Development and Evaluation of a Tailored Knowledge Translation Intervention to Improve Lay Health Workers Ability to Effectively Support TB Treatment Adherence in Malawi.

By

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A thesis submitted in conformity with the requirements for the degree of Doctor of Philosophy in Clinical Epidemiology
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Thesis Abstract

Thesis Title: Development and Evaluation of a Tailored Knowledge Translation Intervention to Improve Lay Health Workers Ability to Effectively Support TB Treatment Adherence in Malawi.
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Background: Task shifting provision of basic health care services to lay health workers (LHWs) is increasingly employed to combat the global shortage of skilled health workers, particularly in low and middle income countries, where the shortage is greatest. Despite evidence for the effectiveness of LHWs in improving access to basic health services and positively impacting a variety of health outcomes, questions remain as to how recognized weaknesses in training and supervision are best addressed. This thesis employed a sequential-concurrent mixed-methods design and is composed of 3 studies with the objective of designing and rigorously evaluating a knowledge translation (KT) intervention tailored to address identified barriers to LHWs ability to function optimally as TB adherence supporters in Zomba district, Malawi.

Methods & Findings: The first study utilized the qualitative methods of focus groups and interviews conducted with LHWs routinely involved in provision of care to TB patients. Lack of TB knowledge and job-specific training were identified as the key barriers to LHWs in their role as TB adherence supporters. Based on these findings, a KT intervention was developed and tailored to the identified training gaps. The second study, evaluated the effectiveness of the intervention in improving TB treatment adherence in a cluster randomized controlled trial, which showed no evidence for effectiveness of the intervention. The third study, conducted concurrently with the cluster trial, employed qualitative interviews to explore LHWs experiences with the intervention to identify
aspects of the intervention found to be helpful and areas in need of improvement. Study 3 found that the intervention was well received and valued, with reported benefits to LHWs through improved knowledge and skills, and increased confidence. Suggestions for improvement varied considerably, with an anticipated concern with the lack of stipends and conduct of training on-site, raised as an issue by a minority of participants.

Conclusion: This thesis suggests that a multi-component KT strategy tailored to address local barriers, was well received and valued by LHWs, and may represent a cost-effective approach to LHW training. However, given the trend for effectiveness did not reach significance in this underpowered study, further research is needed.
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List of Abbreviations

AIDS Acquired Immune Deficiency Syndrome
ART Anti-retroviral Therapy
DOTS Directly Observed Therapy
GEE Generalized Estimating Equations
HIV Human Immunodeficiency Virus
HSA Health Surveillance Assistant
ICC Intra-Cluster Correlation Coefficient
KT Knowledge Translation
LHW Lay Health Worker
LMIC Low and Middle Income Countries
NTP National TB Program
RA Research Assistant
STAT-PALM+ Streamlined Tools and Training: Practical Approach to Lung Health and HIV/AIDS Malawi
SSA Sub-Saharan Africa
TB Tuberculosis
WHO World Health Organization
Chapter 1 – Background

The purpose of this chapter is to:

1) Highlight the scope and importance of both the global healthcare worker shortage and the global TB epidemic;

2) Describe the Malawi context;

3) Provide an overview of known barriers to TB treatment adherence and the potential role of knowledge translation strategies to address them;

4) Outline the conceptual framework of the thesis and introduce the study specific and overarching thesis questions;
Task Shifting and the Global Healthcare Worker Shortage

In 2006 the World Health Organization (WHO) reported that 57 countries had critical shortages of skilled health care workers with an estimated shortfall of 2.4 million doctors, nurses, and midwives globally (1). Recent reports indicate that the shortage has grown with a current estimated shortage of 4.2 million skilled healthcare workers globally (2). Low and middle income countries (LMICs) and Sub-Saharan Africa (SSA) in particular have been disproportionately affected with 1.5 million healthcare workers needed to meet the basic health care needs of the populations of SSA (3).

A variety of factors have led to the chronic healthcare worker shortage including: insufficient recruitment and training of health care workers; loss of healthcare workers to the private sector or non-governmental organizations, and through migration; concentration of health care workers in urban centers; and absence or loss of healthcare workers to personal or family illness or death, particularly in SSA hit hardest by the HIV epidemic (4). In recognition of the urgency of the need for skilled healthcare workers, the WHO has developed a treat, train, and retain strategy as a starting point to addressing the crisis (4), with task shifting a key component to allow for rapid scale up of both HIV and other basic health services (4).

Task shifting refers to the rational redistribution of healthcare tasks from higher trained and skilled healthcare workers to healthcare workers with shorter training and fewer qualifications (4). This approach allows for both more efficient use of the available health workforce and allows for rapid scale up of basic health services through increasing use of lay
health workers (LHWs) who can be trained in a much shorter time frame than can physicians and mid-level health care workers (nurses and clinical officers) (4).

**Lay Health Workers**

Lewin et al. (2010) define lay health workers as “members of the community who have received some training to promote health or to carry out some healthcare services but are not healthcare professionals “(5). While LHWs have a long history, their use has increased in recent years, particularly in LMICs, where they often play a pivotal role as the principle providers of primary healthcare. Lay health workers in these settings are typically faced with high patient volumes and required to perform a variety of basic health care tasks with limited resources and training. Despite this difficult role a recent Cochrane review found promising benefits of LHWs with respect to immunization uptake, breast feeding, improving pulmonary TB outcomes, and reducing child morbidity and mortality (5). The authors note however that “evidence is insufficient to draw conclusions about the effectiveness of LHWs for other health issues or to identify specific LHW training or intervention strategies likely to be most effective”(5).

Although variable across settings levels of education and training among LHWs are generally limited (6), with few opportunities for continuing education due to staff shortages and resource constraints. In addition pre-service training varies considerably across and within LHW programs, ranging from 1 week to 1 year (4), depending in part on whether a generalist or specialist LHW model is employed (6). As a result LHWs may lack disease specific knowledge and skills in patient management, particularly for complex diseases such as TB or HIV and other diseases outside their area of focus or core training. As well, lack of ongoing
training and supervision are acknowledged barriers to LHW effectiveness (6). Despite recognition of its importance information is lacking as to how LHW training and supervision needs may best be addressed in order to maximize the quality and impacts of LHW contributions (5, 6). Given the resource constraints facing many LHW programs a cost-effective and sustainable solution is needed to address LHW knowledge and training gaps on an ongoing basis.

*Treatment Adherence and the Global TB Burden*

One of the tasks commonly shifted to LHWs is provision of outpatient TB care. The World Health Organization estimates that fully 1/3 of the world’s population is currently infected with latent TB (7). Although the average lifetime risk of progression to active TB disease is 10%, the risk is much higher among immune-compromised individuals, including those living with HIV/AIDS (7). In 2010, 8.8 million people became ill from TB and 1.4 million deaths were attributed to TB globally (7), with 13% of new TB cases and 24% of TB deaths occurring in people living with HIV/AIDS (8). Low and middle income countries and SSA in particular are again disproportionately affected, in part due to high HIV prevalence (9), with the greatest proportion of new TB cases per population occurring in SSA and over 95% of TB deaths occurring in LMICs (7).

Optimal medication adherence is critical to treatment success in a wide variety of illnesses. This is particularly true of infectious diseases where poor patient adherence risks, not only poor patient level outcomes, but has important public health implications due to increased or persistent risk of disease transmission and development of drug resistance. Incomplete treatment is an important cause of both the TB epidemic itself with the potential for each
untreated active TB case to infect 10-15 people per year (7) and the increasing incidence of multi-drug resistant TB (10). Although several factors including cost, inadequate drug supplies, and migration due to conflict or disaster play a role, poor adherence remains a significant cause of incomplete treatment with default rates in the literature ranging from 0-82% (11, 12, 13), with the majority between 20 and 55%.

Given the importance of medication adherence a variety of interventions have been designed and evaluated for a variety of diseases but success to date has been limited (14). This is particularly true for conditions requiring long term treatment, such as TB and HIV, where even the most effective interventions have generally led to only small improvements in adherence and treatment outcomes (14). Even directly observed therapy (DOTS) in which daily treatment is monitored by a trusted observer, though widely recommended, has not been consistently effective in improving adherence (15, 16). As the majority of the adherence literature is based on research conducted in high income countries, the generalizability of these results to the low income countries that bear the largest burden of infectious disease and TB in particular is uncertain. In addition, many of the “effective” adherence interventions are not feasible given the resource constraints facing LMIC health care systems or require evidence of effectiveness in these settings before wide spread implementation can be considered.

**The Malawi Context**

As is the case in most of Africa Malawi is experiencing both TB and HIV epidemics, with 20342 new TB cases in 2010 of which approximately two thirds were TB/HIV co-infections (17). Despite initial improvement with the introduction of DOTS in 1984 and near 100%
DOTS coverage, default rates remain an important contributor to the high TB burden in Malawi with default rates for TB and anti-retroviral treatment as high as 16% (18). Failure of DOTS as a single adherence strategy, both in Malawi and in low income countries in general, suggests additional measures are needed to address other factors important in non-adherence in these settings.

Malawi is among the SSA countries most impacted by the healthcare worker crisis, with an average of 2.03 physicians and 36.8 nurses for every 100000 population in 2009 (19). In response to this crisis Malawi has begun to implement an emergency human resources program, an important component of which has been the establishment and incorporation into the formal health care system, of a paid cadre of LHWs termed health surveillance assistants (HSAs). A variety of basic health care services including immunizations, well-child visits, family planning, and disease surveillance have been shifted to this LHW cadre. In addition to these general health care tasks, LHWs have primary responsibility for provision of TB care and assist with decentralized provision of HIV services. TB services provided by LHWs include: TB education, case finding and sputum collection; routine follow-up care of TB patients including medication dispensing and record keeping; and default tracing.

Pre-service training of LHWs in Malawi, consists of a 10 week general program (19), the components of which are outlined in brief in appendix 1 (20), which has recently been extended to 12 weeks with the addition of management of malaria in the community, handling of needles and syringes, and new issues in reproductive health and family planning. While this is the current standard, not all LHWs presently working in Malawi have received this degree of training. TB focus LHWs, general LHWs with an additional 2 weeks of TB
training, are charged with overseeing the provision of TB care at the health center level with
the assistance of general LHWs who they enlist and train for this purpose. As both the
content and duration of this training is left to the discretion of the individual TB focus LHWs,
the quality and comprehensiveness of TB training for general LHWs providing TB care
varies widely. In-service training is typically conducted off-site with healthcare workers
removed from duty and provided with stipends to attend training. This common approach to
training has implications both in terms of cost and disruption of delivery of services. Thus,
with more than 10000 LHWs currently working in Malawi (19), alternative approaches are
essential to ensuring that the continuing training needs of this important group of healthcare
workers are met in a cost-effective manner which minimizes disruption of service delivery.

**Adherence Intervention Targets**

Designing context-appropriate interventions to improve TB treatment adherence requires a
good understanding of the barriers to adherence. Despite the high TB and combined TB/HIV
burden in LMICs few studies in general and fewer high quality studies have investigated
what factors may be causing or contributing to poor adherence in these settings. Across
studies there are often mixed results. For example, while male gender, increased age,
increased distance for medication collection and associated increased cost of transportation,
emerge as risk factors in some studies and settings in Africa (21, 22), other studies, some in
the same settings, have found these same factors to be protective or to have no effect (22,
23). Irrespective of the noted inconsistencies these factors are largely un-modifiable or
require system level interventions.
Two themes emerge from among the small number of studies reporting potentially modifiable risk factors (or protective factors). The first theme might be termed ‘disease specific knowledge and beliefs’. Two studies, that included a combined total of 406 default cases, found that poor understanding of TB and its’ treatment was associated with increased risk of default while higher knowledge was associated with adherence (21, 24). The second theme to emerge, centers around the provider component of care. Two small studies, including a total of 203 TB patients, reported that default was associated with poor patient-provider interactions, poor staff training and morale, and found a protective effect for provider counseling (11, 25).

Two additional studies have examined factors associated with non-adherence in Malawi specifically. Kruyt et al. (1999) compared eight late default cases (patients who started but did not complete treatment) to matched adherent controls and found that default cases were more likely to have a poor understanding of TB treatment (26). The second study by Squire et al. (2005) used government health records to trace smear positive TB cases that never underwent treatment (initial default cases) and interviewed 5 patients and 14 care givers of deceased patients (27). Factors found to be associated with default in this study were principally system issues including the need to attend hospital to collect medications and delay in diagnosis. However one knowledge issue, misunderstanding the meaning of becoming smear negative, emerged as the single potentially modifiable risk factor. Despite the small number of participants in these studies the results provide additional evidence that poor patient TB knowledge may contribute to non-adherence in Malawi.
Based on the modifiable barriers identified in the adherence literature, in developing an adherence intervention an argument may be made for targeting either or both, patients and providers. However, in the Malawi context a provider approach is much more feasible given the logistical issues inherent in a patient targeted approach, principally low patient literacy levels and lack of mailing addresses and access to telecommunication. In addition, targeting providers allows both patient disease understanding to be addressed, through improved provider knowledge and patient education skills, and also allows the second modifiable barrier, patient-provider interactions, to be addressed in the intervention. In view of the identified targets, provider knowledge and skill development, as well as the resource constraints facing the Malawi health care setting and LMIC healthcare systems in general, knowledge translation strategies (as outlined below) seem promising given their fit with the identified intervention targets and relative low cost.

**Potential Role for Knowledge Translation Strategies**

Many terms and definitions have been proposed and utilized in the knowledge translation (KT) literature. For the purpose of this thesis we have adopted the definition of the Knowledge Translation Program, Faculty of Medicine, University of Toronto (2004), which defines KT as "the effective and timely incorporation of evidence-based information into the practices of health professionals in such a way as to effect optimal health care outcomes and maximize the potential of the health system" (28).

A variety of knowledge translation strategies designed to change healthcare provider behavior in order to improve the quality of care provided and ultimately to improve health outcomes have been evaluated. While the effectiveness of many approaches varied across
studies a systematic review conducted by Grimshaw et al. in 2001 found 3 approaches to be more consistently effective: educational outreach, reminders, and multi-faceted approaches targeting barriers to change (29). More recently, Baker et al. (2009) reviewed the evidence for tailoring interventions to address barriers to change, in which barriers were defined as “factors that explain current professional practice and any reasons for resisting new practice”, and found tailored interventions more likely to improve professional practice (30).

Importantly, although gradually improving, the majority of studies evaluating KT strategies to change provider behavior to date have been conducted in high income countries and have evaluated behavior change in physicians (30). However, given the greater diversity of practice settings facing providers in LMICs health care settings, particularly LHWs who typically provide services through community visits as well as within health centers, the theoretical potential for tailoring to improve the effectiveness of KT interventions may be greatest in these settings.

Although only fully evaluated in a single country to date, the remarkable success of the PALSA Plus program in South Africa, which utilizes educational outreach and a streamlined clinical guideline to support decision making, in improving a variety of primary care patient outcomes, including a 18.7% increase in TB treatment completion, suggests that knowledge translation strategies may be a viable option for improving a variety of clinical outcomes at relatively low cost in LMIC settings (31, 32, 33). Given these impressive results this program has recently been modified to meet the needs of the Malawi health care setting, called Streamlined Tools and Training: Practical Approach to Lung Health and HIV/AIDS Malawi (STAT-PALM+), and is currently under evaluation through a cluster-randomized trial in Zomba district health centers (34). Although both PALSA Plus and STAT-PALM+ include
educational outreach training and point of care reminder tools neither specifically target TB treatment adherence and both are designed for mid-level health care providers (nurses and clinical officers) who are not the principal providers of ongoing TB care in the Malawi health care system. Although this approach may be particularly promising for LHWs among whom the knowledge gap is expected to be greater, given their relatively lower level of training compared to mid-level health workers, we were able to identify relatively few studies that utilized and evaluated KT approaches to training at the lay health worker level and only 1 targeting TB. This study, by Clarke et al. (2005), employed a decentralized educational outreach approach to train LHWs as TB adherence supporters for rural farms in South Africa and achieved significant improvement in the successful treatment rate as a result of the intervention (35).

**Thesis Conceptual Frameworks**

Designing and evaluating a context-appropriate knowledge translation intervention to maximize the quality and impact of LHWs contributions to TB care is a complex process, particularly given the resource constraints facing the Malawi health care system. As a result of this complexity, this thesis is based on two conceptual frameworks. The first conceptual framework (Figure 1.1), is the knowledge-to-action framework developed by Graham et al. (2006), and outlines the framework for the process of the development, implementation, and evaluation of the intervention (36).
Figure 1.1 – Knowledge Translation Conceptual Framework: Knowledge to Action

Figure 1.1 is used with permission: Lost in knowledge translation: Time for a map? Graham, I.D., Logan, J., Harrison, M. B., Straus, S. E., Tetroe, J., Caswell, W., and Robinson, N. Journal of Continuing Education in the Health Professions, 26(1). Copyright ©2006. The society for Academic Continuing Medical Educations, and The Association for Hospital Medical Education.
The first component of the framework, knowledge creation, encompasses the preparatory work and first thesis study. This includes the literature review and distillation of these findings to identify key intervention targets. This is followed by the contextualization and tailoring of the intervention through identification of local barriers and facilitators based on knowledge derived through field experience, incorporation of input from key stakeholders, and the findings of the first thesis study. The second component, the action cycle, overlaps with many of the processes outlined above in the knowledge creation phases but extends it to include the implementation process and evaluation of both the effectiveness of the intervention (study 2) and the experience of LHWs with the intervention (study 3), to allow for refinement of the intervention. All stages of the action framework have contributed to this work, with the exception of the final phase, sustained knowledge use. Although not part of the thesis itself we have begun to address this final stage through feedback to local stakeholders and knowledge users. Further work to follow includes the adaptation and improvement of the intervention itself based on the results of the thesis studies and, if found effective, incorporation of the program into routine training.

Figure 1.2, is adapted from Creswell and Plano Clark’s (2007) embedded experimental model and depicts the mixed methods study design which forms the methodological basis of this thesis (37).
The thesis is founded on a paradigm of pragmatism, which emphasises the primacy of the research problem with specific methods chosen to provide the ‘best’ understanding of the problem (38). The framework chosen to best address the research question(s) of this thesis uses mixed methods both sequentially and concurrently. The sequential component, a preliminary qualitative study (chapter 2), was chosen as the best means of understanding the barriers experienced by LHWs in their work as adherence supporters. The results of this initial qualitative study were essential to the tailoring of the intervention and allowed both the process and content of the intervention to be targeted to the perceived needs of the LHWs. The concurrent component encompassed the quantitative evaluation of the effectiveness of the intervention and a qualitative evaluation of the experiences of LHWs receiving the intervention. Consistent with the philosophy of pragmatic mixed methods designs, the intent was not to mix the results but rather for each of the studies to address unique research questions and together to provide information important to both improvement of the
intervention evaluated and to informing future interventions directed toward LHW training and skill development. A key limitation of the during-intervention approach employed is the risk of introducing bias. While this is a recognized limitation of this approach the potential benefits to the design and implementation of future interventions by providing an understanding of changes in experience and use of the intervention over time was felt to outweigh the risk.

**Thesis Overview**

Utilizing the mixed methods design outlined above the overarching goal of this thesis was to develop, implement and evaluate a multi-faceted knowledge translation intervention, tailored to address the knowledge and training needs of lay health workers providing TB care in Zomba district Malawi, with the intent of improving clinical TB outcomes through improved TB treatment adherence.

**Study specific objectives**

Study 1: To identify and explore the perceived barriers and facilitators impacting lay health workers ability to support TB treatment adherence in Zomba district Malawi. Formative qualitative study conducted with lay health workers providing TB care in Zomba district Malawi (Chapter 2).

Study 2: To evaluate the effectiveness of a knowledge translation strategy tailored to the local health care setting and identified needs of lay health workers providing TB care, in improving TB treatment adherence in Zomba district Malawi. Pragmatic cluster randomized trial conducted in health centers providing TB care in Zomba district Malawi (Chapter 4).
Study 3: To provide an understanding of lay health workers experience with the intervention in order to identify aspects of the intervention felt to be helpful and those in need of improvement, and to identify changes in perceptions of the intervention overtime. Concurrent qualitative study conducted with lay health workers participating in the intervention (Chapter 5).

*Mixed Methods Research Question*

Is the tailored KT intervention effective in improving TB treatment outcomes and how do the results of the qualitative studies inform the design of the intervention, contribute to an understanding of the effectiveness of the intervention, and provide insight into aspects of the intervention in need of improvement.
Chapter 2 – Evaluation of lay health workers’ needs to effectively support TB treatment adherence in Malawi

The Purpose of this chapter is to:

1) To identify and explore the barriers and facilitators to LHWs efforts to support TB treatment adherence in Zomba district Malawi;

2) To inform the development and tailoring, with respect to both content and format, of a knowledge translation intervention to address identified barriers;

* In addition to the published article reprinted below we have included the interview/focus group question guide for reference, see appendix 2.

