnecessary exposure to TB bacteria by household members, the possibility of increased negative stigma, and the encouragement of non-compliance, among others (Kaona et al., 2004).

In contrast to the study in Zambia, a study completed in Cambodia by Thim, Sath, Sina, Tsai, Delgado, Shapiro, Barry, Glaziou, and Goldfield (2004) was highly supportive of community-based DOTS as an effective way of treating and curing TB cases in the developing world. T his study by the Cambodian Heath Committee, a non-governmental organization (NGO), reports on a combined treatment program of institutional DOTS and community-based DOTS. It found that this method of treatment resulted in increased reportings of TB and higher

cure rates following treatment (Thim et al., 2004). Eventually, this program expanded to include the use of poverty reduction as a component of community-based DOTS. A food supplementation component, as well as a loan fund and repayment program, was utilized to improve overall health among community members. This organization also focused on increasing awareness of TB, how it spreads, and how it is treated (Thim et al., 2004).

In another study, a group of researchers in China investigated how socio-economic factors impacted the success of TB treatment (Xu et al., 2010). They interviewed individuals from three different economic classifications of development (extensive, moderate, and little) who had tested positive for pulmonary TB and who were receiving DOTS treatment. They also interviewed clinic directors and local health workers about DOTS implementation and practices. This study reported that the involvement of village health workers is a necessary measure of quality control within DOTS (Xu et al., 2004). The health workers are community members who monthly visit TB patients in their homes to supervise treatment, as well as to educate household members about the prevention and spread of TB. The data showed an overall success of treatment rate of 74.7% of the 501 total participants, which includes 50.5% who were cured and 24.2% who completed the treatment, but still tested positive at the end of their treatment (Xu et al., 2004). The researchers found that more home visits from village health workers positively influenced the success of the treatment, as well as supervision of treatment by these health workers (Xu et al., 2004).

This study illustrates the importance of case management quality for each TB patient receiving the DOTS treatment in these areas of China. While this is an important conclusion to the research involving community-based TB treatment, the authors did not clearly point out which communities (more or less economically developed) had higher or lower results of

treatment success. This leaves the question of whether community involvement would be more beneficial in rural and developing settings, or more developed and urban settings, or if there would be no difference.

Another research study investigated the control of TB in Papua New Guinea and how local culture could negatively impact the treatment (Ongugo, Hall, & Attia, 2011). In this study researchers investigated different components of the current DOTS treatment system in Papua New Guinea, including TB case detection, directly observed therapy, and monitoring and evaluation among others, and how they are impacted by the local culture of Papua New Guinea. These three specific components are directly impacted by community interaction and so are of greatest interest to this review. The traditional social and political organization of Papua New Guinea is that of a clan system, under the leadership of clan chiefs. The researchers wanted to investigate the possibility of using this clan system as a method for community involvement in DOTS for TB, due to the rural nature of the country and the lack of access to health care (Ongugo, Hall, & Attia, 2011). In a rural setting, one might imagine that the spread of disease would be reduced, due to the lack of overcrowding. However, a lack of infrastructure, road access, and health knowledge among members in developing, rural communities leads to the spread of disease because community members are unaware of how to prevent it. This is true in Papua New Guinea, a rural nation with high incidence of TB. TB patients often have no way of accessing health care, even if they knew they needed to seek it (Ongugo, Hall, & Attia, 2011).

The DOTS component of TB case detection is affected by the culture and the rural nature of Papua New Guinea. The authors reported that citizens are accustomed to traditional care and are therefore less likely to seek out bio-western medical help when they experience sickness (Ongugo, Hall, & Attia, 2011). Health care facilities are also incapable of testing for TB. Thus,

Papua New Guinea has the lowest rate of TB case detection in the region. The researchers suggest several answers to these areas of concern about TB case detection, including health education, inclusion of local beliefs and traditional healing practices in treatment methods, and formally engaging clan chiefs. They also suggest improving the education of local health workers in order to diagnose and begin treating TB patients earlier (Ongugo, Hall, & Attia, 2011).

