# Effects of on-site support in improving the quality of care for infectious diseases

Dissertation submitted for the degree of Doctor in Medical Sciences at the University of Antwerp to be defended by

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Antwerp 2018

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**Cover picture.** IDCAP Mentor during on-site support. Photo courtesy of IDCAP.

# Table of Contents

## TABLE OF TABLES



## TABLE OF FIGURES

**LIST OF ACRONYMS**

| | |
|---|---|
| Accordia | Accordia Global Health Foundation |
| ACT | Artemisinin-based Combination Therapy |
| ART | Antiretroviral therapy |
| CI | Confidence Interval |
| CQI | Continuous Quality Improvement |
| DHIS2 | Digital Health Information Software 2 |
| EDS | Electronic Data System |
| ETAT | Emergency Triage and Treatment |
| Global Fund | Global Fund to Fight HIV, TB and Malaria |
| HCIV | Health Center IV |
| HCWs | Healthcare workers |
| HMIS | Health Management Information System |
| HIV | Human Immunodeficiency Virus |
| IDCAP | Integrated Infectious Diseases Capacity Building Evaluation |
| IDI | Infectious Diseases Institute, Makerere University |
| IHI | Institute for Healthcare Improvement |
| IMAI | Integrated Management of Adult Illnesses |
| IMCI | Integrated Management of Childhood Illnesses |
| IMID | Integrated Management of Infectious Diseases |
| I-TECH | International Training and Education Center for Health |
| JUMP | Joint Uganda Malaria Program |
| LLW | Lessons learned workshop |
| LMIC | Low- and middle-income countries |
| MLP | Mid-level practitioners |
| MF5 | Medical Form Five |
| NGO | Non-governmental organization |
| NMCP | National Malaria Control Program |
| OR, aOR | Odds Ratio, adjusted Odds Ratio |
| OSS | On-Site Support |
| OTSS | Outreach training and supportive supervision |
| PEPFAR | United States President's Emergency Plan for AIDS Relief |
| PMI | United States President's Malaria Initiative |
| PMTCT | Prevention of mother-to-child transmission of HIV |
| PSI | Population Services International |
| RDT | Rapid diagnostic test |
| RR,aRR | Relative Risk, adjusted Relative Risk |
| RRR, aRRR | Ratio of Relative Risk, adjusted Ratio of Relative Risk |
| SARA | Service Availability and Readiness Assessments |
| SDI | Service Delivery Indicators |
| SMS | Short messaging service |
| SOMREC | Makerere University School of Medicine Ethics and Research Committee |
| SPA | Service Provision Assessments |
| SSA | Sub-Saharan Africa |
| TB | Tuberculosis |
| US | United States |
| USAID | United States Agency for International Development |
| WHO | World Health Organization |

## SUMMARY

Despite recent scale-up of highly effective interventions and declines in deaths due to infectious diseases, HIV, TB and malaria continue to have a disproportionate impact on sub-Saharan Africa (SSA). In this context, the failure to attain expected improvements in infectious disease control is increasingly being linked to poor quality of care. Governments, donors and organizations aiming to improve quality of care are more frequently turning to on-site support (OSS), a broad term used to describe interventions that take place within a health worker's facility and are designed to improve health care worker capacity. For these capacity development programs to be as effective as possible, we need higher quality studies that are focused on infectious diseases in the SSA region and that also compare their relative effectiveness and costs.

The goal of this dissertation was to evaluate the effectiveness of OSS on the management of HIV, TB and malaria in SSA. In a randomized controlled trial, we demonstrated that OSS alone, without other interventions, can improve laboratory staff's ability to conduct HIV rapid testing, TB sputum microscopy and malaria microscopy (Chapter 2). We also found that training combined with OSS may be more effective at improving clinical practices than training alone (Chapter 3). OSS held nine months after an initial training was found to be as effective in improving health facility indicators as OSS held immediately post-training and that bi-monthly visits effectively maintained gains in facility performance (Chapter 4). Also, integrating TB and HIV services, as a component of OSS interventions is associated with reduced mortality (Chapter 5). Finally, use of an electronic tool to guide OSS improved data quality and data use for a malaria case management program, although at a higher cost per visit when compared with a paper-based system (Chapter 6).

We provided evidence that health worker capacity building interventions can be effectively integrated across diseases to simultaneously improve provider practice and facility performance. However, the number of targeted diseases and indicators was related to the magnitude of improvement. Interventions that focused

on fewer diseases and indicators tended to have a more marked increase across their more limited scope. Those with a higher number of diseases and indicators had improvements among a subset of indicators. Other factors we identified that may impact the rate of improvement during OSS include the disease(s) targeted and the frequency and duration of the intervention.

To address the tension between programmatic depth and breadth, we proposed two new models of integrated OSS and made recommendations for improving OSS implementation. The proposed models of integrated OSS are structured integration and diagonal integration. In the structured integration model, health facilities sequentially work to improve the quality of care for one to two diseases and one to four indicators at a time. In the diagonal integration model, routine health systems supervision visits are layered with targeted disease-specific visits. We also recommend that future interventions systematically collect and scale lessons learned to accelerate the impact of OSS. This involves starting small to rigorously test changes before scaling up.

Finally, given the growing recognition that high quality data can strengthen improvement efforts, and that data collection has become easier with the increasing availability of tablets, phones and electronic applications, we recommend that multiple data sources be integrated and used as part of routine infectious disease program management strategies. By triangulating and routinely reviewing health management information system (HMIS), OSS visit, and stock data, health facility staff and program managers can obtain a fuller picture of quality of care and better address key barriers.

This dissertation provides practical guidance to governments, donors and partners as they design and implement training and OSS interventions for infectious diseases in SSA.

**SAMENVATTING**

Ondanks een recente toename van zeer effectieve interventies en een daling van de sterfte ten gevolge van infectieziekten, blijven Hiv, TBC en malaria een onevenredig grote impact hebben in Sub-Saharaans Afrika (SSA). In deze context wordt het falen om de verwachte verbetering te bekomen van de controle van infectie ziekten gekoppeld aan de slechte kwaliteit van de zorg. Overheden, donoren en organisaties die de kwaliteit van zorgen willen verbeteren gebruiken in toenemende mate “on-site support” (OSS), een term die alle interventies beschrijft die tot doel hebben om in gezondheidsinstellingen de capaciteit van gezondheidswerkers te verbeteren. Om effectieve capaciteitsversterkende programma’s te ontwikkelen, zijn kwaliteitsvolle studies nodig die de effectiviteit en kosten van verschillende interventies vergelijken om de kwaliteit van zorgen voor infectieziekten in SSA te verbeteren.

Het algemene doel van dit proefschrift was om de effectiviteit van OSS interventies betreffende de zorgen van Hiv, TBC en malaria te evalueren. In een gerandomiseerde gecontroleerde trial hebben we aangetoond dat OSS op zich, dus zonder andere interventies, de bekwaamheid van laboratoriummedewerkers kan verbeteren om Hiv-sneltesten, TB-sputum en malariamicroscopie uit te voeren (Hoofdstuk 2). We stelden ook vast dat training in combinatie met OSS mogelijk effectiever is in het verbeteren van klinische zorg dan training alleen (Hoofdstuk 3). OSS die negen maanden na een initiële training werd geïntroduceerd, bleek even effectief in het verbeteren van gezondheid indicatoren als OSS die uitgevoerd werd onmiddellijk na de initiële training en dat door tweemaandelijkse bezoeken de prestatiewinsten effectief werden behouden (Hoofdstuk 4). De integratie van TBC- en Hiv-diensten, als onderdeel van de OSS-interventies, verminderde bovendien de mortaliteit (hoofdstuk 5). Tenslotte verbeterde het gebruik van een elektronisch hulpmiddel om OSS te begeleiden de datakwaliteit en het datagebruik van een malaria-case management-programma, maar dit veroorzaakte wel een hogere kost per bezoek vergeleken met een op papier gebaseerd systeem (Hoofdstuk 6).

We toonden aan dat ‘capacity building’- interventies effectief geïntegreerd kunnen worden over ziektegebieden heen om tegelijkertijd de praktijken van verstrekkers en de prestaties van instellingen te

verbeteren. Wel was stond het aantal ziekten en indicatoren in verband tot de omvang van de verbetering. Interventies gericht op een kleiner aantal ziekten en indicatoren vertoonden een tendens tot meer verbetering van de zorg weliswaar op een kleiner gebied. Interventies die gericht waren op een groter aantal ziekten en indicatoren, vertoonden een verbetering op en deel van de indicatoren. Andere factoren die van invloed kunnen zijn op de mate van verbetering tijdens OSS-interventies omvatten het type van ziekte en de frequentie en duur van de interventie.

Om de spanning tussen de programmatische diepte en breedte aan te pakken, hebben we twee nieuwe modellen van geïntegreerde OSS voorgesteld en aanbevelingen gedaan om de OSS-implementatie te verbeteren. De voorgestelde modellen van geïntegreerde OSS zijn de gestructureerde integratie en de diagonale integratie. In het gestructureerde integratiemodel werken gezondheidscentra sequentieel om tegelijkertijd de zorgkwaliteit van één tot twee ziekten en één tot vier indicatoren te verbeteren. In het diagonale integratiemodel, zijn routine supervisiebezoeken van de gezondheidssystemen gelaagd met gerichte ziekte- specifieke bezoeken. We raden ook aan dat in de toekomst interventies systematisch “lessons learned” verzamelen en toepassen om de impact van OSS te versnellen. Dit omvat, op kleine schaal starten om rigoureus veranderingen te testen alvorens over te gaan tot het toepassen op grotere schaal. Tot slot, gezien de groeiende erkenning dat gegevens van hoge kwaliteit verbeteringsinspanningen kunnen versterken, en dat het verzamelen van deze gegevens gemakkelijker wordt door toenemende beschikbaarheid van tablets, telefoons en elektronische toepassingen, raden wij aan dat meerdere gegevensbronnen worden geïntegreerd en gebruikt worden als onderdeel van routine-management strategieën voor controle van infectieziekten. Door triangulatie en het routinematig bespreken van het informatiesysteem voor gezondheidsbeheer (HMIS), OSS-bezoeken en stockgegevens, kunnen de gezondheidswerkers en programmabeheerders een vollediger beeld krijgen van de zorgkwaliteit en kunnen ze de belangrijkste belemmeringen beter aanpakken.

Dit proefschrift bevat praktische richtlijnen voor overheden, donoren en partners bij het ontwerpen en implementeren van trainings- en OSS-interventies voor infectieziekten in SSA.

# Chapter 1:
# General Introduction

## 1.1 BACKGROUND

### 1.1.1 The burden of HIV, TB, and malaria in sub-Saharan Africa

From 2000 to 2015 there has been a rapid decline in the proportion of deaths due to infectious disease, from 23 percent of all deaths to 15 percent globally.[1] A three-fold increase in global health funding since 2000 has contributed to this decline. Much of the funding has focused on reducing the impact of three diseases - human immunodeficiency virus (HIV), tuberculosis (TB), and malaria - that account for half of all deaths due to infectious disease.[1] This funding has led to the development and rapid scale-up of improved diagnostics through the introduction of rapid diagnostic tests; improved treatments, including antiretroviral therapies (ART), artemisinin combination therapies, and new drugs for the treatment of multi-drug resistant TB; and improved prevention efforts, including a the RTS,S vaccine, long-lasting insecticidal nets, intermittent preventative therapy for pregnant women and seasonal malaria chemoprevention for malaria, and male circumcision, test and treat, and pre-exposure prophylaxis for HIV.

Despite these highly effective interventions, HIV, TB and malaria continue to have a disproportionate impact in sub-Saharan Africa (SSA). While the region accounts for 14% of the global population, it accounts for 56% of the deaths due to these three infectious diseases, with nearly 1.6 million deaths in 2015. Too many continue to die due to gaps in the implementation of proven interventions.[2] Along with expanding prevention efforts and increasing access to drugs, equipment and facilities, there is growing need to focus efforts on improving the quality of care – to ensure that these resources are effectively used to decrease the infectious disease burden in SSA.[3–5]

### 1.1.2 The current quality of care

In SSA, only 53% of people living with HIV were on ART by the end of 2016.[6] For malaria, the median proportion of suspect fever cases receiving a diagnostic test was 30% in population-based studies and only

19% of those receiving an antimalarial received the recommended ACT.[7] For TB, while the TB treatment success rate is 83% for those who start on treatment, only 66% of cases were bacteriologically confirmed and treatment coverage is under 50%.[8] Some of these gaps are due to individuals not seeking treatment, but a high proportion is due to poor quality once they seek care. For example, among suspect malaria cases who were treated in public sector facilities only 52% received a diagnostic test, and 70% of those treated with an antimalarial received an ACT.[7] Poor quality is increasingly being linked to failure to attain expected improvements in infectious disease control.[9] In order to reach Sustainable Development Goal 3, to ensure healthy lives and promote well-being for all at all ages, improvements in quality of care will be required.[10]

### 1.1.3 Overview of interventions to improve quality of care for infectious diseases in sub-Saharan Africa

A wide variety of interventions have been implemented in an attempt to improve the quality of care for these infectious diseases including: national guidelines and job aids; training; supervision and supportive supervision. These are often combined with newer interventions such as pay for performance, quality improvement, the use of technology or electronic health support tools, or a mix of these interventions. Here we provide a brief description of each of these interventions and a summary of what is known about their effects on improving the quality of care for HIV, TB, and malaria in SSA.

#### *National guidelines and job aids*

A necessary step in changing the quality of care is to adopt guidelines that clearly describe the desired care practices. The World Health Organization (WHO) undergoes a rigorous review process to develop global clinical practice guidelines, including those for HIV, TB, and malaria, and updates these guidelines on a routine basis as new evidence emerges.[11] Individual governments then review and adapt the guidelines based on the local context and the feasibility of implementation.

A review of guideline implementation strategies found that passive dissemination of guidelines was not an effective strategy for ensuring adoption of guidelines and improved quality of care.[12] However, guideline

content and the methods by which they are developed do have an effect. Evidence-based, non-controversial, specific recommendations, and those that do not require large changes in clinical practice routines were more likely to be implemented, while complex guidelines were less likely.[12,13] Involvement of the end-users in the development and introduction of the guidelines can also increase compliance.[11,14] Job aids are tools based on national guidelines and designed to support providers during patient encounters. These tools specifically describe the steps a provider should take in providing care for a specific disease. While there are few studies of job aids alone, they have been associated with improved clinical decision-making for malaria.[15]

Evaluations of both guidelines and job aids have shown that the development and dissemination of guidelines and job aids is necessary but not sufficient on its own to improve quality of care. The most effective methods combine these tools with training, supervision and other interventions. These additional interventions are described below.

***Training***

Training is the one of the most common methods of improving health worker performance. Governments and donors have long used training programs to support the implementation of new policies and update health workers' knowledge in the diagnosis and treatment of infectious diseases.[16] While training is a broad category of capacity building which can take on multiple modalities, most often it is an off-site, classroom-based education session which involves lecture, demonstration, and/or role-playing, and may also contain some practical or field sessions to practice newly acquired skills.

Many studies on the effectiveness of training assess improvements in knowledge, with fewer assessing behavior change following the intervention.[17] Given the large amount of resources used in implementing training interventions, there are few strong evaluations. Of the studies that have assessed training and its effects on either provider practice or patient outcomes for HIV, TB and malaria case management in SSA, most find a positive effect of training.[17] These findings are consistent with a broader review of continuing medical education programs, a common form of training for health workers, including locations outside of

SSA, which found that training leads to small-to-moderate improvements in professional practice and smaller improvements in patient outcomes.[18]

Donors have primarily funded in-service training for HIV, TB and malaria, with less focus on pre-service education.[19] This was particularly the case early in the expansion of HIV treatment, when there were rapid changes in HIV protocols and a need to quickly expand access to life-saving ART.[20,21] Strengthening pre-service education requires coordination with several national ministries, professional associations, and health training institutions. It may also require substantial revision to many areas outside of infectious disease-specific modules to effectively integrate the knowledge and skills necessary to effectively manage infectious diseases into the curriculum. These aspects result in a longer time-frame for development and increased costs.

When pre-service education materials are not regularly updated with the latest national guidelines, new graduates enter the workforce with outdated knowledge and skills. This, in turn, necessitates additional in-service training to address gaps in pre-service education, wasting scarce resources. There is a recognition that pre-service education needs to be a stronger component of capacity-building strategies for HIV, TB, and malaria managment.[20,22–24] Some interventions have provided technical assistance to redesign curricula and further develop faculty skills' in the delivery of infectious disease content.[20,25,26]

When compared with in-service training pre-service evaluation has a longer timeline for development, implementation and follow-up, often measured in years as compared to the weeks or months for in-service trainings. This has led to a relative paucity of pre-service evaluations of infectious disease programs in sub-Saharan Africa. Only one high quality evaluation of pre-service education on providers' knowledge and skills could be identified.[27,28] Health workers who received the original and revised pre-service curriculum showed similar levels of improvement in knowledge and skills directly after training. However, those who received the revised curriculum retained the knowledge and skills 10 months after the training while those who received the original curriculum saw their scores decline. Similar to the findings of the in-service training evaluations, this was a small but significant difference.

***Supervision***

Alongside training, supervision is another common method used to improve health workers' skills. Supervision falls under a wide range of terms and covers a variety of strategies and activities. Broadly speaking, supervision can be defined as a higher-level professional assessing the activities of a health worker or health facility to ensure that activities are being performed correctly.

Under traditional supervision models, supervisors were focused on inspection and fault finding, providing little guidance to health workers to improve their performance.[29] Supervisors would conduct visits to ensure health workers' compliance, favoring a hierarchical approach which often used ridicule and discipline to push health workers to perform their duties. Consistent with colonial ideology, this approach was largely based on the belief that health workers are unmotivated and require strong controls to adequately perform their tasks.[30]

With the development of supportive supervision, the model has changed from predominantly punitive model to one focused on supporting staff to improve the quality of care they provide. The Maximizing Access and Quality Initiative described supportive supervision as "a process that promotes quality at all levels of the health system by strengthening relationships within the system, focusing on the identification and resolution of problems, and helping to optimize the allocation of resources-promoting high standards, teamwork, and better two-way communication."[30] Supportive supervision is conceived as a more holistic approach with a focus on performance improvement. Rather than a top-down supervision model of enforcing standards, supportive supervision encourages the supervisor, individual health workers and health facility staff as a group to work together to identify challenges and develop solutions that improve the quality of care. Under this model, supervision goes beyond a health facility visit and instead refers to an on-going relationship between health workers and supervisors.

While traditional supervision and supportive supervision describe the two overarching philosophies to the supervision approach, several other terminologies are used to describe specific types or aspects of supervision. For example, managerial supervision is defined as "routine supervision visits by health staff from a centre (such as a district office) to primary health care staff in both urban and rural areas and clinical supervision is defined as "the provision of guidance of clinical practice for qualified health professionals by a more experienced health professional".[31,32]

Other terms are closely related, and often overlap with, supervision. Educational outreach, one of the broadest terms, is defined as "a personal visit by a trained person to health professionals in their own settings."[33] Coaching is defined as a one-on-one activity where a coach attempts to change health worker behavior "through self-awareness and/or by achieving higher levels of skill performance."[34] Mentoring, or clinical mentoring, is defined by the WHO as "a system of practical training and consultation that fosters ongoing professional development to yield sustainable high-quality clinical care outcomes".[36] Coaching and mentoring are similar in their one-on-one approach to staff development. However, mentoring is led by an experienced, practicing clinician outside of the management hierarchy and the focus of mentoring is to develop an individual beyond their current position to take on new responsibilities or a new position.[35] Coaching is led by a supervisor and meant to develop a specific skill to meet expectations for a current position.[35] Another common term that refers to a technique often used during supervision, rather than supervision itself, is audit and feedback, defined as a process by which "an individual's professional practice or performance is measured and then compared to professional standards or targets."[37]

Each of these definitions is comprised of a range of overlapping features that apply to some supervision approaches but not to others. For example, educational outreach is limited only to a visit to a health facility, whereas Marquez and Kean's definition describes supervision as going beyond visits to on-going relationships.[30] Clinical mentoring may cover many of the same areas addressed as part of supervision but tends to focus more, or exclusively, on improving the clinical technical skills of individual health facility

staff and developing individuals professionally, rather than more holistically addressing health facility or team-based quality of care issues.[38]

Multiple reviews have found that supervision can be effective in improving health provider practice and patient outcomes, but that the effect is variable. A global review of educational outreach activities found small to modest improvements in professional performance and healthcare outcomes.[33] A similar review of audit and feedback on professional behavior and patient outcomes at the global level found that results ranged from little or no effect to a substantial effect.[37] Two reviews focusing on supervision in low- and middle-income countries (LMICs) had similar findings, with some studies showing a small benefit on health worker practices, while other studies showed no benefit or were inconclusive.[31,34] Similar results were also found in a review assessing the effects of supervision on primary healthcare services in SSA.[39]

Given the varying definitions and activities covered under the umbrella of supervision, it's not surprising that the systematic reviews found such a broad range of effectiveness. Across these reviews the consistent message is that this broad category of supervision-related activities can improve some components of quality of care when compared with no intervention, although this effect is far from guaranteed. As part of these reviews, the authors also aimed to identify which key factors seemed to be related to a positive effect of supervision. Key factors identified included: attempting to decrease a targeted behavior,[40] focusing on areas that have more room for improvement,[37] including clear targets and an action plans,[37,40] combining supervision with other interventions[33,39] and a non-judgmental supportive relationship between supervisor and supervisee.[39] Reviews differed on whether the frequency of supervision was an important factor. Ivers et al. and Zurovac et al. found that more frequent supervision was associated with improved performance, while Bosch-Capblanch et al. and O'Brien et al. found that intensive supervision was not more beneficial or that the evidence was unclear.[15,31,33,40]

***Other common capacity building techniques***

Outside of training and supervision there are three additional interventions designed to support health workers in improving quality of care which are more recent in their implementation – pay for performance,

quality improvement and the use of technology or eHealth support tools. Pay for performance, also known as results-based financing or performance-based incentives, is defined as "the transfer of money or material goods conditional on taking a measurable action or achieving a predetermined performance target."[41] Through such schemes, health workers are paid to achieve a certain target or standard in quality of care based on pre-defined indicators, with payments coming either to the individual, the health facility, or both. A 2012 review of pay for performance interventions found very few qualified studies from which to draw conclusions regarding their effectiveness.[41] A more recent review, focusing on the effects of pay for performance on maternal and child health in LMICs found an positive effect, although limited, on antenatal quality of care.[42]

Quality improvement can be defined as "the continuous efforts of everyone interacting with the health system (healthcare workers, patients, communities, researchers, managers, educators, and policymakers) to make changes that lead to better patient outcomes, system performance, and capacity development."[43] Quality improvement takes a systems approach to problem-solving and improving the quality of care. Like pay for performance, it is data-driven approach where performance standards are set and routinely reviewed for progress. Facility-level quality improvement teams are developed and supported, often through visits by quality improvement coaches to continually test and evaluate potential solutions to identified barriers.[44] While reviews from developed countries regarding the effects of quality improvement on specific disease areas have found positive results, few experimental or quasi-experimental studies of quality improvement have been published for LMICs.[45,46] Of the few rigorous studies that have assessed the effect of quality improvement on infectious diseases in sub-Saharan Africa, results have been positive. Quasi-experimental studies in Ghana and Malawi found positive effects of quality improvement on maternal and child health and reproductive health services, respectively.[47,48] A study in Zambia found significant improvements in both ART and prevention of mother-to-child transmission of HIV (PMTCT) service provision, while another study on PMTCT in Nigeria had mixed results.[49,50] The intervention improved the proportion of

children receiving an early infant diagnosis for HIV, but did not increase retention in prevention of the child transmission program.[50]

Increasingly, electronic tools are being developed to support health workers in improving quality of care. These include improved data collection and reporting tools, which also help health workers to track patients; point-of-care electronic decision support, which guides health workers through treatment algorithms; provider-to-provider communication, allowing health workers in rural locations to access specialists or peers for advice and support; as well as training and education modules delivered electronically.[51] While few studies of the effectiveness of these interventions exist in this growing area, a recent review found such strategies to be effective in improving some aspects of maternal and neo-natal care in LMICs.[52] For infectious diseases in SSA , one study in Kenya demonstrated that short message service (SMS) reminders improved pediatric malaria case management, while another study in Uganda showed no effect of a SMS, plus phone support system, on HIV treatment outcomes.[53,54] In Tanzania, a study that provided health workers with electronic decision-support tools for Integrated Management of Childhood Illnesses (IMCI) reported a significant improvement in the provider's ability to adhere to the IMCI treatment protocol.[55]

These three capacity building interventions often overlap with training and supervision. They may begin with a training to familiarize health facility staff with the intervention and the quality of care standards. They may also include external visits by managers or supervisors as part of the program strategy to determine performance, assess progress towards targets, and support the development and implementation of actions to achieve the targets.[44,56,57] In the case of electronic tools, they may be embedded within training, supervision or other quality of care programs. Given the overlap in these approaches it becomes even more difficult to isolate the effects of any one type of intervention.