Acknowledgement:

Evaluation of lay health workers’ needs to effectively support TB treatment adherence in Malawi

Abstract

Objective

To identify barriers and facilitators to lay health workers (LHWs) efforts to support TB treatment adherence in Malawi, in order to inform the design of a knowledge translation intervention to improve adherence.

Design

Qualitative study utilizing focus groups and interviews conducted with LHWs providing TB care in Zomba district, Malawi.

Results

Participants identified lack of knowledge, both general (understanding of TB and its treatment) and job specific (understanding of tasks such as completion of treatment forms), as the key barrier to LHWs in their role as adherence supporters. Lack of knowledge among LHWs providing TB care, was reported to lead to a lack of confidence, conflicting messages to patients, poor interactions with patients and errors in documentation. In addition to lack of knowledge, a number of system barriers were identified as limiting LHWs ability to function optimally, including: lack of physical resources, workload, communication delays and ineffective guardians.
Conclusion

Our findings suggest a gap between LHW knowledge and their responsibilities as adherence supporters. The results have informed the development of an educational outreach intervention and point of care tool, to be evaluated in a randomized trial in Zomba district.

Background

TB claimed 1.7 million lives in 2009 (7), with mortality rates for HIV and TB co-infected patients 4 times greater than that of their HIV negative TB peers (39). In 2010 in Malawi there were 20342 new TB case notifications of which approximately two thirds were TB/HIV co-infections (17). Despite ongoing efforts, poor adherence remains an important contributor to the high TB burden in Malawi, with default rates for TB and antiretroviral treatment as high as 16% (18). However, as by definition, default only includes non-adherence for two consecutive months, it is likely that shorter term non adherence rates, i.e. treatment gaps, may be higher (40).

The WHO estimates that 3.5 million additional health care workers in 49 low income countries (LICs) are needed if the Millennium Development Goals are to be achieved on target (41). One strategy suggested to combat the chronic global shortage of skilled health care workers is to shift basic health care tasks to lay health workers (LHWs) (6). In Malawi, in addition to aspects of care related to other acute and chronic health conditions, treatment support for both TB and HIV has been task-shifted to a formal LHW cadre established by the Malawi Ministry of Health, known as Health Surveillance Assistants (HSAs).
Despite evidence of potential for LHWS to improve access to health care and outcomes for vulnerable populations (5, 6), insufficient initial and ongoing training are reported to limit the range and quality of LHW impacts (42). Additionally, there is little evidence on how best to train, supervise, and allocate tasks to LHWs to improve their effectiveness, particularly for large LHW programs (5, 42).

Knowledge translation (KT) includes a complex set of activities involved in advancing knowledge generated from research, into effective changes in health policy and practice (43).

Given that health care tasks in many LICs are increasingly being shifted to LHWs (44), many of whom have limited training and access to evidence based resources, the potential for KT strategies to improve LHW practice may be substantial. Among the knowledge translation strategies more consistently found to produce behaviour change are educational outreach, reminders, and multifaceted strategies targeting barriers to change (29). Knowledge translation strategies tailored to the specific characteristics of the health care settings in which they are to be applied may be more effective, but information is lacking on how tailoring is best achieved (30).

The purpose of this qualitative study was to identify and explore barriers and facilitators to LHWs’ efforts to support TB treatment adherence in Malawi. This study is part of a multi-component project that includes three independent studies employing a combined mixed methods design with an overall objective of developing, implementing and evaluating, an adherence intervention tailored to the barriers and facilitators to LHWs supporting TB adherence operating in Zomba District Malawi. This qualitative study was the first step in the
process, and employed focus groups and in depth interviews with LHWs providing TB care in Zomba district. Barriers and facilitators identified in this study have since been incorporated into an educational outreach intervention and point of care tool to be evaluated in a randomized trial in Malawi.

Methods

Setting/Study Population:

The Malawi National TB Programme (NTP) is a directly observed short course treatment programme. The NTP is integrated into the general health services with medication dispensing and treatment monitoring, principally provided by LHWs beyond the treatment initiation phase. Managerial and supervisory support is provided by staff at central, zonal and district health levels.

The study was conducted with LHWs providing TB care in Zomba district in southern Malawi (population 670,000, 80% rural (45), and utilized qualitative methods. In addition to 3 focus groups, 11 interviews were conducted, to optimize participation from LHWS stationed at remote health centers for whom travel to a central site for a focus group would not be possible.

Participants were selected utilizing an intensity approach to purposeful sampling. This approach was chosen to provide an in-depth understanding of the facilitators and barriers LHWs encounter in their work with TB patients. Cases were selected to include rich information, while avoiding the potential for distortions due to extreme cases (46). TB focussed LHWs, general LHWs with two weeks additional TB training, who are responsible
for provision of TB care at their health center, were the primary targets of the study. TB focus LHWs are assisted by general LHWs and LHW supervisors who are provided training the content and duration of which are of the discretion of each TB focus LHW. In order to assess whether barriers and facilitators varied with LHW training and responsibility level, a sample of general LHWs and LHW supervisor routinely involved in providing TB care were also recruited.

The District Environmental Health Office provided the sampling frame, consisting of a list of TB focussed LHWs assigned to the 28 Zomba district health centers who routinely provide care to TB patients. Site visits were conducted by the principal investigator and a research assistant to introduce the study. During these initial site visits, the list of TB focussed LHWs was supplemented with the names of general LHWs and general LHW supervisors routinely involved in provision of care and support to TB patients. Invitations to participate in focus groups were sent to TB focussed LHWs at health centers located within 2 hours travelling distance from 3 central locations chosen to maximize the potential number of participants, and followed by a phone call from a research assistant to answer any questions. If the TB focussed LHW was unable to attend, the invitation was extended to another LHW who regularly assisted the TB focussed LHW in providing care to TB patients. Transportation costs were reimbursed. Interview participants were recruited by a research assistant during a second field visit in person or by telephone when the LHW was not available on-site. All who were approached to participate agreed. Written Informed consent was obtained from all participants.
The study was approved by both the Malawi National Health Sciences Research Committee and the University of Toronto Research Ethics Board.

**Data Collection:**

The interviews and focus groups were conducted by the same research assistant, who is a native Malawian, fluent in both English and Chichewa, and functions at the level of a socio-linguistic interpreter as defined by Squires (47), who has experience in both techniques. As the research assistant has no clinical background, additional training was provided to ensure that she understood TB treatment and adherence. The research assistant was supported throughout the study by the principle investigator (LPR), a practicing physician, unable to speak the local language, who observed most focus groups and interviews and was available by phone when not present to advise the research assistant. All sessions were conducted in a semi-structured manner and utilized the same interview guide. The guide listed questions covering the LHWs experience in working with TB patients, to identify the barriers and facilitators to their work as adherence supporters. Sessions began with an open question asking about participants’ experiences in working with TB patients, and moved toward progressively closed ended questions as needed, to ensure all topics of interest were addressed. Topics of interest included: beliefs about factors related to treatment adherence, approaches to managing adherence in TB patients, factors found to be helpful or to hinder LHWs efforts to improve patient adherence, and suggestions for improving adherence.

All sessions were conducted in the local language, Chichewa, audio recorded, transcribed verbatim, and translated by the research assistant who conducted the sessions. A translation
check was performed on 3 of 14 sessions (21.5%), 2 early and 1 approximately mid-way, by a second socio-linguistic translator with a clinical background to validate the quality and conceptual equivalence of the translations.

**Analysis:**

Data were analyzed manually using directed content analysis. An initial list of codes was developed by two authors (LPR, MvL) and included commonly reported facilitators and barriers to adherence from the literature, including: disease specific knowledge, patient-provider interactions, and substance abuse. Transcripts were then read independently by the same 2 authors, initially looking for key words corresponding to the pre-defined codes, as well as, for emerging themes. Based on this initial review the coding framework was extended and utilized to organize and code the data. Data were coded by hand separately by the 2 reviewers, and results compared. No discrepancies were encountered with respect to interpretative categories.

**Results**

**Characteristics of Participants:**

A total of 30 LHWs participated, 11 in interviews, and 19 in 3 focus groups of 6 or 7 participants each. Twenty-two participants were currently working as TB focussed LHWs, 2 as general LHW supervisors, and 6 as general LHWs. Participants ranged in age from 24 to 50 years of age, and varied having 1 to 26 years experience working with TB patients. All but 4 participants were male, which based on our site visits and the TB focus LHW list, is representative of the gender distribution of the TB focus LHW population in Zomba district.
LHW lack of knowledge as the key barrier to LHWs role as patient advisors.

Participants identified their role in the health care system as patient advisors providing an essential link between patients and communities, and the hospitals and health care centers that service them.

“We (LHWs) act as a bridge between the community and the hospital, so the big issue here is advising when there are problems. We have to give advice on health matters, so the big part that we have is advising”. (Focus Group 2)

Participants identified 2 main functions of their role as patient advisors; educating patients and supporting treatment adherence. Lack of LHW knowledge was the most frequently cited barrier to LHWs efforts to both educate and support patients. Lack of both general (understanding of TB and its treatment) and job specific (understanding of tasks such as completion of treatment forms) TB knowledge was felt to be particularly problematic among non-TB focussed LHWs, who had not received formal TB training. Lack of knowledge was reported to lead to lack of confidence among LHWs, conflicting messages to patients, and errors in treatment records and at times in treatment. When asked what things could help them to address adherence with their patients, participants commented:

“What can help is special training, because not everyone is confident about their work… he stills needs support from his friends and it is not all times that we are at the office, so the services they give to patients (is poor) because the person does not know a lot”

(TB focus LHW, 5 years TB experience)
“What is needed is to have some words to tell the person …. You just have to know facts about TB, and you explain those”. (TB focus LHW, 1 year experience)

“A lot of people don’t have the necessary skills to work alone …. some don’t know about TB and there are some problems for work to be done properly, so if all LHWs could be given required training regularly, even though we try on our own to teach each other, so that things can go well” (LHW supervisor, 26 years TB experience)

In addition to a lack of TB and job specific training, LHWs noted a lack of training in communication skills as an important barrier to functioning as patient advisors. Teaching techniques were identified as key to success in patient education, however, few participants were able to go beyond simply describing the current practice at their health center, to discussing how specific techniques might contribute to successful patient education. Techniques felt to facilitate teaching and through this, adherence, included: one on one teaching, involving the patient in the discussion, asking what the patient knows and directing the teaching based on this, and having patients repeat back to show they have understood. When asked what approach(s) work well in addressing adherence with patients, participants commented:

“What works well is when we discuss with the patients one by one”

(TB focus LHW, 1 year TB experience)

“I use his questions to explain what he does not understand”

(LHW supervisor, 26 years TB experience)
“We also talk to them through participation, we sit together and talk”

(TB focus LHW, 7 years TB experience)

While participants identified positive patient-provider interactions as essential to supporting patient adherence, few, with the exception of those who had undergone training as HIV counsellors, had received training in techniques to improve communication with patients. Positive interactions felt to facilitate LHWs in supporting patient adherence included: warmly greeting patients, encouraging patients and guardians through regular counselling, maintaining patient privacy (keeping secrets), and home visits to address sensitive topics. Barriers identified included: disrespectful behaviour toward patients, rushing through interactions with patients, and showing disgust or fear of TB patients. When asked what approach(s) participants felt did not work well when working with TB patients, participants noted the following:

“What does not work well is to shout at the patient, because even if you help them, at the end what remains with him is the shouting you have done or the bad things you have said to him”. (LHW supervisor, 26 years TB experience) 

“All health workers should know their duty, to know how to receive a person and make him our friend” (Focus Group 1)

“We want to learn some skills that can help us to handle a patient”

(General LHW, 7 years TB experience)
In addition to the initial lack of TB and job specific training, participants identified a lack of continuing education, particularly with respect to changes in policy or treatment guidelines, as an important contributor to an ongoing lack of LHW knowledge, as reported below;

“We still need trainings, because sometimes, we do get training for maybe 2 or 3 days, but it is found, that maybe we do not cover most of the areas we had to cover”

(TB focus LHW, 3 years TB experience)

“Even if you learn for a long time... you can forget, maybe you learnt 2 years ago, you can forget, but if there was some way to maybe once a year we should assemble together (for training)” (Focus Group 1)

**System Barriers to LHWs role as TB care providers:**

Although lack of knowledge was widely acknowledged by participants as the key barrier, and facilitator for those with adequate training and knowledge, a variety of system issues were also identified as barriers to LHWs functioning optimally as patient advisors. Barriers included: lack of resources, workload, delays in communication, and the guardian system.

Lack of physical resources was the most frequently reported system barrier. This category included, lack of transportation for LHWs to carry out home visits, lack of reference and teaching materials (pamphlets and posters), stock outs of medications and necessary forms, and lack of physical space and therefore privacy for patient encounters.

Workload was also a frequently mentioned system barrier, with participants reporting
frequency of patient contact, particularly of home visits, negatively impacted both by the high volume of TB patients and the competing demands on LHWs time. As noted by one participant, when asked to describe their experiences in working with TB patients:

“It is just that we do a lot of things. Despite me being a TB focus LHW, we also test people for HIV. We also go to the villages to talk to people about general health issues, especially to see how they are taking care of their homes, are they drinking clean water, and do they take their children to the under 5 clinic every month”.

(TB focus LHW, 5 years TB experience)

Communication delays were commonly noted by LHWs in more remote health centers, and included both delayed notification of changes in treatment guidelines and of individual changes to a patient’s treatment plan, which resulted in confusion and at times extra work for the LHWs assuming care of the patient at the community level. In some cases patients arrived to health centers on new treatment regimens which the LHW assuming management of their outpatient treatment was not yet aware of. This was felt to contribute to poor-patient provider interactions.

A final and somewhat unexpected system issue was related to the widespread use of guardians, trusted members of the patients’ community, to directly observe the patient taking their medication on a daily basis. While good guardians were acknowledged to improve patient adherence, participants noted regularly encountering ineffective guardians, who do not fulfill their roles and at times proved a barrier to adherence. Guardians were reported to
act as barriers to adherence most often when they failed to provide necessary instrumental support (provide patient with food/water to take medication) and when patients used multiple guardians due to inconsistent availability of the primary guardian. This was reported to result in patients receiving conflicting instructions from different guardians, and felt to be particularly problematic for patients with limited ability to hear, understand or carry out the instructions provided. Issues with guardians were raised in response to a variety of questions, as noted in the follow quotes:

“Some guardians live far away from the patient, so if they are not taking good care of him .... it can make him not to take their medicine properly” (Focus Group 1)

“Sometimes the guardian just comes when the patient is not feeling okay, and when he starts feeling better the guardian leaves and the problems start” (Focus Group 3)

“The patient can bring one guardian this time and the next time they bring a different guardian. People understand things differently” (TB focus LHW, 5 years TB experience)

With the exception of fear of TB patients identified by participants as a function of lack of knowledge and training, no other emotional or attitudinal factors were identified. Comments regarding LHW attitude as a barrier to their work as adherence supporter, arose in response to questions about what does not work well in addressing adherence with patients;

“It is easy for us to get sick, we are close to the patient, even bosses fear being close to the patient” (Focus Group 3)
“It depends on the character of the person treating the patient, because if you know your job is to deliver health services, because me as a LHW, I am not supposed to be disgusted with TB patients because I know that TB is infectious” (Focus Group 1)

Discussion

Consistent with the reported weakness in LHW training in the literature (5, 6, 42), lack of knowledge as a result of insufficient early and ongoing general TB and job specific training, including communication skills, was identified by LHWs as the key barrier to their role as TB care providers. Given this identified knowledge gap and its perceived negative impact on LHWs ability to fulfill their roles as patient educators and adherence supporters, this seems an important target for further training.

Given the critical shortage of health care providers, and large number of LHWs already working in Malawi, research to develop cost-effective methods to provide both initial and ongoing LHW training, is important to ensure and increase the benefits associated with LHW programs in Malawi. In view of the success and relative low cost of educational outreach and reminder knowledge translation strategies, and fit of KT approaches to the predominantly knowledge barriers identified by our study, we believe this is a promising avenue to addressing LHW training in Zomba, toward improving TB treatment adherence and outcomes. In addition to informing future interventions, we believe that by highlighting system barriers impacting LHWs work as patient educators and adherence supporters, our study provides useful insight into potential targets of relevance to ongoing efforts in Malawi to address larger system issues.
There are several potential limitations to this study. Although TB policy is national, this study was conducted in Zomba district only, so it is possible that, not all findings will be generalizable to other districts in Malawi. In addition, language translation introduces the possibility of mistranslation of words or concepts, and may limit the understanding of the cultural context. However, we believe the themes and sub-themes reported are accurately represented.

**Conclusion**

Consistent with the recognized weaknesses in training and task allocation among LHW programs globally (6), our findings suggest a gap between knowledge and responsibilities among LHWs providing TB care in Malawi. As knowledge gaps and training needs are a function of the culture and health system in which LHWs are embedded, barriers and facilitators to LHWs roles must be carefully identified as a basis for development of interventions to address them.

Based on existing literature that report poor disease understanding and poor interactions between patients and their TB care provider as barriers to adherence from the patients’ perspective, we anticipated gaps in provider TB knowledge and patient interaction skills. However, the specific nature of these gaps, including LHWs limited understanding of the disease itself, lack of training in job specific tasks, and lack of communication skills training, as well as a number of system barriers important in Zomba District were identified and understood through the information provided by the LHW participants in our study. In response to our findings, we have designed a knowledge translation intervention utilizing on-
site peer led training (educational outreach) and a point of care tool (reminder), which are to be evaluated in a randomized trial in Zomba district.
The purpose of this chapter is to:

1) Describe the goals and theoretical framework of the intervention;
2) Outline the steps and inputs used in the selection of content areas and development of the intervention;
3) Provide a description of the intervention and the implementation and evaluation processes;
4) Discuss reported impacts and lessons learned through quarterly meetings with peer trainers and the experiences of the intervention team during implementation.
Goals and Theoretical Models of the Intervention

The goal of the intervention was to improve the way that LHWs provide TB care and support adherence, thus, improving patient adherence to TB treatment and ultimately TB outcomes. We drew on several theoretical models of adult learning in designing the intervention. The educational outreach component of the intervention was based principally on the tenets of experiential and transformative learning which hold that learning occurs by constructing knowledge and meaning through real-life and the learning experience (48, 49). Central to these approaches is learning through collaborative engagement and critical reflection with the role of the educator as that of a facilitator of critical reflection through encouraging questioning and exploration of the limitations and consequences of current knowledge and beliefs (50, 51). Other theoretical models incorporated to lesser degrees include: social cognitive theory (52), self-efficacy (53) and the theory of planned behavior (54). The point of care tool, reminder component, is based on the theory of behavioural learning, with the reminder functioning as an antecedent to behavior (55).

Development of the Intervention

Development of the intervention involved 3 major steps: preliminary work; pilot testing and refinement of the draft intervention; implementation and evaluation. Key local stakeholders were engaged early in the project and collaborated throughout the development process.

Preliminary Work:

Goals of the preliminary work included engagement of stakeholders, identification of the content focus areas for the intervention, selection of the knowledge translation approach(s), identification of barriers and facilitators, and tailoring of the intervention to the local context.
and to identified barriers.

*Stakeholder Engagement:*

Improving the proportion of TB cases successfully treated is an area that the Malawi ministry of health is focusing on. In response to this we met with key stakeholders at all levels of the ministry of health including members of the national TB unit, the director of Zomba Central Hospital (zonal health officer), the district health officer and district environmental health officer in February 2010 during the initial planning phase of the project. During these initial meetings a preliminary description of the project was provided and input sought into all aspects of the project from research question, to dissemination, to how the findings might be incorporated into routine LHW training if found to be effective. In addition, early engagement of the intended end-users, as well as their supervisors and colleagues, was accomplished through field visits to district health care centers, also in February 2010.