Effective DOTS has two responsible parties to be successful: the health care providers and patients. When responsibilities on one or both sides were not met, treatment failed as a result. Often patients' lack of education about the disease and the nature of the treatment led to non-adherence. Similarly, if health care providers did not understand the complicated treatment regimen, they were less likely to appropriately treat their patients and teach them about the importance of daily treatments. Also, easier access to traditional healers for treatment led patients to seek traditional healers instead of complying with the DOTS treatment, resulting in uncured cases and continued spread of the disease (Ongugo, Hall, & Attia, 2011).

The authors suggested several methods for increasing compliance with DOTS, stressing first and foremost the importance of using family members and/or local community members in rural villages to be "DOTS promoters" and to supervise and directly observe the treatment of TB patients. Also, they suggest gaining support from clan chiefs to endorse the use of DOTS to treat TB. This would encourage patients to also seek DOTS care, instead of only traditional methods of care (Ongugo, Hall, & Attia, 2011).

The component of monitoring and evaluating the care of TB patients and treatment record keeping in Papua New Guinea creates a dilemma in the DOTS system, as there is no preorganized system of record documentation in health care facilities (Ongugo, Hall, & Attia, 2011). Patients were asked to keep a record of their own treatment and sickness experiences; however, often this goes uncompleted. Also, because TB medication is required to be taken over the course of at least six months, often patients stop coming to health care facilities for their daily treatment doses once they begin to feel better (Ongugo, Hall, & Attia, 2011). This leads to the relapse and continued spread of TB, as well as difficulties in documenting treatment success among cases. Implementation of a standard system of record keeping for health care facilities and properly trained staff to update records will help with improving documentation and organization of records (Ongugo, Hall, & Attia, 2011).

A randomized control trial completed in Beira, Mozambique, was used to investigate the use of the DOTS method of treatment delivery; however, the DOTS methods was modified (mDOT) and used to treat HIV/AIDS patients with highly active antiretroviral therapy (HAART) (Pearson, Micek, Simoni, Hoff, Matediana, Martin, & Gloyd, 2007). Similarities in the method of HAART treatment delivery to patients is useful in learning about the effectiveness of the DOTS method of treatment. Researchers incorporated a community-based method of treatment by using the system of peer-delivered treatment for HAART. Treatment-delivering peers were provided with training on the protocols of proper treatment delivery. Researchers' goals included identifying specific barriers to compliance with the treatment, increasing patient support from health care providers, and improving the patient-provider relationship. The researchers randomly assigned patients to receive either the peer-delivered HAART mDOT or the standard institutional delivery of HAART (Pearson et al., 2007). They found that participants who had met regularly with a peer or those who had participated in community support groups had higher levels of treatment compliance (Pearson et al., 2007). The researchers stressed the importance of the peer and community involvement in order for treatment success (Pearson et al., 2007).

Overall, patients who participated in the mDOT HAART had greater adherence when compared to the group in standard HAART care. The mDOT patients also showed a greater likelihood to attend support groups, meet with their peers, and complete specific treatment check up appointments.

#### 2.1.1 Drug Resistant M. tuberculosis

Drug resistant M. tuberculosis is usually treated with the DOTS plus method, which is similar to DOTS but includes different medications, called second line drugs that are more effective against the resistant bacteria than the first line treatments. Another study investigates how drug-resistant M. tuberculosis is transmitted and how this transmission affects treatment and control of TB, particularly in rural areas of China (Hu, Mathema, Jiang, Kreiswirth, Wang, & Xu, 2011). The transmission of TB is an important factor in planning prevention and treatment practices. This cross sectional study of rural patients who were found to have drug-resistant M. Tuberculosis over the course of one year examined the typical DOTS TB treatment method (Hu et al., 2011). Despite the use of DOTS, the prevalence of resistant bacteria in rural China continued to increase. Three hundred ninety nine total patients with resistant bacteria participated in the study. The researchers tested the genetic information from each patient's M. tuberculosis bacteria to determine its location of origin and how it had been transmitted to the rural area and to that specific patient. The researchers also collected demographic information from patients and used their TB test results from local clinical records (Hu et al., 2011).