## 1.2 PROBLEM STATEMENT

The quality of care for infectious diseases in SSA is currently low. While studies suggest that attempts to improve the quality of care through national guidelines and job aids, training, supervision, and newer

interventions, such as pay for performance, quality improvement initiatives, and use of electronic tools are likely beneficial, they have shown inconsistent results and lack the evidence-base to definitively prove their effectiveness in improving the management of infectious diseases in SSA. The inconsistency in findings is likely due to the lack of consensus and clarity around the specific components of these interventions. The interventions are often blurred across categories and combined with the aim of implementing more multi-faceted and effective interventions.[17,33] A clear finding of the systematic reviews was that further research is needed to determine the effectiveness of interventions to improve the quality of care provided by health workers. Specifically needed are studies that are higher quality, compare the relative effectiveness of different interventions, and track intervention costs.[17,31,33,34,40,58] There is also a further need to conduct research focused on the management of infectious diseases in SSA to guide the implementation of quality of care interventions in this context.

## 1.3 RESEARCH CONTEXT

### 1.3.1 Infectious Diseases Institute

The Infectious Diseases Institute (IDI) is a non-governmental organization (NGO) based within the College of Health Sciences at Makerere University in Uganda. IDI's mission is "To strengthen health systems in Africa, with a strong emphasis on infectious diseases, through research and capacity development."[59] IDI fulfills its mission through five core programs: 1) HIV prevention, care and treatment, 2) training and capacity development, 3) research, 4) laboratory systems and 5) outreach.

Through the training and capacity program, IDI offers training in the management of HIV and related infectious diseases, targeting health workers in resource-limited settings. IDI tailors training content to suit the needs of participating health care providers and uses classroom-, clinic- and community-based training. The training leverages experiential learning techniques including self-teaching, group participation, case discussions, and hands-on clinical and community practice. Multiple cadres are also trained together in a multidisciplinary learning environment so that the cadres better understand each other's roles and learn how

to effectively complement each other and have the opportunity to collaboratively strategize to address systems-level challenges.

Through the outreach program, IDI aims to increase access to quality and comprehensive health services for HIV/AIDS and other infectious diseases in Uganda, through innovative and strengthened health systems. This includes strengthening strategic information systems, supply chain management systems and laboratory services, as well as improving human resource capacity through training, mentorship, onsite support and infrastructural modifications.

### 1.3.2 Accordia Global Health Foundation (Accordia), now Africare

Accordia was an NGO based in the United States (US) established to bring together global resources to fight infectious disease in Africa. Active from 2003 to 2016, Accordia "helped develop lasting institutional leadership, created evidence-based models, and paved the way for stronger African health systems."[60] A key achievement of Accordia was to support the establishment and growth of IDI, collaborating to develop and implement innovative health models. In July 2016 Accordia merged with Africare, a US-based NGO committed to addressing African development and policy issues by working in partnership with African people to build sustainable, healthy and productive communities.

### 1.3.3 PATH

PATH is an NGO that works across five platforms—vaccines, drugs, diagnostics, devices, and system and service innovations—to accelerate innovations that transform the lives of the world's most vulnerable women and children and help create thriving, self-reliant communities. Through the systems and service innovations platform, PATH helps improve infrastructure and supply systems, advocate for lifesaving policies and priorities, and train and equip health workers.

## 1.4 INTERVENTIONS

### 1.4.1 Integrated Infectious Diseases Capacity Building Evaluation (IDCAP)

The Integrated Infectious Diseases Capacity Building Evaluation (IDCAP) aimed to identify cost-effective methods to build capacity for the care and prevention of infectious diseases among mid-level practitioners (MLP) comprised of clinical officers, nurses and midwives in SSA. IDCAP was funded by the Bill and Melinda Gates Foundation, and implemented through a partnership led by Accordia in collaboration with the IDI, the Uganda Ministry of Health, the University Research Corporation's Center for Human Services and the University of Washington's International Training and Education Center for Health (I-TECH).

IDCAP was implemented at 36 health facilities across the six regions of Uganda and took place between November 2009 and September 2011. IDCAP tested two interventions to improve infectious disease care at primary care facilities: the Integrated Management of Infectious Disease (IMID) training program and on-site support (OSS).[61] As further described below, OSS includes elements of on-site training, supportive supervision and mentoring, and quality improvement interventions. The IMID training course was designed to train MLP in the management of HIV, TB, malaria and related infectious diseases for children, adults and pregnant women. The course was based on content from the WHO's Integrated Management of Adult Illness (IMAI) and IMCI courses, the IDI's Comprehensive Management of HIV including ART and Joint Uganda Malaria Training Program courses and updated national and WHO guidelines for HIV/AIDS, TB and malaria treatment.[62,63] It consisted of a three-week core course conducted at the IDI which included both classroom and clinic-based training, a distance learning component in which trainees recorded difficult cases in a clinical practice logbook for review and discussion, and two one-week boost courses 12 and 24 weeks after the initial training.

OSS was a series of nine monthly visits to health facilities by a team of four clinical faculty: a medical officer with quality improvement experience, a clinical officer, a laboratory technologist, and a registered nurse. The broad term OSS was used to capture the variety of activities done during the health facility visits

and most closely approximates the term educational outreach in the literature. Visits lasted for two days. The first day of the visit included multidisciplinary training sessions, which encouraged health facility staff to learn together and examine systems issues that interfere with patient care, cadre-specific breakout sessions, and one-on-one mentoring for clinical and laboratory staff. The second day was devoted to continuous quality improvement activities, in which facility staff used facility-based data to identify areas for improvement, develop possible solutions and review data to assess whether the solutions were working. The IDCAP teams also facilitated two formal sharing sessions during the nine-month period where CQI teams from multiple facilities came together to share their solutions. A full description of the intervention can be found in Miceli et al.[61]

IDCAP had three main objectives:

1. To evaluate the effectiveness of the IMID training in preparing MLP to perform key clinical tasks corresponding to infectious disease competencies at acceptable standard,
2. To evaluate the effectiveness of OSS in improving clinic performance, and
3. To estimate the cost-effectiveness of OSS.

To complete these objectives, IDCAP had a mixed design with two components: a pre/ post design to evaluate the effect of the IMID training, and a cluster randomized trial to evaluate the effect of OSS.[64] Two MLP from each of 36 health facilities were selected to attend the IMID. From the 36 health facilities, 18 were randomly selected to receive OSS immediately following the IMID training (arm A). The remaining 18 health facilities served as a control group and received the OSS intervention one year later (arm B). The IDCAP study design is explained in Naikoba et al. and the study protocol is available as a supplemental file in Weaver et al.[64,65]

Three types of outcomes were measured: (1) individual competence and practice of IMID participants, as assessed through performance on case scenarios and clinical observations; (2) facility performance indicators, as assessed through outpatient forms and facility registers; and (3) population-based measures of mortality among children less than five years of age, as assessed through a household survey. These

results have been reported in Weaver et al.,[66] Imani et al.,[67] Weaver et al.,[65] Mbonye et al.,[68] Mbonye et al.,[69] and Ssebuliba et al.[70] Additional results supporting the first two objectives are reported as part of this dissertation (Chapters 2, 3 and 4).

### 1.4.2 TB REACH

Following IDCAP, IDI implemented TB REACH from January to October 2012. TB REACH built on the techniques developed during IDCAP but focused on TB case management and provided advanced TB laboratory diagnostics to intervention facilities. TB REACH was funded by Global Affairs Canada and the Bill and Melinda Gates Foundation through the Stop TB Partnership Secretariat. The objective of the intervention was to evaluate the impact of a multidisciplinary training intervention on TB case detection and TB outcomes.

TB REACH was a prospective, quasi-experimental study implemented in 12 former IDCAP sites, with 10 intervention sites and two controls. Intervention sites received nine months of two-day OSS visits modeled on IDCAP but focused only on TB case detection and treatment. These visits were held monthly in the first three months and then bimonthly for the next six months of the intervention, for a total of six visits per facility. The project also provided the 10 intervention facilities with a fluorescence microscope (FM) and Xpert MTB/RIF diagnostic capacity. This was accompanied by a two-day off-site training and practical hands-on training at the healthcare facilities for laboratory staff on their use. As part of this intervention, the OSS teams also supported the health facility staff to integrate TB and HIV services. Facility performance results were shared with the national government and the district teams on a quarterly basis. Findings of this project are reported in Manabe & Zawedde et al.[71] and as part of this dissertation (Chapter 5).

### 1.4.3 MENTORS

From October 2013 to June 2014, IDI implemented the MENTORS study to determine the effectiveness of using on-site clinical mentorship to improve the clinical knowledge, competence, and clinical practice of

MLP in providing HIV and TB care. MENTORS was a cluster-randomized control trial implemented in 10 former IDCAP sites, with five intervention and five control sites. This study built on the mentorship component of the IDCAP intervention with four MLP at each of the five intervention sites receiving a total 48 hours of one-on-one mentoring on TB and HIV care over six visits held during the nine-month intervention, compared to the average of eight hours of mentorship per MLP during IDCAP. At baseline, and immediately after the nine-month intervention, MLP in both the intervention and control arms were assessed on their knowledge (using case scenarios), competence (using clinical observations), and practice (using facility records) in TB and HIV management. Similar to TB REACH, the mentorship teams also supported the health facility staff to integrate TB and HIV services. Findings of this project are reported in Naikoba et al.[72] and as part of this dissertation (Chapter 5).

### 1.4.4 MalariaCare

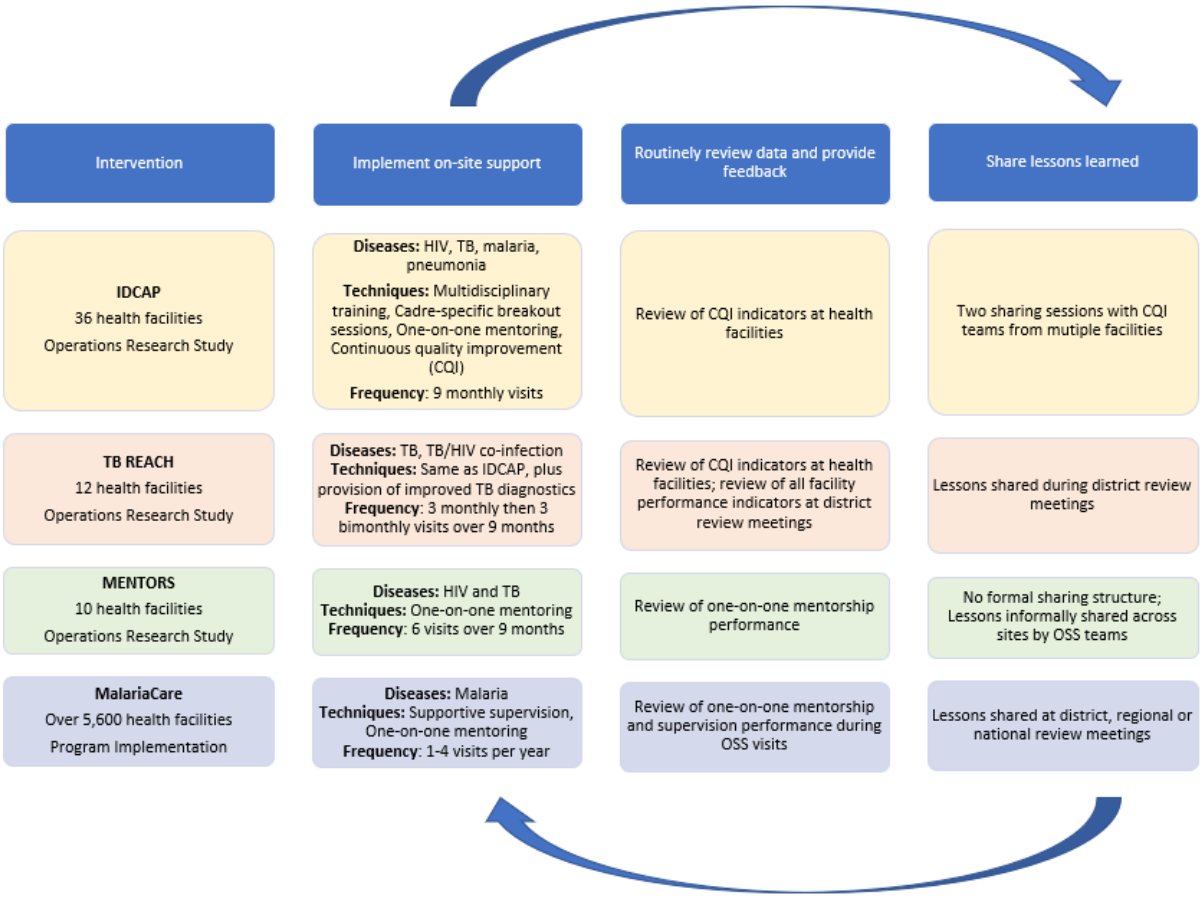
In addition to the projects implemented through IDI, this dissertation also discusses findings related to the MalariaCare project. MalariaCare was a five-year partnership (September 2012 – December 2017) led by PATH and funded by the United States Agency for International Development (USAID) under the United States President's Malaria Initiative (PMI) with the aim to scale up high-quality diagnosis and treatment services for malaria and other febrile illnesses. MalariaCare's quality assurance approach utilized updating of national guidelines and job aids, training and supportive supervision, and elements of continuous quality improvement to improve the quality of malaria case management in health facilities. While MalariaCare was not a research project, the scale of the supportive supervision component, which was implemented across nine countries and nearly 5,000 health facilities, offers an opportunity to observe the effects of these types of interventions at scale. Each facility received between one and four visits per year, depending on the country program. Between visits, lessons learned workshops were held at the district or regional level to review data collected during the visits, identify common high and low performance areas, and agree on actions to address systemic issues, such as widespread stock-outs or lack of training. A full description and

findings of this project are reported in a series of articles submitted to the American Journal of Tropical Medicine and Hygiene and as part of this dissertation (Chapter 7).[73–76]

## 1.5 SUMMARY AND TERMINOLOGY

Each of the projects described above differs in terms of its disease focus and specific interventions. Throughout this dissertation we will use the broad term on-site support to describe all interventions to improve health care worker capacity that took place within a health facility. In Figure 1.1 below we provide an overview of the on-site support process for each intervention through three key steps: implementation of OSS, review of data and feedback, and sharing lessons learned across health facilities and administrative units.

**Figure 1.1 Summary of On-Site Support Interventions**




## 1.6 GOALS AND OBJECTIVES

The overall goal of this dissertation is to evaluate different methods of OSS in improving health workers' knowledge and skills and overall facility performance in infectious disease management.

The specific objectives that the dissertation aims to answer are as follows:

1. Does OSS alone, without other interventions, improve skills?
2. Is training plus OSS more effective than training alone?
3. Does the time period between training and OSS have an impact on the effect of the interventions?

4. Does implementing structural/facility-based changes during OSS, such as integration of services, help to improve quality of care?
5. Are electronic tools effective in improving data quality and data use as part of OSS programs and enable them to more effectively operate at scale?

## 1.7 OUTLINE OF DISSERTATION

### 1.7.1 Training and on-site support (Chapters 2, 3, and 4)

In this section we investigate the effects of integrated infectious disease training and OSS on clinical and laboratory competencies and facility performance indicators. Chapter 2 assesses the effects of OSS alone on laboratory staff's ability to conduct HIV rapid testing and TB sputum and malaria microscopy. Chapter 3 assesses the effects of training alone and training combined with OSS on clinicians' management of HIV patients. Chapter 4 compares the effects of training followed by either immediate OSS or OSS delayed by nine months on HIV, TB and malaria facility performance indicators.

### 1.7.2 Integration of services (Chapter 5)

Chapter 5 reports the effects of reorganizing facility services to integrate TB and HIV care on both TB and HIV outcomes.

### 1.7.3 Use of electronic tools to improve on-site support (Chapter 6)

Chapter 6 describes the use of an electronic tool to guide OSS, including the key features of the tool, the process of introducing it in a large-scale, multi-country OSS program, and the programmatic changes in terms of data quality and data use.

**REFERENCES**


1. World Health Organization. Global estimates for cause-specific mortality, 2000–2015. http://www.who.int/healthinfo/global_burden_disease/estimates/en/index1.html. Published 2016. Accessed December 27, 2017.

2. Dye C. After 2015: infectious diseases in a new era of health and development. *Philos Trans R Soc Lond B Biol Sci*. 2014;369(1645):20130426. doi:10.1098/rstb.2013.0426.

3. Baernighausen T, Bloom DE, Humair S. Human resources for treating HIV/AIDS: Are the preventive effects of antiretroviral treatment a game changer? *PLoS One*. 2016;11(10):1-24. doi:10.1371/journal.pone.0163960.

4. ACTwatch Group, Hanson K, Goodman C. Testing times: trends in availability, price, and market share of malaria diagnostics in the public and private healthcare sector across eight sub-Saharan African countries from 2009 to 2015. *Malar J*. 2017;16(1). doi:10.1186/s12936-017-1829-5.

5. UNAIDS. *Ending AIDS: Progress towards the 90-90-90 Targets*. Geneva, Switzerland: UN Joint Programme on HIV/AIDS (UNAIDS); 2017. http://www.unaids.org/sites/default/files/media_asset/Global_AIDS_update_2017_en.pdf. Accessed December 2, 2017.

6. UNAIDS. *AIDS By the Numbers*.; 2016. http://www.unaids.org/sites/default/files/media_asset/AIDS-by-the-numbers-2016_en.pdf.

7. World Health Organization. *World Malaria Report 2017*. Geneva, Switzerland; 2017. http://apps.who.int/iris/bitstream/10665/259492/1/9789241565523-eng.pdf?ua=1.

8. WHO. *Global Tuberculosis Report 2017*.; 2017. doi:WHO/HTM/TB/2017.23.

9. Akachi Y, Kruk ME. Quality of care: measuring a neglected driver of improved health. *Bull World*

*Health Organ*. 2017;(December 2016):465-472. doi:10.2471/BLT.16.180190.

10. United Nations General Assembly. Transforming our world: The 2030 agenda for sustainable development. *https//sustainabledevelopment.un.org/content/documents/7891Transforming%20Our%20World pdf*. 2015;(1):1-5. doi:10.1007/s13398-014-0173-7.2.

11. World Health Organisation. Guidelines for WHO guidelines. *Glob Program Evid Heal Policy*. 2003:1-24.

12. Prior M, Guerin M, Grimmer-Somers K. The effectiveness of clinical guideline implementation strategies - A synthesis of systematic review findings. *J Eval Clin Pract*. 2008;14(5):888-897. doi:10.1111/j.1365-2753.2008.01014.x.

13. Grol R, Dalhuijsen J, Thomas S, Rutten G, Mokkink H. Attributes of clinical guidelines that influence use of guidelines in general practice: observational study. *Br Med J*. 1998;317:858-861. doi:10.1136/bmj.317.7162.858.

14. Grimshaw JM, Russell IT. Effect of clinical guidelines on medical practice: a systematic review of rigorous evaluations. *Lancet*. 1993;342(8883):1317-1322. doi:10.1016/0140-6736(93)92244-N.

15. Zurovac D, Rowe AK, Ochola SA, et al. Predictors of the quality of health worker treatment practices for uncomplicated malaria at government health facilities in Kenya. *Int J Epidemiol*. 2004;33(5):1080-1091. doi:10.1093/ije/dyh253.