Stakeholders were supportive of the project recognizing a need for additional TB training particularly for general LHWs assisting with TB care. They also felt that the intended KT approach was practical for roll out to LHWs currently working and for incorporation into the core training program if proven effective. They advised that the most appropriate choice for peer trainers were the TB focus LHWs at intervention sites given their responsibility for provision of TB care and training of general LHWs providing TB care at the health center level. They also emphasized a need for relatively simple language based on the education levels of LHWs but felt that the training could be provided in English. However, they recommended that the point of care tool be provided in the local language for benefit of patients who’s English and general literacy might be an issue.
Choosing most suitable recipients for the Intervention:

As outlined in chapter 1, while our review of the literature identified a variety of commonly recognized barriers to adherence, including structural, health system, and socio-economic factors that continue to play a role in the Malawi context (56, 57), these require system level interventions and were beyond the scope of the present project. In addition, recent and ongoing efforts in Malawi have begun to address a number of these higher level barriers including: decentralization of care to reduce travel and improve accessibility to health services; provision of TB diagnostic and clinical services, and TB/HIV medications free of charge to increase accessibility and reduce the financial impact on patients and families; and community based education campaigns to reduce the stigma of TB and encourage earlier presentation for care. With this in mind and in view of the logistical and literacy issues limiting the feasibility of a patient level intervention, LHWs were chosen as the most appropriate recipients of the adherence intervention.

Identification of Intervention Content Focus Areas:

Specific content areas were initially identified through a literature review. This information was supplemented by several additional sources including discussions with stakeholders and local clinicians, and through the formative qualitative study outlined in chapter 2. In addition to the input received through discussion, information was collected through direct observation during field visits by the principal investigator (PI) accompanied by a local clinician or research assistant and through several days of hands on experience with the PI observing and assisting in the TB/HIV clinic at the central hospital.
During our discussions with LHWs on these initial field visits many general LHWs providing TB care noted being inadequately trained with several reporting receiving as little as 1-2 hours of training from their TB focus LHW. General LHWs indicated a need for a better understanding of the disease process of TB including transmission. All LHWs we spoke to, including TB focus LHWs, felt they would benefit from at least some HIV training in view of the high proportion of TB/HIV co-infected patients they provided care to, so they would better understand the relationship of TB and HIV, and be better able to address patients’ questions and concerns. Based on our observations both TB and HIV knowledge appeared to vary considerably with TB focus LHWs and LHWs trained in HIV testing and counselling who are relatively well versed in their area. However, evidence of cross training of TB and HIV providers was not evident. During our observations we also witnessed a number of incidents of poor communication between patients and providers, and poor handling of cases at risk of non-adherence. For example, one patient who presented a few days late for their medication refill was met with open hostility despite our presence, rather than seizing the opportunity to understand and address the reason for their lateness.

Based on this combined input several aspects of LHW knowledge and clinical skills were identified to be addressed in the intervention. Disease specific knowledge was a key focus identified through consultation and the results of the formative qualitative study. Disease specific knowledge areas to be addressed included: understanding the TB disease process from transmission to diagnosis and treatment, understanding the interaction between TB and HIV, and understanding the importance of adherence and risk factors for non-adherence. Clinical skills identified as important targets for the intervention included: improving methods of patient education, developing a good patient-provider relationship, developing an
approach to inquiring about and addressing non-adherence, and encouraging communication with other members of the healthcare team as a means of improving patient care through shared learning and appropriate referral of complex cases.

Selection of the Knowledge Translation approach:

As explained in chapter 1, a multifaceted KT strategy employing educational outreach and reminders tailored to locally identified barriers was chosen based on the success of these strategies in changing provider behavior. Educational outreach strategies have evolved overtime with the term now representing a group of strategies including traditional approaches using visits to individuals or groups of providers, provision of educational materials, and often reminders and/or audit and feedback, to newer variations using social marketing or targeting changes in organization of care delivery (58). For logistical reasons in designing the present intervention we chose to employ elements from early descriptions of educational outreach which utilized a multi-component process including identification of barriers to appropriate practice and tailoring of the intervention to address identified barriers using simple messages delivered by a respected person and reminders which function as prompts for the provider to perform a clinical action (58).

Barriers were identified through broad consultation and the formative qualitative study, and used to identify specific content areas for intervention as outlined above. TB focus lay health workers were chosen as the respected parties to deliver the message in view of their position in the hierarchy as head of TB care at the health center level and their, at least theoretical, higher baseline level of TB knowledge relative to their general LHW peers. Given the breadth of knowledge and skill gaps to be targeted by the intervention simple messages alone
were felt insufficient to adequately address the identified barriers. Therefore, while both the knowledge and skill components were reduced to the essential elements and employed the simplest language possible, a variety of methods were utilized to allow for repetition, practice, and reflection to increase incorporation of the new knowledge. In addition, a point of care tool was developed to further support the adoption of the new practices learned by providing a visual cue to act as a reminder during patient encounters. As TB care is provided on a rotating basis with many LHWs involved with a given patient during the course of treatment, individual provider level data is not a meaningful reflection of the individual providers’ performance and audit and feedback were therefore not employed. Consideration was given to providing feedback on the performance of the healthcare center as a whole, but logistical issues with data collection and reporting made this not feasible given the present record keeping and reporting processes.

**Pilot Testing and Refinement of the Draft Intervention:**

A draft of the intervention package was developed which included a detailed curriculum outline including planned exercises along with a draft of the point of care tool based on our theoretical model and intervention targets identified in the preliminary work. Both the draft curriculum and point of care tool were disseminated widely to national and district ministry of health personnel and local clinician educators for review and comment. In addition, the point of care tool was piloted with four LHWs providing TB care at the busy tertiary hospital’s TB/HIV clinic. Based on this feedback, both were revised for language, content and process including: changing from the term bacteria to the more commonly used term for germ in the local language, adding a section on infection prevention for staff as outlined in the Malawi TB operational guidelines, and changing a picture on the patient side of the tool.
to be consistent with the others and better represent the flow of a patient through the
treatment process. The revised curriculum and point of care tool were re-circulated for input,
with no further changes recommended.

The Final Intervention Package:
The point of care tool was designed as a laminated chart that could be folded for carrying on
field visits or to stand on the desk for reference during patient encounters. The patient side of
the tool (appendix 3) used simple pictorials to illustrate key messages including: a depiction
of a patient’s progress through treatment, the gradual destruction of the TB germs over the
course of treatment, reference to times of increased risk for non-adherence (experience of
side-effects and relief of symptoms), and an image depicting the intake of medication at the
same time each day as the means to reaching the end stage of treatment (cure). The provider
side of the tool (appendix 4) was split into 2 halves vertically. The left side, used 6 key words
to highlight aspects of adherence to be addressed in each patient encounter, with examples of
how to guide or assist the patient at each step on the right side of the tool.

Based on consultation with key stakeholders and the content areas to be covered, 60-90
minutes per session was thought to be a reasonable time to allot to training during regular
work hours. The resultant education package consisted of 6 modules, outlined below in brief
and in greater detail in the training handbook included in appendix 5, each representing a
separate training session. Modules employed a combination of didactic and interactive
techniques in order to efficiently provide specific knowledge as well as allow for practice,
reflection and sharing of ideas.
Module 1: Introducing the Program

The first session was designed to introduce the program and to invite LHWs routinely providing TB care to participate. Information provided included the background, relevance, goals and outline of the program. The exercise involved a discussion of participants’ experiences with difficult to manage TB cases in which they were asked to reflect on their experiences with such cases and bring examples they had personally experienced or were aware of to the next session. Cases were submitted anonymously and incorporated into case based discussions throughout the remainder of the program.

Module 2: Understanding TB from transmission to cure

The second module began with a didactic sessions on the TB disease and treatment process. Exercises included a practice session on how to set up the TB office to minimize exposure risk to staff, generation and discussion of a list of common myths about TB, and case based discussion of side-effect management. During the myth exercise several myths were reported to be common not only among patients but among providers, this led to a discussion of how these beliefs might contribute to non-adherence and/or inappropriate advice from providers, and how participants could contribute to reducing their impact.

Module 3: Understanding HIV and Its interaction with TB

The didactic component of the third module provided a basic understanding of HIV and its treatment, with a specific focus on the interaction of TB and HIV and their combined treatment. In response to the myth that TB could not be cured in the presence of HIV, which was reported to be common among both patients and providers, evidence to the contrary was provided and participants were encouraged to reflect on and share their experiences of
success among TB/HIV co-infected patients. Exercises included case based discussions and role playing to educate and encourage TB patients to go for HIV testing and counselling.

Module 4: Adherence Part 1
This module defined adherence and treatment success for both TB and HIV, explained the importance of and consequences of non-adherence to treatment, and outlined approaches to improving adherence. Exercises included small group break-out sessions to generate a list of both risk factors for non-adherence and protective factors promoting adherence. The lists were then shared with the entire group and a combined list compiled and discussed. Based on this list participants were asked to describe the ideal approach to supporting adherence and to managing non-adherence, and asked to reflect on their own and others approaches to these tasks and how these approaches might be improved.

Module 5: Adherence Part 2
This module introduced the point of care tool and the program’s approach to supporting and addressing adherence. Use of the tool was initially demonstrated by the trainer with participants playing the role of patients. This was followed by small group practice in using the patient side of the tool to educate patients. Each group consisted of 3 participants, one playing the LHW, a second playing the patient, and a third observing, with each role play followed by a discussion of perceptions from each perspective.

Module 6: Communication techniques and Concluding Remarks
The final module began with an introduction to communication techniques, including concepts of patient centered care and motivational interviewing designed to foster improved
patient-provider relationships and better engage patients as partners in their care. The provider side of the tool was used by the trainer to demonstrate how to trigger and support an adherence discussion, and followed by practice in groups of three. Cases were taken from the formative qualitative study and participants’ submissions, and reflected particularly challenging cases. In addition to feedback within the small groups cases were discussed within the larger group to allow for sharing of experiences and for review of any remaining points of interest or concern with the trainer.

**Implementation and Evaluation:**

Peer trainers attended a 3 day training course provided by the principal investigator and a Malawian research assistant. Training included coverage of all content areas and practice with the point of care tool, as well as discussion of methods to foster a safe learning environment, to engage learners, and to facilitate critical reflection by exploring the limitations and consequences of current knowledge and beliefs. As training is part of the TB focus LHWs’ job description, peer trainers were not paid. At the end of training they were provided with a small thank you gift valued at approximately 5 Canadian dollars, which they were not aware of in advance. Visits to peer trainers were conducted on one or two occasions early in the training period by the study co-ordinator to provide support and guidance. In addition, peer trainers were encouraged to contact the intervention team at any time with any questions or concerns. During one such visit, the study co-ordinator’s visit coincided with a training session and he was asked to join in for the last part of the session. Training sessions were not otherwise directly supervised.
Sessions were delivered by a peer trainer on-site during regular work hours in 6 weekly sessions of 60-90 minutes. Initially, the 6 sessions were to occur over a 2 month period but this was later extended to 3 months. The training period was extended for 2 reasons. First, it was extended to accommodate for annual leaves among LHW staff which delayed training at some sites. Second, it was extended in response to the request of one trainer with a relatively large pool of LHWs providing TB care to train a second group so that all LHWs routinely provided TB care could be trained. Following completion of the program, although not required or specifically suggested by the intervention development team, all health centers reported continuing to meet as a group on at least a quarterly basis to discuss difficult cases, share experiences, and at one health center with few TB patients, to practice with the tool.

Primary evaluation of the intervention was undertaken through a cluster randomized controlled trial (chapter 4). A companion qualitative study was conducted to explore the experiences of LHWs with the intervention and to identify areas for improvement and refinement of the intervention (chapter 5). Additionally, informal feedback was gained through quarterly trainer meetings held to allow for sharing of experiences and challenges with the initial training and ongoing use of the point of care tool.

**Reported Impacts and Lessons Learned**

Results of the formal evaluation of the intervention are reported in subsequent chapters. Impacts and lessons learned reported here stem from the minutes of peer trainer quarterly meetings and brief notes made by the study coordinator during field visits early in the training phase of the intervention.
All peer trainers reported enjoying their role as peer trainers and all indicated their willingness to continue in this capacity at their own health centers or elsewhere. However, one trainer admitted difficulty initially and felt that additional support from the development team would have been helpful. Of note, this trainer was found to have some difficulty with the material during the trainer training and as an older LHW may have been challenged both by the length of time since his own TB training and by a generally lower education level common among older age groups in Malawi. This was recognized by the implementation team as an important consideration when selecting peer trainers in the future.

All trainers reported that the training was generally well received by LHWs at their centers who were for the most part eager learners and active participants. While, as anticipated many peer trainers reported that the lack of stipends was raised by LHWs in their teams only 1 reported this to be a significant issue, with a LHW initially refusing to participate without receiving a stipend. However after further discussion and observation of the training, the individual ultimately choose to participate and was reported to have appreciated and valued the intervention.

Encounters with the study team during field visits to conduct qualitative interviews during the course of the trial were appreciated by participants who felt valued and supported by the visits and felt visits represented an opportunity for them to ask questions (although rarely done) relevant to the intervention itself or regarding ideas for handling difficult cases. In addition many participants spoke of their trainers very positively and appeared to view them as clinical mentors, and several peer trainers reported providing onsite support to general LHWs following the initial training period. This may suggest an opportunity to provide
supportive supervision of general LHWs through regular contact with peer trainers at the health center level and to peer trainers through refresher sessions conducted by higher level trainers (individuals who train the peer trainers), by incorporating supervisory skill training and tasks into training of peer and higher level trainers.

Positive impacts of the program reported included: identification of several patients making important medication errors through the use of the tool, better co-operation between LHWs and mid-level health workers within the health center, better relationships with patients and ongoing efforts to improve delivery of TB care through continued regular meetings to discuss difficult cases and in some centers through restructuring the LHW schedule to ensure delivery of TB care by a trained provider. The only reported problem beyond the initial issue with stipends was that the health center copy of the point of care tool was sometimes taken to the field leaving no copy available for use in the office. Limiting the number of copies was to prevent distribution outside of the intervention sites during trial period and this has since been resolved.

**Conclusion**

Anecdotal reports indicated that the training was well received and thought to positively impact both patient care and interactions among health center staff. The willingness of the peer trainers to continue in or even expand their work in this role is encouraging, particularly as trainers were not paid or materially rewarded for this work. Lessons learned from the process included a more realistic appreciation of the time needed for the intervention given the pattern of annual leave common in this setting, with staff typically taking all annual leave in one time block, and the need to incorporate additional support for older peer trainers.
While these anecdotal reports are encouraging and lessons learned valuable, should the intervention be rolled out more widely they must be placed within the context of the findings of the more rigorous evaluation described in the following chapters.
Chapter 4: A knowledge translation intervention tailored to the needs of lay health workers to improve TB treatment adherence in Malawi: A pragmatic cluster randomized controlled trial.

The purpose of this chapter is to:

1) Describe the design of the cluster randomized controlled trial to evaluate the effectiveness of the intervention;

2) Outline the analysis and findings of the trial;
Abstract

Objective: To evaluate the effectiveness of a tailored knowledge translation intervention for lay healthcare workers on TB treatment adherence.

Design: Pragmatic Cluster Randomized Trial

Setting, Participants, & Randomization: The study was embedded within a larger trial, STAT-PALM+, and included all 28 health centers providing TB care in Zomba district. Fourteen health centers randomized as controls in the larger trial were maintained as control sites. Seven of 14 STAT-PALM+ intervention sites were randomized to the lay health worker (LHW) intervention. Sites were stratified by HIV provider status.

Intervention: STAT-PALM+ alone sites, received an educational outreach program targeting mid-level health workers. LHW intervention sites received both the STAT-PALM+ intervention and the lay health worker intervention which employed on-site peer led educational outreach and a point of care tool tailored to the identified needs of lay health workers providing TB care in Zomba district. Control sites received no intervention.

Main Outcome Measures: Primary outcome was proportion of patients successfully completing treatment.

Results: Among the 28 sites there were 178 incident TB cases with 46/80 (0.58) successes in the control group, 44/68 (0.65) successes in the STAT-PALM+ alone group, and 21/30 (0.70) successes in the STAT-PALM+ with LHW intervention group. There was no significant
effect of the intervention on treatment success in the univariate analysis, adjusted $X^2 (2) = 1.098$, $p= 0.578$, or multivariable analysis controlling for covariates with significant model effects, Wald $X^2(2)= 0.548$, $p= 0.760$. The intervention arm by TB type interaction approached but did not achieve significance Wald $X^2(5)= 10.762$, $p=.056$, and was significant only in the control arm, RR of treatment success for pulmonary TB relative to non-pulmonary TB, 1.18, 95% CI (1.05-1.31).

**Conclusion:** Given the identified trend for effectiveness and potential of knowledge translation strategies as low-cost alternative approaches to lay health worker training further studies are needed to explore changes that might achieve a stronger impact and thus improve adherence and successful treatment rates.

**Trial Registration** ClinicalTrials.gov NCT01356095

**Background:**
Globally 1.7 million lives were lost to TB in 2009 (7), with mortality rates up to 4 times greater in individuals co-infected with HIV (39). Among the 20342 new TB case notifications in Malawi in 2010 approximately two thirds were co-infected with HIV (17). Despite ongoing efforts poor adherence remains an important contributor to the high TB burden in Malawi, with default rates for TB and antiretroviral treatment as high as 16% (18), and multidrug resistant TB accounting for 2.3% of new and 7.5% of recurrent TB cases (59).
An estimated 4.2 million skilled health care workers, 1.5 million in Africa alone, are needed to address the chronic shortage of skilled health workers globally (2). Task shifting of less complex health care tasks to lay health workers (LHWs) is an increasingly employed strategy to addressing this shortage (60), particularly in low and middle income countries (LMICs) who have been hardest hit by the health worker crisis. While shown to improve access to preventative and basic health services, and positively impact some health outcomes (5, 6), insufficient training and supervision are recognized barriers to the effectiveness of LHW programs (6). Despite their wide spread involvement in healthcare evidence on how LHW training and supervision needs may best be met is lacking (60).

Although approaches to training in lay health worker programs vary considerably (6), ongoing training frequently involves removing LHWs from the workplace to receive training off-site (61). This approach is problematic because it is expensive in terms of both real costs and opportunity costs (61) associated with the disruption of care provision. Given the resource implications and lack of evidence for effectiveness of this approach to on-going training, research to design and evaluate alternative approaches to training are needed (60).

Malawi has among the lowest healthcare worker to population ratios with 2.03 physicians and 36.8 nurses per 100,000 population in 2009 (4). In response to this crisis a variety of basic health care tasks have been shifted to a formal cadre of lay health workers termed health surveillance assistants (HSA), including provision of outpatient TB care and adherence support. LHWs have a pivotal role in addressing the high TB burden in Malawi with over 20000 new TB notifications in 2010 (17). In a recent study we conducted with LHWs in Zomba district we found lack of initial and ongoing training to be the key barrier to
LHWs in their role as TB care providers and adherence supporters (62). Given the cost implications of the typical training approach with now over 10000 LHWs working in Malawi (4) an alternative approach is essential to ensure that the training needs of this valuable health care resource are met. Given the relative low cost and proven success of knowledge translation (KT) strategies as a training and clinical support tool for mid-level health workers in South Africa (31, 32, 33) and in the KT literature in general (29, 30), these seem a promising approach to addressing the training needs of LHWs in Malawi and in similarly resource constrained health care settings.

This study is part of a multi-component project employing a mixed methods design with an overall objective of developing, implementing and evaluating a tailored knowledge translation intervention to enable LHWs to function optimally as TB treatment adherence supporters, in Zomba District Malawi. The purpose of this study was to quantitatively evaluate the effectiveness of the intervention in improving TB treatment adherence.

Methods:

Study Design

We conducted a pragmatic cluster randomized trial, intended to mimic real world implementation of the intervention (63, 64, 65), to evaluate the effects of a knowledge translation intervention tailored to the needs of lay healthcare workers to improve TB treatment adherence. A cluster design, with health centers as the unit of allocation and TB patients as the unit of analysis, was chosen in order to prevent contamination and to optimize the benefits of the intervention at the patient level, as TB care is provided within a given
health center by LHWs on a rotating basis with LHWs assigned to the health center TB office in weekly blocks at many health centers.

Setting and Participants
Our cluster randomized trial was embedded within a larger cluster trial, STAT-PALM+ (34), employing an educational outreach intervention conducted with mid-level health workers in Zomba district health centers. Of the 30 health centers included in the larger trial, 28 routinely provided care to TB patients and were eligible for inclusion in the present study. In order to prevent contamination of the larger study by introducing an intervention at control sites, only the 14 STAT-PALM+ intervention sites were eligible for allocation to the LHW intervention. All LHWs routinely involved in providing care to TB patients were eligible and invited to participate in the intervention, with refusal to participate the only exclusion criteria.

