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Application of individual-level and health system-level implementation science approaches to HIV and TB prevention in Uganda

by Canice Christian

DISSERTATION Submitted in partial satisfaction of the requirements for degree of DOCTOR OF PHILOSOPHY

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Contributions

The text of Chapter 2 has been published in AIDS Care in 2022 and was written in collaboration with co-authors Jane Kabami, Dalsone Kwarisiima, Blian Beinamatsiko, Hellen Nakato, James Ward Khakshi, Munshi Sulaiman, Annah Komugisha, Harsha Thirumurthy, Diane V. Havlir, Moses R. Kamya, and Gabriel Chamie. This paper has been approved by my committee to be included in this dissertation as it was written principally by Canice Christian as the first author of the manuscripts.

Approved:

Gabriel Chamie, Dissertation Chair

Abstract

Application of individual-level and health system-level implementation science approaches to HIV and TB prevention in Uganda

Canice Elizabeth Christian

HIV and TB remain leading causes of death and disability across the globe. Highly efficacious HIV and TB prevention methods have created opportunities to prevent morbidity and mortality. Advancements in the availability of pre-exposure prophylaxis (PrEP) and postexposure prophylaxis (PEP) have created opportunities to prevent HIV among those at high risk. Additionally, TB remains a leading cause of death among people with HIV. Isoniazid preventive therapy (IPT) reduces the incidence of active TB by approximately 40-60% but despite the breadth of evidence suggesting the benefits of IPT for people with HIV, uptake of IPT has been slow. Given the burden of TB and HIV globally, and the availability of medications to prevent HIV and treat latent TB, implementation science interventions provide an opportunity to do more to get these medications to those who need them most.

In the second chapter of this dissertation, I evaluate the feasibility and preliminary effectiveness of integrating HIV prevention services into existing youth clubs in rural Uganda. As part of the intervention, we provided HIV prevention services, including access to PrEP and PEP. In addition, we taught multiple educational topics, including sexual and reproductive health, vocational training, and life skills, at these clubs over six months. In the third and fourth chapters of this dissertation, I focus on results from an implementation science intervention that was

focused on the mid-level manager level of the health system in Uganda. These chapters used data from the SEARCH-IPT study in Uganda, which included a 3-year intervention among mid-level health managers with collaborative groups and leadership and management trainings to improve the uptake of TB preventive therapy for people with HIV. Overall, this body of work evaluates multiple aspects of individual-level and health system-level interventions to prevent HIV and TB infection in Uganda.

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List of abbreviations

- ABYM Adolescent boys and young men
- AGYW Adolescent girls and young women
- AIDS Acquired immunodeficiency syndrome
- **ART** Antiretroviral Therapy
- COM-B Capability, Opportunity, and Motivation model for Behavior change
- **DALYS** Disability Adjusted Life Years
- ELA Empowerment and Livelihood for Adolescents
- FGD Focus Group Discussion
- HIV Human immunodeficiency virus
- **IPT** Isoniazid preventive therapy
- KIIs Key Informant Interviews
- LBDQ Leadership Behavior Description Questionnaire
- NIAID National Institute of Allergy and Infectious Diseases
- **OKR** Objectives and Key Results
- **PEP** Post-exposure prophylaxis
- **PEPFAR** U.S. President's Emergency Plan for AIDS Relief
- **PrEP** Pre-exposure prophylaxis
- **PWH** Persons with HIV
- **SDGs** Sustainable Development Goals
- SSA Sub-Saharan Africa
- **TB** Tuberculosis
- TMLE Targeted minimum loss-based estimation

- UHC Universal Health Coverage
- UNCST Uganda National Council for Science and Technology
- VMMC Voluntary medical male circumcision
- WHO World Health Organization

Chapter I

Introduction

Global burden of infectious diseases

Infectious diseases remain a significant cause of death and disability across the globe. The Sustainable Development Goals (SDGs), established by the United Nations in 2015, included a goal of "Good Health and Well-being" with Target 3.3 focused on communicable diseases: "By 2030, end the epidemics of AIDS, tuberculosis, malaria and neglected tropical diseases and combat hepatitis, water-borne diseases and other communicable diseases" [1]. Similarly, the End TB Strategy set by the World Health Organization (WHO) in 2015 targeted reducing tuberculosis (TB) deaths by 90% and TB incidence by 80% by 2030 [2]. Using innovative strategies to reduce the burden of HIV and TB globally is essential to achieving the goals set by the SDGs and the WHO.

Across the globe in 2021, approximately 38.4 million people were living with HIV, 10.6 million people became ill with TB, and approximately a quarter of the world's population was living with latent TB [3-5]. Despite wide availability of antiretroviral therapy (ART), HIV/AIDS was the second leading cause of Disability Adjusted Life Years (DALYS) among adults aged 25-49 globally in 2019 [6]. TB deaths, not including those with HIV co-infection, rose from 1.2 million in 2019 to 1.3 million in 2020, the first time TB deaths have risen since 2005 [7]. For this dissertation research, I will focus on HIV and TB prevention in Uganda.

Interventions for infectious disease prevention

Advances in infectious disease prevention have created further opportunities to prevent morbidity and mortality due to infectious diseases. Infectious disease prevention includes interventions to change human behavior and biomedical interventions. For example, HIV prevention interventions include behavioral changes, such as increased condom use and a reduction in the number of sexual partners, and biomedical interventions, such as HIV testing and uptake of prophylactic medications [8]. TB prevention includes interventions preventing TB disease, such as the BCG vaccine for children, and treatments of latent TB infection, including isoniazid preventive therapy (IPT) [9].

Advancements in the availability of pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP) have created opportunities to prevent HIV among those at high risk. When taken daily, evidence has shown that PrEP is highly effective in preventing HIV infection [10, 11]. The WHO has recommended PrEP for high-risk populations since 2015, but despite this, approximately 1.5 million people became newly infected with HIV in 2021 [12, 13]. PrEP uptake in Sub-Saharan Africa (SSA) has increased in recent years [14] but more is needed to reach high risk populations, including sexually active youth.

Even with advances in HIV treatment and availability of ART, opportunistic infections remain a risk for those with HIV. For example, TB remains a leading cause of death among those with HIV. Isoniazid preventive therapy (IPT) reduces the incidence of active TB by approximately 40-60% [15, 16]. Evidence suggests that six months of IPT reduces mortality, even among

people with HIV actively on ART who have high CD4 cell counts [17]. Despite the breadth of evidence suggesting the benefits of IPT for people with HIV, uptake of IPT has been slow. Barriers to implementing IPT include fear of side effects, knowledge gaps among providers, and stock-outs, among other barriers [18]. In the face of these challenges, implementation science interventions aim to overcome barriers in scaling efficacious prevention tools to maximize the effectiveness of available treatments.

Overall, scientific advances in biomedical interventions to prevent HIV infection and advances in preventing active TB among people with HIV provide an opportunity to impact health globally. This body of work aims to evaluate the impact of individual and district-level focused interventions to prevent infectious disease, as well as identify barriers and facilitators that midlevel management faces when working to implement TB prevention among people with HIV.

Implementation science methods for infectious disease prevention

Implementation science provides an essential component to global health research by filling the gap between scientific evidence and policy. Given the burden of infectious disease globally and with the medications now available to prevent HIV and treat latent TB, implementation science provides an opportunity to do more to get these medications to those who need it most. To improve health outcomes on a large scale, the effective implementation of evidence-based practices is essential, particularly in resource-limited health systems [19].

Handley *et al* (2016) describe the three main features of successful implementation science as (1) enabling behavior change, (2) engaging with various stakeholders, and (3) allowing for flexibility to allow for real-life situations [20]. Enabling behavior change to improve health outcomes includes changing behavior at various levels of the health system, including the individual, health provider, clinic, regional, and national levels (Figure 1.1), as well as the international level. Implementation science methods can be used across the various levels of a country's health system to scale the uptake of proven interventions and improve population health. Individual level interventions in practice may also be effective in improving health at the community level. For example, social learning theory supports the notion that if behaviors are changed at the individual level (e.g., the uptake of PrEP among youth in a community), there may be impacts on the community as a whole where peers learn from each other's behavior [21].

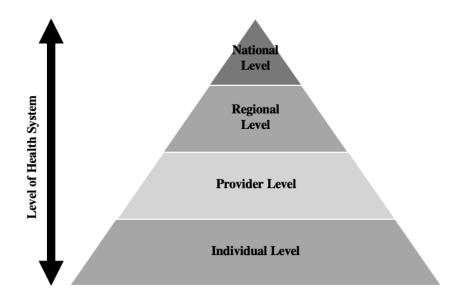


Figure 1.1 Levels of a health system as potential entry points for implementation science interventions

In this dissertation, I will explore both an individual-level intervention focused on HIV prevention, and a district-level intervention focused on TB prevention. The justification for this approach of intervening at multiple levels of the health system is to showcase how implementation science interventions can have an impact at multiple levels of the health system, both by changing individual behavior and strengthening health systems through regional interventions.

Individual and community level interventions to promote infectious disease prevention

One of the key implementation science models used to understand the necessities for *individual and community* behavior change is the Capability, Opportunity, and Motivation model for Behavior change (COM-B). Capability refers to identifying if an individual has the physical or psychological capability to do the required behavior, such as remembering to take a medication, knowing when to attend the clinic, or being physically able to open a pill bottle. Opportunity includes environmental factors, such as being able to travel to a clinic, and social influences, such as societal views influencing a patient's decision to seek care. The motivational component of the COM-B model refers to reflexive motivations, such as goals, intentions, and beliefs about capabilities, and automatic motivation, such as emotional responses and factors relating to supporting the patient to make the right choices [22]. When designing interventions to reach high-risk populations, it is imperative to consider the capability, opportunity, and motivational factors that may impede someone's ability to engage in preventive care.

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Youth, particularly young women, are at high risk of HIV in SSA, and have been identified as key target populations for HIV prevention interventions [23, 24]. However, capability factors that make it difficult for youth to engage in HIV prevention include a lack of knowledge or awareness of PrEP as an option to prevent HIV [25, 26]. To address these barriers, interventions to reach youth can include methods to engage youth in care and educate them about currently available prevention methods. At a community level, interventions that include a club-based approach to change behavior and improve health among youth have shown promise [27].

Opportunity barriers include challenges physically getting to the clinic, including distance to the clinic or other impediments such as the cost of travel [28, 29]. Opportunity considerations also include societal factors like stigma [26]. To address these barriers, youth-friendly interventions that are easy to access, and mitigate stigma by not exclusively focusing on HIV, may increase the use of HIV prevention medications among youth.

Motivational barriers include youth understanding their risk for contracting HIV and feeling empowered to prevent themselves from contracting HIV. Providing youth with information in a supportive, youth-friendly environment may change their motivations for taking action to prevent contracting HIV. Additionally, economic empowerment has been used as a tool for HIV prevention [30]. Evidence of the effect of interventions using income-generating activities for HIV prevention, such as vocational training and microfinance, has been mixed [31], however, recent studies have shown the promise of income-generating activities in HIV prevention practices, which merits further investigation [32-34]. By incorporating income generating activities into HIV prevention interventions, hard-to-reach populations, like youth in SSA, can be motivated to engage in care and provide an opportunity to learn skills that will foster empowerment [27, 35].

Innovative strategies to prevent HIV transmission at the individual and community level are essential to curbing the HIV epidemic. While we have made progress and the rate of HIV transmission is decreasing globally, more is needed to get closer to elimination and address barriers for high-risk populations [24].

District level health system interventions to promote infectious disease prevention

While donors historically have provided large amounts of funds for procuring ART and TB drugs in high-burden settings, proportionately little funding has gone toward developing a health system that can sustainably deliver these medications to the constituents who need them [36]. According to data from the Institute for Health Metrics and Evaluation, globally, in 2016, the human resource sector only received about 4% of the total development assistance for health budget [37]. An adequate workforce to implement interventions and effective leadership and management in health systems is essential for creating a workforce that can adequately address the health of their constituents and be agile enough to adapt to health system challenges.