16. O'Malley G, Perdue T, Petracca F. A framework for outcome-level evaluation of in-service training of health care workers. *Hum Resour Health*. 2013;11(1):1. doi:10.1186/1478-4491-11-50.

17. Wu S, Roychowdhury I, Khan M. Evaluations of training programs to improve human resource capacity for HIV, malaria, and TB control: A systematic scoping review of methods applied and outcomes assessed. *Trop Med Health*. 2017;45(1):1-11. doi:10.1186/s41182-017-0056-7.

18. Forsetlund L, Bjørndal A, Rashidian A, et al. Continuing education meetings and workshops: effects on professional practice and health care outcomes. *Cochrane Database Syst Rev*. 2009;(2):CD003030. doi:10.1002/14651858.CD003030.pub2.

19. Cancedda C, Farmer PE, Kerry V, et al. Maximizing the Impact of Training Initiatives for Health Professionals in Low-Income Countries: Frameworks, Challenges, and Best Practices. *PLoS Med*. 2015;12(6):1-11. doi:10.1371/journal.pmed.1001840.

20. Renggli V, De Ryck I, Jacob S, et al. HIV education for health-care professionals in high prevalence countries: time to integrate a pre-service approach into training. *Lancet*. 2008;372(9635):341-343. doi:10.1016/S0140-6736(08)61119-8.

21. Maritim MC, Otieno CF, Omonge EO, Lule GN. Evolution of HIV training for enhanced care provision in Kenya: challenges and opportunities. 2013;90(12):83-88.

22. Zhao F, Squires N, Weakliam D, et al. Investing in human resources for health: The need for a paradigm shift. *Bull World Health Organ*. 2013;91(11). doi:10.2471/BLT.13.118687.

23. Figueroa-Munoz J, Palmer K, Dal Poz MR, Blanc L, Bergström K, Raviglione M. The health workforce crisis in TB control: A report from high-burden countries. *Hum Resour Health*. 2005;3:1-9. doi:10.1186/1478-4491-3-2.

24. Aidoo M. Factoring Quality Laboratory Diagnosis into the Malaria Control Agenda for Sub-Saharan Africa. *Am J Trop Med Hyg*. 2013;89(3):403-406. doi:10.4269/ajtmh.13-0108.

25. Goosby EP, von Zinkernagel D. The Medical and Nursing Education Partnership Initiatives. *Acad Med*. 2014;89(80):S5-S7. doi:10.1097/ACM.0000000000000346.

26. Stuart-Shor EM, Cunningham E, Foradori L, et al. The Global Health Service Partnership: An Academic–Clinical Partnership to Build Nursing and Medical Capacity in Africa. *Front Public Heal*. 2017;5(July):1-9. doi:10.3389/fpubh.2017.00174.

27. Feldacker C, Chicumbe S, Dgedge M, et al. Mid-level healthcare personnel training: An evaluation of the revised, nationally-standardized, pre-service curriculum for clinical officers in Mozambique. *PLoS One*. 2014;9(7):1-9. doi:10.1371/journal.pone.0102588.

28. Feldacker C, Chicumbe S, Dgedge M, et al. The effect of pre-service training on post-graduation skill and knowledge retention among mid-level healthcare providers in Mozambique. *Hum Resour Health*. 2015;13(1):1-12. doi:10.1186/s12960-015-0011-9.

29. Clements JC, Streefland P, Malau C. Supervision in Primary Health Care - Can it be Carried Out Effectively in Developing Countries? *Curr Drug Saf*. 2007;2(1):19-23. doi:10.2174/157488607779315435.

30. Marquez L, Kean L. Making supervision supportive and sustainable: new approaches to old problems. *Maximising Access Qual Pap*. 2002;30(4):1-28. doi:DOI: 10.1111/j.1471-0528.2005.00718.x.

31. Bosch-Capblanch X, Liaqat S, Garner P. Managerial supervision to improve primary health care in low- and middle-income countries. *Cochrane Database Syst Rev*. 2011;9(9):CD006413. doi:10.1002/14651858.CD006413.pub2.

32. Snowdon DA, Leggat SG, Taylor NF. Does clinical supervision of healthcare professionals improve effectiveness of care and patient experience? A systematic review. *BMC Health Serv Res*. 2017;17(1):1-11. doi:10.1186/s12913-017-2739-5.

33. O'Brien MA, Rogers S, Jamtvedt G, Oxman Andrew D, Odgaard-Jensen J, Kristoffersen Doris T. Educational outreach visits: effects on professional practice and health care outcomes. *Cochrane Database Syst Rev*. 2007;4(3).

34. Vasan A, Mabey DC, Chaudhri S, Brown Epstein H-A, Lawn SD. Support and performance improvement for primary health care workers in low- and middle-income countries: a scoping

review of intervention design and methods. *Health Policy Plan*. 2016;(November 2016):czw144. doi:10.1093/heapol/czw144.

35. Luecke R, Ibarra H. *Coaching and Mentoring: How to Develop Top Talent and Achieve Stronger Performance*. Boston, Massachusetts: Harvard Business School Press; 2004. http://books.google.com/books?id=oVO-Tqxy8GMC&pgis=1.

36. World Health Organization (WHO). *WHO Recommendations for Clinical Mentoring to Support Scale-up of HIV Care , Antiretroviral Therapy and Prevention in Resource-Constrained Settings*. Geneva, Switzerland: WHO Press; 2005. http://www.who.int/hiv/pub/guidelines/clinicalmentoring.pdf?ua=1. Accessed March 27, 2018.

37. Ivers N, Jamtvedt G, Flottorp S, et al. Audit and feedback : effects on professional practice and healthcare outcomes ( Review ) SUMMARY OF FINDINGS FOR THE MAIN COMPARISON. *Cochrane database Syst Rev*. 2012;6(6):CD000259. doi:10.1002/14651858.CD000259.pub3.

38. Schwerdtle P, Morphet J, Hall H. A scoping review of mentorship of health personnel to improve the quality of health care in low and middle-income countries. *Global Health*. 2017;13(1):1-8. doi:10.1186/s12992-017-0301-1.

39. Bailey C, Blake C, Schriver M, Kalumire V, Thomas T, Martin A. A systematic review of supportive supervision as a strategy to improve primary healthcare services in Sub-Saharan Africa. *Int J Gynecol Obstet*. 2016;132(1):117-125. doi:10.1016/j.ijgo.2015.10.004.

40. Ivers NM, Grimshaw JM, Jamtvedt G, et al. Growing Literature, Stagnant Science? Systematic Review, Meta-Regression and Cumulative Analysis of Audit and Feedback Interventions in Health Care. *J Gen Intern Med*. 2014;29(11):1534-1541. doi:10.1007/s11606-014-2913-y.

41. Witter S, Fretheim A, Kessy F, Lindahl A. Paying for performance to improve the delivery of health interventions in low- and middle-income countries (Cochrane Review). *Cochrane Libr*. 2013;(5):82.

42. Das A, Gopalan SS, Chandramohan D. Effect of pay for performance to improve quality of maternal and child care in low- and middle-income countries: A systematic review. *BMC Public Health*. 2016;16(1):1-11. doi:10.1186/s12889-016-2982-4.

43. Wagenaar BH, Hirschhorn LR, Henley C, et al. Data-driven quality improvement in low-and middle-income country health systems: Lessons from seven years of implementation experience across Mozambique, Rwanda, and Zambia. *BMC Health Serv Res*. 2017;17(Suppl 3). doi:10.1186/s12913-017-2661-x.

44. Bardfield J, Agins B, Akiyama M, et al. A quality improvement approach to capacity building in low- and middle-income countries. *Aids*. 2015;29(April):S179-S186. doi:10.1097/QAD.0000000000000719.

45. Tricco AC, Ivers NM, Grimshaw JM, et al. Effectiveness of quality improvement strategies on the management of diabetes: A systematic review and meta-analysis. *Lancet*. 2012;379(9833):2252-2261. doi:10.1016/S0140-6736(12)60480-2.

46. Wells S, Tamir O, Gray J, Naidoo D, Bekhit M, Goldmann D. Are quality improvement collaboratives effective? A systematic review. *BMJ Qual & Saf*. 2018;27(3):226 LP-240. http://qualitysafety.bmj.com/content/27/3/226.abstract.

47. Rawlins BJ, Kim YM, Rozario AM, et al. Reproductive health services in Malawi: An evaluation of a quality improvement intervention. *Midwifery*. 2013;29(1):53-59. doi:10.1016/j.midw.2011.10.005.

48. Singh K, Brodish P, Speizer I, et al. Can a quality improvement project impact maternal and child health outcomes at scale in northern Ghana? *Heal Res Policy Syst*. 2016;14(1). doi:10.1186/s12961-016-0115-2.

49. Kols A, Kim YM, Bazant E, Necochea E, Banda J, Stender S. A standards-based approach to quality

improvement for HIV services at Zambia Defence Force facilities: Results and lessons learned. *Aids*. 2015;29(April):S145-S153. doi:10.1097/QAD.0000000000000720.

50. Oyeledun B, Phillips A, Oronsaye F, et al. The Effect of a Continuous Quality Improvement Intervention on Retention-In-Care at 6 Months Postpartum in a PMTCT Program in Northern Nigeria. *JAIDS J Acquir Immune Defic Syndr*. 2017;75:S156-S164. doi:10.1097/QAI.0000000000001363.

51. Hall CS, Fottrell E, Wilkinson S, Byass P. Assessing the impact of mHealth interventions in low- and middle-income countries - what has been shown to work? *Glob Health Action*. 2014;7(1):1-12. doi:10.3402/gha.v7.25606.

52. Amoakoh-Coleman M, Borgstein AB-J, Sondaal SF, et al. Effectiveness of mHealth Interventions Targeting Health Care Workers to Improve Pregnancy Outcomes in Low- and Middle-Income Countries: A Systematic Review. *J Med Internet Res*. 2016;18(8):e226. doi:10.2196/jmir.5533.

53. Zurovac D, Sudoi RK, Akhwale WS, et al. The effect of mobile phone text-message reminders on Kenyan health workers' adherence to malaria treatment guidelines: A cluster randomised trial. *Lancet*. 2011;378(9793):795-803. doi:10.1016/S0140-6736(11)60783-6.

54. Chang LW, Arem H, Ssempijja V, Serwadda D, Quinn TC, Reynolds SJ. Impact of a mHealth Intervention for Peer Health Workers on AIDS Care in Rural Uganda: A Mixed Methods Evaluation of a Cluster-Randomized Trial. 2012;15(8):1776-1784. doi:10.1007/s10461-011-9995-x.Impact.

55. Mitchell M, Hedt-Gauthier BL, Msellemu D, Nkaka M, Lesh N. Using electronic technology to improve clinical care - Results from a before-after cluster trial to evaluate assessment and classification of sick children according to Integrated Management of Childhood Illness (IMCI) protocol in Tanzania. *BMC Med Inform Decis Mak*. 2013;13(1):1. doi:10.1186/1472-6947-13-95.

56. Gergen J, Josephson E, Coe M, Ski S, Madhavan S, Bauhoff S. Quality of Care in Performance-

Based Financing: How It Is Incorporated in 32 Programs Across 28 Countries. *Glob Heal Sci Pract*. 2017;5(1):90-107. doi:10.9745/GHSP-D-16-00239.

57. Barker P, Barron P, Bhardwaj S, Pillay Y. The role of quality improvement in achieving effective large-scale Prevention of Mother-To-Child Transmission of HIV in South Africa. *Aids*. 2015;29(April):S137-S143. doi:10.1097/QAD.0000000000000718.

58. Buckley GJ, Pittluck RE, Board on Global Health, Institute of Medicine, The National Academies of Sciences, Engineering and M. *Improving Quality of Care in Low- and Middle-Income Countries*. Washington, DC: The National Academies Press; 2015. doi:10.17226/21736.

59. Infectious Diseases Institute. Infectious Diseases Institute. https://www.idi-makerere.com/index.php?option=com_content&view=article&id=17&Itemid=438. Accessed March 30, 2018.

60. Africare. About Accordia. https://www.africare.org/about-accordia/. Accessed March 30, 2018.

61. Miceli A, Sebuyira LM, Crozier I, et al. Advances in clinical education: A model for infectious disease training for mid-level practitioners in Uganda. *Int J Infect Dis*. 2012;16(10):e708-e713. doi:10.1016/j.ijid.2012.07.003.

62. Ssekabira U, Bukirwa H, Hopkins H, et al. Improved malaria case management after integrated team-based training of health care workers in Uganda. *Am J Trop Med Hyg*. 2008;79(6):826-833. doi:79/6/826 [pii].

63. Weaver MR, Nakitto C, Schneider G, et al. Measuring the outcomes of a comprehensive HIV care course: pilot test at the Infectious Diseases Institute, Kampala, Uganda. *J Acquir Immune Defic Syndr*. 2006;43(3):293-303. doi:10.1097/01.qai.0000243047.42827.97.

64. Naikoba S, Colebunders R, van Geertruyden J-P, et al. Design of a cluster randomized trial assessing integrated infectious diseases training and on-site support for midlevel practitioners in Uganda. *Int*

*J Care Pathways*. 2012;16(4):152-159. doi:10.1177/2040402613479342.

65. Weaver MR, Burnett SM, Crozier I, et al. Improving facility performance in infectious disease care in Uganda: A mixed design study with pre/post and cluster randomized trial components. *PLoS One*. 2014;9(8). doi:10.1371/journal.pone.0103017.

66. Weaver MR, Crozier I, Eleku S, et al. Capacity-Building and Clinical Competence in Infectious Disease in Uganda: A Mixed-Design Study with Pre/Post and Cluster-Randomized Trial Components. *PLoS One*. 2012;7(12). doi:10.1371/journal.pone.0051319.

67. Imani P, Jakech B, Kirunda I, Mbonye MK, Naikoba S, Weaver MR. Effect of integrated infectious disease training and on-site support on the management of childhood illnesses in Uganda: A cluster randomized trial. *BMC Pediatr*. 2015;15(1):1-14. doi:10.1186/s12887-015-0410-z.

68. Mbonye MK, Burnett SM, Burua A, et al. Effect of integrated capacity-building interventions on malaria case management by health professionals in Uganda: A mixed design study with pre/post and cluster randomized trial components. *PLoS One*. 2014;9(1). doi:10.1371/journal.pone.0084945.

69. Mbonye MK, Burnett SM, Naikoba S, et al. Effectiveness of educational outreach in infectious diseases management: a cluster randomized trial in Uganda. *BMC Public Health*. 2016;16(1):714. doi:10.1186/s12889-016-3375-4.

70. Ssebuliba DM, Pretorius C, Burnett SM, et al. Evaluating the impact of two training interventions to improve diagnosis and case-management of malaria and pneumonia in Uganda. *Epidemiol Infect*. 2017;145(1):194-207. doi:10.1017/S0950268816002107.

71. Manabe YC, Zawedde-Muyanja S, Burnett SM, Mugabe F, Naikoba S, Coutinho A. Rapid Improvement in Passive Tuberculosis Case Detection and Tuberculosis Treatment Outcomes After Implementation of a Bundled Laboratory Diagnostic and On-Site Training Intervention Targeting Mid-Level Providers. *Open Forum Infect Dis*. 2015;2(Suppl 1):1-8. doi:10.1093/o.

72. Naikoba S, Senjovu KD, Mugabe P, et al. Improved HIV and TB Knowledge and Competence among Mid-level Providers in a Cluster-Randomized Trial of One-on-One Mentorship for Task Shifting. *J Acquir Immune Defic Syndr*. 2017;75(5):e120-e127. doi:10.1097/QAI.0000000000001378.

73. Alombah F, Eliades MJ, Wun J, et al. Effect of supportive supervision on malaria microscopy competencies in sub-Saharan Africa. *Am J Trop Med Hyg*. 2018:#-#.

74. Martin T, Eliades MJ, Wun J, et al. Effect of supportive supervision on competency of febrile case management in sub-Saharan Africa. *Am J Trop Med Hyg*. 2018;#(#):#-#.

75. Eliades MJ, Alombah F, Wun J, et al. Perspectives on implementation considerations and costs of malaria case management supportive supervision. *Am J Trop Med Hyg*. 2018;#(#):#-#.

76. Eliades MJ, Wun J, Burnett SM, et al. Effect of supportive supervision on performance of malaria rapid diagnostic tests in sub-Saharan Africa. *Am J Trop Med Hyg*. 2018;#(#):#-#.

# Chapter 2:
# Effect of On-Site Support on Laboratory Practice for Human Immunodeficiency Virus, Tuberculosis, and Malaria Testing

**Effect of On-Site Support on Laboratory Practice for HIV, TB, and Malaria Testing**

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Am J Clin Pathol; 146(4):469-477. doi:10.1093/ajcp/aqw138; 2016

**ABSTRACT**

**Objectives:** To evaluate the effectiveness of on-site support in improving human immunodeficiency virus (HIV) rapid testing, tuberculosis (TB) sputum microscopy, and malaria microscopy among laboratory staff in a low-resource setting.

**Methods:** This cluster randomized trial was conducted at 36 health facilities in Uganda. From April to December 2010, laboratory staff at 18 facilities participated in monthly on-site visits, and 18 served as control facilities. After intervention, 128 laboratory staff were observed performing 587 laboratory tests across three diseases: HIV rapid testing, TB sputum microscopy, and malaria microscopy. Outcomes were the proportion of laboratory procedures correctly completed for the three laboratory tests.

**Results:** Laboratory staff in the intervention arm performed significantly better than the control arm in correctly completing laboratory procedures for all three laboratory tests with an adjusted relative risk (95% confidence interval) of 1.18 (1.10-1.26) for HIV rapid testing, 1.29 (1.21-1.40) for TB sputum microscopy, and 1.19 (1.11-1.27) for malaria microscopy.

**Conclusion:** On-site support significantly improved laboratory practices in conducting HIV rapid testing, TB sputum microscopy, and malaria microscopy. It could be an effective method for improving laboratory practice, without taking limited laboratory staff away from health facilities for training.

**Key Words:** TB sputum microscopy; HIV rapid testing; Malaria microscopy; Educational outreach; Supportive supervision; Uganda; Laboratory practice; Continuous quality improvement

## INTRODUCTION

In sub-Saharan Africa, more than half of all deaths are due to infectious diseases, such as human immunodeficiency virus (HIV), tuberculosis (TB) and malaria.[1] While efforts to address infectious diseases in Africa have increased substantially,[2] global infectious disease programs have primarily focused on clinical training in prevention and treatment, with limited attention to other aspects of health care. Strong laboratory practices are necessary to ensure reliable test results that lead to appropriate diagnosis and treatment. Despite documentation of poor-quality laboratory practices, insufficient resources have been directed towards their improvement.[2-5]

Within laboratories, quality management practices such as standard operating procedures are key tools to ensure high quality and consistent laboratory testing.[6] Improving adherence to these procedures increases the quality of laboratory testing and leads to more accurate patient diagnoses.[7] Without access to high quality laboratories, patients will continue to be misdiagnosed, leading to inappropriate treatment and increased mortality.[3]

Recent randomized control trials and reviews have shown that on-site support can effectively improve clinical skills leading to improved patient quality of care in resource-limited settings.[8-13] A similar approach could be applied to build laboratory capacity. Past studies of laboratory capacity-building have primarily utilized pre-post designs and focused on training programs[14-17] or training mixed with on-site support,[18-19] usually addressing laboratory tests for a single disease.

The Integrated Infectious Disease Capacity Building Evaluation (IDCAP) was a cluster-randomized trial that aimed to test the effect of training and on-site support (OSS) on clinical competence, clinician practice, facility performance, and population-based mortality of children younger than five years.[8] The OSS intervention involved all staff at the IDCAP intervention facilities, including laboratory staff. As a secondary outcome, laboratory staff practice in conducting laboratory tests for three leading causes of mortality in Uganda (HIV, TB, and malaria) was measured. We evaluated the effectiveness of

on-site support in improving HIV rapid testing, TB sputum microscopy, and malaria microscopy testing processes among laboratory staff.

## METHODS

### Evaluation Design

This evaluation of laboratory practice used a cluster-randomized design. The clusters were 36 health centers IV (HCIVs), comparable private health centers, and small hospitals in Uganda, randomized (1:1) to parallel intervention and control arms. HCIVs act as the highest healthcare referral point for health subdistricts and provide preventive and curative outpatient services to a population of about 100,000 people.[20-21] They offer emergency, surgical, and obstetric procedures accompanied by limited inpatient wards, as well as referral to district hospitals. HCIVs provide daytime laboratory services, while hospitals provide overnight laboratory services through an on-call system. Observations of laboratory staff were conducted at the health facilities between December 2010 and March 2011. The full trial protocol is available as Protocol S1 in Weaver et al.[8]

### Participants and eligibility

The 18 health facilities were drawn from all major regions of Uganda.[20] Facility inclusion criteria have been described previously.[20,22] One inclusion criterion relevant for this analysis was that each facility was required to have a functional laboratory that could conduct the following six investigations: HIV rapid test, malaria blood smear, TB sputum smear, urinalysis, stool analysis, and hemoglobin estimation. All laboratory staff at each facility were eligible and invited to participate in OSS.

### Interventions

OSS visits took place between April and December 2010 and were conducted once a month for 9 consecutive months.[20] OSS included four components: multidisciplinary team training, breakout sessions

by cadre, one-on-one mentoring, and continuous quality improvement. Each visit focused on a specific topic (i.e. HIV, TB, malaria), as well as follow-up on topics from previous visits. The sequence of topics was reported in Naikoba et al.[20] The OSS visits were 2 days each and were implemented by a four-person mobile team: a medical officer, clinical officer, laboratory technologist, and registered nurse. [20] The laboratory technologist is the highest level of training for laboratory professionals in Uganda. Before each OSS visit, the mobile teams were oriented to the OSS training materials designed for that visit. Each mobile team visited the same set of health facilities throughout the 9 months to ensure continuity of the OSS intervention.