The authors found that the genetic information from the TB bacteria showed that the cases of resistant bacteria often appeared in geographic clusters within a village or other small area. The researchers concluded that there was little geographic spread of the resistant strains of

M. tuberculosis in rural China (Hu et al., 2011). From these results, the researchers also concluded that increased case detection within rural villages would be a necessary supplement to the DOTS method of treatment, as well as testing patients for resistant bacteria who are from areas where prevalence of resistant bacteria is high. They warned that without increased control of drug resistant M. tuberculosis, multi-drug resistance or higher levels of resistance will result, which would be even more difficult to treat (Hu et al., 2011).

The future of TB and the DOTS policy for treatment is currently drawing attention from the medical world due to the emergence of totally drug resistant (TDR) M. tuberculosis, which are strains of TB bacteria that are completely resistant to any currently available treatments (Udwadia, Amale, Ajbani, & Rodrigues, 2012). These cases emerged first among patients in Iran and India. Prior to this, strains of multi-drug resistant (MDR) M. tuberculosis as well as extensively drug resistant (XDR) M. tuberculosis had been experienced in India (Udwadia et al., 2012). Due to the substantial length of time that treatment requires, non-adherence often occurs, which leads to mutations occurring within the TB bacteria family and drugs becoming less and less effective as the bacteria evolves (Udwadia et al., 2012).

#### 3.0 METHODOLOGY

Drawing on an eight week internship spent in the province of Gaza, Mozambique, a program evaluation was completed of a community based TB DOTS treatment program, sponsored by a local NGO, World Relief (WR). WR has a community based DOTS program through which it treats and increases awareness about the disease and trains volunteer health workers in the DOTS method of treatment in Gaza. The evaluation was designed to answer this question: is community based DOTS an effective method of treating TB patients in rural developing settings? Gaza, Mozambique is a developing setting and is primarily rural. The objective of this evaluation was to learn how to positively and effectively improve outcomes of TB cases in Gaza, as well as to assess how community based DOTS could improve to better serve this area and its inhabitants.

### 3.1 PARTICIPANTS

The evaluation of this treatment program was comprised of visiting local volunteers in the TB treatment program during four weeks in the summer of 2011. Three of the 10 districts within the province of Gaza, Massingir, Mabalane, and Guija were visited. These districts were selected for participation in the evaluation because they are the most populous districts in the province,

providing the most accurate representation of the population of Gaza province itself. Each village in these districts was visited, and TB treatment volunteers working in the villages were interviewed. Village volunteers were asked about their methods of community health education and their record keeping practices, in order to improve the efficacy of the DOTS treatment program. Visits were also made to each district's central hospital to discuss the method of community based DOTS treatment with the TB nurses at the district hospitals.

In all, 75 volunteers were visited, and 64 were available for interviews. The three district hospitals were visited. Each hospital has one nurse designated for the management and care of TB patients; discussions with three nurses occurred.

#### 3.2 MEASURES

The volunteers were interviewed about their methods for educating their community about the disease of TB and its treatment. They were asked about their training as volunteers for the community based treatment program as well as about their observations of TB trends in their own communities. The initial interview script began with seven questions and was piloted with 16 DOTS community volunteers. The questions are listed below followed by a rationale for explanation of what each question measured:

 What are the structural challenges of the DOTS treatment program? A re there areas in which you need more support (resources, time, training, etc...)? Rationale: To discover what aspects of the treatment protocol make this job difficult for volunteers.