Randomization
The 14 STAT-PALM+ intervention sites were randomly allocated centrally by a research assistant using a computer-generated random numbers list, stratified based on whether the health centers were antiretroviral therapy (ART) initiation sites at the time of randomization. This stratification was chosen as many LHWs involved in TB care also provide services to HIV patients with the potential for LHWs at ART initiation sites to have received additional clinical skills training. Given the nature of the intervention, blinding was not possible. The 14 remaining district health centers involved in provision of care to TB patients remained control sites as previously allocated in the STAT-PALM+ trial.
The study was approved by both the Malawi National Health Sciences Research Committee and the University of Toronto Research Ethics Board. Individual consent was not required from health center staff as the intervention was developed in collaboration with and approved by the national TB program and while participation in training is a routine expectation of health center staff, participants were invited but not required to participate. All outcome data were taken from routinely collected Ministry of Health records with consent from individual patients not required.

**Intervention**

The LHW intervention employed two knowledge translation strategies, educational outreach and a reminder (point of care tool). The educational outreach component employed peer trainer led on-site training using a combination of didactic and interactive techniques including case based discussions and role playing to efficiently provide TB specific knowledge and adherence counselling skills, and to allow for practice and exchange of ideas between LHWs. Topics were initially chosen based on the adherence literature and expanded to address the training needs identified by Zomba district LHWs in a prior study conducted by our group (62). Topics included: TB transmission, natural history, treatment, and consequences of poor adherence; the interaction of TB and HIV; common barriers to adherence and appropriate methods for preventing and addressing non-adherence. The second component was a point of care clinical support tool designed as a laminated chart that can be folded and carried during field visits or stand on the desk to be referenced during patient interactions. One side of the tool provides a visual reminder designed to trigger an adherence discussion during patient interactions and provides clinical support for management of side-effects and a constructive approach to addressing issues with adherence.
The opposite side uses simple pictorials to illustrate key messages, used in patient education and adherence counselling. The tool was pilot tested with LHWs providing TB care at the district hospital.

Peer LHW trainers were selected in consultation with the district environmental health office. Six of the trainers were regularly employed as the TB focus LHWs at intervention sites with the seventh acting in this role due to the prolonged absence of the TB focus LHW at the final health center. TB focus LHWs are general LHWs who have received 2 weeks additional TB specific training and are responsible for provision of TB care at their health centers. General LHWs assigned to assist in providing TB care are in turn trained by the TB focus LHW with the content and duration of this training left to the discretion of the TB focus LHWs.

Peer trainers participated in a 3 day training course covering both the content of the training itself as well as techniques for peer-training. They were then asked to provide a minimum of 6 sessions of 60-90 minutes length over a 2 month period during regular work hours to all the general LHWs routinely involved in provision of care to TB patients at their health centers. Timing of sessions was left to the discretion of the trainer and their team. The training period was extended to 3 months to allow for a second block of training at sites with large numbers of LHWs. In addition contact with the trainer at one site was lost for 6 weeks during which plans to recruit and train an alternate were underway when contact was reinstated and training session begun at the site. Training materials were provided but no incentives were provided to trainers since training of general LHWs assigned to assist with TB care is part of their usual job description and payment of incentives would limit sustainability. Although contamination across arms is unlikely given the distance between and infrequency of contact
between health centers, in order to further reduce the risk of contamination to control or
STAT-PALM+ only sites, the purpose of the study was shared with participants who were
asked not to share information about the training or tool outside of their health center and a
very limited number copies of the tool provided to each center. Peer trainers were brought
together quarterly to provide an opportunity to address any questions or concerns with the
research team and to allow for exchange of experiences with the initial training and ongoing
use of the point of care tool. Supervision of LHWs by LHW supervisors was infrequent as is
usual in all arms.

Lay health workers in the control arms received the usual training at the discretion of their
TB focus LHWs. The STAT-PALM+ intervention was designed for mid-level health workers
(nurses and clinical officers) and is much broader in its clinical focus, see appendix 6 (34).
Near the end of the study period the STAT-PALM+ intervention was rolled out in control
sites and was complete in the majority of sites early in the last quarter of the present trial.
During roll out of the STAT-PALM+ LHWs were permitted to sit in on STAT-PALM+
training sessions at one site. As a result, it is possible that some LHWs providing TB care at
STAT-PALM+ only sites may have received additional training relevant to their work with
TB patients.

Data Collection and Outcome Measures

Outcome data were obtained from routinely collected Ministry of Health records and
included TB patients starting treatment in Zomba district on or after April 1, 2011 and whose
treatment period ended on or before March 31, 2012. Cards were digitized and double
entered by trained data entry clerks. Cases with no outcome recorded on the TB treatment
card were traced back to the health center and updated using the outcome recorded in the TB registers. As a large number of cases also had no outcome noted in the TB register, TB treatment cards were reviewed and the final outcome updated based on the record of administered treatment.

TB outcomes were classified based on World Health Organization definitions (10). The primary outcome of interest was the proportion of treatment successes, defined as the combined total of cases cured (smear positive initially and smear negative in the last month or treatment and on at least once other occasion) plus those who had completed the standard treatment. Secondary outcomes of interest included: proportion of default cases (cases missing 2 or more consecutive months of treatment), the proportions of success and defaults among patients co-infected with HIV, and weight change as a surrogate marker of clinical improvement.

Sample Size
As the present trial was embedded within a larger cluster trial and included all health centers providing TB care in the district, there was no opportunity to increase the number of clusters. A sample size calculation was conducted to determine the number of patients needed per cluster based on the binary outcome of TB treatment success with an alpha of 0.05 and power of 0.80. We estimated a treatment effect size of a 0.15 increase in proportion in successful treatment over the 0.78 successful treatment rate for usual care based on published local treatment success rates and findings of studies with LHWs as adherence supporters in similar settings (35, 66). An intra-cluster correlation coefficient (ICC) of 0.1 was estimated as a mid-range value from a list of ICCs from similar studies in terms of intervention targets,
outcomes, and units of randomization (67). Given these parameters and a total number of 28 clusters available for randomization, we calculated a required sample size of 14 patients per cluster, for a total of 392 patients. Based on the number of TB notifications per year, a trial period of one year was anticipated to be sufficiently long to accrue this sample size.

**Statistical Analysis**

Analysis was by intention to treat, and results reported according to the consort guidelines for pragmatic and cluster randomized trials. Given the relatively small number of clusters, the effectiveness of randomization was evaluated through descriptive statistical comparisons of baseline patient characteristics. Inter-cluster correlations were calculated for outcomes of interest with adjustment for unequal cluster sizes (68). Univariate analysis of the primary outcome of interest, treatment success, and the preplanned subgroup analysis of treatment success by HIV status, was conducted using chi squared analysis of proportions adjusted for clustering (69), to reduce the risk of rejecting the null hypothesis in error known to be elevated with generalized estimating equations (GEE) analysis with small sample sizes (70). As the ICC for treatment success by HIV status was negative an ICC of zero was assumed (71) and unadjusted chi square analysis conducted. Given the inclusion of all 3 trial arms in the primary chi square analysis, odds ratios and confidence intervals were estimated using a GEE with trial arm as the only factor, in order to provide an approximate measure of effect size within the context of the overall chi square result. As odds ratios may be inaccurate with common events, odds ratios were converted to relative risks using the formula outlined in 1998 by Zhang and Yu (72).
Multivariable analysis of the primary outcome was conducted using GEE to account for clustering in assessing the effectiveness of the LHW intervention. The GEE utilized a binary logistic model with robust (sandwich) covariance estimator and an exchangeable correlation matrix, to estimate the treatment effect as an odds ratio and to test for significance. Odd ratios were again converted to relative risk. The model for treatment success was built systematically. First the independent effect of each pre-determined predictor on the outcome of interest was examined with only the predictor and trial arm in the model. Predictors with significant model effects were retained in the final model.

Four health centers accruing no patient level data were eliminated from analysis. This left 1 stratum with only 1 cluster, which precluded a stratified analysis. To adjust for any effects of the stratification variable, strata were assessed in the first step, to be retained if significant. Pair-wise contrasts were conducted to assess the incremental effect of the LHW intervention over that of the STAT-PALM+ intervention alone. TB outcomes were not available for 2 cases in the control arm due to poor visibility of the TB card. These cases were excluded from the primary analysis and a sensitivity analysis conducted to assess their potential impact on the effect of the intervention.

Planned secondary analysis of proportion of default cases could not be undertaken due to the small number of events, < 0.06 of cases. In addition, as both initial and final body weights were recorded in less than 5% of cases analysis with weight change as a surrogate for clinical improvement could not be conducted. All analysis were two-tailed, with p values < or = 0.05 considered significant. Analyses were carried out using IBM SPSS statistics version 20.
**Results:**

*Intervention*

In addition to the 7 peer trainers who continued to provide patient care during the study period, a total of 49 LHWs were reported to have completed the intervention training. This included all LHWs routinely providing TB care at STAT-PALM+ with LHW intervention sites at the start of the study and ranged from 3-12 per site. However this is likely an overestimate as 3 of 36 LHWs interviewed in a companion study reported they had not completed the training. As this was a pragmatic trial undertaken with the understanding that there would be variation in the real world implementation of the intervention, fidelity of the training was not assumed or intended, and therefore not assessed (63, 64). One trainer was laid off at the end of the first quarter, and 7 trained LHWs lost over the course of the study (6 transfers, 1 death). All LHW intervention sites reported meeting as a group 1-2 times per quarter beyond the initial training period to share experiences, discuss challenging cases, and to practice with the point of care tool at less busy centers.

*Baseline Characteristics and Study Flow*

Baseline characteristics were comparable across the 3 trial arms (see table 4.1), with proportion of pulmonary TB cases relative to all TB cases, 0.58 in the control group, 0.74 in the STAT-PALM+ only group, and 0.80 in the LHW intervention group, the only significant difference $X^2$ (2df) = 7.226, p= 0.027.

All 28 eligible health centers agreed to participate. Four health centers accrued no eligible patients and were eliminated from analysis (see figure 4.1). TB outcomes by trial arm are shown in table 4.2. Records were obtained for 178 eligible patients. Two cases could not be
reconciled due to poor visual quality of the TB treatment cards (see figure 4.1). Primary analysis was conducted with these 2 cases eliminated and a sensitivity analysis conducted to ascertain their potential impact.

Table 4.1: Baseline Characteristics by trial arm

<table>
<thead>
<tr>
<th>Factors</th>
<th>Control Group Number (%)</th>
<th>STAT-PALM+ Only Number (%)</th>
<th>STAT-PALM+ and LHW Intervention Number (%)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Cluster Level</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of Health Centers</td>
<td>12</td>
<td>7</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>ART initiation sites</td>
<td>3 (25)</td>
<td>2 (29)</td>
<td>1 (20)</td>
<td></td>
</tr>
<tr>
<td>Cluster Size (range)</td>
<td>6.7 (1-15)</td>
<td>9.7 (5-17)</td>
<td>6 (3-12)</td>
<td></td>
</tr>
<tr>
<td><strong>Patient Level</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of Patients</td>
<td>80</td>
<td>68</td>
<td>30</td>
<td></td>
</tr>
<tr>
<td>Mean Age in years (range)</td>
<td>37.0 (3-72)</td>
<td>39.3 (1-84)</td>
<td>38.7 (5-73)</td>
<td>.719¹</td>
</tr>
<tr>
<td>Women</td>
<td>40/80 (50)</td>
<td>38/68 (44)</td>
<td>17/30 (43)</td>
<td>.716²</td>
</tr>
<tr>
<td>Incident TB cases**</td>
<td>71/72 (99)</td>
<td>59/64 (92)</td>
<td>27/29 (93)</td>
<td>.398²</td>
</tr>
<tr>
<td>Pulmonary TB cases**</td>
<td>45/78 (58)</td>
<td>50/68 (74)</td>
<td>24/30 (80)</td>
<td>.027² *</td>
</tr>
<tr>
<td>HIV positive**</td>
<td>29/63 (46)</td>
<td>24/56 (43)</td>
<td>11/22 (50)</td>
<td>.847²</td>
</tr>
<tr>
<td>6 month weight recorded</td>
<td>3/80 (4)</td>
<td>2/68 (3)</td>
<td>1/30 (3)</td>
<td>.302²</td>
</tr>
</tbody>
</table>

¹ 1 way Analysis of Variance ² chi square
* significant
**Variations in denominator due to missing data

Table 4.2: TB treatment outcomes by Trial Arm

<table>
<thead>
<tr>
<th>TB outcome</th>
<th>Control Group Number (%)</th>
<th>STAT-PALM+ Only Group Number (%)</th>
<th>STAT-PALM+ and LHW intervention Number (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cure</td>
<td>8/80 (10)</td>
<td>13/68 (19)</td>
<td>8/30 (27)</td>
</tr>
<tr>
<td>Treatment complete</td>
<td>38/80 (48)</td>
<td>44/68 (65)</td>
<td>13/30 (43)</td>
</tr>
<tr>
<td>Success*</td>
<td>46/80 (58)</td>
<td>44/68 (65)</td>
<td>21/30 (70)</td>
</tr>
<tr>
<td>Default</td>
<td>4/80 (05)</td>
<td>4/68 (06)</td>
<td>2/30 (07)</td>
</tr>
<tr>
<td>Lost to Follow-up</td>
<td>15/80 (19)</td>
<td>11/68 (16)</td>
<td>3/30 (10)</td>
</tr>
<tr>
<td>Dead</td>
<td>11/80 (14)</td>
<td>9/68 (13)</td>
<td>4/30 (13)</td>
</tr>
<tr>
<td>Transfer Out</td>
<td>2/80 (3)</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Unknown</td>
<td>2/80 (3)</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

* Success defined as total of cases with outcomes of cure or treatment completion
Primary Outcome

Results of the univariate analysis of the primary outcome are presented in table 4.3. The overall proportion of treatment successes was 46/80 (0.58) in the control group, 44/68 (0.65)
in the STAT-PALM+ alone group, and 21/30 (0.70) in the STAT-PALM+ with LHW intervention group. There was no evidence for effect of the intervention in the primary analysis adjusted for the effects of clustering $X^2 (2\text{df}) = 1.098$, $p= 0.578$. Pair-wise contrasts conducted using GEE showed no significant difference between the 3 groups with relative risks and approximate 95% confidence intervals derived from GEE for the 3 comparisons as follows; STAT-PALM+ intervention alone relative to control RR 1.02, 95% CI (0.90- 1.10), STAT-PALM+ with LHW intervention relative to control RR 1.04, 95% CI (0.96-1.11) and STAT-PALM+ intervention alone relative to STAT-PALM+ with LHW intervention RR 1.02, 95%CI(0. 95-1.08). Planned subgroup analysis of success among HIV status groups, also found no effect of the intervention, $X^2 (4\text{df}) = 0.970$, $p= 0.911$. Sensitivity analysis incorporating the 2 missing TB outcomes as successes or non-success had no effect on the findings.

Table 4.3 –Univariate Analysis of Primary outcome, treatment success, and subgroup analysis of treatment outcome by HIV status

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Control Number (proportion)</th>
<th>STAT-PALM+ Only Number (proportion)</th>
<th>STAT-PALM+ and LHW intervention Number (proportion)</th>
<th>Adjusted $X^2 (\text{df})$ **</th>
<th>P</th>
<th>ICC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proportion of Success cases</td>
<td>46/80 (.58)</td>
<td>44/68 (.65)</td>
<td>21/30 (.70)</td>
<td>1.098(2)</td>
<td>0.578</td>
<td>0.069</td>
</tr>
<tr>
<td>Success by HIV status:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HIV positive</td>
<td>19/46 (41)</td>
<td>16/44 (36)</td>
<td>9/21 (43)</td>
<td>0.970(4)*</td>
<td>0.911</td>
<td>-0.045*</td>
</tr>
<tr>
<td>HIV negative</td>
<td>18/46 (39)</td>
<td>20/44 (45)</td>
<td>7/21 (33)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HIV Unknown</td>
<td>9/46 (20)</td>
<td>8/44 (18)</td>
<td>5/21 (24)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*negative ICC assumed to be zero therefore assessed with unadjusted chi square
** adjusted for clustering
Results of the multivariate analysis of the primary outcome treatment success are presented in Table 4.4.

Table 4.4 – Final Model of primary outcome, treatment success

<table>
<thead>
<tr>
<th>Model Effects</th>
<th>Parameter Estimate</th>
<th>Wald 95% CI</th>
<th>Wald $X^2$</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intercept</td>
<td>0.363</td>
<td>-0.400- 1.126</td>
<td>0.867</td>
<td>0.352</td>
</tr>
<tr>
<td>Trial Arm</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>STAT-PALM+ and LHW intervention</td>
<td>-0.900</td>
<td>-1.920-0.120</td>
<td>2.992</td>
<td>0.084</td>
</tr>
<tr>
<td>STAT-PALM+ only</td>
<td>-0.468</td>
<td>-1.486-0.551</td>
<td>0.810</td>
<td>0.368</td>
</tr>
<tr>
<td>TB type</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-Pulmonary TB</td>
<td>-1.065</td>
<td>-1.815(-) -0.314</td>
<td>7.736</td>
<td>0.005</td>
</tr>
<tr>
<td>Trial Arm * TB type</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>STAT-PALM+ and LHW intervention* Non-Pulmonary</td>
<td>1.312</td>
<td>0.341-2.283</td>
<td>7.012</td>
<td>0.008</td>
</tr>
<tr>
<td>STAT-PALM+ Only* Non-Pulmonary</td>
<td>0.435</td>
<td>-0.850-1.719</td>
<td>0.440</td>
<td>0.507</td>
</tr>
<tr>
<td>Gender</td>
<td>Female</td>
<td>-1.006 (-)-0.267</td>
<td>11.380</td>
<td>0.001</td>
</tr>
</tbody>
</table>

Consistent with the univariate analysis, analysis with GEE controlling for gender, TB type and a TB type by intervention arm interaction term, showed no significant effect of the intervention on treatment success, Wald $X^2(2df)$= 0.548, p= 0.760. However, it has been shown that the Wald statistic may be of limited utility in studies with small sample sizes (73). Because of this, we examined the significance of the individual model effects and attempt to interpret them with caution. The effect of the interaction between trial arm and TB type approached but did not achieve significance, Wald $X^2(5df)$= 10.762, p=.056, with the interaction significant only in the control arm, RR of treatment success for pulmonary TB relative to non-pulmonary TB was 1.18, 95% CI (1.05-1.31), p= 0.006. Given the significant
model-effect found for the interaction between trial arm and TB type despite an overall non-significant result we further investigated the interaction through a post-hoc analysis using GEE stratified by trial arm. Results of the post-hoc analysis agreed with those of the full GEE with a significant effect of TB type again found in the control arm only, RR for success in the control arm for pulmonary TB relative to non-pulmonary TB, 1.18, 95% CI (1.06-1.32) Wald $X^2(1df)=8.559, p=0.003$. Again, sensitivity analysis incorporating the 2 missing TB outcomes as successes or non-success had no effect on the model or pair-wise contrasts.

**Secondary Outcomes**

As previously noted planned analysis of the secondary outcomes of interest were not undertaken due to the low event rate of default cases and inadequate recording of patient weights resulting in too few change scores to be analyzed.

**Discussion:**

Although treatment success rates were higher in both intervention arms than in the control and highest in the STAT-PALM+ with LHW intervention group the differences did not reach statistical significance. While this may represent a true finding, it may also be an artefact as our projected sample size was not attained due to the loss of 4 health centers and decreased TB case notification rate during the trial period, which we suspect may have been achieved through the successful rapid scale up of HIV treatment in the district. The resultant loss of statistical power may have reduced our ability to detect an effect of the intervention. It is also possible that the trial’s pragmatic design contributed to the lack of effectiveness where a more intensively supported program may have been more successful. However a heavily supported program would not be feasible in the resource constrained Malawi health care
system. Several additional occurrences during the course of the trial may have diluted the impact of the intervention and contributed to the findings. First, loss of trained LHWs resulted in at least some provision of TB care by untrained workers which may have diluted the potential effects of the intervention. Second, treatment for TB/HIV co-infected patients changed part way through the trial reducing the pill burden on this group of patients which is a known risk factor for non-adherence (74, 75). Third, it is also possible that LHWs did not find the intervention helpful and therefore did not change their approach to patient care. However, we feel this is unlikely based on the findings of our companion study, which found the intervention to be highly valued by LHWs. Fourth, another potential reason for the lack of effect is that intervention failed to adequately address LHW needs or failed to address other factors important to adherence, such as patient and system level factors, with the factors addressed insufficient to make a significant change in adherence. Finally as the STAT-PALM+ intervention was rolled out to the rest of the district late in the course of the present trial it is possible that the impact of the STAT-PALM+ intervention on control arms may have contributed to the findings.