During each visit, laboratory staff attended the didactic multidisciplinary team training with the other clinical staff at the health facility. Following the training, the mobile team laboratory technologist would lead breakout training sessions focused on building laboratory capacity. The content for the laboratory breakout sessions was adapted from the Infectious Diseases Institute's 10-day ''HIV Laboratory Techniques and Good Laboratory Practices'' training to include laboratory techniques for TB sputum and malaria microscopy. The malaria microscopy content was adapted from the laboratory training portion of the Joint Uganda Malaria Program, which has been shown to successfully improve the practice of laboratory diagnosis of malaria.[23] Table 2.1 describes the core competencies included in the breakout sessions.

**Table 2.1 Core Competencies for IDCAP Breakout Sessions for Laboratory Professionals**

| | |
|---|---|
| 1 | Adhere to good laboratory practice and ethical code of conduct for laboratory |
| 2 | Organize the laboratory to maximize productivity |
| 3 | Manage the work area to optimize productivity and safety |
| 4 | Competently manage laboratory inventory |
| 5 | Perform routine and preventive maintenance of lab equipment |
| 6 | Manage specimen collection and processing |
| 7 | Accurately develop, document and disseminate lab activities |
| 8 | Competently perform and interpret laboratory HIV diagnosis in adults and children |
| 9 | Competently and interpret findings in the diagnosis of malaria |
| 10 | Perform, interpret and supervise relevant laboratory tests for the diagnosis of common opportunistic infections in HIV/ AIDS |
| 11 | Competently perform and interpret laboratory diagnosis of tuberculosis |

During mentoring sessions, the mobile team laboratory technologist demonstrated correct laboratory procedures, observed and coached laboratory staff as they conducted the procedures, and provided guidance on infrastructure and systems issues such as the organization of the laboratory and the development of laboratory standard operating procedures. They used the observation checklist to assess the skills of the laboratory staff for the tests that were the focus of the OSS visit. Laboratory staff also participated in the continuous quality improvement teams at their facilities. These teams met during OSS to review facility performance indicators and develop and implement action plans to improve performance.

**Outcomes**

The laboratory practice measures were the proportion of laboratory procedures correctly completed for HIV rapid tests, TB sputum microscopy, and malaria microscopy (Table 2.2). A standardized observation tool was used to assess laboratory staff practice in carrying out the three laboratory tests. Each test had 12 to 20 items to assess proficiency. Each item was phrased as a question and observers were prompted to check a "yes" or "no" as to whether the laboratory staff being observed correctly performed the step. The number of steps done correctly was totaled for each test to produce the proportion of laboratory procedures correctly completed during each observation.

**Table 2.2 Item Analysis at Endline, by Arm**

| | HIV Rapid Test | Intervention N=121 | Control N=56 | Difference |
|---|---|---|---|---|
| 1 | Assemble materials required | 98% | 46% | 52% |
| 2 | Check for kit lot number | 31% | 18% | 13% |
| 3 | Check for kit expiry dates | 35% | 34% | 1% |
| 4 | Wear gloves | 89% | 80% | 9% |
| 5 | Draw the right volume of blood | 99% | 86% | 13% |
| 6 | Label test with the unique identification number | 98% | 79% | 19% |
| 7 | Correctly dispense blood on the test strips | 94% | 75% | 19% |
| 8 | Time the procedure | 36% | 4% | 33% |
| 9 | Interpret HIV rapid test results | 100% | 100% | 0% |
| 10 | Record results legibly | 99% | 100% | -1% |
| 11 | Follow MOH algorithms for HIV testing | 96% | 71% | 24% |
| 12 | Follow safety and infection control procedures | 98% | 88% | 10% |

**Table 2.2 Item Analysis at Endline, by Arm (con.)**

| | TB Sputum Microscopy | Intervention N=36 | Control N=30 | Difference |
|---|---|---|---|---|
| 1 | Explain how to open and close the containers | 94% | 40% | 54% |
| 2 | Explain the importance of sputum examination | 39% | 3% | 36% |
| 3 | Explain how to produce good sputum | 94% | 47% | 48% |
| 4 | Explain how to avoid contamination of the exterior of the container | 75% | 17% | 58% |
| 5 | Explain how to collect and safely deliver the morning sputum to the laboratory | 89% | 57% | 32% |
| 6 | Select new, clean, grease-free, unscratched slides | 100% | 97% | 3% |
| 7 | Use a lead pencil/ Diamond pen to label appropriately | 97% | 77% | 21% |
| 8 | Use the end of an applicator stick or wire loop, to pick purulent part of sputum | 100% | 30% | 70% |
| 9 | Prepare the smear in an oval shape in the center of the slide 2cm long x1cm wide | 97% | 37% | 61% |
| 10 | Place the used stick into a discard container | 100% | 93% | 7% |
| 11 | Use a separate stick for each specimen | 100% | 93% | 7% |
| 12 | Thoroughly spread the sputum | 97% | 47% | 51% |
| 13 | Allow the smear to air dry completely at room temperature | 92% | 97% | -5% |
| 14 | Pass the slide over the flame 2–3 times for about 2–3 seconds each time | 92% | 60% | 32% |
| 15 | Follows all the steps in sputum staining protocol | 100% | 93% | 7% |
| 16 | Examines 100 fields, takes about 5 minutes | 81% | 43% | 37% |
| 17 | Reports sputum results according to WHO criteria | 100% | 100% | 0% |
| 18 | Keep in slide boxes for the blinded rechecking for the EQA by NTLP | 100% | 100% | 0% |
| 19 | Quality control stain using known positive and known negative smears | 56% | 3% | 52% |

**Table 2.2 Item Analysis at Endline, by Arm (con.)**

| | Malaria Diagnosis | Intervention N=133 | Control N=79 | Difference |
|---|---|---|---|---|
| 1 | Prepare the patient for the finger prick | 99% | 61% | 38% |
| 2 | Use pre-cleaned grease free slides | 99% | 100% | -1% |
| 3 | Label patient's identifier | 99% | 89% | 11% |
| 4 | Select the 3rd or 4th finger to be pricked | 98% | 89% | 9% |
| 5 | Clean the site well with alcohol and allow drying | 92% | 71% | 21% |
| 6 | Prick the side of the pulp of the selected finger | 98% | 91% | 7% |
| 7 | Wipe away the first drop of blood with clean gauze or cotton | 47% | 19% | 28% |
| 8 | Discard the used needles and syringes in waste container | 98% | 92% | 5% |
| 9 | Evenly spread film of blood about 1 cm in diameter | 92% | 42% | 50% |
| 10 | Allow the smear to air dry | 76% | 65% | 11% |
| 11 | Stain thick blood films with Field stain | 96% | 65% | 32% |
| 12 | Report result according to WHO criteria | 99% | 63% | 36% |
| 13 | Performs quality control on stain using known positive and negative slides (quality control slides and records available) | 92% | 67% | 25% |

**Sample size**

Sample size calculations were based on facility performance indicators, such as the proportion of malaria suspects with a malaria test recorded, rather than laboratory practice measures.[20] A convenience sample of the laboratory staff who were available on the day of the observation at each of the 36 facilities was observed.

**Ethical Considerations**

The IDCAP protocol was reviewed and approved by the School of Medicine Research and Ethics Committee of Makerere University (reference number 2009-175) and the Uganda National Committee on Science and Technology (reference number HS-722). The University of Washington Human Subjects Division determined that it did not meet the regulatory definition of research under 45 CFR 46.102(d).

Written informed consent was obtained from the observed laboratory staff for secondary analysis of Infectious Disease Institute's training program data, including the laboratory observations.

**Data Collection**

Observations were carried out by the mobile team laboratory technologists between December 2010 and March 2011. Each mobile team was assigned to a region that included intervention and control facilities. In the intervention arm, the observations were conducted by the laboratory technologist who provided OSS at the facility. In the control arm, they were conducted by the laboratory technologist who was assigned to the same region. For each of the three laboratory tests, the observer watched as the facility laboratory staff conducted the test and recorded whether each step on the observation tool was done correctly. The laboratory technologists observed up to seven tests of each type, subject to patient availability.

Data on the total number of laboratory staff at each facility was collected from the facility managers during the first OSS visit. Laboratory staff participation in OSS was collected during each visit.

### Data Analysis

All observations were double entered in EpiInfo3.2® (U.S. Centers for Disease Control and Prevention, Atlanta GA), cleaned, and validated. All analyses were performed with Stata 11 (StataCorp, College Station, TX). Descriptive statistics on laboratory staff's cadre and participation in OSS were summarized.

To test the effect of OSS on laboratory staff practice on each outcome, we utilized a multilevel mixed-effects linear regression model, with each observation as the unit of analysis, controlling for the effect of the laboratory qualification or cadre and clustering on health facility. The main effect was arm, with cadre (laboratory assistant, technician, or technologist) as the covariate.

## RESULTS

### Participant Flow

The flow of facilities and the laboratory participants is shown in Figure 2.1. Out of 36 health facilities, 31 were HCIVs and five were hospitals. Four of the five hospitals were randomly assigned to the control arm. There was no attrition among the 36 enrolled facilities. Of the 128 laboratory staff, 64 (50%) were observed (Table 2.3). All laboratory staff on duty during that day were observed. Table 2.4 also shows participation in OSS in the intervention arm by cadre as a percentage of total laboratory staff, and the observed staff as a percentage of total laboratory staff.

**Figure 2.1 Participant Flow and Recruitment**

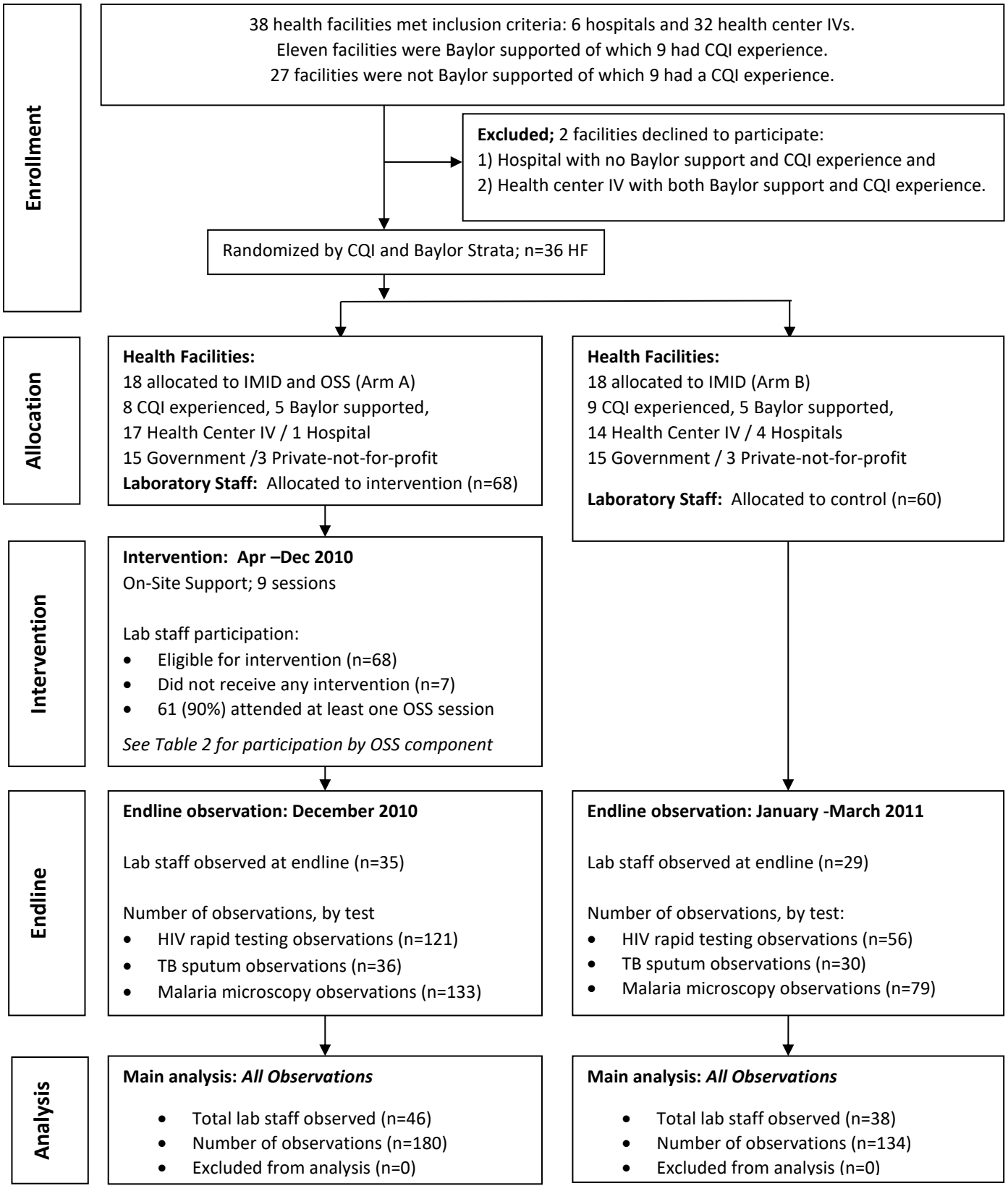

**Table 2.3 Laboratory Staff Demographics and Participation in Intervention**

**Cadre of Laboratory Staff, by OSS and Observation Participation**

| | Intervention Arm | | | Control Arm | |
|---|---|---|---|---|---|
| **Cadre** | **Total Lab Staff** | **Attended at least one OSS session of any type*** | **Observed** | **Total Lab Staff** | **Observed** |
| Laboratory Technologist | 1 | 0 (0%) | 0 (-) | 0 | 0 |
| Laboratory Technician | 22 | 20 (91%) | 13 (59%) | 18 | 8 (44%) |
| Laboratory Assistant | 38 | 34 (89%) | 20 (53%) | 37 | 21 (57%) |
| Other | 2 | 2 (100%) | 2 (100%) | 0 | 0 (-) |
| Missing | 5 | 5 (100%) | 0 (0%) | 5 | 0 (0%) |
| **Total Lab Staff** | **68** | **61 (90%)** | **35 (51%)** | **60** | **29 (48%)** |

OSS, on-site support.

*Attended at least one On-site Support Component (MDT, B/O, CQI or CM) during at least one OSS visit

**Table 2.4 OSS Participation, by Component Type (Intervention Arm)**

| | **Multi-Disciplinary Team sessions** | **Breakout sessions** | **CQI sessions** | **One-on-One Clinical Mentoring sessions** |
|---|---|---|---|---|
| **Total Eligible for OSS (N=68)** | **N (%)** | **N (%)** | **N (%)** | **N (%)** |
| **Attended at Least One Session** | **61 (90%)** | **52 (76%)** | **55 (81%)** | **51 (75%)** |
| **Average Number of Sessions Attended** | **Mean (SD)** | **Mean (SD)** | **Mean (SD)** | **Mean (SD)[+]** |
| Out of all eligible | 4.75 (2.92) | 3.41 (2.49) | 4.29 (2.77) | 3.26 (2.40) |
| Out of those who have attended at least one session | 5.30 (2.56) | 3.80 (2.32) | 4.79 (2.49) | 3.64 (2.24)<br>45min (33min) |
| **Total Observed (N=46)** | **N (%)** | **N (%)** | **N (%)** | **N (%)** |
| **Attended at Least One Session** | **35 (100%)** | **35 (100%)** | **35 (100%)** | **34 (97%)** |
| | **Mean (SD)** | **Mean (SD)** | **Mean (SD)** | **Mean (SD)** |
| **Average Number of Sessions Attended out of those who have attended at least one session** | 6.69 (1.81) | 4.94 (1.75) | 6.03 (1.74) | 4.57 (1.75)<br>50min (36min) |

OSS, on-site support.

[+]Includes average time spent per mentoring session

**Recruitment**

The facilities, and their staff, were recruited between March and September 2009. Consent for the use of the training program data for this evaluation was carried out between January and March 2011. OSS recruitment and registration began in April 2010 and continued throughout the intervention. All staff were encouraged to attend OSS regardless of previous attendance.

**Outcomes and Estimation**

***Item Analysis***

For HIV rapid testing, nine (75%) out of 12 checklist items were done correctly for more than 80% of the observations in the intervention arm, compared to 5 (42%) in the control (Table 2.2). The intervention arm performed more than 20% better than the control in three steps: assembling required materials, timing the procedure, and following Ministry of Health algorithms for HIV testing. In 80% or more of the observations in both arms, laboratory staff wore gloves, drew the right volume of blood, and followed safety and infection control procedures for HIV rapid testing. In 100% of observations across both arms, laboratory staff interpreted HIV rapid test results correctly. In less than 40% of observations in both arms, laboratory staff checked for kit lot numbers and expiry dates and timed the procedure.

For TB sputum microscopy, 16 (84%) out of 19 items were done correctly for more than 80% of the observations in the intervention arm compared with seven (37%) in the control arm. The intervention arm performed more than 20% better than the control arm in 11 steps, such as explaining to the patient how to avoid contamination of the exterior of the sputum container and using a quality control stain with known positive and negative smears. In more than 93% of observations in both arms, laboratory staff followed all steps in the sputum staining. In less than 40% of observations in both arms, laboratory staff explained the importance of the sputum examination to the patient.

For malaria microscopy, 11 (85%) out of 13 items were done correctly for more than 80% of the observations in the intervention arm, compared with five (26%) in the control. The intervention arm performed more than 20% better in seven steps. Only one indicator, wiping away the first drop of blood, was below 50% in both arms.

Focusing on reporting practices, both arms reported HIV rapid tests legibly as shown in HIV rapid test item 10 (99% intervention arm and 100% control arm) in Table 2.2. Both arms reported 100% of TB sputum results according to World Health Organization (WHO) criteria (item 17). The intervention arm reported 99% of malaria test results according to WHO criteria compared to 63% in the control group (item 12). There was no register review or documentation of changes in recording completeness over time.

***Comparing intervention and control arms***

Laboratory staff in the intervention arm performed 18% to 29% higher than the control arm on all three laboratory tests, with mean scores all above 80% (Table 2.5 and Table 2.6). The intervention arm performed 18% higher in HIV rapid testing (adjusted relative risk [aRR], 1.18, 95% confidence interval [CI], 1.10-1.26), 29% higher in TB sputum microscopy (aRR, 1.29, 95% CI, 1.20-1.40), and 19% higher in malaria microscopy (aRR, 1.19, 95% CI, 1.11-1.28) compared with the control arm. Laboratory technicians did not perform significantly better than laboratory assistants in any of the tests with an aRR (95% CI) of 1.02 (0.99-1.05) for HIV rapid testing, 0.97 (0.92-1.03) for TB sputum microscopy: and 1.01 (0.97-1.06) for malaria microscopy.

**Table 2.5 Proportion of Laboratory Procedures Correctly Completed at Endline by Arm[a]**

| | HIV Rapid Testing | | TB Sputum Microscopy | | Malaria Microscopy | |
|---|---|---|---|---|---|---|
| **Characteristic** | **Ind (Obs)** | **Mean % (SD)** | **Ind (Obs)** | **Mean % (SD)** | **Ind (Obs)** | **Mean % (SD)** |
| **Intervention** | 33 (121) | 76% (10%) | 22 (36) | 90% (8%) | 32 (133) | 82% (10%) |
| **Control** | 25 (56) | 69% (12%) | 20 (30) | 60% (13%) | 29 (79) | 77% (9%) |

HIV, human immunodeficiency virus; Ind, unique individuals; TB, tuberculosis.

[a]Mean number of observations per individual: 4.52 for HIV rapid testing, 1.57 for TB sputum microscopy, and 3.48 for malaria microscopy.

**Table 2.6 Proportion of Laboratory Procedures Correctly Completed at Endline by Arm: Regression**

| | RR (95% CI) | | |
|---|---|---|---|
| **Characteristic** | **HIV Rapid Testing** | **TB Sputum Microscopy** | **Malaria Microscopy** |
| **Intervention vs. Control** | 1.18 (1.10-1.26) | 1.29 (1.21-1.40) | 1.19 (1.11-1.27) |
| **Covariates** | | | |
| **Cadre** | | | |
| Laboratory Assistant | Ref | Ref | Ref |
| Laboratory Technician | 1.02 (0.99-1.05) | 0.97 (0.92-1.03) | 1.01 (0.97-1.06) |
| Laboratory Technologist | N/A | N/A | N/A |
| Other | 1.02 (0.94-1.10) | 1.06 (0.85-1.31) | 0.99 (0.87-1.12) |

CI, confidence interval; HIV, human immunodeficiency virus; NA, not available for observation; RR, relative risk; TB, tuberculosis.

## DISCUSSION

OSS significantly improved the practice of laboratory staff in conducting HIV rapid testing, TB sputum microscopy, and malaria microscopy. While several studies have documented the effect of OSS on clinical skills, this is one of the first studies to demonstrate the effects of OSS alone on laboratory practice across multiple tests and diseases.[8] Several key processes in the preparation of laboratory samples, including explaining to patients how to produce good sputum for TB testing, following the algorithms for testing, and correctly dispensing the blood on test strips for HIV testing, and recording results according to WHO criteria for malaria testing were substantially higher in the intervention arm.

Both laboratory assistants and laboratory technicians took part in OSS. There was no significant difference in the practice of laboratory assistants and laboratory technicians in any of the three tests, demonstrating that OSS can improve laboratory skills regardless of cadre. A study in Ghana showed improved diagnostic accuracy among laboratory assistants after establishing a national supervision program, corroborating findings.[19]

This OSS intervention was carried out for 2 days a month over 9 months and covered HIV, TB and malaria testing. By integrating testing for these three diseases, the program was able to improve laboratory practice on multiple tests as part of a single intervention. This is similar to the findings in Sarkinfada et al.,[24] in which a quality assurance program in Nigeria that integrated TB and malaria showed significant improvement across both diseases.

Only 50% of the eligible laboratory staff were observed. A similar level of attendance was seen throughout the intervention, as eligible laboratory staff (Tables 2.3 and 2.4) and clinical staff[8] attended an average of fewer than five out of nine sessions for each of the visit components. Laboratory staff who were observed tended to have higher levels of average attendance, thus the effects of this intervention may have been diluted if all laboratory staff were observed.