A study by the Government of Japan and the World Bank, which assessed the progress toward Universal Health Coverage (UHC) in 11 countries worldwide, identified human resources for health as a critical component of achieving UHC [38]. Leadership in the health system has been identified as a key investment to improve the gap in human resources for health globally [39]. The World Health Organization identified health leadership and management as a key component for achieving UHC and specifically identified mid-level managers as a key resource [40]. Research in this area is important considering the importance of leadership and management on making progress toward UHC and the SDGs. To date, however, few studies have focused on health leadership and management in SSA [41].

How effective leadership, management, and governance influence health at the population level is outlined in a model developed by Management Sciences for Health and modified for this dissertation in Figure 1.2 [42, 43]. Effective leadership in health systems allows for health system managers to *scan* the ecosystem of their health system to understand the needs of their constituents, *focus* the goals of the system and identify priorities, *align* the health system with unified missions and values, and *inspire* their workforce to show trust among those they oversee. Management skills allow managers to *plan* for short- and long-term goals, *organize* the system to incorporate accountability, *implement* activities to streamline efforts across stakeholders, and continue to *monitor and evaluate* progress over time. Good governance is a third component to improve health outcomes through *accountability*, *engagement with stakeholders*, *setting goals* of the system, and *maximizing available resources*. These skills allow managers to increase their capacity for change in the health system and enhance their ability to manage their teams, which leads to improved health services and ultimately improved health outcomes [42].

Leadership	Management	Governance				
Scan	Plan	Cultivate accountability				
Focus	Organize	Engage Stakeholders	~ .	Increased capacity for change		Improved Improved
Align/Mobilize	Implement	Set shared direction	<u>ل</u>	Enhanced system management	$\Box \nearrow$	Health services Outcomes
Inspire	Monitor & Evaluation	Steward resources				

Figure 1.2. A modified model for change designed by the Leadership, Management, & Governance Project by Management Sciences for Health describing the mechanisms of improved leadership, management, and governance practices through to improved health outcomes [43]

Leadership and management skills developed in the business world have the potential to cross over and apply to health systems leadership and management. Providing leadership and management tools to managers in the health system can work to bolster skills so managers can be effective in their positions to improve health services and outcomes as outlined in Figure 1.2. Leadership and management tools developed in the business world have been shown to be effective in various business settings but have yet to be used in health systems strengthening at scale.

A model for change leadership developed by John Kotter (1996) includes an 8-step process for leaders to promote lasting change in their organizations (Figure 1.3). The key components of the model include creating a sense of urgency within the organization for why this change is important and why this change needs to happen now, developing the change vision along with a critical group of people within the organization to push this change forward, communicating this vision with the team while empowering workers to make progress toward this goal, and never letting up to ensure change is incorporated into the work culture [44].

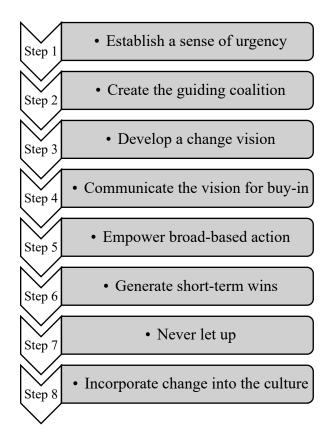


Figure 1.3. The 8-step model for change leadership developed by John Kotter (1996) [44]

Objectives and Key Results (OKRs) is a management technique that monitors progress over time. Objectives are clearly defined goals of what an organization hopes to achieve in a set period of time, and key results are the measurable indicators to monitor progress over time toward these goals [45]. While Kotters' 8-step model for change and OKRs have been used extensively in the business world to generate change in organizations and reach goals, the potential for these tools to be used in the health system context has yet to be extensively explored.

Managers in the health system in Uganda play a pivotal role in implementing guidelines and being the stewards of health for their constituents. Leadership and management skills among health leaders in SSA have shown promise in improving health outcomes [46]. Strengthening leadership and management skills through training has the potential to have large-scale impacts on health outcomes through broader improved health services.

Research in this dissertation

In this dissertation, I focus on implementation science interventions that targeted the individual level and regional level of Uganda (Figure 1.1). In the second chapter, I evaluate an intervention focused on intervening at the individual level. For this intervention, we partnered with BRAC, a global non-governmental organization (NGO), that operates youth clubs across Uganda, to implement an adolescent empowerment and livelihood curriculum over 6 months. We evaluated the feasibility and preliminary effectiveness of integrating HIV prevention services into existing youth clubs. As part of the intervention, we provided HIV prevention services, including access to PrEP and PEP, and sexual and reproductive health was taught to youth at these clubs over 6 months. The findings from this analysis provide the basis for this approach to be emulated in other settings for HIV prevention among youth, a high-risk population for HIV.

In the third and fourth chapters of this dissertation, I focus on results from an implementation science intervention that intervened at the mid-level manager level of the health system in Uganda. These papers used data from the SEARCH-IPT study in Uganda, which included a 3-year intervention among mid-level health managers with collaborative groups and leadership and management trainings to improve the uptake of TB preventive therapy for people with HIV [47]. The third chapter in this dissertation evaluates the perceived leadership and management abilities

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among mid-level managers following the SEARCH-IPT intervention. The fourth chapter of this dissertation includes a qualitative analysis of the perspectives of the mid-level managers on implementing TB preventive therapy for people with HIV. This qualitative analysis includes identifying the mechanisms through which mid-level managers in the intervention group were able to make changes in their district to improve the uptake of TB preventive therapy for people with HIV in their district and shared barriers to scaling TB preventive therapy across districts.

Overall, this dissertation provides insight into interventions at two key levels of the health system to improve infectious disease prevention in Uganda. In addition, this body of work provides the basis for individual-level and regional-level interventions to prevent HIV and TB infection. This research is important because of the high burden of infectious diseases globally. Given the available effective interventions for HIV and TB, we must do more to get these effective treatments to the people who need them.

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Chapter II

Feasibility and preliminary effectiveness of integrating HIV prevention into an Adolescent Empowerment and Livelihood intervention at youth clubs in rural Uganda

Introduction

Adolescent girls and young women (AGYW) make up a disproportionate number of new HIV infections in sub-Saharan Africa, and represent a priority group for HIV prevention interventions [1-3]. However, uptake of biomedical HIV prevention services, including pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP) has been lower among youth (adolescents and young adults) than adults in sub-Saharan Africa [4, 5]. Mechanisms leading to relatively lower PrEP/PEP uptake among youth include insufficient knowledge of prevention options, lack of access, and other barriers such as stigma [6, 7]. Although PrEP is recommended for those at high HIV risk, including AGYW, by WHO and the Ugandan Ministry of Health [3, 8], uptake has remained suboptimal in Uganda: as of September 2020 there were approximately 31,000 Ugandans taking PrEP [9]. In Uganda in 2021, the estimated population of youth aged 15-24 was 10.1 million, and the prevalence of HIV among AGYW was 2.6% and among ABYM was 1.1% [10, 11].

Structural factors, including poverty, low educational attainment, and lack of income generating opportunities, have been associated with increased HIV risk among youth [12-14]. However, interventions that promote income generating activities, such as vocational training and

microfinance, have had variable effects on HIV risk behaviors [14, 15], and though implemented in many settings, their effects on HIV prevention uptake remains unclear. BRAC, an international non-governmental organization (NGO), operates over 1,200 clubs that deliver an Empowerment and Livelihood for Adolescents (ELA) curriculum to youth across Uganda. The ELA curriculum offers life-skills and vocational training, and education on sexual and reproductive health. A prior evaluation of BRAC's ELA curriculum demonstrated a 34% reduction in youth pregnancy over four years [16]. This ELA curriculum has been implemented in South Sudan [17] and Sierra Leone [18] and has shown positive impacts on economic outcomes among young women in the program. However, to date, the ELA clubs have not integrated biomedical HIV prevention services, and the feasibility of integrating HIV prevention education and services into ELA clubs is unknown.

The objective of this pilot study was to determine the feasibility and preliminary effectiveness of integrating HIV education and access to HIV prevention services into youth clubs providing the ELA curriculum in rural Uganda.

Methods

Study participants and setting

We conducted a pilot study in a rural village, Kabura, Ibanda District, in Southwestern Uganda. We selected this village based on proximity to a government-run health center (Rukoho Health Centre IV) offering free biomedical prevention services, including PrEP and PEP. BRAC staff conducted community mobilization by meeting with key community stakeholders and holding informational meetings about the ELA clubs with adult community members in the month prior to the start of the pilot. Local, peer mentors (aged 22-32) were hired to lead the clubs and were trained on the ELA curriculum over five days.

Eligible participants included youth (15-24 years) living in Kabura village who were interested in and willing to participate in the clubs. One club for adolescent boys and young men (ABYM) and one for AGYW were established in separate nearby buildings (<0.5 km). Separate clubs were established to enable the curriculum to be tailored to AGYW and ABYM and to allow for sensitive questions and topics to be discussed freely.

Study design and procedures

We conducted club activities over 6 months (September 2019 through March 2020). Club members met three times per week, apart from national holidays. The BRAC-ELA Curriculum is designed to cover one topic per club meeting, with each lesson lasting 1-3 hours, as previously described [16]. Life-skills curriculum topics include values and goals, communication, and growth and development. Health topics include education on puberty, pregnancy, family planning, and sexually transmitted infections. Apart from life-skills education, other activities include vocational training, indoor and outdoor sports, and mobilizing community support. Clubs offered vocational training, including liquid soap making and reusable menstrual pad making. To mobilize community support and to integrate the adolescents with their social network, the clubs also organized a meeting between BRAC staff and parents of potential club members to answer questions regarding the intervention and address any potential concerns over the content of the curriculum covered in the clubs.

We integrated one-week of HIV prevention education on HIV testing, PrEP, PEP, Voluntary medical male circumcision (VMMC), and general HIV knowledge into the ELA curriculum one month after club initiation. The first session was taught alongside a local clinician to address questions and to ensure medical information was accurate and complete. Thereafter, peer mentors provided a monthly HIV education 'booster' session to review HIV prevention topics. Study staff offered HIV and pregnancy testing one month and six months following club initiation. Staff disclosed all test results privately, with referral to the local clinic for care, if necessary. Peer mentors and study staff offered PrEP referrals to any youth who were interested and provided referral cards that allowed club members to "skip the line" at the local health center. Three months after club initiation, club members went on a field trip to the local health center, accompanied by peer mentors where a clinician showed club participants where to go to access HIV testing, PrEP and PEP.

Measures

At baseline and six months post-enrollment, Independent Evaluation & Research Cell (IERC) of BRAC conducted surveys on HIV knowledge and self-reported risky sexual behavior with participants. A trained field supervisor collected baseline data using a mobile data collection technique. The same enumerator conducted the endline survey.

Outcomes

Feasibility

We evaluated the feasibility of integrating HIV prevention into the BRAC ELA curriculum using metrics of enrollment, participation and delivery of HIV prevention education and services. We aimed to enroll \geq 40 participants and evaluated attendance as a metric for participation. We assessed the ability of peer mentors, with support from a local clinician, to deliver the HIV education curriculum and to conduct a field trip to the local health center. Lastly, we evaluated feasibility of delivering on-site HIV testing at the clubs and referrals for PrEP and PEP to the local health facility.

Preliminary effectiveness

We evaluated preliminary effectiveness by comparing the following metrics at baseline and 6month follow-up: 1) uptake of referral to the local health center for PrEP or PEP; (2) HIV knowledge: defined as the proportion of correct answers to HIV-related questions; and (3) selfreported sexual behavior.

Ethical statement

Ethical approval was obtained by the University of California San Francisco and Makerere University School of Public Health, and research permit from the Uganda National Council for Science and Technology (UNCST). Written informed consent was obtained from all participants.

Results

Feasibility

Feasibility measures, study interventions and outcomes are described in Table 2.1. In August 2019, community mobilization by BRAC staff was conducted. The study team held a community meeting with village leaders and key stakeholders to discuss the establishment of the clubs. The BRAC staff then recruited participants with the help of village leaders. Forty-two participants enrolled in the study (24 AGYW and 18 ABYM), representing 55% of the 76 village residents aged 15-24 years. Out of 62 club meetings offered, the mean number of visits was 18 (SD = 18.7). Peer mentors delivered the baseline HIV prevention course over one week, alongside the local clinician. Peer mentors delivered follow-up refresher courses monthly on key topics in HIV prevention. Nineteen of 42 (19/42, 45%) participants attended the field trip to the local clinic. Club mentors offered PrEP and PEP referrals by providing referral cards that enabled club members to be seen at the clinic faster.