- 2. What are the challenges you face during meetings with treatment recipients? Rationale: To learn how patients accept their medication; to find out if there is difficulty with non-compliance.
- Are there any personal challenges to providing the DOTS treatment to community members?
   Rationale: To identify any specific issues that the volunteer faces: for example, having sufficient transportation or being overwhelmed by seeing too many people in one day of work.
- 4. What is the DOTS treatment for? What is it supposed to accomplish? Rationale: To determine the level of understanding held by the volunteer about TB and of the DOTS treatment program.
- 5. How long is a course of treatment for a recipient?Rationale: To understand the Mozambican protocols followed for treating TB patients.
- How effective is the DOTS treatment?
   Rationale: To identify whether the volunteer sees that the treatment effectively reduces TB or not; to understand if the volunteer thinks that DOTS is an effective way to reduce TB infection.
- 7. Tell me about a typical visit with a DOTS treatment recipient. Rationale: To increase evaluator understanding of the process that occurs in a typical day for a volunteer.
  - a. How many people do you visit in a day?
  - b. What is the typical travel time to a recipient's home?
  - c. How many pills are given out?
  - d. Do you hand out any literature or informational materials to the treatment recipients?
  - e. What kinds of questions do treatment recipients ask you? How do you answer these questions?

However, after thorough discussion with the DOTS program director, manager, and a translator, all of whom spoke the language of the volunteers, it was decided that the seven original questions were too lengthy for the time available for interviews and the time the volunteers would have in the field. A second draft of interview questions was developed, using simpler language for easier translation, which focused more on identifying the level of understanding about TB, its prevention, and its treatment:

- How do you know if someone has TB?
   Rationale: To determine the volunteer's level of understanding of the disease.
- 2. What do you do if you find someone in your community who might have TB? Rationale: To get a picture of the process that the volunteer completes to identify, test for, and treat a patient. To evaluate if the volunteer follows the protocol of record-keeping required by the Mozambique Ministry of Health.
- What do you teach your neighbors about how to prevent the spread of TB?
   Rationale: To determine the volunteer's level of understanding about how to prevent TB.
- 4. How receptive are the families to you when you come to teach them about TB? Rationale: To understand the community's perceived value of the TB prevention education, as reported by the volunteer.
- What do you do if someone who may have TB refuses to go to the hospital or be tested for the disease?
   Rationale: To identify what the volunteer does to reduce non-compliance and to increase understanding about the importance of proper treatment of TB.
- 6. Do you see that the way TB patients are tested and treated is effective? Are there fewer cases occurring now compared with when you were younger? More cases? About the same?
  Rationale: To assess the volunteer's belief in the effectiveness of their actions. To identify if more cases of TB actually being found as a result of the DOTS program.
- 7. What do you think could be done in your village to decrease the amount of people sick with TB?Rationale: To understand if the volunteer, as an insider, sees any specific areas of need that could be met to improve the health situation for their community.

These questions were used in the first interviews with community based DOTS volunteers in several villages in Guija, the first district that was visited. At the end of each interview, gratitude was expressed toward each volunteer to continue their work and told that it would positively impact their family's health and their community's health. B ecause the volunteers were not monetarily reimbursed for their work, it was necessary to ensure that they understood how invaluable their work was to the DOTS program and the health of their communities.

After several interviews, the evaluators again discussed the effectiveness of the questions and developed an even simpler version of interview questions to best glean the necessary information from the volunteers. This third version first identified whether each volunteer was "newer" or had only been volunteering for about a year, or if he or she was "older" and had been volunteering with WR health programs for two or more years.

Newer and Older Volunteers:

- How long have you been volunteering?
   Rationale: To assess if the volunteer is "older" or "newer."
- When someone comes to you who is sick or you hear about someone in your community who is sick, how do you know if they have TB or not? Rationale: To identify whether the volunteer understands the nature of the disease and is able to recognize its symptoms.
- What do you do when someone comes to you or if you identify someone in the community who might have TB?
   Rationale: To understand what process the volunteer completes to identify, test for, and treat a patient. To understand if the volunteer follows the protocol of record-keeping required by the Mozambique Ministry of Health.
- 4. When someone has a positive TB test and they begin taking the medication, do their symptoms start getting better?Rationale: To discover whether the volunteer sees that the TB treatment is effective and cures sick patients.