While reasons for low levels of attendance were not systematically tracked in this study, overnight on-call shifts and attendance at trainings were commonly cited. Attendance was similar to the Uganda Service Delivery Indicators report, which found that only 48% of health care workers were present on a given facility visit, and that 60% of these absences were approved for attending trainings, seminars or another official mission.[25] Despite low attendance, 90% of laboratory staff in the intervention arm benefitted from at least one OSS visit. Given high absence rates, OSS could be a powerful tool for building laboratory capacity without further contributing to absences. When planning future interventions additional steps could be taken to ensure higher rates of attendance. For the IDCAP's clinical training program, participants were required to attend seven of nine OSS sessions to receive a certificate of completion, and the average attendance among this subgroup of clinicians was seven of nine sessions.[8] A similar requirement could be introduced for laboratory on-site support.

The intervention included four main components: team-based multidisciplinary training, breakout sessions focused on laboratory personnel, one-on-one mentoring, and continuous quality improvement sessions. While our evaluation cannot distinguish the relative value of each component, we hypothesize that breakout sessions and mentoring may have led to the documented improvement in laboratory testing. Multidisciplinary training and CQI may lead to increased trust between laboratory staff and clinicians and improved adherence to laboratory results, which was reflected in facility performance data.[8,18] Further research is needed to determine how such interventions impact laboratory skills and appropriate use of laboratory results.

While we originally planned to collect external quality assurance data from national data sources for HIV and TB testing and conduct on-site blinded slide rechecking for malaria microscopy throughout the intervention, these samples were not consistently collected by facility laboratory staff or available at the national laboratory bodies. The lack of routinely collected slides as part of an external quality assurance program demonstrates, in part, weaknesses within the national laboratory supervision programs at the time of the intervention. Previous studies have also documented similar challenges in establishing and

maintaining robust national external quality assurance programs for laboratory testing in Africa, including funding and transportation of samples.[26-27]

As the external quality assurance data was not available, the trial protocol was modified to utilize a postintervention observation of laboratory staff in both arms. With this change in design, valid baseline data were not available, and we were unable to control for differences between the two arms at baseline. Also, a convenience sample of laboratory staff were observed, which may not have been representative. Finally, the observations were carried out by the laboratory mobile team members who were primarily responsible for providing on-site support, which presented an opportunity to bias results in favor of the intervention facilities.

The health facilities selected for this trial all had laboratories capable of conducting a set of standard exams. Given that the provision of basic laboratory supplies and equipment in many health facilities in sub-Saharan Africa remains a challenge, our findings may not be generalizable to all facilities.[28] In addition to building human resource capacity, which was assessed in this evaluation, OSS may also help address commodity and stock issues through a health system strengthening approach.[29] During OSS, supervisors can identify infrastructure gaps and advocate on behalf of the health facilities for the provision of commodities, ensuring that clinicians and laboratory staff have the skills and supplies necessary to provide high-quality care.

Future studies on laboratory capacity building should go beyond assessing the sample preparation and recording process and use blinded slide rechecking or proficiency testing to assess the sensitivity and specificity of laboratory staff readings. Future interventions could also include more advanced diagnostics, such as fluorescence microscopy or Xpert MTB/RIF (Cepheid, Toulouse, France) for TB and malaria rapid diagnostic tests, which may further reduce error and increase testing in rural facilities.[30-31] Finally, studies should be done to determine how such interventions could be taken to scale and integrated into a national laboratory management and support programs that ensure quality across all laboratory tests.

## CONCLUSION

OSS significantly improved the practice of laboratory staff in conducting HIV rapid testing, TB sputum microscopy and malaria microscopy. Integrated OSS could be an effective method for improving laboratory practice, without taking laboratory staff away from health facilities.

**Authors' contributions:** MKM, AR, MRW, and KSW conceived and designed the experiments. SZ performed the experiments. SMB, MKM, TR, and MRW analyzed the data. SMB, MKM, and MRW wrote the paper. AR RM RC and YM reviewed the manuscript to meet submission requirements. All authors reviewed and approved final submission.

**Acknowledgement of sources of support:** This work was supported through grant number 94298 to Accordia Global Health Foundation from the Bill & Melinda Gates Foundation. The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript. The findings and conclusions contained within the manuscript are those of the authors and do not necessarily reflect positions or policies of the Bill & Melinda Gates Foundation.

**REFERENCES**


1. Institute for Health Metrics and Evaluation. *The Global Burden of Disease: Generating Evidence, Guiding Policy*. Seattle, Washingon 2013.
2. Nkengasong JN, Nsubuga P, Nwanyanwu O, et al. Laboratory systems and services are critical in global health: Time to end the neglect? *Am J Clin Pathol*. 2010;134:368-373.
3. Birx, Deborah; de Souza, Mark; Nkengasong, John N. Laboratory Challenges in the Scaling Up of HIV, TB, and Malaria Programs: The Interaction of Health and Laboratory Systems, Clinical Research, and Service Delivery. *Am J Clin Pathol*. 2009;131:849-851.
4. Green SF. The cost of poor blood specimen quality and errors in preanalytical processes. *Clinical Biochemistry*. June 2013;46:1175-1179. doi:10.1016/j.clinbiochem.2013.06.001.
5. Wolpaw BJ, Mathews C, Chopra M, et al. The failure of routine rapid HIV testing: a case study of improving low sensitivity in the field. *BMC Health Services Research*. March 2010;10(73):doi:10.1186/1472-6963-10-73.
6. Vetter LP. Management Functions. p. 23-42. *In*: Garcia LS, ed. *Clinical Laboratory Management*. *Second Edition.*Washington, DC: ASM Press; 2004. doi: 10.1128/9781555817282.ch2
7. Nkengasong JN, Birx D. Quality matters in strengthening global laboratory medicine. *Afr J Lab Med*. 2014;3(2): http://dx.doi.org/10.4102/ajlm.v3i2.239.
8. Weaver MR, Burnett SM, Crozier I, et al. Improving Facility Performance in Infectious Disease Care in Uganda: A Mixed Design Study with Pre/Post and Cluster Randomized Trial Components. *PLoS ONE*;9(8):e103017. doi:10.1371/journal.pone.0103017.
9. Fairall LR L, Zwarenstein M, Bateman E, et al. Effect of educational outreach to nurses on tuberculosis case detection and primary care of respiratory illness: pragmatic cluster randomized trial. *British Medical Journal*. November 2005;331(7519):750-754. doi: 10.1136/bmj.331.7519.750.

10. Fairall L, Bachmann M, Lombard C, et al. Task shifting of antiretroviral treatment from doctors to primary-care nurses in South Africa (STRETCH): a pragmatic, parallel, cluster-randomised trial. *The Lancet*. 2012;380(9845):889-898. doi: 10.1016/S0140-6736(12)60730-2.

11. Ferguson JTB, Peterson ED, Coombs LP, et al. Use of continuous quality improvement to increase use of process measures in patients undergoing coronary artery bypass graft surgery: a randomized control trial. *Journal of the American Medical Association*. 2003;290(1):49-56. doi:10.1001/jama.290.1.49.

12. Engels Y, van den Hombergh P, Mokkink H, van den Hoogen H, van den Bosch W, Grol R. The effects of a team-based continuous quality improvement intervention on the management of primary care: a randomised controlled trial. *British Journal of General Practice*. 2006;56(531):781-787.

13. Ayieko P, Ntoburi S, Wagai J, et al. A Multifaceted Intervention to Implement Guidelines and Improve Admission Paediatric Care in Kenyan District Hospitals: A Cluster Randomised Trial. *PLoS Med*. Apr 2011;8(4): e1001018.

14. Moura S, Fancony C, Mirante C, et al. Impact of a training course on the quality of malaria diagnosis by microscopy in Angola. *Malaria Journal*. 2014;13(437): http://www.malariajournal.com/content/13/1/437

15. Kiggundu M, Nsobya SL, Kamya MR, et al. Evaluation of a Comprehensive Refresher Training Program in Malaria Microscopy Covering Four Districts of Uganda. *Am. J. Trop. Med. Hyg.* 2011;84(5):820-824.

16. Reji P, Aga G, Abebe G. The role of AFB microscopy training in improving the performance of laboratory professionals: analysis of pre and post training evaluation scores. *BMC Health Services Research*. 2013;13(392): doi: 10.1186/1472-6963-13-392

17. Addo KK, Yeboah-Manu D, Dan-Dzide M, et al. Diagnosis of Tuberculosis in Ghana: The Role of Laboratory Training. *Ghana Medical Journal*. March 2010;44(1):31-36.

18. Ssekabira U, Bukirwa H, Hopkins H, et al. Improved malaria case management following integrated team-based training of health care workers in Uganda. *American Journal of Tropical Medicine and Hygiene*. 2008;79(5):826-33. http://www.ajtmh.org/content/79/6/826.long

19. Bates I, Bekoe V, Asamoa-Adu A. Improving the accuracy of malaria-related laboratory tests in Ghana. *Malaria Journal*. November 2004;3(38): http://www.malariajournal.com/content/3/1/38

20. Naikoba S, Colebunders R, Van Geertruyden JP, et al. Design of a cluster randomized trial assessing integrated infectious diseases training and onsite support for mid-level practitioners in Uganda. *International Journal of Care Pathways*. 2012;16(152): doi: 10.1177/2040402613479342.

21. Ugandan Ministry of Health. *Health Sector Strategic and Investment Plan 2010/11 – 2014/15*. Kamapala 2010; pg. 5

22. Miceli A, Sebuyira L, Crozier I, et al. Advances in Clinical Education: A Model for Infectious Disease Training for Mid-Level Practitioners in Uganda. *International Journal of Infectious Diseases*. Disease, 2012 (16): e708–e713 2012;16:e708–e713.

23. Namagembe A, Ssekabira U, Weaver MR, et al. Improved clinical and laboratory skills after team-based, malaria case management training of health care professionals in Uganda. *Malaria Journal*. 2012;11(44): http://www.malariajournal.com/content/11/1/44

24. Sarkinfada F, Aliyu Y, Chavasse C, Bates I. Impact of introducing integrated quality assessment for tuberculosis and malaria microscopy in Kano, Nigeria. *J Infect Developing Countries*. 2009;3(1):20-27.

25. Wane W, Martin GH. *Service Delivery Indicators: Education and Health Services in Uganda*. pg. 2. Washington DC: World Bank; 2013.

26. Sakandé J, Nikièma A, Kabré E, et al. Implementation of a National External Quality Assessment Program for Medical Laboratories in Burkina Faso. *Am J Clin Pathol*. 2014;141:181-187. DOI: 10.1309/AJCPXC83HIBBSRDT.

27. Mukadi P, Gillet P, Lukuka A, et al. External quality assessment of malaria microscopy in the Democratic Republic of the Congo. *Malaria Journal*. 2011;10(308): http://www.malariajournal.com/content/10/1/308

28. Petti CA, Polage CR, Quinn TC, Ronald AR, Sande MA. Laboratory Medicine in Africa: A Barrier to Effective Health Care. *Clinical Infectious Diseases*. 2006;42:377-82.

29. Bazan E, Sarkar S, Banda J, et al. Effects of a performance and quality improvement intervention on the work environment in HIV-related care: a quasi-experimental evaluation in Zambia. *Human Resources for Health*. 2014;12(73): http://www.human-resources-health.com/content/12/1/73

30. Manabe YC, Zawedde-Muyanja S, Burnett SM, et al. Rapid improvement in passive TB case detection and TB treatment outcomes following implementation of a bundled laboratory diagnostic and on-site training intervention targeting mid-level providers. *Open Forum Infectious Diseases*. 2015 Mar 31;2(1):ofv030. doi: 10.1093/ofid/ofv030.

31. Bruxvoort , Kalolella A, Nchimbi H, et al. Getting antimalarials on target: impact of national roll-out of malaria rapid diagnostic tests on health facility treatment in three regions of Tanzania. *Tropical Medicine and International Health*. October 2013;18(10):1269-1282: doi:10.1111/tmi.12168

# Chapter 3:
# Synergistic Impact of Training Followed by On-Site Support on HIV Clinical Practice: a Mixed Design Study in Uganda with Pre/Post and Cluster Randomized Trial Components

**Synergistic impact of training followed by on-site support on HIV clinical practice: A mixed design study in Uganda with pre/post and cluster randomized trial components**

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J Acquir Immune Defic Syndr 2018;77:467–475

**ABSTRACT**

**Background:** Task-shifting can expand antiretroviral therapy access, but little is known about effective approaches to improve clinical practice among midlevel practitioners (MLP) such as clinical officers, nurses, and midwives. The Integrated Infectious Diseases Capacity-Building Evaluation compared training alone to training combined with on-site support (OSS).

**Methods:** Two MLP each from 36 health facilities attended the 5-week Integrated Management of Infectious Disease training. After training, 18 facilities randomly assigned to arm A received OSS for 9 months, whereas 18 arm B facilities did not. Clinical faculty assessed MLP HIV clinical practice on 6 tasks: history taking, physical examination, laboratory investigations, diagnosis, treatment, and patient education. We analyzed the effect of training alone and training combined with OSS as the pre/post change within each arm. We analyzed the incremental effect of OSS with a difference-in-difference analysis that compared changes between arms.

**Results:** Training alone and training combined with OSS significantly improved clinical practice in patient history taking (13% and 24% increase, respectively), physical examination (54% and 71%), laboratory investigations (32% and 20%) and diagnosis (31% and 51%). Combined training and OSS also improved patient education significantly (72% increase). Effect sizes for training combined with OSS were larger than for training alone except for laboratory investigations, and the effects were robust in sensitivity analyses. The incremental effect of OSS on diagnosis was significant [adjusted relative risk=1.23; 95% confidence interval =1.00-1.50).

**Conclusions:** Combined training and OSS improved MLP HIV clinical practice over training alone and can contribute to continued expansion of access to antiretroviral therapy.

**Key Words:** midlevel practitioners, clinical practice, quality of health care, education, capacity, HIV/AIDS care, infectious diseases, Africa, south of the Sahara, Uganda

## INTRODUCTION

Global efforts have rapidly increased access to antiretroviral therapy (ART); the percentage of people living with HIV on ART increased from 23% in 2010 to 53% by the end of 2016.[1] Despite more than doubling access in 5 years, 1 out of 2 people who need life-saving ARTs are not receiving them, and each year, an estimated 2.1 million more people become infected. To reach the Fast-Track Target of 95% of people living with HIV receiving ART by 2030, access to ART must continue to expand rapidly.[2] Although access to drugs, equipment, and facilities have dramatically increased, lack of qualified human resources remains a major constraint.[2] To close the gap, a surge in the number of health professionals trained to provide high-quality HIV treatment is required over the next 10 years.[3] Task-shifting from doctors to midlevel practitioners (MLPs), which include clinical officers, nurses, and mid-wives, could support continued scale-up of ART.[4,5] Not only are there more MLPs than physicians within existing health systems, they are more likely to work in rural and underserved areas.[6] Reviews have demonstrated that task-shifting can meet patient needs without sacrificing quality.[7,8] However, few studies have compared the effectiveness of capacity-building interventions to prepare MLPs to manage patients with HIV infection.

The Integrated Infectious Diseases Capacity Building Evaluation (IDCAP) project compared the effectiveness of 2 approaches to build capacity for the care and prevention of infectious diseases among MLPs in sub-Saharan Africa: a training program for MLPs on the integrated management of infectious diseases (IMID) and IMID training combined on-site support (OSS).[9] We report the results for HIV clinical practice; results on clinical competence, pediatric clinical practice, and facility performance were previously reported.[10–14]

## METHODS

### Study Design

The evaluation of clinical practice was conducted between January 2010 and March 2011 and used a mixed design with pre/post and cluster-randomized trial components. Among 36 selected health facilities,

2 MLPs from each facility attended a 5-week IMID training. In addition to IMID, 18 facilities randomly assigned to arm A participated in OSS for 9 months, while 18 facilities in arm B did not. We assessed HIV clinical practice before (time 0) and after (time 1) the interventions and compared changes within and across arms. The full protocol is available as a supplementary file in Weaver et al.[12] consort checklist is available as Supplemental Digital Content File 1, http://links.lww.com/QAI/B128.

## Participants and Eligibility

### *Health Facilities*

The 36 health facilities (31 health centers IV, 5 hospitals) were drawn from the 6 regions of Uganda. Health centers IV are the health subdistrict referral facilities and provide preventive and curative outpatient services to catchment populations of 100,000.[12,15] Two key facility inclusion criteria were accreditation to provide ART and a laboratory with the capability to perform 6 laboratory tests: HIV rapid test, tuberculosis (TB) sputum smear, hemoglobin estimation, malaria blood smear, urinalysis, and stool analysis.[9,16]

### *Trainees*

Two MLPs were selected from each of the 36 health facilities. To be eligible for participation in the evaluation, the MLP had to be a clinical officer, registered nurse, or registered midwife, devote at least 80% of their time to clinical care in outpatient and ART clinics, and available to participate throughout the evaluation. Clinical officers received first priority, followed by registered nurses then registered midwives.

### *Patients*

Patients were a convenience sample who attended the HIV clinics on days that the clinical faculty conducted the assessments.

## Interventions

The 72 selected MLPs attended IMID training, a 3-week core course, followed by two 1-week boost courses 12 and 24 weeks after the initial training. The course was based on content from the World Health Organization's (WHO) Integrated Management of Adult Illness and Integrated Management of

Childhood Illness courses, the Infectious Disease Institute's Comprehensive Management of HIV including ART and Joint Uganda Malaria Training Program courses and updated national and WHO guidelines for HIV/AIDS, tuberculosis and malaria treatment.[17,18] The case-based course covered a range of HIV-related issues, from HIV testing and routine HIV patient care to treating pregnant women and children, and managing complex cases.

After the IMID, arm A facilities received monthly 2-day OSS visits for 9 months from a team of 4 clinical faculty: a medical officer with continuous quality improvement (CQI) experience, a clinical officer, a laboratory technologist, and registered nurse. During OSS, the MLPs and other health facility staff participated in multidisciplinary training, cadre-specific breakout sessions, one-on-one mentoring, and CQI sessions. The multidisciplinary training was designed to foster teamwork between clinical and laboratory staff while building capacity. The CQI sessions used facility-based data to identify areas for quality improvement and then monitor the improvements. During one-on-one mentoring, the OSS faculty developed the MLPs' clinical skills by observing MLP practice and providing individualized feedback. Each month the OSS visit focused on a new topic. Four of the 9 OSS visits focused on HIV management with the following topics: Comprehensive HIV care, ART follow-up and monitoring, pediatric ART, and prevention of mother-to-child transmission. To receive a certificate of completion, MLPs had to attend at least 7 of the 9 OSS sessions. A detailed description of the IMID and OSS content is reported in Miceli et al.[16]

**Outcomes**

The outcomes were HIV clinical practice on 6 tasks. Clinical faculty used a standardized HIV Clinical Observation Form (Supplemental Digital Content File 2, http://links.lww.com/QAI/B111), based on Brentlinger et al., to record information on patients and MLPs' clinical practice.[19,20] Patients were heterogeneous, so some items were required for all patients, and additional follow-up items were required based on information learned about the patient during the consultation. It was necessary to record patient

information to document that additional items were required. For example, a question about history of fever was required for all patients, and the patient's response was recorded. When a patient had a history of fever, a follow-up question was required about the duration of fever. The number of required items varied across patients, and all items were weighted equally for the required items for each patient. For example, a trainee with a score of 5 of 7 items for a patient would have a higher score than a trainee with 7 of 11 items for a different patient.

After the MLPs completed the patient history and physical examination, the clinical faculty asked additional history questions or examined additional systems to complete missing information or correct errors made by the MLPs. To distinguish patient information obtained by the MLPs from that obtained by the clinical faculty on the same form, the MLPs' clinical findings were recorded in blue or black ink and the faculty members' were recorded in red ink. The items that were required for all patients are described below, and a full list of items is in Supplemental Digital Content File 2, http://links.lww.com/QAI/B111.

***History taking (7-11 items)***

Number of questions asked given each patient's history and presenting symptoms, including weight, current cotrimoxazole and ART status, history of fever and cough, functional status, and other symptoms and concerns.

***Physical examination (5-6 items)***

Number of physical systems examined given each patients' history, and initial findings of physical examination, including a general examination, examination of 4 systems (mouth, skin, lungs, abdomen), and other systems.

***Laboratory tests (1 item)***

Summary score for laboratory and other tests based on the differential diagnosis.

***Diagnosis (2 items)***

The first item was on diagnosing eligibility for ART for patients not on ART and treatment failure for patients on ART. The second item was a summary score for diagnosis of opportunistic infections and other diagnoses for all patients, plus ART side effects for patients on ART.

***Treatment (2-3 items)***

Number of treatments correctly prescribed among cotrimoxazole and other treatments for all patients, plus ART for patients on ART.

***Patient/caregiver education (2 items)***

Number of patient/caregiver education messages provided correctly among positive prevention and recommendations to use a mosquito net.

***Changes after trial commencement***

There were no major changes to the study outcomes; however, there were modifications to the items included for each task due to missing data at baseline, as noted under data management.

**Sample size**

Trainees were each assessed on 5 patients with HIV per time point. The number of facilities was based on testing the effect of OSS on facility performance using 2 malaria indicators as reported in Naikoba et al.[9] The number of MLPs participating in IMID training and the number of patients observed were based on budget and program feasibility. With a sample size of 180 patients in each arm and time point (36 MLP with 5 patient each) we could detect an increase in tasks performed correctly from 60% to 75% with a power of 0.84, and 70%-85% with a power of 0.91.

**Randomization**

Health facilities were assigned to the 2 study arms after baseline data collection (1:1 balance) by stratified random selection, with stratification for 2 on-site interventions that would have potentially contaminated the trial: (1) previous experience with the Health Care Improvement Program, a CQI program for HIV prevention, care, and treatment; and (2) current or previous participation in the Baylor International

Pediatric AIDS Initiative on-site intervention. Randomization was performed using random number generation in Stata 10.1 after the completion of the baseline assessment. This study was not blinded during the intervention or endline assessments.

**Data Collection**

At baseline and endline, clinical faculty were trained to conduct the clinical assessments with a 1-day training and 2 days of pilot testing at non-study facilities. Fourteen of the 17 clinical faculty were trained in the IMID course. Two clinical faculty that participated at baseline left their positions and were replaced at endline.