Table 2.1. Feasibility metrics, interventions, and outcomes during the implementation of youth clubs implementing the BRAC ELA curriculum with club-based HIV testing and referrals for PrEP and PEP in a rural village in Ibanda district, Uganda

Community	Feasibility	Feasibility study	Outcome
Actor	Measure	intervention	
BRAC staff	Club acceptance by community stakeholders and adults	Mobilization activities and meetings with adults and stakeholders in the community to describe the intervention and answer questions in the one month prior to club start	Adults and stakeholders attended community meetings and agreed to have the youth club proceed in the community
Youth attendees	Youth interest and enrollment (target of \geq 40 participants) in the club	Community mobilization and outreach to engage youth to participate in the club in the one month prior to club start	A total of 42 (55%) participants out of 76 youth in community were enrolled
Youth from community	Club participation	Community outreach prior to enrollment, provision of ELA curriculum 3x/week and vocational training activities, and on-site HIV and pregnancy testing	Out of 62 club meetings offered over 20 weeks, the mean number of meetings attended was 18 (SD = 18.7)
Local clinician & Peer mentors	Integrated delivery of the HIV prevention curriculum	Provision of HIV prevention curriculum and review with local clinician prior to implementation at the clubs	HIV prevention curriculum covered at both the boys and girls club, and peer mentors provided monthly refresher trainings
Local clinician & Peer mentors	Implementation of a field trip to the local health center	Consultation with the local physician about field trip visit and coverage of topics and clinic areas during the field trip visit	Nineteen youth (45%) attended the field trip with health center introduction provided by the local physician
Peer mentors	Club referrals to PrEP or PEP at the local clinic	Club members were provided referral cards that allowed them the ability to skip the line at the clinic for expedited visits	5/18 (28%) sexually active, HIV-negative AGYW received referral cards, went to the clinic for PrEP, and started on PrEP. One ABYM was referred for PEP.

Community	Feasibility	Feasibility study	Outcome
Actor	Measure	intervention	
Study staff	Implementation of on-site HIV testing	Working with study staff and local health facility to enable testing on-site at youth clubs	At baseline, 24/42 (57%: 15/24 AGYW and 9/18 ABYM) participants tested for HIV. At 6-months, 13/39 (33%: 8 AGYW and 5 ABYM) of baseline HIV-negative club members tested for HIV.

Youth club participants

The mean age of all participants was 20.1 years (SD = 2.5). Overall, 24% (10) of participants were enrolled in school, 74% (31) had dropped out, and one participant had never been enrolled in school. Youth enrolled in school had lower attendance compared to those who had dropped out (mean number of visits of 3.9 and 21.3, respectively). Out-of-school senior members of the ELA program were eligible for participating in the vocational activities. Of those eligible, eighteen club participants (18/32, 56%) attended at least one of the vocational training exercises. Thirty-nine participants (93%) were available for the follow-up survey.

Among ABYM, 10 (56%) and 7 (39%) reported having ever heard of PrEP and PEP, respectively, at baseline. A greater proportion of female club members reported ever having heard of PrEP (n=16, 67%) and PEP (n=15, 63%) (**Table 2.2**).

	Study Participants, No. (%)		
Characteristics	Total	Male (n=18)	Female (n=24)
Age, Mean (SD)		· · ·	· · ·
Education	20.1 (2.5)	19.9 (2.8)	20.3 (2.3)
Currently Enrolled in School	10 (24%)	5 (28%)	5 (21%)
Dropped Out	31 (74%)	13 (72%)	18 (75%)
Never Enrolled	1 (2%)	0 (0%)	1 (4%)
Attendance by education status			
Overall number of visits, mean (SD)	18 (18.7)	14 (18.0)	21 (19.1)
Currently Enrolled in School	4 (6.5)	6 (8.8)	2 (3.0)
Dropped Out	21 (18.4)	18 (19.7)	24 (17.6)
Never Enrolled	55 (0)	N/A	55 (0)
HIV Knowledge			
Have you ever heard of PrEP? (Yes), n (%)	26 (62%)	10 (56%)	16 (67%)
Have you ever heard of PEP? (Yes), n (%)	22 (52%)	7 (39%)	15 (63%)
Sexual Behavior			
Have you ever had sexual intercourse? (Yes), n (%)	33 (79%)	13 (72%)	20 (83%)
Have you ever been tested for HIV? (yes), n (%)	40 (95%)	16 (89%)	24 (100%)
What was the result of your last HIV test?			. ,
HIV-negative, n (%)	37 (92.5%)	15 (94%)	22 (92%)
HIV-positive, n (%)	3 (7.5%)	1 (6%)	2 (8%)

Table 2.2. Study participant characteristics and HIV knowledge and sexual behavior at baseline in a pilot study on the feasibility and preliminary effectiveness of a club-based intervention for HIV prevention among youth in Ibanda, Uganda (n=42)

Preliminary effectiveness

At baseline, no participants accepted referral to PrEP, whereas 5 of 18 (28%) sexually active, HIV-negative AGYW accepted referral to PrEP during the last month of the pilot. During follow-up, one ABYM of 18 (6%) was referred to PEP. At baseline, 95% of the participants (24/24 AGYW and 16/18 ABYM) had reported having ever been tested for HIV. At baseline, 24/42 (57%: 15/24 AGYW and 9/18 ABYM) participants tested for HIV at the club. At end of study, 13/39 (33%: 8 AGYW and 5 ABYM) of HIV-negative at baseline club members tested for HIV. Three participants self-reported being HIV-positive at baseline: 1 of 16 ABYM (6%) and 2 of 24 AGYW (8%). Two ABYM (one sexually active) did not answer the question about HIV status. None of the study participants who were tested seroconverted during the pilot.

At baseline, most participants reported that condom use during sex can prevent HIV (93%, n=39) and that VMMC can reduce the risk of HIV infection (88%, n=37), but fewer had knowledge of PrEP and PEP (62% and 52%, respectively). All HIV knowledge questions yielded higher correct or positive responses at follow-up compared to baseline, except for knowledge of VMMC (**Table 2.3**).

At baseline, 45% (15/33) of sexually-active participants reported that they did not use a condom during their most recent sexual intercourse, versus 26% (8/31) at follow-up. Fewer sexually active AGYW reported engaging in transactional sex at baseline as compared to follow-up (13/20 (65%) vs 5/19 (26%)).

	Study Participants, No. (%)			
HIV Questions	Baseline (n=42)	Follow-up (n=39)	Difference	
HIV can be prevented by using condom during sex (true)	39 (93)	39 (100)	+7%	
There is a pill that can prevent HIV if taken daily (true)	33 (79)	33 (85)	+6%	
There is medication that you can take for one month after having unprotected sex with someone with HIV that will prevent you from getting HIV, if you are not infected with	24 (57)	21 (70)		
HIV (true)	24 (57)	31 (79)	+22	
For a man without HIV, getting circumcised can help reduce his chances of getting HIV in the future (true)	37 (88)	30 (77)	-11%	
For a person infected with HIV, taking daily HIV medication under a doctor's care, controlling the virus, and staying healthy can reduce his/her chances of passing HIV to his/her partner (true)	29 (69)	36 (92)	+23%	
For a woman with HIV, taking daily HIV medication under a doctor's care, controlling the virus, and staying healthy can reduce her chances of passing HIV to her child during pregnancy (true)	39 (93)	39 (100)	+7%	
For a woman with HIV, taking daily HIV medication under a doctor's care, controlling the virus, and staying healthy can reduce her chances of passing HIV to her child during				
breastfeeding (true)	34 (81)	37 (95)	+14%	
Have you ever heard of PrEP? (Yes)* $(n=15)$	26 (62)	14 (93)	+31%	
Have you ever heard of PEP? (<i>Yes</i>)* $(n=18)$	22 (52)	17 (94)	+42%	

Table 2.3. Changes in HIV knowledge from baseline to 6 months post-intervention start among study participants in a pilot youth club in Ibanda, Uganda

*PrEP and PEP knowledge at follow-up only asked among those who reported 'no' to the same question at baseline

Discussion

In a pilot study, we found that integration of HIV education and biomedical HIV prevention services into an existing, evidence-based youth empowerment and livelihood club intervention (ELA curriculum) was feasible, with preliminary evidence of effectiveness in increasing HIV prevention behaviors, including PrEP and PEP uptake. Novel components of this intervention include the combined interventions of vocational training, HIV and pregnancy testing, PrEP and PEP referrals from a peer mentor-led youth club, and a youth-tailored field trip to a local clinic to introduce and ease barriers to PrEP/PEP. Club attendance was higher among youth who had dropped out of school, who are a group at increased risk of HIV [12]. Our findings suggest preliminary effectiveness of this integrated club model in increasing PrEP uptake among AGYW, increasing knowledge about HIV prevention, and decreasing risky sexual behavior.

Integration of HIV prevention education and services into youth clubs offering vocational and life-skills training, as well as social activities, has the potential to increase engagement in HIV prevention by leveraging youth demand for income-generating training. Several studies, prior to widespread implementation of PrEP, have evaluated similar approaches. For example, the "Street Smart" pilot program that provided HIV prevention education along with vocational training among youth (aged 13-23) in Uganda observed a decreased self-reported number of sexual partners and increase in abstinence and condom use after two years [19]. The SHAZ intervention in Zimbabwe enrolled AGYW into a vocational training program with micro-grants and social support with life-skills and health training, and found that those who received the intervention reported reduced transactional sex and increased condom use after two years [20]. More recently, an evaluation of programs implementing the DREAMS initiative found an overall decrease in new HIV diagnoses among AGYW across multiple settings in which DREAMS was implemented [21]. BRAC implemented ELA models in Uganda, Tanzania, South Sudan, Liberia, and Sierra Leone. The feasibility of this pilot is important given the potential for rapid scale-up by linking an existing ELA curriculum with Ministry of Health clinics providing PrEP/PEP. As

prevention options increase, such as the dapivirine vaginal ring (DVR) and long-acting injectable PrEP, having more entry points, such as this club-based model, to reach AGYW and ABYM will be critical to maximize prevention coverage for at-risk youth.

Although PrEP referral from the club was feasible and increased among sexually active HIV negative AGYW, the lack of PrEP uptake among ABYM suggests that other approaches may be needed for at-risk ABYM. Given the well-documented challenges in engaging men and boys in HIV testing and prevention services, efforts to reach ABYM for early introduction to HIV prevention services and education are essential to achieving HIV targets across the globe [22]. Our findings suggest that youth clubs incorporating HIV education and prevention services for ABYM are feasible and offer an opportunity for early engagement. Our preliminary finding that clinic field trips and introduction to PrEP clinic staff can increase AGYW PrEP uptake is consistent with prior evidence that youth-friendly services can increase PrEP use among AGYW [23].

Knowledge of HIV prevention increased from baseline to follow-up, suggesting that youth clubs offering life skills education and vocational training may be an effective way to reach at-risk youth who drop out of school. The decrease in self-reported risky sexual behavior reported also suggests that our club-based model may lead to behavioral changes among participants. The decline in risky sexual behavior may also explain why some participants did not feel the need to initiate PrEP. In rural, resource-limited settings, dissemination of information regarding emerging prevention options among adolescents remains a challenge [24]. Our pilot combined HIV education, club-based HIV testing, in-person introductions to providers offering PrEP/PEP

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and a visit to a local clinic, so as to improve both general understanding of HIV infection and practical knowledge of how to access prevention services.

This study has limitations. First, the club pilot was conducted in one village, limiting generalizability. However, these pilot data provide initial evidence of feasibility, supporting further evaluation of this approach in other settings. Second, the duration of the pilot was six months, limiting our ability to evaluate potential long-term impacts. In addition, our effectiveness measures relied on self-reported outcomes, and are subject to social desirability bias and underreporting of risk behavior. Additional studies that assess effectiveness of ELA curriculum with HIV prevention interventions on STI/HIV incidence are necessary. Nonetheless, our findings of preliminary effectiveness, particularly in PrEP adoption, are encouraging and merit further evaluation on BRAC's ELA model and also other club or group-based adolescent interventions with similar purposes.