Do you visit your neighbors to teach them about TB?
 Rationale: To evaluate whether the volunteer actively completes her duties and visits her community and teaches about TB prevention education.

a. What do you teach your neighbors about how to prevent TB from spreading? Rationale: To assess if the volunteer understands how to prevent TB.

b. How receptive are the families to learning when you teach them? Rationale: To understand the community's perceived value of the anti-TB education, as reported by the volunteer.

Questions just for older volunteers:

- When you first started volunteering, how common was TB in your village? Rationale: To discover if TB was common 10-20 years ago, as reported by the volunteer. To understand if community members at that time knew what TB was, as reported by the volunteer.
- If you think back to when you were younger, do you see more or fewer people sick with TB then or now?
   Rationale: To assess if incidence of TB is increasing or decreasing in this community over time, as reported by the volunteer.

In addition to these questions, volunteers were also asked when, where and by whom they had been trained in the community-based DOTS program. The interviews lasted from 15 to 25 minutes and were usually held in the volunteers' homes. A translator who spoke the local language of Shangaana, the national language of Portuguese, and the evaluator's language of English was utilized in the interviewing process. In each village, the one TB community based DOTS volunteer was interviewed. Each district had between 12 and 31 villages.

During the final week of data collection, each district's central hospital was visited. The TB nurse at each institution was given the data about patients receiving community-based DOTS that were collected from each village within his or her district. The hospitals had one nurse

assigned to the management and care of patients with TB; in all, the evaluator spoke with three TB nurses. These nurses recognized each patient by name and knew about the type of treatment each received; that is, community based or hospital based. The nurse provided information about the total numbers of TB cases in their districts, as well as about total community-based treatment participants. The evaluator also inquired about their opinion of the effectiveness of the community-based DOTS method of treatment.

The Mozambican Ministry of Health (MOH) requires a register of patient information, test results, and treatment progress, as part of the protocol of the community-based method of treating TB. Each of the village volunteers has a register to fill out for each of his or her patients. Each volunteer also has several copies of a reference letter used to refer potential TB cases to the district hospital to complete a sputum test. The volunteer signs the reference letter and gives it to the individual who potentially has TB. The sick person goes to the hospital and gives the letter to the TB nurse, who completes the test and writes the result (positive or negative) on the reference letter. The nurse tears the reference letter in half and keeps half for the hospital record and sends the other half back to the village community based DOTS volunteer with the sick individual. Without this paper record of which patients are utilizing the community based method of DOTS treatment, the MOH will not recognize community based DOTS as a viable treatment method and will not provide funding for the method.

#### 4.0 RESULTS

The community DOTS volunteers were asked about the number of current patients in their village participating in community-based DOTS. The total patients for each district as reported by volunteers were as follows: Guija: 38; Mabalane: 20; and Massingir: 11. The average number of patients per village were 1.65 (Guija), 2.36 (Mabalane), and 0.61 (Massingir), calculated from the number of patients receiving community based DOTS in each village where data were collected in each of the three districts. The data for Mabalane are potentially skewed because data were collected from only 14 out of 31 villages. Certainly, visits with each volunteer in every village in these districts would have been ideal, yet the data compiled from the completed visits remain representative of community-based treatment of TB patients in each district.

During the weeks that volunteers were visited, their supervisors notified them that they would be visited by the managers of the organization, who would want to hear about how the volunteers' work was going. Even so, some volunteers were unavailable when they were visited. After comparing the names of patients provided by the village volunteers with the records kept by the district TB nurses, the actual numbers of community-based DOTS participants in every village (as recorded by each district hospital) were determined to be: Guija 82; Mabalane 30; Massingir 12.