**Data Management and Statistical Methods**

Data were coded by 2 Ugandan medical doctors (N.M. and P.I.) and entered into Epi Info 3.2 (U.S. Centers for Disease Control and Prevention, Atlanta, GA). The data were checked for consistency and cleaned with reference to the paper forms, and analyzed using Stata 11.1 (StataCorp, 2009 College Station, TX). Descriptive statistics for patient characteristics were calculated by arm and time.

For each outcome, we used the change in arm B from baseline to endline to test the effect of IMID, the change in arm A to test the combined effect of IMID and OSS, and the comparison of change between the 2 arms to test the incremental effect of OSS. The data were analyzed using a generalized linear model with a Poisson family and log link with main effects for arm, time, and their interaction to estimate relative risks and ratio of relative risks. The unit of analysis was the patient with the number of tasks performed correctly as the numerator, and the number of required tasks for that patient as the denominator. Regression analyses were clustered on the MLPs with robust variance estimation to adjust for using the Poisson family and for overdispersion. Random effects for MLPs nested within health facility did not affect the results and were not included in the reported models. Although there were multiple comparisons, a 5% level of significance was used.

To address any residual confounding, we adjusted for MLP cadre, case complexity as measured by whether the patient presented with an opportunistic infection, and the 2 strata (facility participation in the Health Care Improvement program and Baylor International Pediatric AIDS Initiative). Some MLPs may have learned from the assessment and improved their practice on subsequent patients, so we controlled for patient order. Given the potential for differences across clinical faculty, we controlled for cadre, and whether they had attended IMID and the baseline and endline assessment trainings. To address the change in clinical faculty from baseline to endline, sensitivity analyses were conducted with the subsample for which clinical faculty were balanced across arms and time points.

The primary model included the complete cases for each task, where information was reported on each item within the task. For patient history, 3 items were not included because data were missing for 35 patients or more at baseline: night sweats, weight loss, and recent history of contact with a patient with tuberculosis. For physical examination, 4 systems were not included because data were missing for 24 or more patients at baseline: cardiovascular, genital, muscle, and neurological. Additional sensitivity analyses were performed with 2 alternative assumptions about the missing values: 1) all missing values were interpreted as the item not being performed, that is missing values were equal to zero, and 2) all missing values were interpreted as being performed, that is missing values were equal to one. Regression diagnostics were also performed to identify outliers, and influential observations and estimates were obtained excluding these observations.

**Ethical Considerations**

IDCAP was reviewed and approved by the School of Medicine, Research and Ethics Committee of Makerere University (Reference Number 2009-175), and the Uganda National Council for Science and Technology (Reference HS-722). The University of Washington Human Subjects Division determined that the evaluation did not meet the regulatory definition of research under 45 CFR 46.102(d). During the evaluation, the MLPs participating in the study gave written informed consent for secondary analysis of their training program data for the evaluation. On the day of the assessment, patients and their caregivers

were introduced to the assessments and asked to provide verbal informed assent/consent before the consultation. The patient data were anonymous.

## RESULTS

### Recruitment and Enrollment

Thirty-eight health facilities were assessed for eligibility and met the inclusion criteria. However, one facility declined to participate, and one facility was excluded because it was participating in another research project. Four of the 5 hospitals were randomized to arm B (Figure 3.1). Of the 72 selected MLPs, there were 48 clinical officers, 20 registered nurses, and 4 registered midwives. Seventy-two percent and 61% of the MLPs were clinical officers in arm A and arm B, respectively. All midwives were at arm B facilities. All 72 selected MLPs participated in the three-week IMID course. One MLP in arm A and 3 MLP in arm B were not available to participate in at least one boost course. All 36 MLPs in arm A participated in at least 1 OSS session and 29 (81%) attended at least 7 of the 9 sessions.

Clinical assessments were completed and forms were available for 35 health facilities. At baseline, all 36 MLPs in arm A and 33 MLPs in arm B had analyzable clinical assessments. At endline, 35 MLPs in arm A and 33 in arm B had analyzable clinical assessments. Thirty-five MLPs in arm A and 32 in arm B had assessments at both time points and were included in the analysis. While the aim was to observe each MLP providing care to 5 patients with HIV at each time point, 4 had fewer and 9 had more, with a maximum of 15 patients across both time points. A total of 680 patients were included in the analysis. Most patients with HIV in the sample were adults 18 years of age or older visiting for a cotrimoxazole and/or ART refill (Table 3.1). The most common presenting complaints were cough and fever.

**Figure 3.1 Participant flow and recruitment for the HIV clinical assessments**

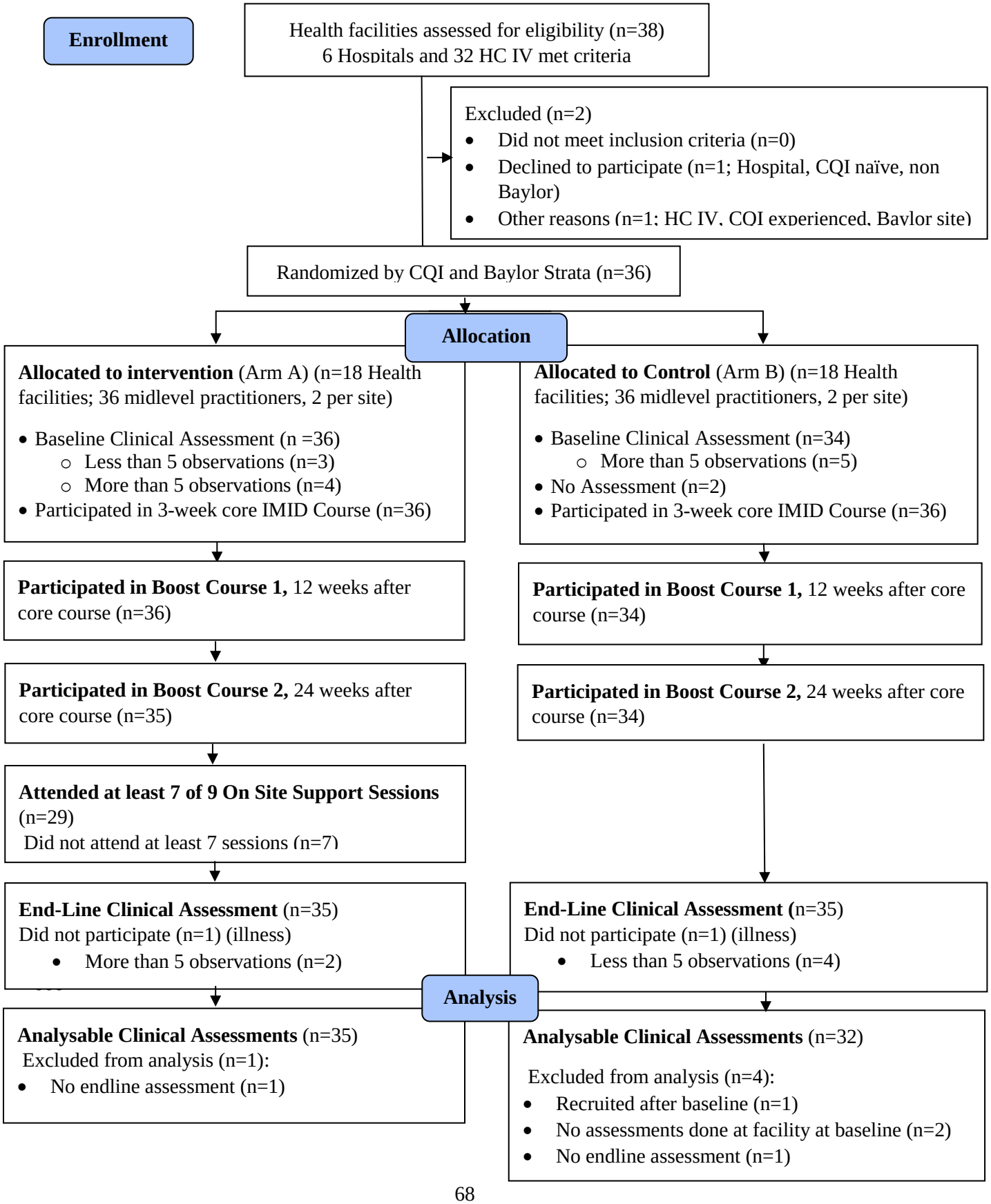

**Table 3.1 Patient Characteristics During Clinic Visits***

| | Baseline | | | Endline | | |
|---|---|---|---|---|---|---|
| | **Arm A** | **Arm B** | **Total** | **Arm A** | **Arm B** | **Total** |
| | **N=174 N (%)** | **N=169 N (%)** | **N=343 N (%)** | **N=178 N (%)** | **N=159 N (%)** | **N=337 N (%)** |
| Female | 108 (62) | 114 (68) | 222 (65) | 115 (65) | 114 (68) | 222 (66) |
| Age >18 | 167 (96) | 164 (97) | 331 (97) | 166 (93) | 150 (94) | 316 (94) |
| Fever | 48 (28) | 44 (26) | 92 (27) | 37 (21) | 52 (33) | 89 (26) |
| Cough | 55 (33) | 51 (31) | 106 (32) | 63 (35) | 51 (32) | 114 (34) |
| Night sweats | 25 (19) | 11 (9) | 36 (14) | 20 (11) | 22 (14) | 42 (13) |
| Weight loss | 21 (17) | 17 (14) | 38 (16) | 29 (16) | 23 (15) | 52 (16) |
| Abdominal pain | 40 (23) | 36 (21) | 76 (22) | 26 (15) | 34 (21) | 60 (18) |
| Shortness of breath | 10 (6) | 8 (5) | 18 (5) | 9 (5) | 18 (11) | 27 (8) |
| Burning sensation | 14 (8) | 9 (5) | 23 (7) | 14 (8) | 14 (9) | 28 (8) |
| Chest pain | 30 (17) | 19 (11) | 49 (14) | 21 (12) | 27 (17) | 48 (14) |
| Diarrhea | 17 (10) | 18 (11) | 35 (10) | 6 (3) | 7 (4) | 13 (4) |
| General malaise | 8 (5) | 4 (2) | 12 (3) | 11 (6) | 20 (13) | 31 (9) |
| Genital sores | 18 (10) | 23 (14) | 41 (12) | 16 (9) | 22 (14) | 38 (11) |
| Headache | 37 (21) | 24 (14) | 61 (18) | 29 (16) | 41 (26) | 70 (21) |
| Loss of appetite | 24 (14) | 32 (19) | 56 (16) | 23 (13) | 33 (21) | 56 (17) |
| Oral sores | 10 (6) | 6 (4) | 16 (5) | 5 (3) | 6 (4) | 11 (3) |
| Muscle aches | 6 (3) | 4 (2) | 10 (3) | 13 (7) | 21 (13) | 34 (10) |
| Nausea | 9 (5) | 11 (7) | 20 (6) | 5 (3) | 8 (5) | 13 (4) |
| Skin problems | 32 (18) | 33 (20) | 65 (19) | 41 (23) | 24 (15) | 65 (19) |
| Pain on swallowing | 7 (4) | 6 (4) | 13 (4) | 8 (4) | 1 (1) | 9 (3) |
| Vomiting | 5 (3) | 4 (2) | 9 (3) | 2 (1) | 11 (7) | 13 (4) |
| Cotrimoxazole refill | 160 (93) | 144 (86) | 304 (89) | 149 (84) | 144 (91) | 293 (87) |
| ART refill | 88 (89) | 68 (81) | 156 (85) | 105 (83) | 84 (79) | 189 (81) |
| Any presenting opportunistic infection | 63 (40) | 43 (28) | 106 (34) | 46 (26) | 43 (27) | 89 (26) |

*The total sample varies from item to item. Percentages are based out of the total with responses.

**Outcomes**

Figure 3.2 shows the unadjusted average proportion of items performed correctly by task comparing the 2 arms at baseline (time 0) and endline (time 1)**.** Clinical practice was comparable at baseline. Although both arms improved for all tasks over time, arm A had higher scores at endline in unadjusted analyses.

Testing the effect of IMID, clinical practice significantly improved in arm B by 13% for patient history [95% confidence interval (CI) = 1.03 to 1.24], 54% for physical examination (95% CI = 1.29 to 1.83), 32% for laboratory investigations (95% CI = 1.04 to 1.67) and 23% for diagnosis (95% CI = 1.04 to 1.45) (Table 3.2).

**Figure 3.2 Unadjusted average proportion of appropriate tasks performed correctly by arm and time period**

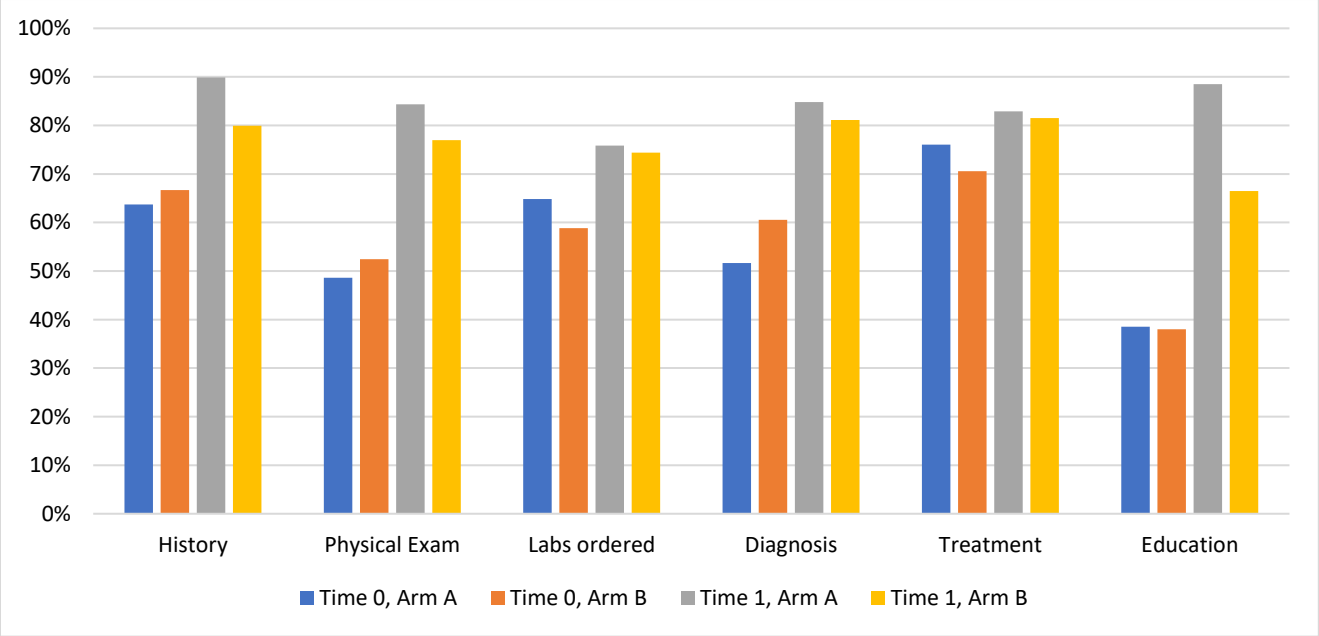

**Table 3.2 Relative risks (95% confidence intervals) across time periods and arms of performing task correctly, adjusted full sample**

| | Sets of Clinical Tasks | | | | | |
|---|---|---|---|---|---|---|
| Effects | History RR (CI) | Physical Exam RR (CI) | Investigations RR (CI) | Diagnosis RR (CI) | Treatment RR (CI) | Patient Education RR (CI) |
| Sample Size | N=621 | N=608 | N=645 | N=650 | N=608 | N=580 |
| Arm A vs. Arm B at time 0 | 1.03 (0.93-1.14) | 1.01 (0.84-1.22) | 1.16 (0.93-1.45) | 0.88 (0.74-1.04) | 1.03 (0.98-1.09) | 0.94 (0.68-1.29) |
| Arm B (IMID): Time 1 vs. time 0 | 1.13* (1.03-1.24) | 1.54*** (1.29-1.83) | 1.32* (1.04-1.67) | 1.23* (1.04-1.45) | 1.04 (0.99-1.09) | 1.27 (0.99-1.64) |
| Arm A (IMID & OSS): Time 1 vs. time 0 | 1.24*** (1.15-1.34) | 1.71*** (1.44-2.03) | 1.20* (1.01-1.43) | 1.51*** (1.31-1.74) | 1.02 (0.96-1.08) | 1.72*** (1.33-2.23) |
| Change in arm A vs. Arm B (OSS), RRR | 1.10 (0.98-1.24) | 1.11 (0.89-1.37) | 0.91 (0.69-1.20) | 1.23* (1.00-1.50) | 0.98 (0.91-1.06) | 1.36 (0.95-1.93) |

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

Testing the combined effect of IMID and OSS, clinical practice significantly improved in arm A by 24% for patient history (95% CI = 1.15 to 1.34), 71% for physical examination (95% CI = 1.44 to 2.03), 20% for laboratory investigations (95% CI = 1.01 to 1.43), 51% for diagnosis (95% CI = 1.31 to 1.74), and 72% for patient education (95% CI = 1.33 to 2.23). When compared to IMID alone, the combined effect of IMID and OSS was larger for 4 of these 5 tasks.

Assessing the incremental effect of OSS, there was a 23% significant increase in diagnosis (95% CI = 1.00 to 1.50). There were also increases in the percentage of correct history, physical examination, and patient education items that were not statistically significant.

The balanced sample included 30 MLPs from arm A and 27 from arm B and 427 clinical assessments, with 113 in arm A and 105 in arm B at baseline, and 113 and 99, respectively, at endline. At baseline arm A performed significantly better for treatment (Table 3.3). Adjusting for covariates, IMID was associated with an improvement of 30% in physical examination (95% CI = 1.07 to 1.58) and 45% in patient education (95% CI = 1.04 to 2.03).

As in the full sample, the combined effect of IMID and OSS was larger than IMID alone. Table 3.3 shows a 23% improvement in history taking (95% CI = 1.13 to 1.35), 43% in physical examination (95% CI = 1.22 to 1.68), 27% in laboratory investigations (95% CI = 1.02 to 1.57), 57% in diagnosis (95% CI = 1.31 to 1.89) and 69% in patient education (95% CI = 1.19 to 2.40). OSS was associated with incremental improvement of 19% in history taking (95% CI = 1.04 to 1.35) and 37% in diagnosis (95% CI = 1.02 to 1.83).

In additional sensitivity analyses, we imputed missing clinical items as equal to zero or one. The direction and significance of the changes in practice were the same for all tasks, with one exception. The effect of IMID on history taking was not statistically significant when missing data was assumed to mean the items were performed correctly (adjusted relative risk =1.06; 95% CI = 0.99 to 1.13).

**Table 3.3 Relative risks (95% confidence intervals) across time periods and arms of performing task correctly, adjusted balanced sample**

| | Sets of Clinical Tasks | | | | | |
|---|---|---|---|---|---|---|
| Effects | History RR (CI) | Physical Exam RR (CI) | Investigations RR (CI) | Diagnosis RR (CI) | Treatment RR (CI) | Patient Education RR (CI) |
| Sample Size | N=393 | N=372 | N=403 | N=407 | N=371 | N=379 |
| Arm A vs. Arm B at time 0 | 0.98 (0.89-1.08) | 1.00 (0.83-1.21) | 1.02 (0.78-1.33) | 0.88 (0.71-1.09) | 1.10*** (1.04-1.15) | 1.08 (0.73-1.62) |
| Arm B (IMID): Time 1 vs. time 0 | 1.04 (0.94-1.16) | 1.30** (1.07-1.58) | 1.19 (0.93-1.53) | 1.15 (0.91-1.45) | 1.01 (0.96-1.06) | 1.45* (1.04-2.03) |
| Arm A (IMID & OSS): Time 1 vs. time 0 | 1.23*** (1.13-1.35) | 1.43*** (1.22-1.68) | 1.27* (1.02-1.57) | 1.57*** (1.31-1.89) | 0.97 (0.93-1.02) | 1.69** (1.19-2.40) |
| Change in arm A vs. Arm B (OSS), RRR | 1.19* (1.04-1.35) | 1.10 (0.86-1.41) | 1.07 (0.78-1.47) | 1.37* (1.02-1.83) | 0.97 (0.91-1.03) | 1.16 (0.73-1.86) |

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

## DISCUSSION

This is one of the first studies to use a cluster-randomized trial to compare interventions to improve HIV clinical practice among MLPs. This study included a direct comparison of arms with training alone and training combined with OSS. Training alone showed a significant improvement for 4 tasks. In sensitivity analyses with a balanced sample, only the findings for physical examination and patient education were robust. Results were more consistent for the combined effect of training and OSS, which showed a significant and robust improvement for 5 tasks. The MLPs were already performing well in treatment with average scores above 70% at baseline, leaving less room for improvement. At endline, trainees in the combined training and OSS arm scored 80% or higher in 5 tasks, compared to only 3 tasks in the training alone arm. Although a comparison of effect sizes between arms indicates an additional effect of OSS for 4 tasks, we were only able to definitively identify the incremental contribution of OSS for diagnosis.

A comprehensive history and physical examination are important components of the clinical practice. Long patient queues with few attending clinicians are often cited as reasons clinicians are not able to complete these tasks during consultation. However, in this study, we observed that clinicians saw on average 5.5 or fewer patients per day, a finding that was replicated in the Institute for Health Metrics and Evaluation's Access, Bottlenecks, Cost, and Equity survey in Uganda.[21,22] In cases of high patient loads, more skilled clinicians may be able to perform these tasks more efficiently, and mentors can support development of these skills.

In a recent review of task-shifting interventions, 7 of the 10 studies focused on health facility staff and described the interventions used; 3 used training alone, 3 used training plus mentorship, and 1 used educational outreach alone.[7] Six of the studies improved HIV patient management, the one that was not effective used training alone.