Conclusion

The integration of the BRAC-ELA curriculum with HIV prevention interventions at youth clubs was feasible and suggests preliminary effectiveness in increasing PrEP uptake among AGYW and HIV-related knowledge among youth, and in reducing self-reported risky sexual behaviors among club participants. Evaluation of effectiveness of this strategy for HIV prevention among youth merits further study.

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Chapter III

The impact of leadership and management training on perceived abilities among health system mid-level managers participating in a cluster randomized trial in Uganda

Introduction

Across many countries in sub-Saharan Africa (SSA), healthcare "middle managers" oversee the implementation of national guidelines at the sub-national level, and as such, are a critical component of health system functioning. As sub-national leaders and managers, they operate at the nexus of guidelines and implementation, setting healthcare priorities, managing frontline providers, and overseeing budgetary, education, and operational aspects of healthcare service delivery, often for thousands of people. Despite these responsibilities, mid-level healthcare managers are often clinicians with little or no formal leadership and management training. Leadership and management have been identified by the WHO and the Lancet Commission on Health Systems as key areas of interest in health systems strengthening and governance [1, 2]. A lack of training in this area may limit effectiveness of mid-level managers in their roles, given that effective leadership skills have been associated with positive health outcomes.

Although several studies of interventions to improve leadership abilities among health care professionals in SSA have been published, few have evaluated the effects of leadership training interventions on health outcomes. A recent scoping review of interventions aimed at strengthening leadership capabilities of health professionals in SSA found that 13 of 27 studies identified also included management training, but only 4 of 27 (15%) evaluated health or health systems outcomes [3], including improvements in hospital performance standards [4] and health

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services coverage [5]. Similarly, only 7 of 27 (26%) studies in the review evaluated learning of leadership and management skills. Given the central role mid-level health managers play in healthcare service delivery in SSA, further evaluation of interventions aimed at improving leadership and management skills of this cadre of managers is needed.

In the SEARCH-IPT trial, a multi-component intervention among mid-level managers in Uganda resulted in an increased uptake of isoniazid preventive therapy (IPT) for persons with HIV (PWH) compared to standard care (i.e. control group), after taking into account a 100-day push led by the Ministry of Health in Uganda and the U.S. President's Emergency Plan for AIDS Relief (PEPFAR). One key component of the trial's intervention was annual leadership and management training provided to mid-level managers by international business professionals over three years, as previously described [6]. What role changes in leadership and management may have had on the SEARCH-IPT trial's outcomes remains unclear.

To address this question, we sought to evaluate self-reported leadership and management skills among mid-level managers who participated in the SEARCH-IPT trial by study arm. We also sought to identify perceptions of frontline providers on the quality of the supervision of these mid-level managers to better understand how the SEARCH-IPT trial's intervention led to changes in IPT initiation among PWH.

Methods

Study design

We conducted a cross-sectional survey assessing leadership and management skills among district-level health system managers in Uganda at the time they completed participation in the

SEARCH-IPT trial. The SEARCH-IPT trial is a cluster-randomized trial that evaluated the effect of a multi-component intervention among district-level health managers on IPT initiation rates for persons with HIV and in care in three regions of Uganda. We have previously published the trial's methods and results [6]. In brief, the trial enrolled district health officers, the highestranking Ministry of Health leaders in each district, and TB supervisors who oversee TB-specific activities and report to health officers. Each district in Uganda has one district health officer and one TB supervisor. We created 14 pair-matched groups of these health managers (with 4-7 managers per group) and randomized the groups 1:1 to the SEARCH-IPT intervention or control.

As a key component of the SEARCH-IPT intervention to enable IPT use, we offered intensive one-day, interactive leadership and management training courses at annual "mini-collaborative" meetings among intervention managers over three years. Each course was designed and led by two international business consultants and our study team, with courses emphasizing tools to improve leadership and management skills adapted to a Ugandan context. The three courses in this "Mini-MBA" curriculum focused on: (1) Kotter's 8-Step Model for Change, (2) Objective Key Results (OKRs), (3) and the Start Stop Continue Retrospective technique for team feedback [7-9].

In the present study, we sought to compare leadership and management skills by arm in an endof-study survey among managers participating in the SEARCH-IPT trial. The survey evaluated the use of the specific tools covered by the "Mini-MBA" curriculum in the intervention arm, as well as general leadership and management capabilities using two established questionnaires from the leadership/management literature: the Change Leadership Questionnaire and the Leadership Behavior Description Questionnaire [10, 11]. We collected survey data from September 2021 to February 2022.

To understand the impact of the intervention on healthcare workers supervised by managers participating in the trial, we also conducted a survey among a sample of frontline providers after the first year of the SEARCH-IPT trial, between February and August 2019. We surveyed a convenience sample of frontline providers from clinics in intervention and control districts in the Southwest and East regions of the trial, based on proximity to study offices and quality of road to the clinics. At each clinic, we invited frontline providers to participate in the study, including nurses, clinical officers, counsellors, peer educators, midwives, and lab technicians. We surveyed frontline providers from eight districts in total (four control and four intervention districts).

Outcomes and measures

'Mini-MBA' curriculum content questionnaire

We asked five questions about the frequency of use of skills taught during the 'Mini-MBA' curriculum using a Likert scale that ranged from 1=rarely to 4=always, and calculated an aggregate score of the 5 questions for each respondent.

Change leadership questionnaire

The Change Leadership Questionnaire is a survey designed for self-assessment of leadership skills in five areas representing leadership qualities: visionary, inspirer, supporter, problem

solver, and change manager. We created a modified version of the Change Leadership Questionnaire, shortened to reduce survey completion time (See Appendix), and calculated an aggregate score for each of the five areas assessed.

Leadership Behavior Description Questionnaire

The LBDQ (Self-assessment LBDQ-XII) is a 100-item questionnaire designed to measure selfperceived leadership and management abilities [12]. Each question describes a behavior and asks the participant to rank how often they engage in that behavior from 'Always' to 'Never'. The LBDQ is divided into 12 subcategories (see Table 2.4), each of which receives a score ranging from a maximum of 25 or 50, depending on the category, with higher scores representing high self-assessed abilities and lower scores representing low abilities in that area [11].

Frontline provider survey

We designed the frontline provider survey to better understand TB specific practices in a subset of health centers in districts participating in the trial. One question in the survey, relevant to the present study, evaluated frontline provider perceptions of the quality of guidance and supervision received from district-level health managers (both district health officers and TB specific managers) during the trial. We scored responses to this survey question using a 5-point Likert scale, with scores ranging from 1=very low quality, to 5=very high quality.

Statistical analysis

We used a targeted minimum loss-based estimation (TMLE) to compare survey responses between trial arms, accounting for the clustering of the districts in the trial design and adjusting for missingness [13, 14]. For each of the survey questions and for survey sub-domains, as applicable, we evaluated the difference in average responses between intervention and control groups. For the specific content from the 'Mini-MBA', we compared scores for each question individually and an overall score, calculated by summing the scores of the five questions. Likewise, for the Change Leadership Questionnaire, we compared scores for each of the five sub-domains and an overall score, again calculated by summing all scores. For the LBDQ, we compared the scores of the 12 sub-domains as outlined by the published survey [11]. For the frontline provider survey, TMLE was also used to evaluate the difference in the average rating of the manager's quality of guidance and supervision by trial arm. All analyses were prespecified, and hypothesis testing conducted with a two-sided test at the 5% significance level.

Ethical approval

Approval was obtained by the Institutional Review Boards at the School of Medicine Research and Ethics Committee at Makerere University School of Medicine, the University of California, San Francisco, and the Uganda National Council for Science and Technology. Written, informed consent was obtained by all study participants prior to study activities.

Results

Study population

Of 163 managers participating in the SEARCH-IPT trial, 119 (73%) completed leadership and

management survey, with at least one manager surveyed from 78 (94%) of the 83 districts in the

trial. Forty-eight (40%) of survey respondents were lead managers whereas 71 (60%) were TB-

specific managers (Table 3.1).

Table 3.1. Characteristics of the districts involved in the SEARCH-IPT trial in Uganda and the participants who completed leadership and management survey at the end of Phase I

	Intervention	Control				
Characteristics of districts in the SEARCH-	Characteristics of districts in the SEARCH-IPT Trial[6]					
Clusters: District mini-collaboratives	7	7				
(intervention) or mini-groups (control)						
Number of Districts	43	39				
Regions						
Southwest	13	12				
East	12	11				
East-Central	18	16				
Median districts per cluster (IQR)	5 (5 - 6)	5 (5 - 6)				
Mid-level managers enrolled in trial	86	77				
Characteristics of participants completing le	adership & managemer	nt survey				
Cadre of Managers responding to survey						
Lead manager	32 (45%)	16 (33%)				
TB-specific manager	39 (55%)	32 (67%)				
Total	71	48				
Sex of survey respondents						
Male	63 (89%)	42 (87.5%)				
Female	8 (11%)	6 (12.5%)				
Region of survey respondents						
Southwest	26 (37%)	21 (44%)				
East	16 (23%)	14 (29%)				
East-Central	29 (41%)	13 (27%)				

"Mini-MBA" content

When asked about content covered in the "Mini-MBA" curriculum, the intervention group had higher average overall survey scores compared to the control group (+3.64, 95% CI: 1.98, 5.30, p<0.001) indicating the intervention group reported using leadership and management skills taught as part of the SEARCH-IPT intervention more frequently than control (Table 3.2). When evaluating specific skills used, intervention group managers reported more frequent use of Kotter's 8-Step Model for Change (Change +1.09; 95% CI: 0.68, 1.50; p<0.001), communication of their change vision (+1.19, 95% CI: 0.67, 1.72; p<0.001), and use of "Start, Stop, Continue" team feedback (+0.79, 95% CI: 0.23, 1.35; p=0.007), compared to control group managers.

Table 3.2. Average scores on survey assessing use of skills taught as part of the SEARCH-IPT intervention (i.e., the "Mini-MBA" curriculum) among intervention and control mid-level managers participating in the SEARCH-IPT trial in Uganda (n=119 survey respondents).

'Mini-MBA' Content Questions	Intervention Average Scores (95% CI)	Control Average Scores (95% CI)	Difference: Intervention vs. Control (95% CI)	P-value
Overall 'Mini-MBA' content	14.18 (13.31, 15.05)	10.54 (9.12, 11.96)	3.64 (1.98, 5.30)	< 0.001
Kotter's 8-Step Method I use Kotter's 8-Step Model to create a change vision for key performance indicators in my district.	2.46 (2.32, 2.60)	1.37 (0.99, 1.76)	1.09 (0.68, 1.50)	<0.001
Communicates change vision Using Kotter's principles, I communicate and emphasize the change I want to see at every opportunity.	2.65 (2.35, 2.96)	1.46 (1.03, 1.88)	1.19 (0.67, 1.72)	<0.001
Short-term wins I celebrate short term wins or improvements in performance with my team to motivate them.	3.24 (2.99, 3.50)	2.86 (2.55, 3.17)	0.38 (-0.02, 0.78)	0.062
Objective Key Results <i>I use "Objectives and Key</i> <i>Results (OKRs)" to set goals</i> <i>and measure progress in my</i> <i>district.</i>	3.19 (3.09, 3.29)	2.92 (2.56, 3.28)	0.27 (-0.10, 0.65)	0.146
Start, Stop, Continue I use the "Start, Stop, Continue" model to evaluate what strategies do and do not work in my district every quarter.	2.62 (2.30, 2.95)	1.84 (1.38, 2.29)	0.79 (0.23, 1.35)	0.007

Change leadership questionnaire

The overall change leadership score across the five areas assessed (Visionary, Inspirer,

Supporter, Problem Solver, and Change Manager) did not show significant differences between

intervention and control managers (Table 3.3).

Table 3.3.