When asked about how to recognize a possible case of TB, all volunteers were able to describe a cough lasting for more than two weeks, bloody sputum, night sweats and fever, weight

loss, and general fatigue. The majority of the volunteers were able to accurately describe how to prevent the spread of TB as well; evaluators estimated 90% of volunteers were competent in this area of the community based TB treatment program. They accurately described the practices of mouth covering during coughing, hand washing, increasing airflow in the household where someone was infected to reduce the spread, as well as the importance of testing for TB as soon as possible. Other methods of prevention were suggested by volunteers, like having infected family members use their own plate, cup, and spoon, and keeping those separate from use by healthy family members.

Volunteers discussed how previously TB had been misunderstood in their communities. It had been believed that TB was a sexually transmitted infection, because it often occurred in individuals with HIV/AIDS. Education about the prevention of HIV/AIDS and its sexually transmitted nature that had been brought to their communities in the past was simply applied also to TB. But volunteers went onto explain that with the current community-based DOTS education component, communities now generally understood that TB was spread through the air, particularly when a sick individual coughs.

In response to questions about perceptions of the effectiveness of TB medication, most volunteers reported that once their patients began their treatment their symptoms started to improve. Contrasting what the evaluators expected, only one volunteer mentioned a patient who did not respond to the medication. This patient had been sick and tested positively for TB. But after starting the first line medication, his symptoms were not alleviated. This is possibly an example of MDR TB. Because of the highly contagious nature of TB, it was unexpected that there could only be one patient experiencing MDR. Evaluators suspected that there were other instances of MDR that went unreported.

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Volunteers responded quite differently about seeing more TB at present compared with when they were younger. Some said they saw many more cases now, and that it was because now they just knew how to identify it; in the past people had been sick but were unaware that they had TB. Some described seeing far fewer cases of TB infections at present than their experiences in years past. Still others reported that they felt the frequency at which they heard about or saw cases was the same at present compared with when they were younger.

The volunteers reported having significant difficulty with following the protocol required by the Mozambique MOH. Several volunteers were unable to read or write, and as such, were unable to fill out the forms required by the MOH. Several other volunteers had reading and writing skills but did not understand how to fill out the forms. For both of these reasons, volunteers often left the forms blank.

In response to the questions about training, the volunteers explained that their training had occurred at the central district hospital and had been conducted by the TB nurse there and the supervisor from WR for each district. Depending on the district, the volunteers had either been trained in December 2010 or May 2011 (Mabalane and Guija), or February 2011 (Massingir). In all three districts, most volunteers had not actually begun actively participating in the treatment program until June 2011. This is when they began teaching their communities about TB prevention and began keeping track of TB patients and their treatment.

## 4.1 RESULTS: EVALUATION OUTCOMES: AREAS OF STRENGTH

From the interviews with the village TB DOTS volunteers, several areas of strength about WR's community-based DOTS program became apparent. Volunteers describe having gone from struggling with patient non-compliance with treatment and community indifference, to TB education, to an increase in general knowledge about the disease and its curability with subsequent decrease in non-compliance. The education about TB and treatment provided to the community by the volunteer reportedly works very well to increase general knowledge about the disease and how it can be treated. Volunteers reported that in their villages, they perceive that people are listening to what they teach and that at present they see that levels of knowledge about TB and TB prevention are very high among community members. Volunteers also report that they have noticed that as they deliver more education about how to prevent TB, the number of cases being treated also increases. This is an encouraging trend, as more identified and treated cases means less spread of TB in the future and a potential decrease in the overall rate of TB occurrence.

Another area of reported strength in the DOTS program is the support provided to the volunteers. Most volunteers reported feeling very supported by their supervisors and the other health volunteers in their village or neighboring villages. This is evidenced by all of the volunteers reported being visited by supervisors at least monthly.