In keeping with the findings of others we found significant model effects of gender, with females more likely to successfully complete treatment (76). In addition we found a trend for an effect of TB type, significant only in the control arm, with lower success rates among non-pulmonary TB cases. A potential explanation for this finding based on our perception that non-pulmonary TB was generally less well understood by patients, is that the enhanced patient education provided by intervention sites eliminated the effect by improving patient TB disease knowledge, known to improve adherence (21, 24). Based on theoretical grounds and the findings of others (75) we hypothesized a significant effect of HIV co-infection.
Interestingly no significant effect of HIV status alone or as an interaction term was found. A variety of factors may have contributed to this finding including the relative low HIV positive rate for this region in the study population and the change to a combined TB/ART medication which equalized the pill burdens among the groups. The hypothesized role of TB type in adherence and the present finding, suggest that further study is needed.

This study had several strengths. Randomization by health center rather than at the level of the individual provider minimized contamination. Inclusion of all district health centers increased generalizability of the results. Employing a pragmatic design revealed a number of challenges that suggest a need for increased supervision and support of trainers should this method of training be adopted.

There are several limitations to consider with our trial. Peer trainers may have been motivated in part by a desire to please the principle investigator who conducted their training and may have been regarded as a mentor. While this would not affect the outcomes of interest directly, peer trainers may have worked harder than might be otherwise expected. In addition, not all LHWs completed the training and several trained LHWs were lost during the course of the study, which may have diluted the effects of the LHW intervention. It is possible that interviews conducted in the concurrent qualitative study during the trial period could have provided supervision to participants. However, few participants were interviewed at each time point and the interviews would have been much less salient in the minds of participants than the training would have been, so it is unlikely that the interviews would have constituted supportive supervision. Finally, due to the nature of the ministry of health TB records, outcome assessors could not be blinded to health center. As a standardized
approach was utilized in determining final outcomes, we feel this is unlikely to have
impacted the classification of findings. In addition, the direct generalizability of the study
findings is limited by the tailoring of the intervention to the context and expressed needs of
local LHWs.

**Conclusion:**
In our study we did not identify a significant effect of a KT intervention on TB treatment
success however a trend for effectiveness was evident, particularly for the combination of the
two interventions together. Given the urgent need for low cost approaches to LHW training
to ensure quality of services and improve health outcomes further evaluation of tailored KT
strategies as a means of LHW training in Malawi and other LMICs is warranted.
Chapter 5 - Lay Health Workers experience of a tailored knowledge translation intervention to improve TB care

The purpose of this chapter is to:

1) To explore the experiences of LHWs who received the intervention to understand which aspects of the intervention they perceived as helpful in their work;

2) To identify areas of the intervention that may benefit from improvement and to gather ideas of how improvements might be made;
Abstract

Background: Like many Sub-Saharan African countries, Malawi is facing a critical shortage of skilled healthcare workers. In response to this crisis, a formal cadre of lay health workers (LHW) has been established and now carries out several basic health care services, including support for TB care. While ongoing training and supervision are recognized as essential to the effectiveness of LHW programs, information is lacking as to how these needs are best addressed. The objective of this qualitative study was to explore LHWs responses to a tailored knowledge translation intervention designed to address a previously identified training and knowledge gap.

Methods & Findings: Forty-five interviews were conducted with 36 healthcare workers. Six individuals were interviewed more than once and 14-16 interviews done during each of 3 evenly spaced time blocks over a one year period. Reported benefits of the intervention included: increased TB, HIV, and job specific knowledge; improved clinical skills; and increased confidence and satisfaction with their work. Suggestions for improvement were less consistent across participants, but included: increasing the duration of the training, changing to an off-site venue, providing stipends or refreshments as incentives, and adding HIV and drug dosing content.

Conclusion: Despite the significant departure of the study intervention from the typical approach to training employed in Malawi the intervention was well received and highly valued. Given the relative low-cost and flexibility of the methods employed this appears a promising approach to addressing the training needs of LHW programs, particularly in LMICs where resources are most constrained.
**Background:**

Low and Middle income countries (LMICs) and Sub-Saharan Africa (SSA) in particular, have been hardest hit by the global shortage of skilled healthcare workers with an estimated 1.5 million healthcare workers needed to meet the basic health care needs of the SSA population (3). One strategy increasingly employed to address this shortage is to shift some health promotion and prevention tasks, and the delivery of simple treatments, to Lay Health Workers (LHWs) (3, 61). While shown to improve access to basic health services and positively impact a variety of health outcomes (5, 6, 61) lack of ongoing training and supervision are recognized barriers to LHW effectiveness (6). Despite this awareness information is lacking as to how LHW training and supervision needs may best be addressed in order to maximize the quality and impacts of LHW contributions (5, 6).

Ongoing training is typically provided offsite with staff absent from the workplace for days to weeks, with significant associated actual and opportunity costs, and frequently with disruption of care delivery (61). Given the resource constraints facing LMIC healthcare systems and limited evidence for effectiveness of ongoing training delivered as outlined above (61), efforts to develop and rigorously evaluate alternative low-cost training approaches are needed. While relatively few studies have examined the use of knowledge translation (KT) strategies to improve health care outcomes in LMICs KT strategies may be ideally suited to addressing the ongoing training needs of LHW programs given their success and relative low cost.
Malawi has one of the most severe shortages of healthcare workers in SSA, with an average of 2.03 physicians and 36.8 nurses for every 100000 population in 2009 (19). In response to this crisis Malawi has significantly expanded its formal cadre of LHWs, termed health surveillance assistants (HSAs), and shifted a variety of basic health care services including delivery of outpatient TB care, for which they are primarily responsible, to this LHW cadre. Given the implications of the typical approach to training with over 10000 LHWs currently working in Malawi (19), alternative approaches are essential to ensuring that the training needs of this important group of healthcare workers are met.

Context

In our recent study LHWs in Zomba district in Malawi identified lack of TB disease specific knowledge and clinical skills as the key barrier to their work as TB adherence supporters (62), with many reporting a lack of both initial and ongoing training. Based on these findings we developed and evaluated a KT intervention to address the identified training gaps. The intervention combined 2 KT strategies with proven success in changing provider behavior: educational outreach and reminders (28).

The educational outreach component involved a minimum of six training sessions of 60-90 minutes each, held onsite during regular work hours over a 3 month period. Sessions were provided by participating health centers TB focus LHWs who received training in the intervention itself and as peer trainers. Sessions employed a combination of didactic and interactive techniques, and emphasized case based role playing and discussion of challenging cases to allow for efficient provision of TB specific knowledge, clinical and adherence counseling skills, and opportunities for practice and exchange of ideas between participants.
The training handbook and sessions were provided in English and employed the simplest language possible, with clarification from the peer trainer in the local language Chichewa as needed. The point of care tool was provided in Chichewa to facilitate interaction with patients of relatively low literacy common among women, the elderly and in remote areas. The point of care tool was designed to be referenced during patient interactions, with a guide to inquiring about and addressing adherence issues on one side, and pictorials to aid in patient education on the opposite side. Both the format and content of the training and point of care tool were initially based on the adherence and knowledge translation literature then tailored to be context appropriate in consultation with the National TB program and to address the training needs identified in the formative qualitative study (62).

The purpose of this qualitative study was to complement the quantitative evaluation (chapter 4) of the intervention by exploring the experiences of LHWs who received the intervention in order to understand what aspects of the intervention they found helpful and to identify areas in need of improvement.

**Methods:**

**Setting/Study Population:**
The study was conducted in Zomba district in southern Malawi (population 670,000, 80% rural) (45) and utilized qualitative methods. Interviews were conducted with LHWs who had completed the adherence training. Ten to fifteen interviews were planned at each of 3 time blocks over the course of the 1 year intervention trial, with 3 participants to be interviewed at all 3 times in order to assess for change across and within individuals over time.
Participants were selected utilizing mixed purposeful sampling (46). A list of trained LHWs compiled by the peer trainers provided the initial sampling frame. Participants were randomly selected from the list of trained LHWS, with at least one participant from each of 7 sites selected and a maximum of 3 from sites with a large number of trained LHWs. If a selected participant was not available and not expected to become available during the time block, an alternate was selected.

During the initial round of interviews participants were asked if they would be willing to be re-interviewed in both of the subsequent time blocks and all agreed. In selecting participants to be re-interviewed, the goal was to select a subsample representing the range of initial responses. As there was little variation in LHWs perceptions during the first interview round (few concerns or negative perceptions) we selected participants to represent the range of length and detail provided in the initial interviews, 1 short with little detail, 1 long and detailed, and 1 midrange in length and detail.

Participants were recruited in person by a research assistant (RA) during field visits at each time block or by telephone when the LHW(s) selected was not available on-site. All approached to participate agreed. Written informed consent was obtained from all participants.

The study was approved by both the Malawi National Health Sciences Research Committee and the University of Toronto Research Ethics Board.
Data Collection:

Interviews were conducted in 3 time blocks (months 3&4, 7&8, and 11 &12) over the one year trial period. Interviews were conducted by two RAs with all interviews in a given time block conducted by the same RA. Both RAs are experienced interviewers, native to Malawi, fluent in both English and Chichewa, and functioning at the level of a socio-linguistic interpreter (47). All interviews were conducted using the same semi-structured interview guide (appendix 7) with basic LHW characteristics collected at the start of each interaction. Interviews began with open-ended questions asking about participants’ experiences with the training and using the point of care tool and moved toward progressively closed-ended questions as needed, to ensure all topics of interest were addressed. Topics of interest included: aspects of the training and/or tool felt to be helpful and not helpful, any concerns with the training or tool, and suggestions for improvement.

Sessions were conducted in the local language, Chichewa, audio recorded, transcribed verbatim, and translated by the RA who conducted the interview. A translation check was performed on 9 of 45 interviews (20%), three in each round of interviews, by a second socio-linguistic translator to validate the quality and conceptual equivalence of the translations.

Analysis:

Our approach to analysis was that of qualitative content analysis (77), with interviews as the unit of analysis and aimed at exploring the experiences of LHWs with the intervention in order to understand those aspects of the intervention thought to be helpful and those in need of improvement. Interpretation of this qualitative data preceded the analysis of and is independent of the results of the cluster randomized trial. Transcripts were read
independently by 2 authors (LPR, MvL), looking for emergent themes and changes in participants’ perceptions overtime, both within individuals interviewed more than once and across the participant groups over the 3 time blocks. NVivo 7 (QSR International Inc, Southport, UK) was utilized to organize and code the data into themes and subthemes. Discrepancies were resolved by discussion and with input from the study RAs where provision of additional context and cultural perspective was needed to ensure clarity of interpretation of meaning.

Results:

Characteristics of Participants:

Thirty-six healthcare workers participated in 45 interviews, with 14-16 interviews conducted at each time point and 3 participants interviewed at all 3 time points, as planned. To ensure participation from all intervention sites at each time point, 2 participants were interviewed twice as a result of a lack of LHWs available for interview during the final round. One additional participant was interviewed twice in error. All but 1 participant, a nurse, were general LHWs. All routinely provided care to TB patients. Although all were reported by the trainers to have finished the training, 3 acknowledged they had completed most but not all of the training at the time of their interview. Participants ranged from 26 to 57 years of age, with 2 to 20 years experience working with TB patients. Fifty-six percent of participants were male.

Experience with the Lay Health Worker Intervention as a whole:

Without exception, participants described the intervention as valuable. They reported improved confidence and ability to perform their role as adherence supporters as a result of
the knowledge and skills acquired, and use of the point of care tool. While both components were highly valued, the point of care tool was noted to be particularly important functioning both as a reference during patient interactions and as a general reminder/training refresher.

“I have been working in TB services for four years but was just briefed on it and didn’t really know our role in TB care, but now the tool guides and reminds us in our work.” (LHW, 5 years TB experience)

Details of the reported benefits, and suggestions for improvement, are outlined below. Perceptions of neither the intervention as a whole nor its specific components were found to vary across the 3 time periods, either within or across individuals. No harms or detrimental effects of the intervention were reported.

**Reported Benefits of the Intervention:**

*Increased knowledge:*

While the degree of improvement varied by participant, all reported having increased TB disease specific knowledge as a result of the training.

“The education was like in service training, that has strengthened my weak areas and reminded me some forgotten areas” (LHW, 10 years TB experience)

“The training has been quite helpful to me since I have acquired a lot of new knowledge and it has also advanced my ability such that I am now able to offer services that I couldn’t before” (LHW, 6 years TB experience)
Among the most commonly reported areas of improvement were understanding of the TB disease process and the interaction of TB and HIV.

“The training went on well and I found it helpful to me in that I gained new knowledge, like about the signs and symptoms of TB infection” (LHW, 4 years TB experience)

“I had little knowledge about TB, but through this education I am now more knowledgeable, particularly about the interaction between TB and the AIDS epidemic” (LHW, 3 years TB experience)

Other frequently reported benefits of training included: understanding the importance of treatment adherence and consequences of non-adherence, and increased ability to recognize and appropriately manage treatment side-effects.

“Previously I could just issue the relevant drugs to clients and advise them to continue with medication since I had no knowledge to teach the client about the effects of adhering and not-adhering to treatment” (LHW, 11 years TB experience)

“The training was good especially issues to do with medication, since sometimes I used to meet clients who presented some complications and usually I could just regard such difficulties as normal. But through the training, I have learnt a big lesson, since I am now able to assess cases that require a clinicians attention and those that do not and advise the client accordingly” (LHW, 2 years TB experience)
In addition to increased disease specific knowledge, participants reported gaining job specific knowledge as a result of case based discussions with their fellow LHWs. Reported job specific knowledge gains included: increased awareness of the need for confidentiality and improved understanding of job specific tasks, including treatment documentation and medication dispensing.

“I also learnt to keep everything I discuss with a patient confidential and be in doors to assure him of this” (LHW, 6 years TB experience)

“For example, it was difficult for me to issue drugs to patients correctly unless in the presence of a colleague, but I can now do it alone effectively after the training. I am able to calculate time periods at which a patient should come to collect drugs; this was confusing to me before the training” (LHW, 5 years TB experience)

“One of the useful aspects is about documenting drugs in the registers. This has been a big problem here since we work in shifts at the work station, so information could be given and recorded wrongly. So this training has somehow helped us to follow one universal documentation of TB drugs dispensed” (LHW, 10 years TB experience)

*Improved Clinical Skills/Benefits:*

Foremost among the reported clinical skills gained through the training was an awareness of the importance of developing skills to foster a positive patient-provider relationship.
“I learnt how to openly interact with the patient. I didn’t learn this initially, hence hard for me to interact well with the patient, so he would leave for home unsatisfied. Now after being taught I have seen that patients are now free to speak their mind, telling us about issues affecting them” (LHW, 3 years TB experience)

Other prominently reported clinical skills were an improved ability to provide patient education and an enhanced approach to patient follow-up, both in clinic and during tracing visits to the community.

“It is easier to interact with patients with the tool than without it, there is a smooth flow of information when using the tool and the patient can easily understand the treatment process” (LHW, 11 years TB experience)

“It is helpful especially to us working in remote health centers where many people have low literacy level, so drawings on the chart aid some clients to grasp the information easily” (LHW, 2 years TB experience)

“Because we are now asking them questions we are able to detect that this person is not taking medication properly and that is able to give us a way to help the patient” (LHW, 3 years TB experience)

“The training made us look like experts, because we do defaulter tracing for people with TB and HIV/AIDS, and it gave us skills that when we go in the villages to look for those people we are able to reach out to them without problems because with the tool we were given we
are able to talk to the person, we use it as a guide and because we now know those things by heart we are able to help the person” (LHW, 3 years TB experience)

A final reported clinical benefit of the intervention was an increased confidence in their abilities and personal satisfaction or a sense of pride in their work, as a result of appreciation expressed by patients and LHWs perceptions of improvements in their job performance.

“The other thing that was helpful is the provision of the point of care tool. We are now able to know that this patient is here (stage in the treatment process) and that has empowered us, because when I am talking to the patient I am confident knowing that what I am telling them is not just what I have made up but it is something that is written to help sick people and that I think is a good thing.” (LHW, 3 years experience)

“(Since the training) I can see that there is some improvement in the way I discharge my duties as compared to previous times” (LHW, 4 years TB experience)

“The training and tool helped me a lot since I have experienced a big change in me and now the patients do appreciate the services they are receiving from our clinic”(LHW, 4 years TB experience)

**Suggestions for Improvements:**
Several participants felt the training period should be extended, with one suggesting it be extended from 6 weekly sessions to run several months. A number suggested that the training would be better conducted in the usual manner, with LHWs taken off-site for several
days to a week for training and provided with stipends and/or refreshments as incentives for training.

“My concern is that the training period was short as we were having one session per week in order to give room to routine activities. It would be better if you organized a special venue and teach us there for one whole week.” (LHW, 18 years TB experience)

“The training was being conducted at the very (health) center where we discharge our routine duties hence subject to some disturbances. Our trainer was sometimes being interrupted, this was disturbing as the sessions were not running smoothly, hence it was sometimes difficult to follow.” (LHW, 3 years TB experience)

“Include training allowances to motivate participants since many HSAs (LHWs), admire their colleagues who receive a little something whenever they attend some training.” (LHW, 3 years TB experience)

Others reported, the on-site training to work well, and indicated that while stipends would be appreciated, they would prefer to have training without stipends than to not have the training.

“To me the training was conducted very well because our meeting hour was convenient most of the times in that there were no disturbances and even our trainer showed keen interest in teaching us.” (LHW, 4 years TB experience)
“The provision of stipends should not cause a worry to you. All I can request is that such trainings should be taking place regularly because it is often times helpful to us.” (LHW, 6 years TB experience)

Many participants suggested that quarterly refresher meetings would be helpful, with all sites reporting holding such meetings at least once per quarter. Some felt that refreshers should be conducted off-site with LHWs from multiple sites brought together.

“I think it would also be helpful in our work if you organize regular joint meetings with fellow HSAs (LHWs) from other centers, so that together we can identify weak areas and also motivate one another.” (LHW, 5 years TB experience)

Others felt, that refreshers should be conducted on-site in the same way the original training had been conducted.

“Like it was done, I think if the same arrangement happens quarterly so as to refresh us after discharging our duties for a period of time. If it so happens that we encounter some obstacles in the process, we will bring that up during such meetings and gain new knowledge” (LHW, 16 years experience)

A number of participants reported appreciation for the RAs visits to conduct interviews at the health centers, and suggested regular “support “visits.
“Just to request you to keep visiting since your keen interest in the program makes us feel encouraged and motivated to work hard” (LHW, 12 years TB experience)

While a number of minor additions were suggested for both the training and tool only 2 were noted by several participants, increased coverage of HIV management and inclusion of a drug dosage reference.

“It would be better if you combined both TB and HIV since there are many ailments associated with HIV, so we need to be guided on ways of taking care of co-infected patients” (LHW, 6 years TB experience)

“Add on the chart the aspect of dosage correspondent to age of a patient and the stage of treatment” (LHW, 5 years TB experience)

Others specifically suggested that the tool not be changed for fear that it would become complicated and as a result less useful.

“I can say that the tool is fine because if we add more it will just spoil it” (LHW, 3 years TB experience)

**Discussion:**

To our knowledge few studies have employed and examined LHWs experiences with multi-component knowledge translation strategies tailored to address identified knowledge gaps. Many of the findings of the present study are in keeping with the few other studies conducted
with similar techniques and in similar settings. For instance, although designed for mid-level health workers, an early evaluation of the STAT-PALM+ intervention also conducted in Zomba district Malawi and employing educational outreach and a clinical support tool, reported that participants felt empowered to provide better services as a result of the training and clinical support tool (78). These findings are consistent with the reports of LHWs in the present study of increased knowledge and clinic skills allowing them to provide better care. In addition, some participants in the STAT-PALM+ study viewed the on-site approach favorably indicating that it saved travel time and costs, but many viewed lack of stipends as de-motivating (78). This again, is consistent with our findings of generally mixed views on the conduct of the intervention on-site and without stipends.

In addition, two studies with LHWs in LMICs found similar knowledge and skills gains, and improved clinical abilities reported by their LHW participants. Although not strictly educational outreach, Joseph et al. (2012) report the experience of LHWs in Lesotho trained onsite through both didactic and hands-on training throughout the work day. The LHWs expressed gratitude for the knowledge and skills gained and for the impact they were able to have on patients (79). Finally, a study by Alcock et al. (2009) with LHWs in India who had received training offsite with similar clinical skill development content to the present study and picture cards to assist with patient education, found positive changes in terms of increased knowledge, confidence, and clinical skills, and found the pictures to be helpful in illustrating teaching points to patients (80).