Results of the modified change leadership questionnaire between the intervention and control mid-level managers participating in the SEARCH-IPT study in Uganda (n=119)

Subscale Domains	Intervention Average Scores (95% CI)	Control Average Scores (95% CI)	Difference: Intervention vs. Control (95% CI)	P-value
Overall Change Leadership	83.19 (80.56, 85.81)	84.24 (81.36, 87.12)	-1.05 (-4.95, 2.85)	0.589
Visionary	17.26 (16.90, 17.61)	17.46 (16.94, 17.97)	-0.20 (-0.83, 0.43)	0.526
Inspirer	16.34 (15.75, 16.93)	16.84 (16.19, 17.48)	-0.50 (-1.37, 0.38)	0.257
Supporter	16.70 (16.04, 17.35)	16.66 (16.03, 17.29)	0.03 (-0.88, 0.95)	0.939
Problem Solver	16.08 (15.19, 16.97)	16.40 (15.65, 17.15)	-0.32 (-1.48, 0.84)	0.583
Change Manager	16.82 (16.29, 17.34)	16.80 (15.89, 17.71)	0.02 (-1.03, 1.06)	0.975

Leadership Behavior Description Questionnaire

For each of the 12 subscale domains, the intervention group did not show significantly higher self-reported leadership skills as compared to control (Table 3.4). For the sub-domain 'Tolerance and Uncertainty', the control group reported higher skills in this area compared to intervention (difference = -1.9, 95% CI: -3.5, -0.3; p=0.024).

Table 3.4. Results of the Leadership Behavior Description Questionnaire conducted among midlevel managers in the intervention and control arms of the SEARCH-IPT trial in Uganda (n=119)

Subscale Domains	Intervention Average Scores (95% CI)	Control Average Scores (95% CI)	Difference: Intervention vs. Control (95% CI) Average Scores	P-value
1. Representation* "Speaks and acts as the representative of the group"**	21.0 (20.5, 21.5)	21.0 (20.1, 21.9)	0.0 (-1.1, 1.0)	0.979
2. Demand reconciliation* "Reconciles conflicting demands and reduces disorder to system"**	18.8 (18.3, 19.2)	19.3 (18.4, 20.2)	-0.5 (-1.5, 0.5)	0.303
3. Tolerance of uncertainty "Is able to tolerate uncertainty and postponement without anxiety or upset"**	32.3 (31.6, 33.0)	34.1 (32.7, 35.6)	-1.9 (-3.5, -0.3)	0.024
4. Persuasiveness "Uses persuasion and argument effectively; exhibits strong convictions"**	38.5 (37.9, 39.0)	39.9 (38.4, 41.3)	-1.4 (-3.0, 0.2)	0.076
5. Initiation of structure "Clearly defines own role, and lets followers know what is expected"**	43.2 (42.6, 43.9)	43.9 (42.7, 45.0)	-0.6 (-2.0, 0.7)	0.329
6. Tolerance and freedom "Allows followers to scope for initiative, decision and action"**	37.9 (37.2, 38.6)	38.7 (37.1, 40.3)	-0.8 (-2.6, 0.9)	0.341
7. Role assumption "Actively exercises the leadership role rather than surrendering leadership to others"**	39.3 (38.4, 40.2)	40.1 (38.9, 41.2)	-0.8 (-2.2, 0.7)	0.299
8. Consideration "Regards the comfort, well being, status, and contributions of followers"**	40.1 (39.5, 40.6)	40.8 (39.5, 42.1)	-0.8 (-2.2, 0.6)	0.281
9. Production emphasis <i>"Applies pressure for productive output"</i> **	40.4 (39.7, 41.1)	41.5 (40.4, 42.6)	-1.1 (-2.4, 0.3)	0.109
10. Predictive accuracy* <i>"exhibits foresight and ability to predict outcome accurately"**</i>	19.0 (18.6, 19.4)	18.9 (18.0, 19.7)	0.2 (-0.7, 1.1)	0.713

Subscale Domains	Intervention Average Scores (95% CI)	Control Average Scores (95% CI)	Difference: Intervention vs. Control (95% CI) Average Scores	P-value
11. Integration* <i>"maintains a closely knit organization; resolves inter-member conflicts"**</i>	22.9 (22.4, 23.4)	23.6 (23.0, 24.1)	-0.6 (-1.3, 0.1)	0.089
12. Superior orientation <i>"maintains cordial relations</i> <i>with superiors; has influence</i> <i>with them; is striving for</i> <i>higher status"**</i>	41.4 (40.5, 42.2)	41.6 (40.3, 42.9)	-0.3 (-1.8, 1.3)	0.741

*Scores in these subscales are comprised of 5 questions for a maximum of 25 points. All other subscales are out of 50 points.

**Definitions of the sub-scales are directly from the LBDQ manual[11]

Frontline providers

One-year after trial intervention initiation, 54 frontline providers completed the survey. Providers in intervention group districts reported an average score for quality of guidance and supervision by their district-level managers of 4.19 (95% CI: 3.69, 4.63): an average score ranging between "high quality" and "very high quality" guidance and supervision. In contrast, providers in control group districts reported an average score of 3.08 (95% CI: 2.29, 3.87), which translates to "moderate quality" guidance and supervision. Overall, the average score reported for quality of guidance and supervision was significantly higher among the sample of frontline providers from intervention districts than control districts (average score 1.08 units higher; 95% CI: 0.63, 1.53, p=0.001).

Discussion

In a cross-sectional evaluation of mid-level health managers across Uganda who participated in the SEARCH-IPT trial to increase IPT initiation for persons with HIV, in which the trial intervention provided annual leadership and management training, managers reported more frequent use of leadership and management tools in intervention than control group districts. Furthermore, frontline providers sampled from districts in the trial reported a higher quality of guidance and supervision from managers in intervention compared to control group districts. As previously described, the SEARCH-IPT trial's multi-component intervention resulted in increased IPT knowledge and collaboration among managers. It led to significantly increased IPT initiation rates after accounting for large increases in IPT from a national "100-day IPT push," in Uganda during the trial [6]. The post-trial survey findings of greater use of specific leadership/management tools by managers and higher quality supervision perceived by providers in intervention districts, suggest that improvements in leadership and management contributed to the intervention effects found in the SEARCH-IPT trial.

The increased use of specific leadership and management skills from the 'Mini-MBA' training by the intervention group suggests that the training curriculum provided practical and actionable tools that intervention managers applied in their districts, as intended. Interestingly, control group managers also reported using "Objective, Key, Results" (OKRs) as a leadership/management tool at a high frequency, albeit less frequently than intervention managers. The provision of additional leadership and management tools, such as Kotter's 8-Step Model for Change and the Start/Stop/Continue Retrospective technique, may have expanded the "menu" of tools available to intervention managers and allowed for greater flexibility in their role as leaders and managers. Whereas OKRs and Start/Stop/Continue Retrospective techniques are designed to be simple and easy to use, Kotter's 8-Step Model for Change is relatively more complex and explicitly geared toward implementing changes within organizations in a lasting, sustainable way [7]. Taken together, these findings indicate that although there was some familiarity with leadership/management techniques among both control and intervention managers, our 'Mini-MBA' curriculum of three, one-day courses adapted to a Ugandan context, led to higher reported use of specific leadership and management tools. These tools were acceptable and usable by intervention managers and may have contributed to the higher quality of supervision reported by frontline providers in intervention districts, as well as the intervention effects found in the SEARCH-IPT trial.

In contrast, when using previously established leadership and management questionnaires (the LBDQ and Change Leadership Survey), we did not find significant differences in self-assessed leadership or management skills, apart from one sub-domain in the LBDQ (the Tolerance of Uncertainty sub-domain) in which control group managers reported higher competency than intervention managers. To date, although the LBDQ has been used to evaluate leadership skills across a wide variety of fields (i.e. business [15], education [16], military [17], etc.), its use to evaluate health care providers and managers has been limited. For example, in one study the LBDQ was used to evaluate leadership among cardiopulmonary resuscitation teams, and found an association between enhanced communication and collaboration among resuscitation teams and patient outcomes [18]. One potential explanation for the lack of difference between trial arms in these established questionnaires, despite the leadership and management curriculum provided to intervention group managers, is over-confidence in skills and abilities among control group managers. Specifically, the "Mini-MBA" curriculum may have raised awareness of intervention group managers' areas for improvement or the broader scope of available leadership and management skills and techniques, resulting in relatively lower self-reported skills than

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control group managers: a finding consistent with the Dunning-Kruger effect [19]. As such, the intervention group managers may have underestimated their skills, and/or the control group managers may have overestimated their skills (i.e., not realizing what they do not know), resulting in the lack of significant differences observed.

Despite the lack of differences observed in the LBDQ and Change Leadership Survey, frontline providers overseen by intervention managers reported a higher quality of guidance and supervision compared to providers overseen by control group managers. Studies have found associations between improved leadership and management among supervisors and improved outcomes at the clinic level and more efficient use of resources [20, 21]. In a study based in Kenya and South Africa, the relationship between managers and frontline providers at the subnational level was an important factor in the success of accountability mechanisms and reaching health outcome targets at the clinic level [22]. Our finding that frontline providers in intervention districts noted higher quality of guidance and supervision from their managers reinforces our finding of higher reported use of the "mini-MBA" leadership and management tools among intervention group managers. Though limited to a sample of frontline providers from intervention and control districts, this finding suggests that the leadership and management training component of the SEARCH-IPT multi-component intervention contributed to the higher IPT initiation rate in intervention vs control districts in the SEARCH-IPT trial [6].

This study has limitations. First, our assessment of leadership and management skills in the endof-study survey relied on self-report and, as such, has the potential for reporting bias due to overinflation of skills, which may have biased our results to a null effect. To address this limitation,

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leadership and management assessments were supported by survey data collected from frontline providers overseen by district-level health managers. Second, we collected survey data crosssectionally at the end of the trial, precluding evaluation of change in leadership and management skills over time due to a lack of baseline data. However, any differences at baseline are likely to have been small, with mid-level managers having comparable baseline leadership and management skills, given the randomized study design of the SEARCH-IPT trial.

Conclusion

Leadership and management training provided as part of an intervention for mid-level managers in Uganda was associated with greater reported use of leadership/management tools in intervention compared to control districts and resulted in higher perceived quality of supervision among frontline providers in intervention vs control districts. Together, these findings suggest that improved leadership and management among managers contributed to intervention effectiveness in increasing IPT use among PWH in the SEARCH-IPT cluster randomized trial.

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Chapter IV

Mid-level managers' perspectives on implementing Isoniazid Preventive Therapy for people living with HIV in Ugandan health districts: a qualitative study

Introduction

TB is a leading cause of death among people with HIV (PWH) globally [1]. Isoniazid Preventive Therapy (IPT) reduces TB cases and death, even among PWH on antiretroviral therapy (ART) with suppressed HIV viral load [2, 3]. However, IPT uptake has remained suboptimal in Sub-Saharan Africa and barriers, including supply issues and knowledge gaps, persist [4, 5].

Multiple studies have focused on and identified provider and patient-level barriers to IPT among PWH [6]. Provider-level barriers have included staff shortages, knowledge gaps, communication challenges with patients, and negative attitude/fears surrounding IPT efficacy, side effects and drug resistance [6]. For example, frontline providers in Eritrea described barriers to IPT for people with HIV, including knowledge gaps among providers, particularly around fear of adverse effects of IPT, and inadequate systems for laboratory testing [7]. Patient-level barriers have included knowledge gaps about the benefits of IPT, fear of side effects, HIV/TB related stigma, socio-demographic characteristics (i.e. age, educational level, and sex), lack of motivation, and financial burden, including transportation costs and lost time at work due to time spent in clinic [6]. A study in Kampala, Uganda similarly identified insufficient understanding of IPT and fear of side effects as patient-level barriers to IPT [8]. Less is known about district level health system and mid-level management barriers to scaling IPT for people with HIV.

The SEARCH-IPT cluster randomized trial intervened at the level of district health officers: midlevel managers in the health system of Uganda. Mid-level managers in the health system in Uganda oversee health care delivery in their districts. These mid-level managers bridge the gap between Ministry of Health (MoH) guidelines and practical implementation at the district level. Mid-level managers have been shown to play an important role in implementing evidence-based practices globally [9]. The SEARCH-IPT trial (the primary results of which have been previously published) compared an intervention among mid-level managers to standard practice across multiple regions of Uganda, and found that the mid-level manager intervention led to an increase in the number of patients started on IPT compared to standard practice, after taking into account national secular trends that influenced IPT implementation [10]. The SEARCH-IPT intervention included bi-annual collaborative meetings with district managers to address challenges to scaling IPT, district-level data feedback at each meeting, leadership and management training for mid-level health managers annually, and an SMS platform to ease communication over a 3-year study period.