These results highlight the potential for OSS to build clinical officers', nurses', and midwives' capacity in HIV clinical practice. When planning to task-shift HIV care, governments and program

implementers should complement training with OSS by experienced clinical faculty to reinforce skills learned during training. Clinicians often face complicated cases that fall outside of the typical cases reviewed in the classroom setting. Managing HIV and related conditions requires complex clinical decision-making skills, which take time and experience to develop. Combining training with longer term support can help clinical staff to translate classroom learning into their real-life work, strengthening their ability to adapt to situational constraints, and devise new solutions to complex problems.[16]

**Limitations**

This study was subject to several limitations. First, 2 clinical faculty at baseline did not conduct endline assessments and were replaced by new clinical faculty members. To address this, we conducted a sensitivity analysis with the balanced sample that no longer represented the full, randomized sample. Second, missing information on patient history and physical examination at baseline could have affected the results. Although results in arm A were robust in sensitivity analyses, the effect of IMID on history taking was not statistically significant when missing data on that task were assumed to mean it was performed. Third, these findings are based on observations, and clinicians may behave differently when not being observed. Fourth, we controlled for 2 facility-based HIV programs that could have caused systematic differences across arms, but we did not control for all other training programs. However, the selection of 36 health facilities from 25 districts controlled for contamination from district-level trainings that would have affected only a few sites. The authors were not aware of any national HIV-training programs during the trial. Fifth, the clinical faculty and the MLPs were not blinded to allocation of facilities at endline. To reduce observer bias, clinical faculty did not conduct endline assessments at facilities where they provided OSS but could have been biased in favor of the intervention arm. Sixth, we used a convenience sample of patients rather than a random sample, although it is unclear how patient selection may have biased the results. Seventh, IDCAP's eligibility criteria focused on subdistrict referral facilities within Uganda. However, to the extent that these facilities are similar to health facilities throughout sub-Saharan Africa these results would be generalizable to task-shifting interventions in other settings. Finally, we maintained

a 5% level of significance despite multiple comparisons and may have erred (Type 1 error) in concluding that the effects of the interventions were statistically significant.

## CONCLUSIONS

Training and OSS were associated with improvements in history taking, physical examination, laboratory investigations, diagnosis, and patient education. OSS provided incremental improvements in diagnosis. Combined training and OSS improved HIV clinical practice among of MLPs over training alone.

**Authors' contributions:** MKM and MRW conceived and designed the experiments. SMB, LF, PI, and MRW analyzed the data. SMB, NM, and MRW wrote the paper. RC and YM reviewed the manuscript to meet submission requirements. All authors reviewed and approved final submission.

**Acknowledgements:**

Accordia Global Health Foundation led an IDCAP partnership with Ugandan Ministry of Health, Infectious Diseases Institute, International Training and Education Center for Health, and University Research Co. LLC. The authors would like to thank the IDCAP Steering Committee for guidance, including: Drs. Geoffrey Bisoborwa, Alex Coutinho, Beatrice Crahay, Warner Greene, King Holmes, Nigel Livesley, Fred Wabwire-Mangen, M. Rachad Massoud, Alex Opio, W. Michael Scheld, and Gisela Schneider. The authors thank the IDCAP mobile team for providing OSS and clinical faculty for conducting the assessments, and the IDCAP trainees for their enthusiastic participation. The IDCAP investigators are grateful to the facility in-charges and hospital superintendents, and the HIV positive patients and their caregivers who accepted to participate in the clinical assessments. Special recognition goes to the District Health Offices who ensured that participating health professionals were not transferred out of the sites during the trial.

**Acknowledgement of sources of support:** This work was supported through grant number 94298 to Accordia Global Health Foundation from the Bill & Melinda Gates Foundation. The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript. The findings and conclusions contained within the manuscript are those of the authors and do not necessarily reflect positions or policies of the Bill & Melinda Gates Foundation.

**REFERENCES**


1. UNAIDS. *Ending AIDS: Progress towards the 90-90-90 Targets*. Geneva, Switzerland; 2017. http://www.unaids.org/sites/default/files/media_asset/Global_AIDS_update_2017_en.pdf.
2. UNAIDS. *Fast-Track: Ending the AIDS Epidemic by 2030*. Geneva, Switzerland; 2014. doi:ISBN 978-92-9253-063-1.
3. Baernighausen T, Bloom DE, Humair S. Human resources for treating HIV/AIDS: Are the preventive effects of antiretroviral treatment a game changer? *PLoS One*. 2016;11(10):1-24. doi:10.1371/journal.pone.0163960.
4. Samb B, Celletti F, Holloway J, Van Damme W, De Cock KM, Dybul M. Rapid Expansion of the Health Workforce in Response to the HIV Epidemic. *N Engl J Med*. 2007;357(24):2510-2514. doi:10.1056/NEJMsb071889.
5. World Health Organization. *Guideline on When to Start Antiretroviral Therapy and on Pre-Exposure Prophylaxis for HIV*. Geneva, Switzerland; 2015. doi:978 92 4 150956 5.
6. Lemière C, Herbst CH, Dolea C, Zurn P, and Soucat A. Rural-Urban Imbalance of health workers in sub-saharan Africa. In: Soucat A, Scheffler R, Ghebreyesus TA, eds. The Labor Market for Health Workers in Africa: A New Look at the Crisis. Washington, DC: The World Bank; 2013: 147–168.
7. Kredo T, Adeniyi FB, Bateganya M, Pienaar ED. Task shifting from doctors to non-doctors for initiation and maintenance of antiretroviral therapy. *Cochrane Database Syst Rev*. 2014;(7). doi:10.1002/14651858.CD007331.pub3.www.cochranelibrary.com.
8. Callaghan M, Ford N, Schneider H. A systematic review of task-shifting for HIV treatment and care in Africa. *Hum Resour Health*. 2010;8(1):8. doi:10.1186/1478-4491-8-8.
9. Naikoba S, Colebunders R, van Geertruyden J-P, et al. Design of a cluster randomized trial assessing integrated infectious diseases training and on-site support for midlevel practitioners in Uganda. *Int J Care Pathways*. 2012;16(4):152-159. doi:10.1177/2040402613479342.
10. Weaver MR, Crozier I, Eleku S, et al. Capacity-Building and Clinical Competence in Infectious

Disease in Uganda: A Mixed-Design Study with Pre/Post and Cluster-Randomized Trial Components. *PLoS One*. 2012;7(12). doi:10.1371/journal.pone.0051319.

11. Imani P, Jakech B, Kirunda I, Mbonye MK, Naikoba S, Weaver MR. Effect of integrated infectious disease training and on-site support on the management of childhood illnesses in Uganda: a cluster randomized trial. *BMC Pediatr*. 2015;15(1):103. doi:10.1186/s12887-015-0410-z.
12. Weaver MR, Burnett SM, Crozier I, et al. Improving facility performance in infectious disease care in Uganda: A mixed design study with pre/post and cluster randomized trial components. *PLoS One*. 2014;9(8). doi:10.1371/journal.pone.0103017.
13. Mbonye MK, Burnett SM, Burua A, et al. Effect of integrated capacity-building interventions on malaria case management by health professionals in Uganda: A mixed design study with pre/post and cluster randomized trial components. *PLoS One*. 2014;9(1). doi:10.1371/journal.pone.0084945.
14. Burnett SM, Mbonye MK, Naikoba S, et al. Effect of educational outreach timing and duration on facility performance for infectious disease care in Uganda: A trial with pre-post and cluster randomized controlled components. *PLoS One*. 2015;10(9):1-17. doi:10.1371/journal.pone.0136966.
15. Government of Uganda Ministry of Health. Health Sector Strategic Plan III 2010/11–2014–15. Available at: http://www.health.go.ug/docs/HSSP_III_2010.pdf. Accessed June 17, 2017.
16. Miceli A, Sebuyira LM, Crozier I, et al. Advances in clinical education: A model for infectious disease training for midlevel practitioners in Uganda. *Int J Infect Dis*. 2012;16(10):e708-e713. doi:10.1016/j.ijid.2012.07.003.
17. Ssekabira U, Bukirwa H, Hopkins H, et al. Improved malaria case management after integrated team-based training of health care workers in Uganda. *Am J Trop Med Hyg*. 2008;79(6):826-833. doi:79/6/826 [pii].
18. Weaver MR, Nakitto C, Schneider G, et al. Measuring the outcomes of a comprehensive HIV care course: pilot test at the Infectious Diseases Institute, Kampala, Uganda. *J Acquir Immune Defic Syndr*. 2006;43(3):293-303. doi:10.1097/01.qai.0000243047.42827.97.

19. Brentlinger PE, Torres J V, Martinez PM, et al. Clinical staging of HIV-related illness in Mozambique: performance of nonphysician clinicians based on direct observation of clinical care and implications for health worker training. *J Acquir Immune Defic Syndr JAIDS*. 2010;55(3):351-355. doi:http://dx.doi.org/10.1097/QAI.0b013e3181e3a4cd.

20. Brentlinger PE, Assan A, Mudender F, et al. Task shifting in Mozambique: cross-sectional evaluation of non-physician clinicians' performance in HIV/AIDS care. *Hum Resour Health*. 2010;8(1):23. doi:10.1186/1478-4491-8-23.

21. Mbonye MK, Burnett SM, Naikoba S, et al. Effectiveness of educational outreach in infectious diseases management: a cluster randomized trial in Uganda. *BMC Public Health*. 2016;16(1):714. doi:10.1186/s12889-016-3375-4.

22. Institute for Health Metrics and Evaluation (IHME). Assessing Facility Capacity, Costs of Care, and Patient Perspectives. *Access, Bottlenecks, Costs and Equity (ABCE)*. 2014.

# Chapter 4:
# Effect of Educational Outreach Timing and Duration on Facility Performance for Infectious Disease Care in Uganda: a Trial with Pre-Post and Cluster Randomized Controlled Components

**Effect of educational outreach timing and duration on facility performance for infectious disease care in Uganda: a trial with pre-post and cluster randomized controlled components**

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PLoS ONE 10(9): e0136966. doi:10.1371/journal. pone.0136966

**ABSTRACT**

**Background:** Classroom-based learning is often insufficient to ensure high quality care and application of health care guidelines. Educational outreach is garnering attention as a supplemental method to enhance health care worker capacity, yet there is little information about the timing and duration required to improve facility performance. We sought to evaluate the effects of an infectious disease training program followed by either immediate or delayed on-site support (OSS), an educational outreach approach, on nine facility performance indicators for emergency triage, assessment, and treatment; malaria; and pneumonia. We also compared the effects of nine monthly OSS visits to extended OSS, with three additional visits over six months.

**Methods:** This study was conducted at 36 health facilities in Uganda, covering 1,275,960 outpatient visits over 23 months. From April 2010 to December 2010, 36 sites received infectious disease training; 18 randomly selected sites in arm A received nine monthly OSS visits (immediate OSS) and 18 sites in arm B did not. From March 2011 to September 2011, arm A sites received three additional visits every two months (extended OSS), while the arm B sites received eight monthly OSS visits (delayed OSS). We compared the combined effect of training and delayed OSS to training followed by immediate OSS to determine the effect of delaying OSS implementation by nine months. We also compared facility performance in arm A during the extended OSS to immediate OSS to examine the effect of additional, less frequent OSS.

**Results:** Delayed OSS, when combined with training, was associated with significant pre/post improvements in four indicators: outpatients triaged (44% vs. 87%, aRR=1.54, 99% CI=1.11, 2.15); emergency and priority patients admitted, detained, or referred (16% vs. 31%, aRR=1.74, 99% CI=1.10, 2.75); patients with a negative malaria test result prescribed an antimalarial (53% vs. 34%, aRR=0.67, 99% CI=0.55, 0.82); and pneumonia suspects assessed for pneumonia (6% vs. 27%, aRR=2.97, 99% CI=1.44, 6.17). Differences between the delayed OSS and immediate OSS arms were not statistically significant for any of the nine indicators (all adjusted relative RR (aRRR) between 0.76-1.44, all p>0.06). Extended OSS was associated with significant improvement in two indicators (outpatients triaged: aRR=1.09, 99%

CI=1.01; emergency and priority patients admitted, detained, or referred: aRR=1.22, 99% CI=1.01, 1.38) and decline in one (pneumonia suspects assessed for pneumonia: aRR: 0.93; 99% CI=0.88, 0.98).

**Conclusions:** Educational outreach held up to nine months after training had similar effects on facility performance as educational outreach started within one month post-training. Six months of bi-monthly educational outreach maintained facility performance gains, but incremental improvements were heterogeneous.

**Keywords:** educational outreach, capacity building, quality improvement, in-service training, Uganda

## INTRODUCTION

With 24% of the global burden of disease and only three percent of the world's health workers, the shortage of healthcare workers (HCWs) in sub-Saharan Africa is a major barrier to meeting the Millennium Development Goals.[1] At the same time, these existing HCWs require on-going capacity development to continuously update their knowledge and skills to align with changes in national health policies and treatment guidelines.

Several studies have demonstrated that didactic, classroom-based, in-service trainings, a common form of capacity development throughout the world, are not sufficient to ensure adherence to clinical guidelines.[2-4] These trainings also take HCWs away from busy health facilities, leaving these facilities even further understaffed. A recent study in Uganda found that 15% of HCWs were absent from their facility due to trainings.[5] Capacity building methods that allow HCWs to remain on-site in understaffed health facilities may be particularly suited for low-resource settings.

Donors and organizations implementing capacity development programs have shown increasing interest in educational outreach and continuous quality improvement as key methods for building HCWs' capacity and improving the quality of care.[6-10] Educational outreach is described as "a personal visit by a trained person to health professionals in their own settings". [11] Continuous quality improvement is made up of three essential features: systematic data guided activities, designing with local conditions in mind, and iterative development and testing.[12] In addition to reduced time away from health facilities, these interventions offer staff development activities that are directly relevant to HCWs' work environment and provide increased opportunities for team-based interaction.[6]

Recent randomized control trials and reviews reveal that educational outreach, which sometimes include continuous quality improvement activities, can improve the quality of patient care.[11,13-18] However, less is known about the required timing, duration and frequency of such interventions.[11,19] In a cluster randomized control trial of the World Health Organization's Integrated Management of Childhood Illnesses

(IMCI) program in Benin, HCWs and those who received on-going supervisory visits (with two visits every three months as the recommended frequency) maintained a higher level of performance, even though only 29% of planned visits occurred compared to those who received one supervisory visit one month after IMCI training. [20] Both groups maintained their performance on three quality of care indicators three years after the initial training.[21]

Our study adds new information about the effect of timing, duration, and frequency of educational outreach activities on facility performance. This article presents the results from Phase 2 of the Integrated Infectious Disease Capacity Building Evaluation (IDCAP).[6,13] In Phase 1, IDCAP conducted a cluster randomized control trial to test the effect of the Integrated Management of Infectious Disease (IMID) training program based at the Infectious Diseases Institute in Kampala and on-site support (OSS), an educational outreach intervention with continuous quality improvement activities, on individual clinician competence[22] and practice, facility performance[13,23] and population-based mortality of children less than five years. [6] The two objectives of this Phase 2 analysis were to: a) test the combined effect of training and OSS when they are given sequentially compared with a nine-month delay and b) test the effect of extended OSS on facility performance. We examined indicators in three program areas with pre/post improvements in Phase 1. Results from the arm with delayed implementation provide an opportunity to examine the effects of timing of the interventions. When reporting the phase 1 trial results for the performance indicators[13], we recommended continuing OSS over longer time period and concentrating effort on specific indicators. The results from phase 2 are an opportunity to examine the effects of continued OSS.

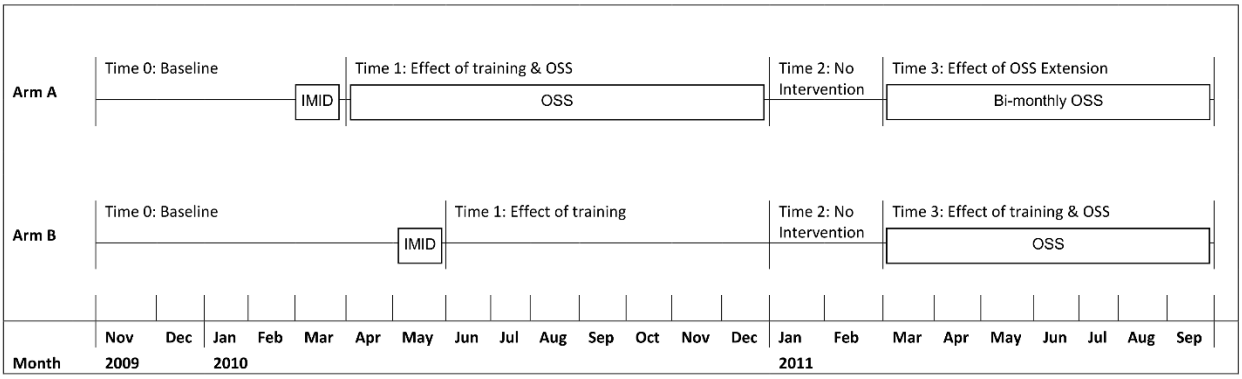
## METHODS

### Study Design

This study was conducted at 36 health centers IV or comparable facilities in Uganda. Each health facility acted as a cluster and was randomized (1:1) to parallel arms. Health facility data were collected prospectively from November 2009 to September 2011. The two time periods in Phase 1 were baseline

(time 0) and randomized trial (time 1) of OSS (Figure 4.1). Time 0 started November 2009 and ended in March 2010 for arm A and May 2010 for arm B. Two mid-level practitioners at each of the 36 sites attended the IMID training program beginning in March 2010. In time 1, 18 sites in arm A received nine monthly OSS visits from April 2010 to December 2010, and 18 sites in arm B did not. The two time periods in Phase 2 were a brief period with no intervention (time 2), January and February 2011, and the delayed intervention period (time 3), March to September 2011. In time 3, arm A received three additional OSS visits every two months (extended OSS), while arm B sites received the eight monthly OSS visits, nine months after their IMID training (Figure 4.1).

**Figure 4.1. Evaluation Design**




The effect of timing of OSS was tested by comparing the combined effect of training and delayed OSS on arm B (time 3 vs. time 0) to the combined effect of training and immediate OSS on arm A (time 1 vs. time 0). The effect of the duration of OSS was tested by comparing arm A during extended OSS (time 3) to the same facilities during training and immediate OSS (time 1).

The study design is summarized in Naikoba et al. [6] and the study protocol can also be accessed as Protocol S1 in Weaver et al.[13] and Mbonye et al. [24]. The CONSORT checklist for this trial is in S1 Table. Anonymous data for the analyses reported below are available for public use on the Global Health Data Exchange website http://ghdx.healthdata.org/record/uganda-integrated-infectious-disease-capacity-building-evaluation-facility-level-data-2009.

***Participants and eligibility***

Two mid-level practitioners (MLP), consisting of clinical officers, registered nurses, or registered midwives from each of the 36 health centers IV or comparable small hospitals in Uganda participated in the IMID training program. Health centers IV act as initial referral facilities with limited inpatient wards for the health subdistricts within Uganda and provide basic preventative and curative care and referral services for health sub-districts' populations of about 100,000.[25] Inclusion criteria for facilities and IMID participants have been described previously.[6] All facility staff were invited to participate in the OSS intervention. All outpatients at the facilities participated as part of their routine process of care.

***Interventions***

The Integrated Management of Infectious Disease (IMID) training program included a three-week core course, two one-week boost courses at 12 and 24 weeks after the core course and distance learning as described in Miceli et al.[26] The course was taught at the Infectious Diseases Institute in Kampala. As described in Naikoba et al., OSS visits were two-day visits by a four-person mobile team: a medical officer, clinical officer, laboratory technologist, and registered nurse.[6] During time 1, OSS visits were conducted once a month for nine consecutive months in arm A.[6] During time 3, arm A received an OSS visit every other month, for a total of three additional OSS visits, while arm B received an OSS visit every month for a total of eight visits. Over each two-day visit, the mobile team conducted four activities: multidisciplinary team training, one-on-one mentoring, break-out sessions by cadre, and continuous quality improvement. Each visit would focus on a specific topic based on the training program materials, as well as follow-up on topics from previous visits. Although the topics presented were the same in both phases, the sequence in time 1 was reported in Naikoba et al., and the sequence in time 3 in Miceli et al.[6,26] During the OSS extension period for arm A the three sessions focused on pediatric ART, TB case management, and fever and malaria case management.

***Outcomes***

The outcome measures were nine facility performance indicators across three of four areas that showed improvement in time 1: emergency triage, assessment, and treatment; malaria; and pneumonia (Table 4.1). [13] The fourth area of care, enrollment in HIV care, will be addressed in a separate manuscript.