Consistent with the generally positive views of LHWs to training and support tools to date, and that participants in the present study overwhelmingly perceived the intervention as
helpful to them in their work, this appears to be a viable option for addressing LHW training needs and for providing one means of ongoing clinical support. While some resistance was expected regarding the lack of incentives common to typical training approaches, specifically stipends and removal from work to attend training, these issues were raised by a minority of participants. As such it may represent a less significant barrier to employing educational outreach methods than anticipated. Given the urgent need for cost-effective methods to address the training needs of LHWs, particularly in resource constrained settings, the KT approaches employed here may be particularly well suited considering their relative low-cost and flexibility.

There are several limitations to this study. While the RAs conducting the interviews played no role in delivery of the intervention and specifically encouraged critical input, participants feeling supported by these visits may have been reluctant to provide negative feedback. Also, although TB policy is national, it is possible that not all findings will be generalizable to other districts of Malawi as the study was conducted in Zomba District only. In addition, as the intervention was tailored to the local setting direct adoption of the program by other TB programs, particularly outside Malawi, may not be appropriate. We do believe however, that the general approach employed with tailoring to local barriers and needs is likely to have similar results. Finally, language translation introduces the possibility of mistranslation of words or concepts and may limit the understanding of the cultural context. However, based on the translation check of 20% of interviews, we believe that the themes reported are accurately represented.
**Conclusion:**

Our findings suggest that a multi-component KT strategy based principally on the tenets of experiential and transformative learning employing educational outreach and reminders, was well received and perceived as valuable by LHWs. In addition, lack of stipends and conduct of training on-site proved a much less important issue than expected, and as such, may not represent a significant obstacle to use of this approach. Given these findings and the relative low-cost of the KT interventions utilized, if proven effective, the strategy employed here may well be a feasible option to addressing LHW training needs in Malawi and perhaps more widely in LHW programs in other LMICs.
Chapter 6 – Discussion and Conclusions

The purpose of this chapter is to:

1) Summarize the three studies comprising the thesis;

2) Discuss the strengths and limitations of the thesis;

3) Outline implications and recommendations of this work for program developers and policy makers;

4) Discuss the context and contribution of this thesis to the literature in this area

5) Suggest directions for future research;
Thesis Summary

In a series of chapters and studies we have presented the development, implementation, and evaluation of a tailored multifaceted knowledge translation intervention. The goal of this work was to improve TB treatment adherence and through this, clinical outcomes, by improving the clinical care provided to TB patients by LHWs in Zomba district Malawi.

This thesis employed a mixed methods design with both sequential and concurrent components as outlined in chapter 1, figure 1.2, to answer the overarching thesis question: Is a tailored knowledge translation intervention effective in improving TB treatment outcomes and how do the results of the qualitative studies inform the design of the intervention, contribute to an understanding of the effectiveness of the intervention, and provide insight into aspects of the intervention in need of improvement. As each study was designed to address a unique research question, the studies were analyzed and reported separately (no mixing of results) but together contribute to a comprehensive understanding of how the present intervention might be improved before wider implementation in Malawi and outline an approach to guide the development, implementation and evaluation of similar interventions in future.

The sequential component involved a preliminary qualitative study designed to inform the development and tailoring of the intervention. In this first study (chapter 2) we explored the barriers and facilitators facing LHWs in their role as TB treatment adherence supporters. Lack of TB disease knowledge and job specific skills were identified by LHWs as the key barriers to their work as TB adherence supporters and were reported to result in lack of confidence, conflicting messages to patients, poor patient-provider interactions and errors in
documentation. These results supported the findings of the literature review which identified lack of patient TB knowledge and negative patient-provider interactions, as modifiable risk factors for non-adherence, with high levels of provider knowledge and clinical skills hypothesized to be necessary to ensuring adequate patient education and to fostering positive patient-provider relationships. In addition, a number of additional training needs specific to LHWs providing TB care in Zomba were identified. These included; knowledge of the interaction of TB and HIV in terms of disease process and implications for treatment, and understanding of the importance of and approaches to managing issues with adherence, as well as a number of job specific skills, including interviewing and communication skills, recognition and management of serious side-effects. These findings, augmented those of the literature review and results of our stakeholder consultations and field observations (outlined in chapter 3), and allowed for tailoring of the intervention to address the identified barriers.

The concurrent component of the mixed methods design, involved the quantitative evaluation of the interventions effectiveness (study 2, chapter 4) and qualitative evaluation of LHWs perceptions of the intervention (study 3, chapter 5).

In the second study (chapter 4) we evaluated the effectiveness of the knowledge translation intervention tailored to identified barriers in improving TB treatment completion rates in a cluster randomized controlled trial embedded within a larger cluster trial evaluating an intervention aimed at improving clinical care provided by mid-level health workers in the same district. Although a trend for effectiveness of the interventions was noted, the trial was underpowered and the results therefore inconclusive, due to the loss of several clusters and a significant reduction in TB case notifications leading to the study accruing only about half of
the required sample size to detect the predicted effect. The trend is interesting, however, with the proportion of successfully treated cases higher with the mid-level health worker intervention alone and higher still with the addition of the LHW intervention, suggesting a potential synergy between the interventions worthy of further exploration. In addition, the finding of an interaction between intervention arm and TB type in the control arm only suggests there may have been an effect of the intervention on disease understanding among patients with non-pulmonary TB in the two intervention arms. This finding is worth further exploration given the relatively high proportion of non-pulmonary TB cases in this setting.

In the final study (chapter 5), we explored the perceptions of LHWs who received the training to understand how the intervention was received by participating LHWs, what aspects of the program they felt were helpful to them in their work and to identify areas of the intervention in need of improvement before implementation on a wider basis. Findings indicated that the intervention was well received and highly valued with reported gains in knowledge and clinical skills leading to increased confidence and satisfaction in their work. With the exception of increasing the duration of training, suggestions for improvement varied considerably with conflicting views reported on whether training should occur at work or at an off-site venue and whether additions to the point of care tool would be helpful or risk making it overly complicated and as a result less useful. Additionally, while lack of training stipends was an anticipated challenge to the LHW intervention this was raised as an issue by a minority of participants only and therefore may not represent a significant obstacle to use of this approach.
Together the 3 studies contributed to the tailoring of the intervention to address identified barriers, rigorously evaluated the effectiveness of the intervention, and provided an understanding of the aspects perceived by LHWs to be effective and those in need of improvement. Although further research is needed, together these 3 studies demonstrate a potential role for tailored knowledge translation strategies, and educational outreach and reminder strategies in particular, to address the training needs of LHWs in Malawi and perhaps more widely in other resource constrained settings with careful contextualization and tailoring to locally identified barriers.

**Thesis Strengths**

This project benefited from the early and extensive engagement of key stakeholders from all levels of the Malawi ministry of health. Collaboration from stakeholders throughout the process ensured that the research questions and program were locally relevant and context appropriate by providing an important additional source of inputs into both the design and implementation process. This degree of engagement and collaboration facilitated buy in and a sense of ownership on the part of stakeholders and may, as a result, contribute to uptake of the research findings. The pragmatic approach employed and inclusion of all health centers providing TB care in the district gave a more realistic view of challenges to implementing the program on a system wide basis than would an efficacy study design and provides feasibility information important to program planning.

**Thesis Limitations**

The main limitation of the thesis was the loss of 4 health centers who did not accrue eligible patients during the study period and drop in TB case notification rate. This resulted in a total
sample of size of approximately half of what was expected and may have reduced our ability to detect an effect of the intervention.

A potential limitation of this thesis was the use of standard TB outcomes. While this allows for consistency with the TB literature and comparison between studies and within Malawi over time, the definition of default as missing 2 or more consecutive months of treatment, fails to recognize and evaluate the impact of the intervention on potentially important gaps in treatment, which while less than 2 consecutive months may require adjustment or extension of treatment. Additionally the relatively low number of proven default cases and poor recording of patients’ weights precluded planned analysis that may have contributed to our understanding of the impact of the intervention.

A second potential limitation was the use of a concurrent design. Collection of qualitative data from LHWs at intervention sites during the intervention trial risks introducing bias into the evaluation of the interventions effectiveness by changing provider behavior as a result of the interaction. There are two main options to addressing this risk of bias: to collect data unobtrusively without interaction with participants or to collect qualitative data at all sites. Given the nature of the qualitative information sought, understanding experiences of LHWs with the intervention, neither option was felt a viable solution. It is therefore important to acknowledge this as a limitation given the positive relationship between the intervention team and lay health worker participants which would tend to bias the findings in favor of the intervention.
A final potential limitation of this thesis is the competing goals of my roles as intervention developer, implementer, and evaluator. The developer and implementer are both focused on building and delivering the best program possible and are more invested in seeing the intervention work than in ensuring it is rigorously evaluated. The evaluator is focused on providing the best possible evaluation of the intervention. As the intervention was evaluated in a cluster randomized controlled trial with the outcome measures strictly defined apriori and objectively evaluated measurement of effectiveness is unlikely to be biased. Several measures were taken to reduce the risk of bias in the analysis and interpretation of the qualitative evaluation of LHWs perceptions of the intervention and included: maintenance of an awareness of the risk of bias, active efforts by interviewers who were not part of development of the intervention to probe for and encourage negative input from participants, and engagement of an impartial second data analyzer. Nevertheless, we cannot fully exclude the possibility that LHW perceptions were not overstated, and we will take care to mention in our reports to the ministry of health, the need for further evaluation if implemented more widely.

**Implications**

A number of implications for development, tailoring, and implementation of knowledge translation interventions for LHWs arise from this study.

The first is the valuable insight gained by incorporating multiple means to identify barriers to be targeted in the intervention including: stakeholder consultations, field observation, and the formative qualitative study. As evidence is currently lacking on how tailoring may best be achieved, this thesis adds to the literature on the topic. Based on this experience where
different inputs added new information or nuanced our understanding of the barriers to be targeted, we would argue for the value of including multiple sources of inputs and the formative qualitative component in particular.

Second, during the training of peer trainers and implementation it became clear that LHWs with limited baseline education struggled with the material. We would therefore recommend that individuals selected to be peer trainers have at least 8 years of schooling and if not possible that the trainer training be extended and additional support be provided to peer trainers. We believe the former to be more important, particularly in Malawi where there is a general willingness to accept training from younger peers or individuals relatively lower in the system hierarchy but with recognized special training or experience. However, as this may not be the cultural norm in other settings, selection of peer trainers may need to be based on hierarchy or other cultural factors such as age, and the amount of supervision and support provided to trainers adjusted accordingly.

Finally, while the focus of this thesis was on the development and evaluation of the LHW intervention both informal and formal feedback from peer trainers and LHW participants suggest that with minor adjustment supportive supervision might be incorporated into the intervention. Encounters with the study team during field visits to conduct qualitative interviews during the course of the trial were appreciated by participants who felt valued and supported by the visits and felt visits represented an opportunity for them to ask questions (although rarely done) relevant to the intervention itself or regarding ideas for handling difficult cases. In addition many participants spoke of their trainers very positively and appeared to view them as clinical mentors. This may suggest an opportunity to provide
supportive supervision through intermittent refresher training sessions and regularly through the peer trainers at the health center level by incorporating supervisory skill training and tasks into training of peer and higher level trainers (individuals who train the peer trainers). Again, as this was not directly evaluated in this work it would be important to evaluate the effectiveness of this type of supervision before adopting it on a wide scale.

In addition to the implications for improving or expanding the intervention outlined above, a number of policy implications are suggested by this work.

Current Malawi policy emphasizes broad based LHW pre-service training. While this is consistent with some recommendations (42), it may insufficient for LHWs working in specialized areas given that the training period is relatively short. This was certainly the expressed view of many LHWs we encountered during this work, many of whom had little TB specific knowledge and job specific training for the routine tasks of their role as providers of outpatient TB care. While the intent to have the TB focus LHWs overseeing TB care at the health center provide the training is practical, it appears to require some support in the form of a curriculum of expected teaching and follow-up with accountability to ensure the training occurs. Adoption of an onsite training approach which provides a curriculum and teaching tools, such as the program evaluated here with the addition of support and monitoring, may represent a feasible means of ensuring essential job specific training is provided to LHWs beyond the initial broad based pre-service training.

The typical training approach in Malawi involves; removal of trainees from work, provision of stipends, and often travel and accommodation costs associated with gathering of trainees
off-site for training. As a result provision of clinical services is often impacted or disrupted due to staff absences to attend training. Given the high costs associated with this training culture, which limits that amount and frequency of training that can be provided, a policy shift is needed. Based on our findings the issue of on verses off-site training appears easily overcome and the fact that stipends were raised by a minority of participants is promising. Together these suggest potential for a shift in policy away from the typical approach to more low cost methods such as those evaluated in this thesis. However, given how embedded the current training model is at present, provision of alternative rewards such as training certificates and refreshments during training, may be a prudent initial approach to smoothing the transition to alternative training methods.

**Context and Contribution of Thesis to the Literature**

Despite the important and increasing role of LHWs in delivering a wide variety of basic health services globally and evidence of effectiveness of LHWs in improving access to health care and some health outcomes, gaps remain in our understanding of how the contributions of this valuable human resource may be optimized. A key recognized barrier to maximizing LHW impacts is lack of training and supportive supervision. However, research demonstrating effective solutions to addressing LHW training and supervision needs, particularly for large LHW programs, is lacking to date (5, 42).

In reviewing the LHW training literature we identified relatively few studies that provided sufficient detail of the intervention to allow for comparison with our approach. The first is a study by Daniels et al. (2005) that trained LHWs to support TB care in South Africa (81). The training involved 5 modules, each one week long covering TB, HIV and family health,
first aid, and home based care, and employed an experiential learning approach. Training and ongoing supervision were provided by registered nurses who were assigned groups of LHWs. It is unclear where and when the sessions were conducted. Similar to our findings participants reported increased knowledge and enjoying the opportunity. LHW perceptions of the supervision were not reported. In addition, the intervention was evaluated in a cluster randomized trial and found to improve TB treatment completion rates (35).

Two studies evaluated perceptions of LHW interventions using visual aids to assist with patient care. Omer et al. (2008) evaluated a LHW intervention using an embroidered cloth as a counselling tool to improve safe motherhood practices in Pakistan (82) with outcomes evaluated in a trial randomized at the level of the community. LHWs in the intervention groups were reported to receive training in the use of the tool and usual supervision but no details of either were provided. Results of the trial indicated improvement in targeted outcomes including increased LHW visits and improved prenatal and newborn care. In keeping with our findings participants liked the tool and felt it helped patients relate and improved their interactions with patients. Perceptions of the training were not reported.

A second study evaluated LHWs perceptions of a brief training intervention accompanied by picture cards to aid in patient care in urban slums of Mumbai India (80). Training included a 12 day induction provided through a variety of talks and discussions about pre/peri/post-natal beliefs and practices, followed by weekly planning and review meetings. Again, it is unclear where the training and weekly meetings took place. Similar to the previous study and our findings LHWs found the picture cards helpful in illustrating concepts to patients and
reported increased knowledge and communications skills as a result of the intervention. Patient health outcomes were not reported.

A final article reports the evolution and qualitative evaluation of a LHW training program to assist with HIV care in rural Lesotho (79). Similar to our intervention all training occurred in the work place and although not specifically stated, training appears to have occurred during regular work hours. Early in the programs evolution training and support were provided by the sites medical doctor beginning with a preliminary training week, followed by regular pre-clinic sessions where knowledge and tasks were reviewed or discussed. This evolved into a 4 week formal training program with standardized curriculum and teaching tools provided by LHW peers with sufficient experience to function as trainers. Again LHWs were found to be thankful for the new skills acquired and felt good about the impact they were having on others and where evaluated appeared to have a positive effect on access to care, health practices, and outcomes.

Together the studies noted above are consistent in their findings that training targeting job specific knowledge and skills is well appreciated and that provision of visual tools to assist in their work is valued by LHWs. Interestingly, although most studies mentioned supervision, none evaluated the potential role of trainers as supervisors.

This thesis further contributes to the knowledge in this area by providing the results of a rigorously designed and evaluated intervention employing components found of benefit in the above noted studies and with proven success in the knowledge translation literature, as well as lessons learned through the development, implementation, and evaluation process.
Several aspects of our development approach contribute to the literature in this area. First, we found the knowledge to action framework (36) helpful in guiding our thinking through all stages of the project and would recommend it as a useful tool to guide KT projects of this type. Second, field observations of LHWs at work conducted as part of our preliminary work identified and clarified content themes important to the development of the intervention. We found little mention of this as a component of the development process in the literature, but based on our experience would suggest this be added to the preliminary development work where possible. Third, although suggested as a potential step in the development and evaluation of complex interventions (83) this is one of few studies to incorporate a formative qualitative study as a component of a formal tailoring process. In our setting the formative study was relatively easily undertaken and allowed for a greater degree of tailoring of the intervention than would have been possible otherwise. Given that tailoring has been shown to improve effectiveness of KT interventions, this method provides an easily reproduced means of incorporating tailoring into LHW program development.

In addition, a number of components of the mixed methods study design, approach to analysis, and findings contribute to the literature in this area. First, we found the pragmatic approach employed particularly well suited to the goals of this work, which was to support real world policy decision making. Although challenging, this approach provided a realistic view of the issues facing routine use of the KT approaches employed, important to both wider implementation of the present intervention, as well as to the design and implementation of future interventions of this type. Second, consistent with the findings of others LHW participants in our study found the intervention to be helpful to them in their
work by improving their knowledge and clinical skills, and through this improving their confidence and feelings of satisfaction in their work. In addition, inclusion of a concurrent qualitative study provided information valuable to improving the intervention and provided some reassurance for wider implementation of the intervention by suggesting that the deviation of the intervention from the typical approach to LHW training in this setting (training off-site with provision of stipends) does not present a significant obstacle to use of this approach. Third, while translation is widely used in qualitatively research to our knowledge relatively few studies report use of formal translation checks to ensure accuracy of translation, although it is possible that accuracy of translation is evaluated and not reported. Given the potential impact on the interpretation and thus findings of inaccuracy of translation in terms of wording and cultural meaning, this is an important step and we argue should not only be conducted but incorporated into routine reporting of qualitative studies. Finally, although underpowered and therefore inconclusive, the trend for improved clinical outcomes in the intervention groups found in our trial suggests potential for effectiveness of the LHW intervention particularly when added to the STAT-PALM+ mid-level worker intervention now implemented throughout the district. As this thesis seized the opportunity of embedding itself within an ongoing cluster randomized trial there was no opportunity to increase the number of clusters or extend the trial to address the lack of statistical power due to loss of health centers and reduced TB case notification rates. However, the findings will acquire more value when incorporated into the next systematic review of LHW interventions, the authors of which have expressed interest in including the present study in the next update. In addition to the contribution of the specific study findings, this thesis adds to the evidence for the feasibility and utility of including randomized controlled trials as a component of the
evaluation of health system interventions in LMICs, argued to have been met with mixed success in health system research to date (84).

**Directions for Future**

First and foremost the findings of this thesis suggest that although the KT intervention employed was well structured and acceptable to LHW participants the effect was small and the confidence interval included the null hypothesis, suggesting that the intervention requires further development and evaluation before widespread implementation. Given that the STAT-PALM+ mid-level health worker intervention has now rolled out through the district and suggested synergy between the interventions with the highest treatment adherence rates occurring at sites that received both interventions, wider evaluation of the LHW intervention is warranted. Ideally this would be accompanied by improved treatment records to allow for assessment of weight as a clinical surrogate marker of effectiveness. While a randomized trial is the ideal design given the urgent need for LHW training in this area and low if any risk of the intervention, a pre-post design may be most appropriate next step in this district. Alternatively if there is sufficient stakeholder interest and costs are manageable, a larger cluster trial including additional districts might be undertaken and allow for assessment of the LHW intervention as an add-on to other adherence improvement measures employed elsewhere in the country. As noted above, investigation of the potential role of trainers as supportive supervisors merits consideration in future work, given the need for supervision and apparent mentorship role of trainers in our study.

An additional area for future work is suggested by the data difficulties encountered with the TB treatment cards as the primary data source for the cluster trial. Efforts to simplify the card
itself or to provide a reference to assist in calculating treatment timelines and recording, should be developed and evaluated. Improved data would benefit not only studies utilizing these outcome measures but also improve the accuracy of routinely collected TB data which would be useful for policy and program planning.