In this analysis, we sought to identify and describe the mechanisms by which the SEARCH-IPT intervention influenced the abilities of mid-level managers to increase IPT uptake in their districts. We also sought to describe shared barriers faced by both intervention and control managers that were not addressed by the SEARCH-IPT intervention.

Methods

Study design

The SEARCH-IPT study was a cluster randomized trial, where the unit of randomization was a cluster of districts in Uganda. The primary results of the trial and further description of the intervention have been published elsewhere [10]. In brief, we enrolled mid-level health managers beginning in November 2017 and follow-up ended in September 2021. The primary outcome of interest was the initiation of Isoniazid Preventive Therapy (IPT) among adults with HIV. The intervention was based on the PRECEDE model for behavioral change [11]. Predisposing and reinforcing factors of the intervention included collaborative groups where leadership and management skills were taught through a 'Mini-MBA' course over a 3-year period. Study staff shared data on IPT uptake, and other district-level TB metrics, throughout the follow-up period to enable the tracking of progress overtime. Mini-collaboratives met every 6-months, with new leadership and management training material taught annually and reinforced at intervening collaborative meetings.

Data for this analysis were derived from transcripts of annual Focus Group Discussions (FGDs), Key Informant Interviews (KIIs), and participant observation field notes. FGDs and KIIs were conducted annually during the SEARCH-IPT intervention, starting at baseline, through three years of follow-up. Mid-level managers in intervention districts participated in FGDs, whereas a sample of managers in control districts participated in KIIs. KIIs were conducted among control districts instead of FGDs to avoid the creation of collaborative groups (similar to the intervention) among control managers. Study staff conducted participant observations at the majority of mini-collaborative meetings during the SEARCH-IPT intervention.

Study population

The study population includes all mid-level managers (district health officers and district tuberculosis supervisors) who participated in the SEARCH-IPT trial. Details on sample selection in the SEARCH-IPT trial have been published elsewhere [10]. Managers from 25 districts in the Southwest (12 control and 13 intervention districts), 23 districts in the East (11 control and 12 intervention districts), and 34 districts in the East Central (16 control and 18 intervention districts) enrolled. Overall, 163 mid-level managers were enrolled from 82 districts, representing 61% of the districts in Uganda. We conducted 6 FGDs and 23 KIIs over the 3-year study period. At the FGDs, the number of participants ranged from 7 to 12. All FGDs included two cadres of mid-level managers from the SEARCH-IPT trial (district health officers [lead manager] and district-level tuberculosis supervisors [who report to the district health officer]), except the baseline FGDs in the Eastern region, when a separate FGD was conducted among district health officers and district tuberculosis supervisors due to the number of FGD participants. Study staff conducted participant observations at 12 meetings throughout the 3-year follow-up in the southwestern and eastern regions.

Data collection

A team of trained qualitative researchers collected the data. Researchers conducted all FGDs and KIIs in English. All meetings where participant observations occurred were conducted in

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English; field notes were taken to capture discussions. FGDs and KIIs were audio recorded and transcribed verbatim for analysis.

Topic areas of the FGDs included general feedback on the mini-collaborative meetings, how mini-collaborative meetings compared to other meetings supervisors had attended, the most interesting and challenging components of the meetings and cross-district collaboration, the effects of seeing IPT and TB data compared between districts, challenges with IPT delivery and motivations for making change in their districts. KIIs consisted of semi-structured interviews using open-ended questions. Topics covered in the KIIs included discussion of the burden of TB in their districts, standard TB control practices, challenges related to IPT delivery, changes to TB prevention policy, and motivations for change in their district. Focus groups lasted between 71 – 147 minutes (average = 111 minutes) and the KIIs lasted 17 – 76 minutes (average = 37 minutes); in the results below, individual participants in FGDs are denoted ('P1', 'P2', etc.). Study staff developed participant observation field notes from observations at meetings, including general observations of the conduct of the meeting, interactions between participants and study staff, as well as some direct quotes from the participants.

Data analysis

Dedoose qualitative software was used to analyze data from FGDs, KIIs, and participant observation reports. A framework analysis approach, which falls within the qualitative research tradition of thematic analysis, was used for this study [12]. We used a hybrid approach to code the data, involving both *a priori* codes that were informed by theory, and focused inductive coding, in which the categories of meaning were derived directly from review of the empirical

data. For the development of the initial codes, the first author conducted focused inductive coding on the sample of transcripts (approximately 20% of the data), developed the initial coding framework, then applied the framework to the remainder of the data [13-15]. The *a priori* codes were informed by a set of theories, including diffusion of innovation theory [16] and social learning theory [17]. Following the inductive coding phase, the first author and last authors developed an analytical framework based on the initial set of transcripts, the sample of data, and categories of grouped codes. The first author then applied the codes to the remaining transcript data using the identified codes and categories. The first and last author developed framework tables for reducing and synthesizing data, as described by Gale (2013), and with subsequent interpretation, including across-case analysis to identify the emergent themes presented here [12].

Ethical approval

Institutional Review Boards at the School of Medicine Research and Ethics Committee at Makerere University School of Medicine, the University of California, San Francisco, and the Uganda National Council for Science and Technology approved this study. Prior to study activities, all study participants provided written, informed consent.

Results

Four overarching themes emerged from the data when mid-level managers discussed factors that either enabled or impeded them from making positive changes in their districts: agenda setting, collaboration, availability of resources, and motivations (Table 4.1). When discussing factors that enabled positive outcomes, intervention managers described feeling ownership over interventions, supported by the leadership and management training they had received, and the importance of collaboration. In contrast, when discussing factors that impeded their ability to make changes, intervention and control managers described external funders setting agendas, lack of collaboration in some meetings, inadequate supplies and staffing, and lack of motivation among frontline providers. Quotes and elaboration of these themes are below.

Table 4.1. Key themes and sub-themes identified by mid-level managers in Uganda to implementing changes for IPT uptake in the SEARCH-IPT trial

Themes	Sub-theme
Barriers and enablers identified by intervention managers	
Agenda	• Managers feeling of ownership over local strategies to promote IPT
Setting	• Power to set agendas impeded by external funders and implementing partners*
Collaboration	 Collaborating with other districts enabled sharing of best practices Positive effect of the pressure of social comparison and recognition
	 Collaboration within districts between cadres of mid-level managers (district health officers and district tuberculosis supervisors) enabled scaling of IPT
	• Ministry of Health meetings were top-down and did not facilitate collaboration or district input
Barriers and enablers shared by intervention and control managers	
Availability of	• Inadequate INH stocks and inconsistent supplies was a barrier to
resources	IPT uptake
	• Collaboration within districts and with other districts to redistribute available supplies
	 Frontline provider turnover and knowledge gaps was a barrier for scaling IPT
Motivations	• Managers motivated by improving the health of their constituents
	• Lack of motivation of frontline providers was a barrier to IPT uptake
	• Lack of political leadership and prioritization of IPT scale up

*Described as an enabler in intervention districts, and as a barrier by control managers.

Agenda Setting

Managers feeling of ownership over local strategies to promote IPT

The trial intervention's leadership and management training curriculum provided several tools, taught in interactive sessions with coaching by international business professionals and Uganda HIV/TB expert clinicians. These tools were designed to identify challenges managers faced and to develop strategies to overcome these challenges and accomplish their goals. During all focus group discussions (FGDs) with managers in the intervention group (6 of 6 FGDs), managers mentioned the feeling of ownership over local strategies to promote IPT as motivation for scaling IPT in their districts. Many of these local strategies were developed by managers during collaborative meetings as part of the trial intervention. This manifested in a sense of independence in deciding how change was enacted in one's district to realize a goal: in this case, the scaling of IPT.

P8: To me I can say that it is motivational because you can identify the problem yourself.
It motivates you to actually look at the problem yourself, and put in place strategies.
P7: And you take the charge, you become responsible, you feel it is yours. – Focus Group
Discussion (FGD) at 2 Year Follow-up with trial intervention district health officers in
the Southwest

Managers discussed the expected long-term sustainability of the SEARCH-IPT intervention after trial completion, in part because the intervention promoted the use of available resources and the mid-level managers' self-motivation to take ownership of local strategies they developed to promote IPT. For example, an intervention manager in the East said, *"This has made us use the*

resources that we have, which means if [the SEARCH-IPT study] is not to be there, the implementation with IPT would go on."

Power to set agendas impeded by external funders and their implementing partners

However, managers also felt that the role of external funders and implementing partners counteracted their sense of control and ownership. During 4 of 6 FGDs (67%) and 11 of 23 KIIs (48%), managers discussed the roles that implementing partners play in scaling IPT in their districts, including implementing strategies to improve health, allocating funding, and establishing trainings. This finding contrasted with the intervention managers' discussion of the benefits of independence in deciding how change is enacted in one's district to realize the goal of scaling IPT. Intervention and control managers described frustration with implementing partners setting the agenda and determining what steps to prioritize to improve IPT implementation, particularly concerning funding allocation and local intervention strategies.

Some [Implementing Partners] come to support activities, say for TB programs, when as a district, you have other areas that need support because at the district, you know your problems more than these [Implementing Partners] do. But when they come at the district, they tell us that they are going to support this and this program, but we tell them 'please, me I want support in this and this'. - FGD at 3 Year Follow-up with trial intervention district health officers and district tuberculosis supervisors in Southwest

An intervention manager argued that managers should not always be dependent on the implementing partners: *"If you have issues in your house, you do not expect another man to keep*

coming to solve them; implementing partners should not be depended on. "– Participant observation field note at the trial intervention baseline meeting in Southwest Uganda.

Intervention managers also reported challenges associated with losing funding for a particular project or support for activities and how that made it difficult to plan and execute TB prevention and TB treatment.

You find that when the [Implementing Partner] moves, they move with the program or projects... They tell you that in the next two months, they will not be supporting you in this program because the donors have withdrawn the money and the district does not have the money to take over the program that this [Implementing Partner] has been managing and you find yourself in a mix. – FGD at 2 Year Follow-up with trial intervention district health officers in Southwest

Collaboration

Collaborating with other districts enabled sharing of best practices

Managers discussed ways in which the intervention helped them to cope with or devise strategies to address challenges. Intervention managers mentioned collaboration with other districts as an enabler to IPT uptake in all FGDs (6 of 6, 100%). This included the discussion of how mini-collaborative meetings in the SEARCH-IPT trial helped with troubleshooting challenges and developing implementation strategies to address IPT uptake.

You find that your colleagues share best experiences of how they have carried out an activity... It motivates you to say 'I can also do it.' If a certain district can perform to this level, then I can also improve. - FGD at 2 Year Follow-up with trial intervention district health officers in Southwest

Positive effect of the pressure of social comparison and recognition

Intervention managers discussed being motivated to improve IPT uptake in their district by comparisons to other districts during the study intervention. During the mini-collaborative meetings, study staff presented dashboards to each district that included quarterly data from the Ministry of Health on TB cases and the number of people with HIV started on IPT. Researchers tracked progress over time and presented an anonymized summary of progress to the group during the meeting, which enabled each district to see how they compared to other districts without sharing which districts fell on the ranking. During the meetings, managers were trained on tools for setting short- and long-term objectives and key results (OKRs) which allowed them to set goals and monitor progress and discuss their goals as a group. A manager in an intervention district in the Southwest said, *"If you are there alone, you may think that you are doing very well or you may think that this is not important. But after sitting as a team, you see how [a different district] is doing and you realize that 'I am sleeping.'"*

Similarly, control managers discussed wanting feedback to be able to make these comparisons so they could better understand how other districts are faring in the scaling of IPT. A manager in a control district in the Southwest said, *"I would like to have frequent feedback, so that we can be able to know how we stand, because internally I might be thinking that I am doing well in my* district when actually my neighbors are doing better, and so eventually I could learn from them."