The TB nurses in each district hospital were knowledgeable about the numbers of patients in their districts who were participating in community based DOTS. Their knowledge and involvement was recognized by the volunteers in the villages.

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## 4.2 RESULTS: EVALUATION OUTCOMES: AREAS IN NEED OF IMPROVEMENT

Speaking with several TB volunteers revealed two general areas where improvement could be made in WR's community based TB DOTS program. A general issue is the record-keeping abilities of the volunteers. Due to a lack of understanding by the majority of the volunteers, most were filling out their paper work incorrectly or not at all. Evaluators estimated that 10% lacked the ability to read and write at all.

Recording accurate results of the TB tests of patients is a large part of the record-keeping responsibility. Observations of the volunteers showed that many did not know how to accurately fill out the paperwork, and so they either left the pages blank, or only filled in patient names, but provided no test results and no record of treatment and dates.

Another area for improvement is for volunteers to be more proactive about collecting the results of the TB tests of patients they have referred. For the volunteer to simply wait for the patient to bring back the test results often ends with the volunteer never hearing back from the patient at all. The volunteers need to visit the patient's home as soon as he or she returns from the hospital to ask about the results and collect the half-sheet reference letter the patient brings back from the hospital. The volunteers noted that the lack of these results makes it appear that they are not working or referring any patients, and that is discouraging to them.

#### 5.0 **DISCUSSION**

The data for this evaluation were collected to determine whether the community based DOTS strategy was an effective method for treating TB patients in rural developing settings. Based on the results of the data collected from volunteer interviews, there are areas where improvements can be made, and also where the program of TB treatment is very successful.

As shown in the results, the volunteer in each village supervises up to three patients. As reported by the volunteers, this is an appropriate and manageable proportion considering the volunteers' other responsibilities. In villages with higher populations, where numbers of patients receiving treatment are higher, adding more volunteers would be appropriate. If volunteers caring for multiple patients have questions or feel stressed by their responsibilities, support comes from the mentoring relationship with his or her district supervisor, who can come alongside the volunteer and aid in areas of need.

As well as addressing the issues and questions raised in the above paragraphs about the results of volunteer interviews, there are some suggestions for increasing the effectiveness of WR's community based DOTS program. Volunteer selection is the first place that improvements can be made. Currently, volunteers who are not able to read and write have responsibilities requiring these skills. As these skills are essential to the proper record-keeping of treatment and reference-letter data for the Mozambican Ministry of Health, in the future, only volunteers with the ability to read and write should be chosen. It is understandable that there is a

significant population of adults on rural Mozambique who are non-literates. Because of the country's 17 year long civil war following decolonization by Portugal, education was unavailable to this now-adult population. However, because of the regulations required by the government, it is unacceptable for non-literate individuals to have these responsibilities. Even if the non-literate volunteers were aided by literate partners, the efficiency of the program and accuracy of records could be reduced.

More time during training dedicated to the proper way to fill out the forms would be beneficial during volunteer training. At present, volunteers are trained, but then not followed up with soon enough after the training to ensure that they understand their responsibilities. It would be beneficial for volunteers to begin working in their communities as soon as possible after being trained as well as for supervisors to visit them sooner and more frequently, to check on their methods of community education and patient treatment. Also, the supervisors themselves need to be more intentional with their observations and assessments when they visit the volunteers in their district. The supervisors need to ask the volunteers specific questions about how they fill out the forms and about how they oversee patient treatment. This accountability and mentorship would improve TB care at the village level.

Volunteers need to understand how to accurately complete the records they are asked to keep, especially to the DOTS program. Proper use of the reference letter and the register of TB patients participating in the community based DOTS program is essential to its success, as the Ministry of Health requires documentation of treatment in order for cases and outcomes to be considered factual. The larger issue that arises here is that if TB cases being treated by community-based DOTS are not properly recorded, the government will not see any positive results from the community-based treatment program and will not support this new method of

treatment. One way volunteers could improve the accuracy of their recording would be by visiting patients to collect the test results soon after they return from the hospital.