**Conclusions**

The focus of this thesis was on the development, implementation and evaluation of a tailored knowledge translation intervention employing educational outreach and reminders to improve the care provided by LHWs and through this to increase TB treatment adherence and improve clinical outcomes. To our knowledge this thesis is one of the few efforts to develop and evaluate knowledge translation strategies to train LHWS as TB adherence supporters in a low income country setting. Although inconclusive, the findings of this thesis leave open the possibility that this intervention could achieve an impact on TB treatment adherence perhaps through modification of the intervention, such as increased length of training or the addition of supportive supervision. Given the urgent need for alternative strategies to LHW training, further research to develop and modify the intervention evaluated here, as well as to adapt and evaluate these approaches to address other important topic areas is warranted.
## Appendix 1: Overview of Malawi general LHW training curriculum*

<table>
<thead>
<tr>
<th>Module</th>
<th>Topics Included</th>
</tr>
</thead>
<tbody>
<tr>
<td>1- HSA job description</td>
<td>Overview of LHWs roles and responsibilities</td>
</tr>
<tr>
<td>2- Introduction to EHP</td>
<td>Overview of the Malawi Essential Health Package</td>
</tr>
<tr>
<td>3- Reproductive Health</td>
<td>Family planning, safe motherhood, antenatal care, care during delivery, postnatal care, and elimination of harmful reproductive health practices/reduction of domestic violence and infertility</td>
</tr>
<tr>
<td>4- Nutrition</td>
<td>Nutrition essentials and food sources, education and assessment of nutritional status, nutrition education and counselling, when to refer, follow up of malnourished children discharged from hospital</td>
</tr>
<tr>
<td>5- Growth Monitoring</td>
<td>Assessing growth and monitoring growth</td>
</tr>
<tr>
<td>6- Immunization</td>
<td>Introduction to Malawi extended program of immunization, overview of EPI diseases, vaccination administration, storage and handling of vaccines</td>
</tr>
<tr>
<td>7- Common Diseases</td>
<td>Malaria, Acute respiratory tract infections, diarrhoeal diseases, preparation or oral rehydration solution and home management of diarrhoea and dehydration, sexually transmitted infections, HIV/AIDS, TB, Bilharzia, Worm infection</td>
</tr>
<tr>
<td>8- Village water supply</td>
<td>Protection of water supplies, chlorination, water quality improvement</td>
</tr>
<tr>
<td>9- Vector Control</td>
<td>Common vectors, methods of vector control</td>
</tr>
<tr>
<td>10- Village sanitation</td>
<td>Basic sanitary requirements and sanitation improvement activities</td>
</tr>
<tr>
<td>11- Food Hygiene</td>
<td>Food hygiene practices, food and premises inspection</td>
</tr>
<tr>
<td>12- Village Inspection</td>
<td>Planning and conducting village inspections</td>
</tr>
<tr>
<td>13- Community assessment</td>
<td>Health and vital statistics, planning and reporting community assessments</td>
</tr>
<tr>
<td>14- Village Health Committees</td>
<td>Formation, training, and utilization of village health committees</td>
</tr>
<tr>
<td>15- Social Mobilization and Health Education</td>
<td>Introduction to health education, interpersonal communication and counselling, advocacy, effective use of teaching materials</td>
</tr>
<tr>
<td>16- Planning Health Activities</td>
<td>Monthly work plans, record keeping and reporting activities</td>
</tr>
<tr>
<td>17- Use and Maintenance of a Bicycle</td>
<td>Use, parts, maintenance and repair</td>
</tr>
<tr>
<td>18- Formation of Village support group</td>
<td>Village support groups, types of support groups in the community and their functions</td>
</tr>
<tr>
<td>19- Patient follow up</td>
<td>Preparation for and conduct of follow-up of patients in the community</td>
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</tbody>
</table>

*The above noted table has been constructed based on the 10 week Malawi LHW (HSA) curriculum outlined in: Malawi Ministry of Health, Health Surveillance assistants Training Curriculum: “n.d.” (reference 20 in thesis reference list)
Appendix 2: Question guide for study 1 (chapter2): Evaluation of Lay Health Workers’ Needs to Effectively Support TB

Question Guide:

1. **Do you have any questions?**
   
   If yes, answer questions.
   
   If no, may we proceed with the interview/focus group now then?

2. **First I would like to ask you a few questions about yourself.**

   Gender  M/F
   
   Age  ___
   
   Current Job  HCW/TB focus HSA
   
   Location  ZCH/Rural HC
   
   Years in current position ___
   
   Previous experience as HCW or TB focus HSA  Y/N
   
   If Yes, location of previous experience  ZCH/Rural HC/both
   
   total years of experience ___

3. **Please tell me about your experiences in working with TB and TB/HIV patients?**

4. **In your experience, are there any patient characteristics that make it more or less likely that a patient will take their medications properly?**
5. Have you noticed any differences between patients on TB treatment only and those receiving both TB and ARV medications?

   - is either group more or less likely to comply with treatment?
   - why might this be the case?

6. Could you tell me about your approach to managing treatment adherence in TB and TB/HIV patients?

   - Do you routinely address medication adherence with TB and/or ARV patients?
   - If No, Why Not?
   - If yes, How?
   - What have you found works well?
   - What doesn’t work?
   - When is the best time(s) to address adherence?

7. Are there any factors or circumstances that make it easier for you to address adherence with your patients?

   - patient factors?
   - job setting factors?
   - other?

8. Are there any factors or circumstances that make it difficult for you to address adherence with your patients?

   - patient factors?
   - job setting factors?
9. Do you have any suggestions for improving patient treatment adherence?
   - anything that might help the patients?
   - anything that might help you to address adherence better?

9. Do you have anything you want to add or clarify?

10. Do you have any questions?

11. Thank you for your time.
### ASK
- Did you have any trouble taking your tablets?
- Did you miss any tablets?

### ASSESS
- Reasons for non-adherence
- Risk Factors for non-adherence

### ADVISE
- Stress need to adhere

### ADDRESS
- Address reasons/risk factors
- Focus on strengths & resources

### AGREE
- Make an action plan together

### ACT
- Plan followed → congratulate
- Plan not followed → Follow-up

<table>
<thead>
<tr>
<th>ASK</th>
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<tbody>
<tr>
<td>• Did you have any trouble taking your tablets?</td>
<td>• Adherence = taking tablets within 1 hour before or after time due every day</td>
</tr>
<tr>
<td>• Did you miss any tablets?</td>
<td>• Ask at every patient contact</td>
</tr>
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</table>

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<thead>
<tr>
<th>ASSESS</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>• Understanding reason(s) for non-adherence is key to helping</td>
<td>• If no problems, encourage to continue</td>
</tr>
<tr>
<td>• Important to be supportive and show understanding</td>
<td>• If problems, ask why or what problems they had</td>
</tr>
</tbody>
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<table>
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<tr>
<th>ADVISE</th>
<th></th>
</tr>
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</table>
| • Remind patient that TB is curable if take full course of treatment, and that non-adherence makes the TB stronger and difficult to treat | • If adherent, ask about risk factors for non-adherence: side-effects of treatment, feeling better so think don’t need to continue, alcohol, ...

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<tr>
<th>ADDRESS</th>
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<tbody>
<tr>
<td>• Problem solve together about ways to address their reason(s) for non-adherence, or their risk factors for becoming non-adherent</td>
<td>• Encourage them by focusing on their strengths, and reminding them of the resources available to them</td>
</tr>
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<tr>
<th>AGREE</th>
<th></th>
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<tbody>
<tr>
<td>• Make a realistic plan together to support their adherence</td>
<td>• Make a realistic plan together to support their adherence</td>
</tr>
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<tr>
<th>ACT</th>
<th></th>
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<tbody>
<tr>
<td>• If plan is followed, congratulate and encourage to continue</td>
<td>• This might be: more frequent health center visits, changing the patients guardian, referral to the clinician for serious side effects,....</td>
</tr>
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<tbody>
<tr>
<td>• If plan is NOT followed, ACT early (day2 or 3): call or visit patient, speak with guardian, follow up with clinician to find out what the plan for the patient was (admitted, sent to central hospital), .....</td>
<td></td>
</tr>
</tbody>
</table>
Appendix 5: TB Adherence Handbook for Trainers

TB adherence handbook for trainers

This handbook contains the teaching materials, cases & discussion points for use in training your HSA colleagues who provide care to TB patients at your health center. We ask that you conduct at least 6 training sessions over the next 6 to 8 weeks. Each session must be at least 1 hour in length to count as a session, and your colleagues must attend all 6 to receive their certificates. For this reason 1-2 extra sessions may be necessary depending on who is able to attend. The date, topic, and names of those who have attended the session should be entered in your log book. The timing of the sessions is up to you and your group, but must occur during regular work hours at the health center. Many groups find that afternoons on days that are typically more quiet work out best. All HSAs who provide care to TB patients should be invited and encouraged to attend.

Thank you for your enthusiasm during the training, and for sharing your ideas and experiences, many of which have been included in this handbook as teaching cases. You may wish to change or add new cases for discussion or practice as you or your TB HSA team encounter challenging or difficult cases during your work. Working through such cases together is often an excellent learning opportunity and may be helpful to the HSA dealing with the difficult case when they see these patients next. Of course in sharing such cases care must be taken to ensure no one not involved in care of these patients becomes aware of the case.

Please remember that this program is being tested in only 7 health centers in Zomba district. Over the year that the study is underway we will be visiting you and your colleagues to ask about your experiences with the training and point of care tool, to allow us to improve both before implementing more widely in zomba and throughout Malawi if it is successful. It is therefore very important that you and your HSA colleagues not share the training or point of care tool with friends/colleagues at other health centers.

Your continued enthusiasm and commitment to the program are key to its success. Keep up the good work we started together in Zomba!
Outline of training sessions

The program has been broken into 6 sessions as outlined below. Sessions may be repeated as needed for HSAs unable to attend and may be covered over more than one session where you or your group feel this would be useful.

Day 1 – Program introduction, Background/relevance, goals of program

Day 2- TB from transmission to Cure
   - transmission, how TB works once in the body, symptoms and signs, treatment, managing treatment side-effects & complications

Day 3 - HIV and TB/HIV interaction
   - transmission, how HIV works in the body, symptoms and signs, how HIV interacts with TB, treatment of TB in TB/HIV co-infected patients, managing treatment side-effects & complications

Day 4 - Adherence 1
   - defining treatment success and adherence, importance of adherence, risk factors and protective factors

Day 5 - Adherence 2
   - approaches to improving adherence, what works/what doesn't, why we choose our approach, introduction to our approach

Day 6 - Improving adherence through our interactions with patients
   - patient centered care, techniques to improve communication, motivational interviewing
   - putting it all together, review of our approach, goals, intended use, lots of practice!!
Background/Relevance

- Global TB Epidemic
  - It is estimated that 1/3 world’s population is currently infected with each untreated case infecting 10 to 15 people per year
  - 1.6 million lives were lost to TB globally in 2005
  - Multi-drug resistant TB (MDR TB) rates are increasing

- Incomplete treatment main cause of BOTH, with the Global HIV epidemic important contributor
  - In 2008, there were 2.7 million new HIV cases and 2.0 million HIV deaths
  - TB is the leading cause of death among people living with HIV/AIDS
Background/Relevance

- Default rates range from 0 to 85%, with rates in most countries falling between 20 and 40%

- DOTS not enough!
  - DOTS does Help
  - It has been the main strategy to date, and is widely implemented
  - BUT, meeting WHO target cure goals in only 3 of 22 highest burden countries

Background/Relevance

- Malawi Data
  - 48000 new TB cases and 14000 TB deaths in 2007
  - MDR-TB rates: 2.3% for new cases & 7.5% for recurrent cases
  - 64% of TB patients are HIV positive
  - 68000 HIV deaths in 2007

- Malawi Default data
  - Default rates >50% pre-DOTS
  - As high as 16% in TB/HIV co-infected patients
Background/Relevance

- Risk factors for non-adherence
  - Many vary with country, location (city/rural), and culture
  - Some difficult to address or already being addressed in Malawi
  - 2 that can be targeted and that seem to be important everywhere including Malawi are:
    - Patient TB knowledge
    - Patient-provider interaction
  - These are the main target of this program

- Program based on highly successful program in south africa
- BUT, adapted to Malawi health care system and needs identified by HSAs providing TB care in Zomba District
- Two parts to program:
  - On-site training by peer trainers
  - Point of Care Tool
- Will be tested in 7 Health Centers over a year
- If successful will be implemented/tested more widely in Malawi
Goals of Program

- Improve TB/HIV treatment outcomes in Malawi!!!
- By:
  - Filling in training gaps identified by HSAs working with TB patients in Zomba
  - Testing a new training model
  - Evaluating a new tool to help HSAs educate and support adherence among TB and TB/HIV patients
  - Learning and practicing new techniques to engage and communicate with patients
  - Examining common myths/beliefs about TB and HIV treatment

Program Outline

- Day 1 – Introduction (today)
- Day 2 – TB
- Day 3 – HIV and TB/HIV interaction
- Day 4 – Adherence
- Day 5 – Adherence
- Day 6 – Improving adherence throughout interactions with patients, Putting it all together

* Each session will be at least one hour long, and occur at work during regular work hours. To receive a certificate for completing the program you must attend the 6 sessions above in full.
How long have humans been battling TB?
How long have humans been battling TB?

Oldest evidence of human TB infection found in a grave from 5000 BC

How long have we had effective treatment for TB?
How long have we had effective treatment for TB?

Over 50 Years!
Yet TB continues to plague society and remains a leading cause of illness and premature death especially among patients living with HIV/AIDS!

Outline

- TB Transmission/Infectivity
- How it works once in the body
- Symptoms and Signs
- Treatment
- Managing Treatment Side-effects & Complications
Transmission/Infectivity

TB transmission/infectivity

- TB caused by mycobacterium tuberculosis
- Most transmission is by droplet inhalation
- Some from drinking unprocessed cows milk
- Most cases occur from prolonged and repeated exposure
TB transmission/infectivity

- For every 100 people exposed to TB
- 10 will be infected (90% won’t)
- 5 will develop active disease soon after exposure
- 5 will be infected but initially contain the infection (latent TB)
- Under the right circumstances these people can progress to active disease
  - 10% of people with latent TB develop active TB in the first 2 years
  - After 2 years the rate falls to 0.1% per year after

- Despite this, it is estimated that each untreated person infects 10-15 people per year

How TB works in the body

- Inhaled or swallowed
- Enters the blood stream
- Can travel anywhere in the body
- Most often infection occurs in the lungs (75-80%)

- Once TB reaches its destination one of 2 things happens:  
  - Immune system is able to contain it there (latent TB)
  - Immune system unable to contain it there (active TB)
  - Latent TB remains inactive until the immune system is no longer able to contain it (old age, or illness, including HIV)
Symptoms & Signs Depend on where TB landed/lodged

- General
- Lungs
- Pleura
- Heart/pericardium
- Abdomen
- Lymph nodes
- Brain/Meninges
- Spine/Bones
- Skin

Symptoms & Signs Depend on where TB landed/lodged

- General: Fever, weight loss
- Lungs: Cough, chest pain, shortness of breath, haemoptysis
- Pleura: Shortness of breath, chest pain
- Heart/pericardium: Shortness of breath, swelling of legs and abdomen
- Abdomen: swelling of abdomen (ascites), abdominal pain
- Lymph nodes: enlarged lymph nodes, most often in neck
- Brain/Meninges: headache, stiff neck, confusion
- Spine/Bones: pain, tender swelling, may have leg weakness
Classification

- Pulmonary only or pulmonary plus other site = pulmonary TB
- Extra-pulmonary only = extra-pulmonary TB
- Both important but early recognition and treatment of smear positive cases are key to controlling spread of TB

Treatment

- All by DOTS
- New Cases
  - Initial phase : RHZE (2 months)
  - Continuation phase : RH (4 months)
- Recurrence, Relapse, Return after default, Treatment failure or TB meningitis
  - SRHZE x 2months
  - RHZE x 1 month
  - RHE x 5 months
- TB meningitis, Pericardial effusion, Constrictive pericarditis, or large pleural effusion
  - Add prednisilone
- HIV positive regardless of CD4 count
  - Start ARTs at 2 weeks
Managing side-effects/complications

Patients experiencing side-effects should generally be referred to a clinician for assessment & management.

Minor Side Effects - Continue treatment

- Abdominal pain, nausea (R) → take tablets last thing at night
- Burning feet (H) → give pyridoxine 50-75mg
  - Consider prevention with 10mg
- Joint Pains (Z) → give Aspirin or NSAID
- Red Urine (R) → reassurance
  - Better yet warn them before they start !!

- Note: women on Rifampicin should use additional contraception
Major Side Effects – Stop Treatment

- Deafness (S) $\Rightarrow$ Examine to rule out wax, if no cause for deafness stop streptomycin and use ethambutol
- Dizziness (S) $\Rightarrow$ dizzy only no nystagmus try reduced dose x 1 week, if nystagmus or no better with lower dose stop streptomycin and use ethambutol
- Generalized Reactions, including shock, purpura (R, H, S) $\Rightarrow$ stop all medications, use a different combination of drugs

Major Side Effects – Stop Treatment

- Skin Itching $\Rightarrow$ stop anti-TB drugs
- Visual impairment (E) $\Rightarrow$ visual exam, stop ethambutol
- Jaundice $\Rightarrow$ stop all anti-TB drugs until jaundice and liver function tests return to normal
- Severe vomiting/confusion $\Rightarrow$ Urgent liver function tests, if not available stop all anti-TB meds and observe
Case 1 – Provide only the information below and ask participants to work through the case in small groups, then discuss as a group

- 26 year old female
- 1 month on treatment
- Complaining of abdominal pain since started TB treatment

- What do you want to know?
- What do you want to do?

Case 1 – answers/key points to be reviewed with group after group discussions

- Refer to clinician
- Ask enough questions to be sure nothing else is going on?

- If nothing else:
  - help patient understand this is not serious
  - should continue treatment
  - change dosing to before bed
Case 2 Provide only the information below and ask participants to work through the case in small groups, then discuss as a group -

- 35 year old male with recurrent TB
- 1 month on treatment
- Complaining of decreased hearing

- What do you want to know?
- What do you want to do?

Case 2 - answers/key points to be reviewed with group after group discussions

- Recurrent, so on streptomycin
- Refer to clinician
- Thorough exam to rule out other causes ie. Ear wax
- If no other cause stop streptomycin
HIV, TB/HIV Interaction

Transmission to Long-term Viral Suppression

Outline

- HIV the virus
- Transmission/Infectivity
- How it works once in the body
- Symptoms and Signs
- How it interacts with TB
- Treatment
- Managing Treatment Side-effects and Complications
HIV the Virus

- Discovered in 1981
- Caused by a retrovirus
- Two types:
  - Most cases HIV1 – quicker progression to disease, better response to treatment than HIV2
- Estimated 0.6% of world's population infected
  - 12% in Malawi, 16% in Zomba
- Effective treatment (HAART) available since 1996
  - Unlike TB currently no cure, instead goal is long-term viral suppression

Transmission/Infectivity

- Transmission through exchange of bodily fluids
- 4 main means of transmission globally:
  - Unsafe sex, contaminated needles, mother to child, blood products
  - Heterosexual sex main method of transmission in sub-Saharan Africa
  - Infectivity per “act” varies
  - BUT: Best to consider any fluid exchange a transmission risk and use preventative measures
    - Abstinence, monogamy, consistent condom use, gloves, clean needles
How it works in the body?

- Like TB, HIV gets into the blood stream
- 1st phase – rapid viral replication → acute infection (2-4 weeks)
- Immune system response, making more killer cells and antibodies, leads to seroconversion **
- Virus levels drop and virus initially contained in lymph nodes
- BUT, replication continues, CD4 counts drop and viral load rises → chronic infection *
- This is the stage where ARTs helps

- Note: without treatment viral load gets higher and higher, kills more and more immune cells, and immune system fails → AIDS

True or False: Acute HIV infection is easy to recognize?

Ask group to vote true or false, afterwards go over answer together
True or False: Acute HIV infection is easy to recognize?