Both intervention and control managers reported being motivated by accountability and recognition as a key driver to scaling IPT. For example, a manager from an intervention district in the Southwest said, *"There is a way you can feel motivated, and you will say, yes I can continue doing this because you are being appreciated; your achievement is being noticed somewhere."*

Collaboration within districts between cadres of mid-level managers (district health officers and district tuberculosis supervisors) enabled scaling of IPT

One positive effect of the trial intervention was improved collaboration and alignment of priorities between district health officers (i.e., lead manager in each district) and district TB supervisors (i.e., TB-specific managers that report to lead managers), supported by the leadership and management training provided in the SEARCH-IPT intervention. This improved within-district collaboration and generated buy-in and support from the district health officer for TB-specific manager activities. Participants discussed the importance of this support, resulting in greater ease in addressing inadequate IPT uptake.

For example, I am a [district tuberculosis supervisor]. However, the people that I supervise, I do not have absolute power or authority towards them and say 'you have not done the work'. But... when a big drum like the [district health officer] talks about something people tend to pick it up... Now that would also give us power as the [district tuberculosis supervisors]; you also stand firm because people will hear you because of

your boss. - FGD at 1 Year Follow-up with trial intervention district tuberculosis supervisors in East

Control managers also mentioned that the involvement of the district health officer in their district may help make changes in their district. A manager in the East said, "*I feel if the [district health officer] is involved much, the other frontline health workers will be taking my words a bit more seriously.*"

Ministry of Health meetings are top-down and did not facilitate collaboration or district input

Additionally, intervention managers discussed the benefits of collaborating with neighboring districts and taking leadership roles at the mini-collaborative meetings. Participants compared the intervention meetings to meetings held by the Ministry of Health and other entities where they perceived meetings to be more directive or "top-down". An intervention manager in the Southwest said, "[Ministry of Health meetings], it is do this, do this; it is like a directive. But here [at the collaborative meetings] we look at what had been done and we suggest on how to improve, on how to go and implement."

Availability of Resources

Inadequate INH stocks and inconsistent supplies was a barrier to IPT uptake

Managers in intervention and control districts frequently mentioned inadequate resources as barriers to IPT uptake, including insufficient drug stock. For example, an intervention manager in the Southwest said, "*The truth is that we created demand. But over time, the supplies we had* *for adults were nowhere to be seen.* "There was also a discussion about how inadequate stock not only interrupts the prescription of IPT in the near term but also affects the long-term uptake of IPT. When frontline providers remove IPT from regular prescribing practices due to frequent stockouts, they are slow to prescribe it when IPT does become available because it is not what they have been doing routinely.

If you really know that this [IPT prescribing] is 'what I am supposed to do' and you are not interrupted by [INH] stock outs... but when there is a stock out, people [front line providers] again forget that 'this is what I am supposed to do routinely'. Then the medicine[s] come, [but] people again relax and they are not taking it as part of what they are supposed to do. So, that makes it difficult. - FGD at 1 Year Follow-up with trial intervention district tuberculosis supervisors in East

There were also discussions of challenges with requesting stock from Uganda's centralized National Medical Stores (NMS) as a barrier to IPT uptake. Clinic staff may not request stock because they are used to a 'push' system for certain drugs where the NMS allots drugs to clinics without clinics placing orders. However, the system for IPT is different, as it requires the clinic to order medication (i.e., a "pull" system). Managers suggested training on proper ordering may be beneficial to mitigating this barrier.

Delivery of [IPT] depends on facilities because it's a 'pull' system with TB drugs and [IPT]. If a facility doesn't make an order in two months, it will not get the supply... This has come maybe from knowledge gap in ordering. And some facilities are used to the 'push' system, like essential drugs, and that's where the problem is. - KII at 2 Year Follow-up with a control TB-specific Manger in East

Intervention and control managers also mentioned inadequate funding limited their ability to access clinics due to a lack of transportation and lack of fuel. One intervention manager in the Southwest said, *"Initially we had some programs that were giving out motorcycles, but then the challenge was that when they give you a motorcycle, then fuel becomes an issue."*

Intervention and control managers also perceived insufficient staffing as a barrier to IPT. One manager in a control district in the East said, "*the challenge in handling TB/HIV is really understaffing*."

Collaboration within districts and with other districts to redistribute available supplies

Intervention and control group managers discussed resourcefulness in redistributing IPT stock to maximize the use of available stock in their district and region. Intervention group managers mentioned redistribution within districts (i.e., between health centers) as well as between districts, reflecting efforts of the SEARCH-IPT trial intervention to promote between-district collaboration, whereas control group managers mentioned redistribution within their districts.

We also discovered that some facilities with [IPT] were over stocked and this made us to do some re-distribution and take [IPT] to facilities where the consumption was high. – FGD at 1 Year Follow-up with trial intervention district health officers in East

Frontline provider turnover and knowledge gaps was a barrier for scaling IPT

Another perceived resource-related barrier to IPT uptake included gaps in frontline providers' knowledge of IPT. This included providers lacking confidence in prescribing IPT due to

inadequate training or supervision. For example, a control manager in the East said, "Some health workers didn't have the knowledge [of IPT] so they would even fear to initiate clients for fear of the side effects."

Managers also perceived the turnover of frontline providers, resulting in new replacement frontline providers with inadequate training in prescribing IPT, as a barrier.

The main challenges we have are experience in the sites where IPT is given, for instance you go to such a site and mentor a number of staff who are working in that clinic, and maybe two, three months down the road, transfers happen and a particular provider has been moved to another facility, and most times you find it is from high to low volume site, meaning that the capacity we will have built in that person goes to another site that is actually not offering this service. So, we tend to have issues of knowledge gaps created by transfers, whereby the trained person has been moved, and the one coming in is not well oriented, meaning that we have to continuously do mentorships in such clinics if we are to keep the standards. – KII at 2 Year Follow-up with control district tuberculosis supervisors in Southwest

Motivation

Managers motivated by improving the health of their constituents

Many intervention and control managers reported being motivated by positive health outcomes in their districts. Participants discussed seeing improvements in patients' health as a motivation to work hard in their positions. A manager in an intervention district in the Southwest said, "They come to you in pain, they are crying but by the time they leave you, they are smiling and you see their quality of life improving day by day. That is good enough to make you say that I can even take an extra mile to do this other thing."

Lack of motivation of frontline providers was a barrier to IPT uptake

In contrast, participants perceived frontline providers' negative attitudes as a challenge in scaling IPT. Managers said frontline providers are reluctant to be close to contacts of known TB cases and those who may be eligible for IPT due to fear of being infected with TB. A manager from an intervention district in the East said, "*The issues of attitude in case the frontline health workers, [when they] hear about TB, they may not even wish to go near the patient because they think they should first have a mask before they treat, so even if we say this is a TB contact, they even want to disassociate themselves with the contact.*"

Lack of political leadership and prioritization of IPT scale up

Lastly, another motivational barrier was a perceived lack of political leadership to scaling IPT. Intervention and control managers discussed the importance of galvanizing politicians, community leaders, and clinic-in-charges to scale IPT. They described the lack of political will as demotivating in their work to improve health outcomes because of feeling unsupported.

If you have supervisor, in this case I am talking about the political leadership of the local government and they are blinded, they cannot hear. Even if you play the best tune, they cannot dance to it because they are deaf and blind, they do not see what you are seeing

and yet they are your supervisors. - FGD at 1 Year Follow-up with trial intervention district health officers in Southwest

Both intervention and control managers mentioned politics influencing the uptake of IPT, including agenda setting and political will for the scaling of IPT. One control manager in the East said, "We have a lot of political interference and that is quite discouraging. You want to do things in a certain way and without any reasonable reason, somebody who doesn't even know what he is talking about wants you to do things just to suit his political interests."

Discussion

This qualitative study provides insights into the perceptions of mid-level managers in the Ugandan health system on the barriers and facilitators to increasing IPT uptake. This study also highlights the mechanisms by which the SEARCH-IPT trial's intervention may have impacted IPT uptake among people with HIV (the trial's primary outcome), by comparing perspectives of intervention to control managers who participated in the trial. We found that the SEARCH-IPT intervention, which included leadership and management training, allowed managers to design and implement strategies to improve IPT uptake in their districts, in contrast to the 'top-down' approach perceived by managers to be typical of external funders and implementing partners. Other features of the SEARCH-IPT intervention that enabled IPT uptake included collaboration between districts and the positive impact of accountability through comparing performance with other districts at the meetings. In addition, resourcefulness through the strategic redistribution of resources was employed by both intervention and control managers to scale IPT while dealing with inadequate supplies, though intervention managers relied on the cross-district collaboratives

created by the SEARCH-IPT intervention, rather than just within-district redistribution as reported by control managers, to address this challenge.

Health managers' ownership of locally generated implementation strategies was a motivational enabler to scaling IPT, in contrast to a top-down approach of agenda setting. While the evidence of the effects of decentralization on health systems is mixed [18], strengthening district governance and decision-making have shown promise [19-21]. In Uganda, research has demonstrated that mid-level health managers have felt limited in their abilities to make changes [22]. In contrast, the SEARCH-IPT intervention allowed managers to have greater ownership and creativity in developing local strategies to promote IPT, supported by leadership and management training, by using available resources to maximize uptake. Managers discussed that this approach was likely to have lasting effects and potential sustainability, compared to "top down" strategies.

Intervention managers were also motivated by accountability and comparisons between districts at the collaborative meetings. This is consistent with findings from other studies which focus on decentralization and the shifting of accountability and monitoring progress toward mid-level managers [20]. The Community and District-management Empowerment for Scale-up (CODES) study in Uganda focused on aiding districts in identifying health system bottlenecks for child health. The CODES intervention provided data to managers in participating districts to better monitor and address health system challenges and showed positive effects of the intervention on child health outcomes [20]. Accountability and monitoring of data were likely to be key factors in the success of the SEARCH-IPT and CODES studies in Uganda [10, 20].

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Managers frequently mentioned the lack of sufficient supplies, including IPT stock, funding for transportation, and inadequate staffing as barriers to scaling IPT in Uganda. These findings are consistent with other initiatives focused on improving district management of health interventions in Uganda [23]. Despite implementing partners providing funding and resources, the managers described frustration in not having control over which implementation strategies were funded. In contrast, the SEARCH-IPT study approach focused on shifting decision-making power to the district managers who were able to develop their own strategies to reach their goals, supported by management training and tools. Managers discussed being aware of deficits in resources available in their districts and felt that having more input into spending would help in addressing these gaps. In addition, the SEARCH-IPT intervention allowed for collaboration among managers from other neighboring districts, aiding managers in identifying solutions to shared challenges, and within shared contexts, among peers.

This study has limitations. This study did not involve stakeholders outside district health officers or district tuberculosis supervisors, such as decision-makers from implementing partners, frontline providers or other members of the Ministry of Health outside of mid-level managers. However, we collected data from district health officers and district tuberculosis supervisors over three years, providing a breadth of experience working in this space. Additionally, while this study included managers across three regions of Uganda, the results may not be generalizable to other regions in Uganda, or other national health systems. However, the perspectives of midlevel managers have not been fully captured when evaluating barriers and enablers to IPT in the past [6] and this study is among the first to provide insight into their experiences.

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Our findings suggest that involving mid-level health managers in decision-making, supported by leadership and management training, may allow managers to have a greater sense of ownership in achieving goals in their districts. Creating a space for regional collaboration and comparison may galvanize managers to improve outcomes and allow for sharing of successful interventions.

Conclusion

In Uganda, mid-level managers' perceptions of barriers to scaling IPT include limited power to set agendas and control funding, inadequate resources, lack of motivation of frontline providers, and lack of political prioritization. We found that the SEARCH-IPT intervention, composed of leadership and management training and inter-district collaborative groups, enabled managers to design and implement strategies to improve IPT uptake, which may have contributed to the overall positive intervention effect in increasing the uptake of IPT among people with HIV.

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Chapter V

Conclusion

Overview of findings

The findings of this dissertation provide evidence supporting the effectiveness of two implementation science interventions to promote HIV and TB prevention in Uganda that intervene at the individual and regional-level, respectively (Figure 1.1). In this dissertation, I determined the feasibility and preliminary effectiveness of integrating HIV prevention into youth clubs implementing empowerment and livelihood training for adolescents (ELA) in rural Uganda. Integration of HIV prevention services into the established ELA curriculum at mentorled youth clubs in rural Uganda was feasible, and PrEP uptake increased among sexually active adolescent girls and young women during the intervention [1].