Based on analysis of the qualitative data collected from district hospital TB nurses, another suggestion to improve TB treatment within the community is to increase TB nurse involvement in their respective communities. These nurses are an untapped resource for the village volunteers, and if they can be involved in ensuring proper care for patients, the treatment will be more effective. Also, it would be beneficial to the program for the supervisors to meet regularly with the nurses to see how they can collaborate to improve TB patient care and treatment in the community as well as to improve DOTS volunteer education.

The results about the level of understanding of the disease and its treatment held by the volunteers are helpful for improving training and in treating TB. The interview question responses also revealed possible sources of bias. For example, when asked about their perceptions and observations of current TB case frequency compared to when the volunteers were younger, some reported seeing far fewer cases now. This is certainly possible at the village level; however, it is more likely that cases would increase, as more and more cases are identified as awareness about how to identify the disease increases. With this in mind, it is possible that volunteers, in an effort to think positively about their efforts with the community based DOTS program, wanted to report that their communities were becoming healthier. A nother possible source of bias is that the evaluator was American, a rare nationality in rural Mozambique. The visit of an American, as well as the manager and supervisor of the community based DOTS program could be intimidating to the village volunteers, pushing them to respond more positively to interview questions in order to make the best impression of their work and their community's health, not wanting to complain or possibly be disrespectful.

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#### 6.0 CONCLUSIONS

After an overview of the tuberculosis infection, a review of the current literature available about the concept of treating TB with the DOTS method at the community level was provided. The methods of data collection and the interviewing process were discussed. Then, the results of this data were given. Finally, a discussion of the implications of these results followed.

From the interviews with village TB DOTS volunteers and the data collected, it is apparent that the community based DOTS treatment is a successful method in rural areas, like Gaza province in Mozambique. Treatment availability at the community level allows for an increase in cured cases of infectious diseases like TB, and the education provided by the volunteers in the community brings about heightened awareness about the disease, its treatment, and its prevention (Pearson et al., 2007). C ommunity education about TB provided by the village volunteers is reportedly very effective in increasing community knowledge as well as encouraging the start of treatment for those who are sick. However, the need for volunteers with greater understanding of the paperwork involved with community based DOTS and the ability to complete it remains, as does the necessity for volunteers to be more persistent in retrieving patients' results of the TB tests.

There are limitations to this research. Not all of the villages in the province of Gaza were visited, as time did not allow for it. Sometimes volunteers were not at home, so they could not be interviewed. The data collected were based on the record-keeping of each volunteer and then

cross checked with the records of the hospitals. Neither of these sources, however, provided data free of errors. One source of confusion was that some volunteers did not record the dates that their patients began and completed treatment. Some patients about whom data were collected had been treated in 2009 or 2010, causing inaccuracies when trying to include only cases from 2011. Other limitations of this evaluation were language and cultural barriers, which prevented a complete understanding of the volunteers' responses to open-ended interview questions. Another source of bias encountered was in volunteers' responses to interview questions. The volunteers knew their responses would be used to evaluate the efficacy of the DOTS program, and so it is possible that they phrased their responses to make their work appear more effective than it was in reality. In a similar way, because of the nature of an evaluative study, the interviewees may have depicted a more positive situation than reality in order to have a positive evaluation result.

It is encouraging to see that the community-based treatment is effective as a means of administering medication. In two of the three districts that were visited, over 50 percent of all the TB cases were being treated in the community, as opposed to in a hospital. A community based treatment option is essential in reducing the overall occurrence of TB, particularly in this rural area (Wright et al., 2004). Community-based treatment methods are necessary alongside hospital-based treatments in order to have improved success of treatment for first line drug-affected cases as well as for drug-resistant cases. WR's community-based DOTS program will continue to be effective in treating TB, and with some improvements will allow more positive outcomes to occur. TB impacts whole communities, and its treatment should do the same.

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