FALSE – a wide variety of symptoms may be seen with acute HIV infection, some so mild patient may not notice them

Main symptoms of Acute HIV infection

- **Systemic**
  - Fever, weight loss, malaise, headache, myalgias (muscle aches)
- **Mouth/throat/esophagus**
  - Pharyngitis (sore throat), mouth sores, thrush, esophagitis
- **Lymph Nodes**
  - lymphadenopathy
- **Skin**
  - Rash
- **Liver/Spleen**
  - enlargement
- **Stomach**
  - Nausea, vomiting
Symptoms & Signs - Chronic Infection

- Symptoms of chronic HIV infection can take years to develop
- Few or no symptoms may be present
- Main symptom early on is persistently enlarged lymph nodes
- Once CD4 very low (especially below 200)
- Begin to have opportunistic infections
- OI can affect any organ, and can be any type (bacterial, fungal, protozoal, viral, malignancies)
- Many of these are among the AIDS defining illnesses (currently there are 29)

How HIV interacts with TB

- HIV reduces the immune systems ability to contain TB
- HIV accelerates the progression of TB from latent to active TB and from infection to disease
- TB incidence is up to 8.3 times higher among HIV positive
- HIV patients have higher rates of TB recurrence, and more morbidity and mortality from TB
- TB is now the leading cause of death among people with HIV

In Malawi:
- 64-70% of TB cases are HIV positive
- 38% of HIV cases have TB
True or False: (ask participants to vote, afterwards go over answers together)

TB cannot be cured in patients living with HIV/AIDS?  

It is unsafe to take TB and HIV treatment together?  

TB patients do better if their HIV is also treated?
HIV treatment guidelines

Treatment is based on stage of Disease
Goal is long-term and consistent viral suppression

• Note: HIV treatment and management of side-effects are included here to improve your understanding. Patients will of course continue to be managed by the HIV team and HIV patients also on TB treatment referred to a clinician for management

WHO Clinical Stages

• 1 – Asymptomatic
  • Asymptomatic, persistent generalized adenopathy
• 2 – Mild symptoms
  • Respiratory tract infections, recurrent (sinusitis, tonsillitis, otitis media, pharyngitis
  • Herpes zoster
  • Angular cheilitis
  • Oral ulcerations, recurrent
  • Papular pruritic eruptions / Fungal nail infections
  • Moderate weightloss <10%, unexplained
  • Seborrhoeic dermatitis
WHO Clinical Stages

3 – Advanced symptoms
- Fever, persistent unexplained (intermittent or constant, >1 month)
- Oral hairy leukoplakia
- Pulmonary tuberculosis (current), Pulmonary tuberculosis within the last 2 years
- Anaemia, unexplained < 8 g/dl
- Neutropaenia, unexplained < 500 /mm.
- Thrombocytopaenia, chronic < 50,000 /mm.
- Severe weightloss >10% and/or BMI <18.5kg/m², unexplained
- Diarrhoea, chronic (>1 month) unexplained
- Oral candidiasis
- Severe bacterial infections (pneumonia, empyema, pyomyositis, bone/joint, meningitis, bacteremia)
- Acute necrotizing ulcerative stomatitis, gingivitis or periodontitis

WHO Clinical Stages

4 – Severe/very advanced symptoms
- Pneumocystis pneumonia
- Candidiasis of oesophagus, trachea, bronchi or lungs
- Extrapulmonary tuberculosis
- Kaposi’s sarcoma
- HIV encephalopathy
- Cryptococcal meningitis or other Extrapulmonary cryptococcosis
- Disseminated non-tuberculous mycobacterial infection
- Cryptosporidiosis, chronic with diarrhoea or Isosporiasis >1 month
- Disseminated mycosis (coccidiomycosis or histoplasmosis)
- Symptomatic HIV-associated nephropathy or cardiomyopathy
- Progressive multifocal leukoencephalopathy
- Cerebral or B-cell non-Hodgkin lymphoma
- HIV wasting syndrome (severe weightloss + persistent fever of severe weight loss + chronic diarrhoea)
- Bacterial pneumonia, recurrent severe
- Chronic herpes simplex infection (oral/abial, genital / anorectal >1 month or visceral at any site)
- Cytomegalovirus infection (retinitis or infection of other organs)
- Toxoplasmosis of the brain
- Non-typhoidal Salmonella bacteraemia, recurrent
- Invasive cancer of cervix
- Leishmaniasis, atypical disseminated
Eligible for ART treatment if

- HIV positive and know implications of ART
- Stage 3 or 4 regardless of CD4 count
- Stage 2 with CD4 <1200
- Stage 1 with CD4 <250

- Note: TB makes patients stage 3 and therefore eligible for ART treatment regardless of CD4

HIV treatment

- Note: goal here is long-term viral suppression

- First line treatment in Malawi = Stavudine (d4T) + Lamivudine (3TC) + Nevirapine (NVP)
- Plus CPT prophalaxis if stage 2-4, cd4 <500, pregnant

- Second line treatment available for severe side-effects and treatment failure

- Currently tablets are taken twice daily
Side-effects & Management

- Stavudine
  - Severe peripheral neuropathy, Lactic acidosis, Lipodystrophy syndrome, pancreatitis → switch to (AZT + 3TC + NVP)
- Neviripine
  - Skin reactions, hepatitis → switch to (d4T + 3TC + EFV)
- Other options for persistent minor reactions

- Note: several areas of overlap with TB treatment and neviripine → therefore introduce TB treatment first, add ART at 2 weeks
Case 3 – provide only this information and allow participants time to work through in small groups

- 33 year old male, recurrent TB
- 6 weeks on treatment
- Complaining of dizziness

- What do you want to know?
- What do you want to do?

Case 3 – key points to go over as a group after small group discussions over

- Refer to a clinician for assessment & management
- Examine to see if nystagmus present
- If not present, reduce streptomycin dose and follow up in 1 week

- If nystagmus present OR if no better or reduced dose, stop streptomycin and substitute ethambutol
Case 4 – share only this information and give time for participants to discuss in small groups

- 21 year old female
- 3 weeks on treatment
- Brought in my family for persistent vomiting and unusual behavior (a bit sleepy, saying strange things, sometimes not making sense)

Case 4 – key points to go over with the group once small group discussions over

- This patient is SICK!
- Take to the clinician for urgent assessment & management
- Needs urgent liver function tests, if not available, stop all anti-TB treatment and observe
Adherence

Treatment success
Defining Adherence
Importance of Adherence
Risk Factors & Protective Factors
Approaches to Improving Adherence
Our Approach!

What is considered successful treatment for TB?

For HIV?

For Both?
Treatment Success

• TB treatment success
  • Ideally CURE for smear positive cases
  • Treatment completion also considered a success

• HIV treatment success
  • Achieving AND maintaining maximum suppression of the virus

• In Co-infected patients, success is to achieve both!

The Key to treatment success is adherence

• If TB medications are taken consistently and properly:
  • TB transmission to others is prevented
  • Patients are cured and no longer need treatment
  • Morbidity and Mortality are reduced
  • Patients enjoy a better quality of life
The Key to treatment success is adherence

- If HIV medications are taken consistently and properly:
  - Viral replication is prevented
  - Viral load falls
  - CD4 rises
  - Morbidity and Mortality are reduced
  - Patients enjoy a better quality of life

What is the definition of Adherence?
Adherence Means taking medication exactly as prescribed

This means Taking

- The right drug(s),
- In the right doses

- In the right way
  - Some medications have dietary restriction
  - If not followed may not absorb all of drug $\rightarrow$ lowers dose $\rightarrow$ treatment failure

- At the right time(s) each day
  - Important to take at same time(s) each day
  - Generally okay within 1 hour window on either side of time
  - If twice a day (HIV), best 12 hours apart
  - BUT best to stress exact
Importance of Adherence

- Adherence is the most important factor for successful TB and HIV treatment and improved health status
- Poor adherence is the most frequent cause of treatment failure and the development of resistance

Medications only work when taken and taken properly

Importance of Adherence

- Non-adherence leads to:
  - Continued infectivity and transmission
    - An important cause of the TB epidemic
  - Development and transmission of drug resistant TB/HIV
    - These are much more difficult and can be near impossible to treat
    - Leading to increased morbidity and mortality
  - Treatment Failure
    - Disease progress, increasing illness, and early death
How much adherence is enough?

- Poor adherence is a problem with all diseases
  - Especially those that require long-term treatment
  - On average only 50% of people take their medications as prescribed
  - For most diseases 80% adherence is considered successful
- However, with TB and HIV the consequences of poor adherence are higher than with many other chronic diseases
  - Both to the patients and society
- And, resistance develops more easily
  - Even missing just a few tablets of ART allows the virus to replicate

100%
Risk Factors & Protective Factors

- Vary by:
  - location (country, city, village)
  - Culture
  - Over time
  - By disease
  - AND from person to person

- Key is to consider what might be a factor for that individual patient!

Give participants time to work through this in small groups, then discuss together

What are some Risk Factors you have found to be important?

What are some Factors you have found to be protective?
Factors Affecting Adherence

- Disease Characteristics
  - Recurrent TB, prior opportunistic infection
- Medication
  - Number, food/fluid restrictions, side effects
- Patient Characteristics
  - Knowledge, attitude, beliefs, age, gender, education, alcohol, depression, social supports
- Health Services
  - Distance, hours/availability, confidentiality, friendly staff/environment
- Patient-Provider Relationship
  - Trust, communication, work together

Risk Factors

- Common:
  - Poor patient understanding of their disease
  - Un-supportive/bad relationship with health care provider
  - Alcohol or drug abuse
  - Very sick
  - Serious/unpleasant side-effects
  - Need to take many medications
  - Medications that must be taken many times a day

  ** this will be specifically targeted in our approach
Protective Factors

- Common:
  - Good understanding of disease
  - Good relationship with health care provider
  - Belief that they can be cured/helped
  - Disclosure
  - Good social supports

Give time for participants to work through in small groups, then come together to discuss

From your experiences:

What are some good approaches?

What are some bad/not so good approaches?
Approaches that have been tried

- DOTS
- Education – to patient and/or provider
- Feedback - to patient or provider
- Reminders – calendars, alarms, special pill boxes, phone calls/text messages/emails/ letters in the mail
- Close monitoring/frequent clinic visits
- Pamplets/education sessions
- Plays/video clips

Success of approaches

- Some help, some don’t, some help sometimes
  - Dots generally helpful (but not enough)
  - Reminders can be helpful
  - Feedback can be helpful
  - Education is helpful initially, needs repetition for lasting effect
- Training to improve patient provider interactions not well studied for adherence, does work in other areas
- Appears combining a few approaches is most successful
- Many not practical for regular use
  - Expensive
  - Time consuming
  - Require technology
Why this approach?

- Training model based on program with proven success

- Adherence approach:
  - Includes more than one approach to improving adherence
  - Addresses 2 most consistent risk factors for non-adherence
  - But, allows for other risk factors to be addressed
  - And to take advantage of protective factors
  - Can be used anywhere, anytime
  - Allows for repetition!
  - Allows for sharing of current difficult cases to improve patient care
  - Cost effective – so can be used widely

Point of Care Tool

- Two Sides:
  - Patient side
    - Pictures to help in teaching patient about disease
    - Go over with patient in full first visit
    - Then revisit specific areas as patient progresses through treatment
  - Provider side
    - Left side = Key words remind points to be covered each visit
    - Right side = explanations and ideas for how to approach issues for each key word
    - Based on patient centered care and motivational interviewing, both known to improve patient-provider relationships, and adherence
Point of Care Tool

- First visit to health center (after discharge from hospital)
  - Should educate patient about TB and its treatment by going through entire patient side of tool with them
- After first visit
  - Go over the parts of the patient side important at that time
  - This might be reminding them where they are in the treatment process or at the 2 month visit that soon then will feel well but will need to continue treatment or become sick again and risk developing resistance
  - Can be used as go through provider side to discuss reasons or risk factors for non-adherence in the assess or address stage

Demonstrate use of tool with a HSA acting as a patient
Day 3 - Overview

Patient Centered Care
Motivational interviewing
Practice with Point of Care tool
Wrap up, Next Steps

“The greatest problem with communication is the belief that it has occurred”

Attributed to:
George Bernard Shaw
Models of patient provider interactions

- Traditional
  - Provider leads interaction
  - Provider asks closed ended questions (yes, no)
  - Often very directive
  - Patients generally not involved in health care decisions
- Patient Centered
  - Provider begins with open ended questions (how can I help you, tell me about, when, how, what)
  - Allows patient to describe their concerns/symptoms
  - Closed ended questions only at end of interview to clarify
  - Provider invites questions and encourages patient participation in decision making

Goals of patient centered care

- See the person as a person with an illness not just an illness
- Understand both the problem and the patients feelings/understanding of the problem
- Understand how the illness impacts the life of the patient and their family
- Help the patient to understand their illness and what is needed to make them better
- Encourage them to take “ownership” of their health
- Work together with the patient to make the treatment plan fit the patients life as much as possible
- **patients involved in their care are more likely to adhere!!**
Techniques for good communication

- Maintain eye contact
- Relaxed body posture
- Provider at same level as patient (both sitting)
- Ensure enough privacy
- Use active listening = show the patient you are listening
- Watch for non-verbal cues
- Avoid interrupting
- Start with open ended questions
- Summarize/paraphrase to check you have understood
- Remember some patients will have difficulty understanding
- Have them repeat back to be sure they have heard and understood

Brief Motivational Interviewing

- Goal is to motivate patient to want to change/do better/adhere
- Principles of MI
  - Partnership honours patients expertise and perspective
  - Provides an atmosphere that encourages change (not pressured)
  - Based on belief the resources to change lie within the person
  - Helps patient find motivation from within themselves, by respecting their values, goals and perceptions
  - Provider reinforces patients right to choose and facilitates informed choice
- Especially useful with difficult patients!
Brief Motivational Interviewing

- **4 Parts:**
  - **Express Empathy**
    - Shows patient you understand their point of view
    - Does not mean you agree with them
  - Help patient see both sides/points of view
    - “you do not want to finish tb treatment but you also do not want to get sick again”
  - When hit a block, Change approach
    - when patient appears to be getting angry/or not making progress in discussion, move onto another topic/approach
    - Lets talk about ------ (new topic)
  - Support self-efficacy
    - If you believe the patient can do better, they will too!

Brief MI Techniques

- **Reflection**
  - Simple – acknowledge disagreement
    - “I understand that you feel taking both medicines is unsafe”
  - Double-sided – capture both sides of argument
    - “I understand that you do not want to continue treatment but that you also do not want to become sick again”
Brief MI Techniques

• Shifting focus
  • Turn patients attention away from what seems a block
    • If patient is saying they can’t adhere because they didn’t do so last time treated → might say “let talk about the resources you have to help you this time” (such as good guardian, your relationship with the patient, family, etc.)

• Reframing
  • Acknowledge patients feelings but give a new interpretation
    • “I understand that you are angry that you have TB, is it possible that you feel you should have been able to prevent it?”

• Agreeing with a twist
  • Agree in a way that helps them see the right way
    • if patient says “No one can make me take TB treatment” → you might say “you are right no one can make you take treatment, you must be a full partner in your treatment”

• Emphasizing personal choice and control
  • Give information, but emphasis right to choose
    • If patient says “why are you telling me about TB, are you telling me I have to take treatment” → you might say “I am giving you information to help you in making your own choice, but the choice is yours”
Putting it all together

Practice

Several cases are given, but feel free to add cases from your/your groups experience, or even cases you are currently working through

Practice Cases

- Break into groups of 3, 1 act as patient, 1 as provider, 1 as observer
- Tell provider and observer what is on first slide only
- privately tell patient what is on the second
- Idea is for provider to find out the problem by using what we have learned, patient centered care, good communication skills, motivational interviewing, and the point of care tool
- Then to develop a plan **WITH** the patient to solve the problem
- Afterwards group should talk about what went well, and how it could have been done better
Case 1: A TB patient first refused to give her 2 month sputum.

Case 1: A TB patient first refused to give her 2 month sputum, when finally done, it was still positive. She has come for her appointment with you today.
Case 2: A patient has missed taking his TB treatment for 1 month.

Case 2: A patient has missed taking his TB treatment for 1 month. He lost his identity card and was afraid health workers would yell at him.
Case 3: A TB patient has come early for their medication. It is found to be sharing their medication with their relatives.
Case 4: A tb patient is late to pick up his medicines for the 2\textsuperscript{nd} time. Each time he is 2 weeks late. Patient is found to be living with more than one women and moving from house to house.
Case 5: patient denies to HSA that they are HIV positive but card says that they are

Patient was tested and is positive but is uncomfortable admitting it or discussing it even with their health care provider
Case 6: Patient comes each visit with a different guardian or no guardian.

Guardian is not helpful to patient and is not regularly monitoring their medication intake.
Case 7: Patient who was 2 days late last month, and 3 days late this month. Patient is late because has not disclosed to husband/family, and can’t leave home to come to get medications when husband is home because afraid he will find out.
Case 8: Patient refusing to take TB treatment, because god will cure him/her.

There is no right answer here: idea is to practice good communication, and if can’t convince to take meds, leave the door open for them to return “if you want to talk more, or start feeling worse, or change your mind about taking the medicine, please come and see me.”
Next Steps!

Important to use tool right away while still comfortable with it.
Help each other with ideas/practice together early on.
Once good with tool it will allow you to cover more with your patients but still work quickly.

Congratulations!

Just a reminder.
Because we are testing to see if and how well this program works, you must not share the training or point of care tool with HSAs at other sites or take them with you to other health centers if sent to help out or transferred.
Appendix 6: Description of STAT-PALM+ intervention

Acknowledgement:


The Intervention:

The intervention centers on the PALM PLUS guidelines and adapted training method, which are a Malawi-specific adaptation of the proven PALSA PLUS guidelines implemented in South Africa. PALM PLUS guidelines are symptom-based, integrated guidelines for HIV/AIDS, tuberculosis and common primary care conditions. They have been modified to comply with existing Malawian national disease and condition-specific guidelines, and through consultations with Ministry of Health personnel (at local and national levels), front-line Malawian nurses and clinical officers, and other stakeholders like the Medical Council of Malawi and the Nursing and Midwifery Council of Malawi. The reviewers are expected to check that the content is correct and appropriate and that the algorithms flow properly and reflect available drugs/resources in Malawian Health Centers. Guideline and algorithm development will follow a collaborative and iterative development process to ensure local relevance to frontline healthcare workers, to promote local ownership and to facilitate identification and resolution of any barriers to its implementation (e.g. inadequate access to diagnostic...
investigations for excluding TB). Key messages covering the content have been developed; these are short, summary information vectors, which provide a content framework for otherwise learner-directed teaching, and which are simple enough to be easily remembered during patient consultations.

Training follows the proven innovative and evidence based model called educational outreach, a form of point-of-care training that provides case-based, on-site training to primary care providers in the clinical settings where they work. Trainers will be front-line peer healthcare workers (from government or mission/institutional health centers) who will be trained to provide outreach training and support to their fellow front-line healthcare workers during focused (1-2 hours), intermittent, interactive sessions. Two Master Trainers will be responsible for the initial facility-trainer training, which is conducted offsite during a one-week intensive course in which the facility trainers are equipped with the necessary content, and their training skills developed and evaluated using an iterative process of training and feedback.

Trainers will be expected to lead between 6 to 10 training sessions at each health centre, targeting all nursing and clinical staff working at the health centre, over a maximum period of 12 weeks, but they may conduct additional training sessions if they wish. Point-of-care guideline tools will be developed and distributed (e.g. a thin (about 30 pages) sturdy laminated ring binder containing the entire guideline, colourful and easy to follow algorithms designed to be on the primary care provider’s desktop during each patient encounter, as well desk blotters with key PALM PLUS messages.)
Appendix 7: Discussion guide study 3 (chapter5): Lay Health Workers experience of a tailored knowledge translation intervention to improve TB care

Discussion Guide:

1. Do you have any questions?
   
   If yes, answer questions.
   
   If no, may we proceed with the interview/focus group now then?

2. First I would like to ask you a few questions about yourself.
   
   Gender  M/F
   
   Age  ___
   
   Current Job  HCW/TB focus HSA
   
   Location  ZCH/Rural HC
   
   Years in current position  ___
   
   Previous experience as HCW or TB focus HSA  Y/N
   
   If Yes,
   
   location of previous experience  ZCH/Rural HC/both
   
   total years of experience  ___

3. Have you completed the TB/HIV adherence training?
   
   If yes, when?  ____________
   
   If no, did you attend any session?  Y/N
   
   If yes, how many?  ____________
   
   If no, why not?  ____________
* if they have not attended any sessions, they will be thanked for their time and the interview terminated.

4. Please tell me about your experiences with the TB/HIV adherence training?

5. What if any aspects of the training did you find useful, and how?

6. What if any aspects of the training did you not find useful, and why?

7. Do you use the point of care tool? If so, how often do you use it? What aspects of the point of care tool, do you find helpful and why?

8. What aspects of the point of care tool, do you not find helpful and why?

9. Do you have any suggestions for improving the training or tool, for example is there anything you feel should be added to or removed from the training or point of care tool?

10. Do you have any concerns with the training or tool?

11. Do you have anything you want to add or clarify?

12. Do you have any questions?

13. Thank you for your time.
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