I also sought to evaluate the components of the SEARCH-IPT intervention to better understand how the intervention led to increased uptake of IPT among adults living with HIV in Uganda [2]. These analyses first involved assessing leadership and management skills among district-level health managers in Uganda participating in the SEARCH-IPT randomized trial. We found that leadership and management training increased the use of leadership/management tools among mid-level managers. Additionally, this training resulted in higher perceived quality of supervision among frontline providers in intervention vs. control districts in Uganda.

Lastly, I sought to identify the barriers mid-level managers face in scaling IPT in Uganda and the mechanisms by which the SEARCH-IPT trial intervention influenced their abilities to increase

IPT uptake. In Uganda, mid-level managers' perceptions of barriers to scaling IPT included limited power to set agendas and control over funding, inadequate resources, lack of motivation of frontline providers, and lack of political prioritization. However, we found that the SEARCH-IPT intervention allowed managers to design and implement strategies to improve IPT uptake and collaborate between districts which may have contributed to the overall intervention effect in increasing the uptake of IPT among people with HIV compared to standard practice.

Together the findings of the assessments of the SEARCH-IPT intervention suggest that the effect of analyzing data and tracking progress toward goals through mini-collaborative meetings, a shared sense of purpose through collaboration with colleagues, and bolstered used of leadership and management tools taught in the 'mini-MBA' curriculum, may have led to increased uptake of IPT among adults living with HIV in the districts overseen by managers in the intervention group. The importance of the collaborative nature of this intervention in scaling IPT is consistent with literature on the importance of social networks in Master of Business Administration (MBA) programs in team effectiveness, performance, and overall benefit of the MBA training [3, 4].The findings from chapter 3 and 4 of this dissertation suggest that greater quality of leadership and management, in conjunction with collaboration with other districts to allow for sharing of resources and best practices, enabled mid-level managers to make progress toward scaling IPT in their districts.

Translation of findings to action

The findings presented in this dissertation can be translated into action through further evaluation of these approaches in other settings and can inform ongoing efforts to prevent HIV and TB

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globally. This includes informing strategies employed by NGOs, similar to the BRAC organization, and country-level efforts to strengthen leadership and management skills among managers in health systems.

Integration of HIV prevention into youth clubs

The evidence from this dissertation suggests that integrating HIV prevention curriculum into existing youth clubs is feasible and shows preliminary effectiveness in increasing the uptake of HIV prevention services. While interventions involving income-generating activities have shown promise [5], to date, few studies have used these types of interventions to improve PrEP uptake among high-risk youth [6]. Given the findings of this pilot on the preliminary effectiveness of integrating HIV prevention, including PrEP and PEP access, to youth in an empowerment and livelihood training, researchers should further explore these types of interventions. Incorporating biomedical HIV interventions into existing youth club programs and income-generating activities across the globe has the potential to prevent HIV among high-risk youth.

Organizations running existing youth clubs may be able to use this study as a model to incorporate HIV prevention into their clubs. The BRAC ELA curriculum has been taught in Uganda, Tanzania, South Sudan, Liberia, and Sierra Leone [7]. The ELA curriculum has covered sexual and reproductive health and an empowerment curriculum, but until this research project, it had not incorporated HIV prevention. The breadth of the BRAC organization globally provides the potential to scale this intervention to other BRAC clubs teaching the ELA curriculum.

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The findings from this dissertation show the preliminary effectiveness of the club-based model for getting youth engaged in care. This pilot also sought to create a youth-friendly environment by using peer mentors to deliver the curriculum content. As demonstrated by this research, using a peer model can potentially improve PrEP uptake among youth. This finding is consistent with other studies in SSA, which have found that peer-led strategies and youth-friendly environments are beneficial for PrEP uptake [8, 9]. Youth-friendly interventions for sexual and reproductive health have shown that having convenient hours and being close to their home also help engage youth in care for sexual and reproductive health [10]. This research can provide a model for incorporating HIV prevention into similarly structured youth clubs to promote empowerment.

The findings of this study are consistent with other studies that have used youth clubs to promote HIV prevention [11]. These findings suggests that NGOs and multilateral organizations should consider using this intervention as one part of multi-component approaches to improve the uptake of HIV prevention interventions among youth in SSA.

Training-of-trainers curriculum for the leadership and management: SEARCH-IPT Phase II

The findings from Chapter 3 & 4 of this dissertation suggest that improved leadership and management among managers contributed to increased uptake of TB preventive therapy in intervention districts in the SEARCH-IPT trial. Leadership and management trainings, designed and taught by global business leaders and adapted to a Ugandan context by our study team, are an integral component of the SEARCH-IPT intervention. The skills taught during these sessions were packaged into a curriculum (referred to as a "Mini-MBA" course) which included Kotter's 8-step model for change, Objective Key Results (OKRs), Start Stop Continue retrospective, and

Gap Analysis [12, 13]. Managers use these methods to set goals, monitor progress, and achieve desired results in addressing health challenges in the districts of Uganda. While these methods have been used extensively in business strategy and the private sector, to our knowledge these skills have yet to be deployed at scale for public health interventions.

To maximize the SEARCH-IPT intervention's impact and translate these findings into action, scale-up and sustainability are essential. Training-of-trainer (ToT) programs have been successful in transferring knowledge sustainably by scaling up interventions through a training cascade [14, 15]. ToT models have been used in various settings for public health interventions and have shown promising results in the ability to transfer knowledge and skills from master trainers to a new cadre of trainers [16-18].

Following the findings of the first Phase of SEARCH-IPT, the study investigators used the 'TRAIN' framework (Talent, Resources, Alignment, Implementation, Nurture) to develop and implement a ToT curriculum explicitly designed for transferring the 'Mini-MBA' curriculum from the master trainers (global business leaders) to middle management in the Ugandan health system (DHOs) [19]. The DHOs then taught their District Health Teams using the 'Mini-MBA' curriculum during existing quarterly meetings. This model of scaling the curriculum to other members of the district health management team can be emulated in different health systems. In addition, using the ToT model will enable the sustainability of the intervention, after the initial trainings of the trainers.

Generalizability of results

Engagement of youth in care

This research shows promise for individual-level implementation science projects focused on infectious disease prevention. Specifically, this research provides the basis for a methodology for reaching and engaging youth in HIV prevention, a high-risk population that has historically been difficult to engage in care. While this study focused only on youth in rural Uganda, these findings provide the basis for a feasible and effective way to engage youth in care in other regions in eastern Africa as well as across the globe.

Decentralization and district level management for health system strengthening

Leadership and management training among health system mid-level managers has the potential to improve health services and health outcomes at the population level [20]. The findings of this dissertation can apply to other health systems in resource-limited settings where the health system can be bolstered through improved leadership and management, particularly in settings where mid-level managers have increasing power in the decision-making process for health.

Many health systems across SSA, South Asia, and the world are shifting toward a decentralized structure. While the evidence of the effects of decentralization on health systems is mixed [21, 22], strengthening decision-making and governance among district managers has shown promise [23, 24] and will be critical to supporting decentralization. Given country health systems are

shifting toward a system where district and regional managers have more decision-making power, bolstering leadership and management skills has the potential to lead to a more efficient management system, increased capacity for positive change, which in turn can lead to improved population health outcomes [20].

How this research moves the field of public health

This research moves the field of public health by contributing to the body of research on implementation science and infectious disease prevention. Given the medications available to prevent HIV and treat latent TB, the next step is to get these medications to those who need it most. This research provides evidence on two interventions that address individual-level and district-level interventions to improve the uptake of proven preventive medications. This dissertation can provide a basis of information for further research and can help inform regional or national strategies to address gaps in infectious disease prevention.

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Appendix

Change Leadership Questionnaire - *Modified from Gilley (2005)* [1]

Skill Area: Visionary

- 1. I have a "leader vision" of health services in my district, including its potential and capabilities.
 - 1. Rarely
 - 2. Sometimes
 - 3. Frequently
 - 4. Always
- 2. I am creative, able to envision that which does not yet exist.
 - 1. Rarely
 - 2. Sometimes
 - 3. Frequently
 - 4. Always
- 3. I draw people in and build networks of people working toward a common goal.
 - 1. Rarely
 - 2. Sometimes
 - 3. Frequently
 - 4. Always
- 4. I am confident in my ability to lead others.
 - 1. Rarely
 - 2. Sometimes
 - 3. Frequently
 - 4. Always
- 5. I willingly and enthusiastically share the purpose and vision of the health department of my district to ensure that the health workers I supervise "own the vision".
 - 1. Rarely
 - 2. Sometimes
 - 3. Frequently
 - 4. Always

Skill Area: Inspirer

- 1. I allow health workers in my district to participate in the development of the district's health vision.
 - 1. Rarely
 - 2. Sometimes
 - 3. Frequently
 - 4. Always
- 2. I work collaboratively with health workers in my district to accomplish the district's health goals and objectives.
 - 1. Rarely
 - 2. Sometimes
 - 3. Frequently
 - 4. Always
- 3. I am the first to incorporate new ways and change into my daily routine.
 - 1. Rarely
 - 2. Sometimes
 - 3. Frequently
 - 4. Always
- 4. I help people to see "what's in it for them" with regard to impending change.
 - 1. Rarely
 - 2. Sometimes
 - 3. Frequently
 - 4. Always
- 5. My behaviors are consistent with my words.
 - 1. Rarely
 - 2. Sometimes
 - 3. Frequently
 - 4. Always

Skill Area: Supporter

- 1. I identify and eliminate barriers to change within my district.
 - 1. Rarely
 - 2. Sometimes
 - 3. Frequently
 - 4. Always

- 2. I encourage people to share their opinions, concerns, and suggestions for improvement.
 - 1. Rarely
 - 2. Sometimes
 - 3. Frequently
 - 4. Always
- 3. I am an advocate for my health workers and pursue needed resources aggressively.
 - 1. Rarely
 - 2. Sometimes
 - 3. Frequently
 - 4. Always
- 4. I develop a solid communication pattern with health workers in my district in terms of frequency and depth.
 - 1. Rarely
 - 2. Sometimes
 - 3. Frequently
 - 4. Always
- 5. I hold myself accountable for the performance of my health workers and the success of our projects.
 - 1. Rarely
 - 2. Sometimes
 - 3. Frequently
 - 4. Always

Skill Area: Solver

- 1. I am able to gather data, draw conclusions, propose and assess alternatives, and recommend viable solutions.
 - 1. Rarely
 - 2. Sometimes
 - 3. Frequently
 - 4. Always
- 2. I demonstrate resourcefulness in my approaches to new and existing problems or opportunities.
 - 1. Rarely
 - 2. Sometimes
 - 3. Frequently

- 4. Always
- 3. I work collaboratively with health workers to evaluate the status of change efforts and modify as needed.
 - 1. Rarely
 - 2. Sometimes
 - 3. Frequently
 - 4. Always
- 4. I think "outside the box" and encourage the same in others.
 - 1. Rarely
 - 2. Sometimes
 - 3. Frequently
 - 4. Always
- 5. I think broadly to generate alternatives and engage in thorough analysis of what strategies are possible to implement.
 - 1. Rarely
 - 2. Sometimes
 - 3. Frequently
 - 4. Always

Skill Area: Change Manager

- 1. I understand the immense complexities of change, including planning, implementation, and human reactions.
 - 1. Rarely
 - 2. Sometimes
 - 3. Frequently
 - 4. Always
- 2. I openly communicate with health workers to meet their needs and help them work through change.
 - 1. Rarely
 - 2. Sometimes
 - 3. Frequently
 - 4. Always
- 3. I work with health workers to collaboratively set realistic, challenging, yet attainable goals and expectations.

- 1. Rarely
- 2. Sometimes
- 3. Frequently
- 4. Always
- 4. I understand that resistance to change is natural yet can be overcome.
 - 1. Rarely
 - 2. Sometimes
 - 3. Frequently
 - 4. Always
- 5. I understand the importance of goal setting and its relationship to health worker motivation.
 - 1. Rarely
 - 2. Sometimes
 - 3. Frequently
 - 4. Always

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