***Variable definitions and data sources***

Definitions of the nine indicators are presented in Table 4.1 as originally reported in Weaver et al.[13] and Mbonye et al.[24] All nine indicators used a modified version of the Ministry of Health's Medical Form 5 (MF5), an outpatient record.[6,24]

**Table 4. 1 Definitions and data sources for facility performance indicators**

| | Program Area and Performance Indicators | Definition |
|---|---|---|
| **Emergency Triage, Assessment, and Treatment (ETAT)** *Definitions presented in Kinoti et al., unpublished manuscript* | | |
| 1 | Proportion of outpatients triaged | **Numerator:** Number of outpatients triaged, meaning that the patient was classified as emergency (ABCDO triage categories: Airway; Breathing difficulty; Circulation / Coma / Convulsion / Confusion; Dehydration; and Other), priority (3TPR-MOB priority signs: Tiny baby (sick child of less than 2 months of age); Temperature (child is very hot); Trauma or other urgent surgical condition; Pallor (severe); Poisoning; Pain (severe); Respiratory distress; Restless (lethargy or continuously irritable); Referral; Malnutrition (severe wasting); Oedema of both feet; and Burns), or queue, or an emergency sign was noted in the triage section of the form. **Denominator:** Number of outpatients |
| 2 | Proportion of emergency and priority patients who were admitted, detained or referred | **Numerator:** Number of emergency and priority patients admitted, detained or referred for care. **Denominator:** Number of outpatients classified as emergency or priority or an emergency sign was noted in the triage section of the form |
| 3 | Estimated proportion of emergency patients who received at least one appropriate treatment | **Numerator:** Number of emergency patients who received at least one emergency drug. The drugs that could be used for emergency care and that were listed in the revised Medical Form 5 were artesunate, aspirin, benzyl penicillin (X-pen), chloramphenicol, cloxacillin, diazepam, gentamycin, intravenous fluids, magnesium, oxygen, oral rehydration solution, phenytoin, quinine, and salbutamol. Use of the following eight "other" drugs also met the criteria for appropriate treatment: ampicillin, benzathine penicillin, ceftriaxone, cefuroxime, epinephrine, paraldehyde, pencillin (generic), and phenoxymethyl penicillin. For emergency patients who were prescribed treatment and data on drug availability were missing, we applied the "in-stock" rate for patients with those data. **Denominator:** Number of outpatients classified as emergency or an emergency sign was noted in the triage section of the form |
| **Case management of fever and malaria** *Definitions presented in Mbonye et al.*[23] | | |
| 4 | Proportion of malaria suspects with a malaria test result recorded | **Numerator:** Number of malaria suspects with a result for a laboratory test or rapid diagnostic test for malaria, where the definition of a malaria suspect was all patients with a fever, referred for malaria laboratory testing, or given a clinical diagnosis of malaria as evidenced by either a record of malaria diagnosis or an antimalarial prescription. **Denominator:** Number of malaria suspects |
| 5 | Estimated proportion of malaria cases who received an appropriate antimalarial | **Numerator**: Number of outpatients treated with appropriate anti-malarial(s), where appropriate antimalarial treatments were quinine or artesunate and the following ACTs: artemether & lumenfantrine, artesunate & amodiaquine, or dihydroartemisinin & piperaquine phosphate (Duocotecxin). For patients who were prescribed an antimalarial and data on drug availability were missing, we applied the "in-stock" rate for patients with those data. **Denominator**: Number of outpatients treated for malaria |
| 6 | Proportion of patients with a negative malaria test result | **Numerator:** Number of patients with a negative malaria test result prescribed any antimalarial including the appropriate antimalarials listed above and three drugs that did not comply with |

| | Program Area and Performance Indicators | Definition |
|---|---|---|
| | who were prescribed an antimalarial | Uganda national guidelines: amodiaquine alone, chloroquine, and sulfadoxine-pyrimethamine. **Denominator:** Number of patients with a negative malaria test result |
| 7 | Proportion of patients with a positive malaria test result who were prescribed an antibiotic | **Numerator**: Number of patients with a positive malaria test result prescribed any antibiotic(s). Any antibiotic treatment referred to 12 drugs listed on the MF5: amoxicillin, benzyl penicillin, chloramphenicol, ciprofloxacin, cloxacillin, cotrimoxazole, doxycycline, erythromycin, gentamicin, metronidazole, PPF/procaine penicillin, tetracycline. Data on these drugs was elicited by checking boxes on the MF5. It also included 19 antibiotics recorded as ''other drugs:'' Ampiclox (ampicilllin & cloxacillin), ampicillin, ampicillin & gentamicin, azithromycin, cefalexin, cefixime, ceftriaxone, cefuroxime, co-amoxiclav, dapsone, dicloxacillin, gatifloxacin, levofloxacin, nalidixic acid, nitrofurantoin, ofloxacin, pencillin (generic), perfloxacin, phenoxymethyl penicillin. **Denominator:** Number of patients with a positive malaria test result |
| **Case management of respiratory illness** *Definitions presented in Weaver et al.*[13] | | |
| 8 | Proportion of pneumonia suspects aged under 5 years assessed for pneumonia | **Numerator:** Number of child pneumonia suspects with at least one of the three following assessment results recorded: 1) abnormal chest sounds, 2) chest in-drawing, and 3) rapid breaths per minute. A pneumonia suspect was defined as any child aged under five years presenting with cough or who received a diagnosis of "pneumonia" or "cough/cold no pneumonia"**. Denominator:** Number of child pneumonia suspects**. Note:** The definition of suspect focused on children with cough; difficulty in breathing was inadvertently omitted from the form. |
| 9 | Estimated proportion of patients aged under 5 years diagnosed with pneumonia who received appropriate antibiotic treatment | **Numerator:** Number of children diagnosed with pneumonia treated with appropriate antibiotic, where appropriate antibiotic treatment referred to six drugs on the revised Medical Form 5: amoxicillin, benzyl penicillin, erythromycin, chloramphenicol, gentamicin, cotrimoxazole, and 11 other drugs that were specified: ampicillin, azithromycin, cefixime, ceftriaxone, cefuroxime, co-amoxiclav, gatifloxacin, levofloxacin, penicillin, phenoxymethylpenicillin, ampiclox (amoxicillin and cloxacillin). For patients who were prescribed an antibiotic and data on drug availability were missing, we applied the "in-stock" rate for patients with those data. **Denominator:** Number of children diagnosed with pneumonia |

***Sample size***

Sample size calculations were included in the protocol and reported in Naikoba et al. [6]. Data from Ssekabira et al. were used to calculate the sample size required to detect an effect of OSS on facility performance on two malaria indicators with the facility as the unit of analysis: 1) the percentage of malaria suspects with a malaria test recorded, which had a baseline of 38% among children less than five years and

increased by 16%, and 2) the percentage of patients with a negative malaria test result who were prescribed an antimalarial, which had a baseline of 48% among children less than five years and decreased by 16%.[27] Using the health facility as the unit of analysis, we calculated the number of facilities required to detect a 20% absolute difference between the intervention and control arms with a power of 80% and an alpha of 0.05.

***Randomization***

The identification and selection of sites was conducted by the investigators and project staff. The 36 facilities selected to participate in the study were stratified to control for two other interventions: 1) previous participation in a national HIV continuous quality improvement program and 2) the on-going Baylor International Pediatric AIDS Initiative.[28,29] Within these strata, the 36 sites were randomized to parallel arms (1:1 balance). On February 23, 2010, the IDCAP biostatistician randomized the 36 facilities. A random number generator in Stata was used to assign sites to the two arms – with the mean of the generated random numbers acting as a cut-off point. Numbers less than the mean were allocated to arm A and those above the mean were allocated to arm B.[6,23] The project staff and health workers at the facilities were blinded during four months of baseline data collection, but not blinded during the intervention.

***Ethical Considerations***

The School of Medicine Research and Ethics Committee of Makerere University Kampala, Uganda (reference number 2009-175) and the Uganda National Council for Science and Technology (reference number HS-722) reviewed and approved the IDCAP protocol. The University of Washington Human Subjects Division determined that IDCAP did not meet the regulatory definition of research under 45 CFR 46.102(d). Participants in the infectious disease training course provided written informed consent. OSS participants were not asked to provide informed consent for facility performance data, because the facility performance data were used to evaluate facility rather than individual performance. Informed consent of patients was waived for the MF5 data.

***Data Collection***

Data were collected on every outpatient visit from November 2009 to September 2011 using the revised MF5 forms, which were completed by records staff, clinicians, lab personnel and drug dispensers. Beginning in March 2010, data entry assistants stationed at each facility entered the revised MF5 data in an Epi Info® database (Version 3.2, U.S. Centers for Disease Control and Prevention, Atlanta, GA). The data entry assistants electronically transmitted the revised MF5 data to the Infectious Disease Institute on a monthly basis, where the data were merged using Microsoft Excel® (Microsoft Corporation, Redmond, WA, USA), cleaned, and exported to Stata® version 11 (StataCorp, College Station, Texas, USA) for analysis.

***Data analysis***

Data collected from November 2009 to September 2011 were analyzed, and the facility-month was the unit of analysis. The Phase 1 time periods of time 0 (baseline) and time 1 (intervention) remain the same as reported in Weaver et al. and differed by arm (Figure 4.1). [13] For arm A, time 0 was from November 2009 to March 2010 and time 1 was from April 2010 to December 2010. For arm B, time 0 was from November 2009 to May 2010 and time 1 was from June 2010 to December 2010. In Phase 2, two additional time periods covered the same months in each arm. The period after OSS ended in arm A and before OSS started in arm B, time 2, was from January 2011 to February 2011. Delayed OSS in arm B and OSS extension in arm A, time 3, was from March 2011 to September 2011.

To determine the effect of the timing of OSS, we compared the combined effect of training and immediate OSS on arm A during OSS implementation (time 1 vs. time 0) to training and delayed OSS on arm B during OSS implementation (time 3 vs. time 0). To determine whether facility performance was maintained, improved, or declined during the OSS extension period in arm A, we compared the extended OSS period (time 3) to the period of training and OSS implementation (time 1).

As described in Weaver et al. and Mbonye et al., the data were analyzed using the generalized linear model with a Poisson family and log link to estimate the relative risks (RR) for the proportion of patients

managed appropriately for a given indicator with main effects for arm, time period, and their interaction.[13,24] The unit of analysis was the facility month.

All regression analyses were clustered by facility to adjust for random facility effects and used robust standard errors to adjust for using the Poisson instead of the binomial family and for overdispersion. To address the multiple comparisons, tests were based on a one percent level of significance, and the results are presented with 99% confidence intervals (CI). All analyses adjusted for facility type, facility level, data entry assistant stationed at the site, staffing and previous participation in the national HIV continuous quality improvement program and the on-going Baylor International Pediatric AIDS Initiative, as described in Weaver et al.[13] All analyses were performed with Stata® version 11 (StataCorp, College Station, TX, USA).

## RESULTS

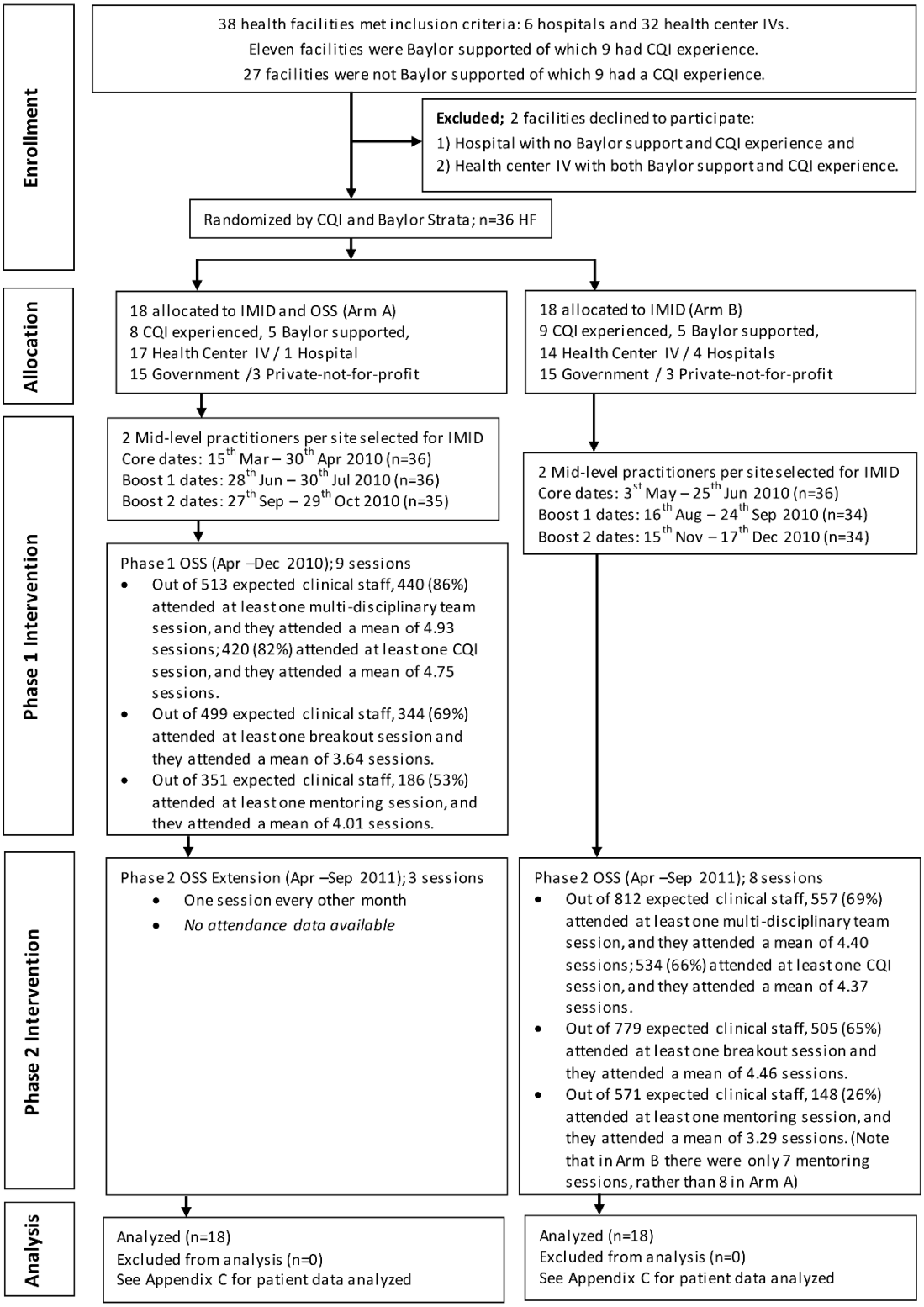
### Participant Flow

The flow of facilities and individuals in infectious disease training program and OSS is shown in Figure 4.2. Of the 36 health facilities, 31 were health centers IV and five were hospitals. Four of the five hospitals were randomly assigned to arm B. There was no attrition among the 36 enrolled facilities. Participation in Phase 1 of the study is reported in Weaver et al..[13] Among the 72 training participants, three in arm A and four in arm B discontinued seeing patients in the outpatient department during the course of the study. Arm B in Phase 2 had lower OSS attendance than arm A in Phase 1. Only 557 out of 812 (69%) clinical staff attended at least one multi-disciplinary team training session during OSS, compared to 86% in arm A Phase 1. This difference was primarily due to the hospitals in arm B. In arm A, the hospital staff accounted for 10% of the 513 clinical staff expected to attend OSS, whereas in arm B, hospital staff accounted for 45% of the 812 expected clinical staff. Comparing attendance at multi-disciplinary team training sessions in only health centers IV, both arms had an 80% attendance rate. The four hospitals in arm B had a lower attendance rate (55%), whereas the one hospital in arm A had a 90% attendance rate. Lower

attendance among hospitals in arm B could be explained by staff assignments to evening and night shifts which would lead them to being off-duty during some of the OSS sessions, as well as differences in management across hospitals. Among the four hospitals in arm B attendance rates varied from 31% to 81% of the expected facility staff. Attendance data were not available for the OSS extension period in arm A.

A total of 1,275,960 outpatients were seen in the 36 facilities over 23 months, from November 2009 to September 2011. For all indicators the response rate was over 99% for the expected facility months. The total number of patients used in each of the analyses is presented in S1 Figure. For one emergency triage, assessment, and treatment indicator (outpatients triaged), a total of 1,656 facility month observations (36 facilities over 23 months broken into two age groups) were expected. For the two pneumonia indicators, which focused on children under five, only 828 observations were expected. For the rest of the indicators the number of facility months available for analysis depended upon whether any patients meeting the denominator definition were seen that month. For example, 237 facility months had no emergency patients identified, thus there were only 1,413 observations possible for the estimated proportion of emergency patients who received at least one appropriate treatment indicator.

**Figure 4.2 Recruitment and Participation Flow Chart**



**Recruitment**

The facilities were recruited between March and September 2009. The IMID participants were recruited between June 2009 and February 2010. Registration and consent for the training was carried out between December 2009 and March 2010. OSS recruitment and registration began in April 2010 and continued throughout the Phase 1 and Phase 2 interventions. All staff were encouraged to attend OSS sessions regardless of previous attendance.

**Baseline**

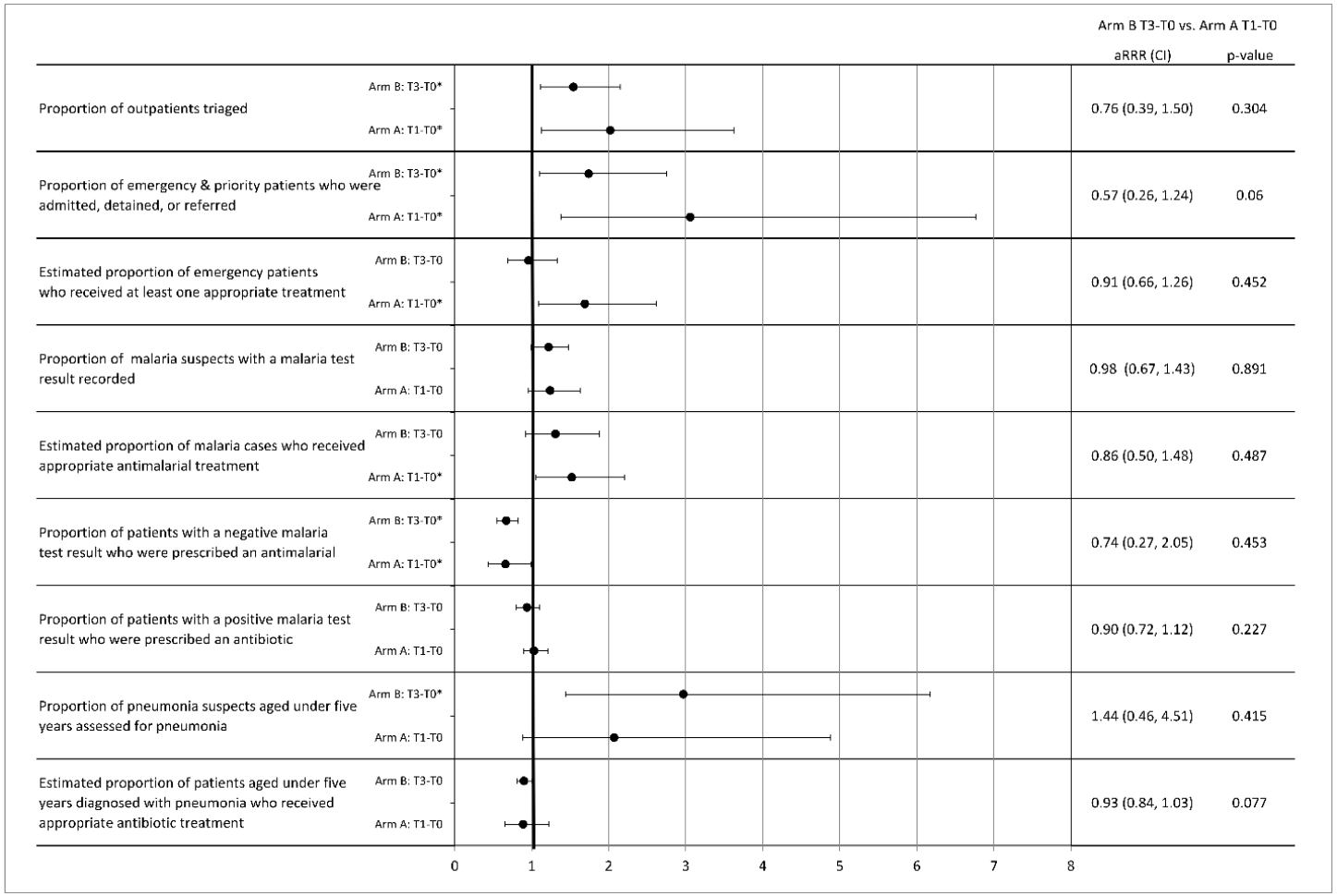
Baseline data on each indicator by arm were reported in Weaver et al. [13] and are shown in S1 Figure. Baseline performance for all nine indicators was below 60%. For two of the indicators, a lower proportion represented higher quality of care: 1) Proportion of patients with a negative malaria test result who were prescribed an antimalarial, and 2) Proportion of patients with a positive malaria test result who were prescribed an antibiotic. In five out of the nine indicators arm B performed better than arm A at baseline, with the absolute advantage ranging from 3% to 17%. For the remaining four indicators at baseline, arm A performed better than arm B with an absolute advantage ranging from 1% to 7%.

**Outcomes and Estimation**

***Effect of Delayed OSS Intervention in Arm B***

The results of three tests are reported in Figure 4.3: 1) whether or not performance improved in the delayed OSS arm, arm B, between time 0 and time 3 is reported as the relative risk of the indicator in time 3 compared to time 0, 2) whether or not performance improved in the immediate OSS arm, arm A, between time 0 and time 1 (which has previously been reported in Weaver et al. [13] with minor differences due the additional time periods), and 3) whether or not the magnitude of the improvement in the delayed OSS arm B was less than arm A is reported as the ratio of relative risk in arm B time 3 to time 0 to the relative risk in arm A time 1 to time 0.

**Figure 4.3 Adjusted relative risk ratios comparing the effect of training and OSS on study arms**




*p<0.01

Time 0 (T0) is baseline for both arms. Time 1 (T1) for arm A and time 3 (T3) for arm B are the time periods after both the Integrated Management of Infectious Disease (IMID) training and the on-site support (OSS) educational outreach interventions. Arm B T3-T0 vs. arm A T1-T0 compares the change in the arm B to the change in arm A before and after the two interventions.

In the multivariate analysis there was a significant combined effect of training and delayed OSS in four out of nine indicators in arm B when comparing time 0 and time 3, the same as the combined effect for training and immediate OSS in arm A when comparing time 0 and time 1 (Figure 4.3). Three of the four indicators that showed improvement were the same: outpatients triaged (arm B: 44% vs. 87%, aRR=1.54, 99% CI=1.11, 2.15; arm A: 27% vs. 86%, aRR=2.02, 99% CI=1.13, 3.63), emergency and priority patients who were admitted, detained, or referred (arm B: 16% vs. 31%, aRR=1.74, 99% CI=1.10, 2.75; arm A: 11% vs. 37%, aRR=3.06, 99% CI= 1.38, 6.77), and patients with a negative malaria test result prescribed an antimalarial (arm B: 53% vs. 34%, aRR=0.67, 99% CI=0.55, 0.82; arm A: 46% vs. 30%, aRR=0.66, 99% CI= 0.44,0.99). The proportion of pneumonia suspects aged under five years assessed for pneumonia showed significant improvement in arm B (6% vs. 27%, aRR=2.97, 99% CI=1.44, 6.17) but not arm A (3% vs. 16%, aRR=2.07, 99% CI= 0.88, 4.88). The estimated proportion of malaria cases who received appropriate antimalarial treatment improved significantly in arm A (44% vs. 72%, aRR=1.52, 99% CI=1.05, 2.20) but not arm B (55% vs. 75%, aRR=1.31, 99% CI=0.92, 1.88).

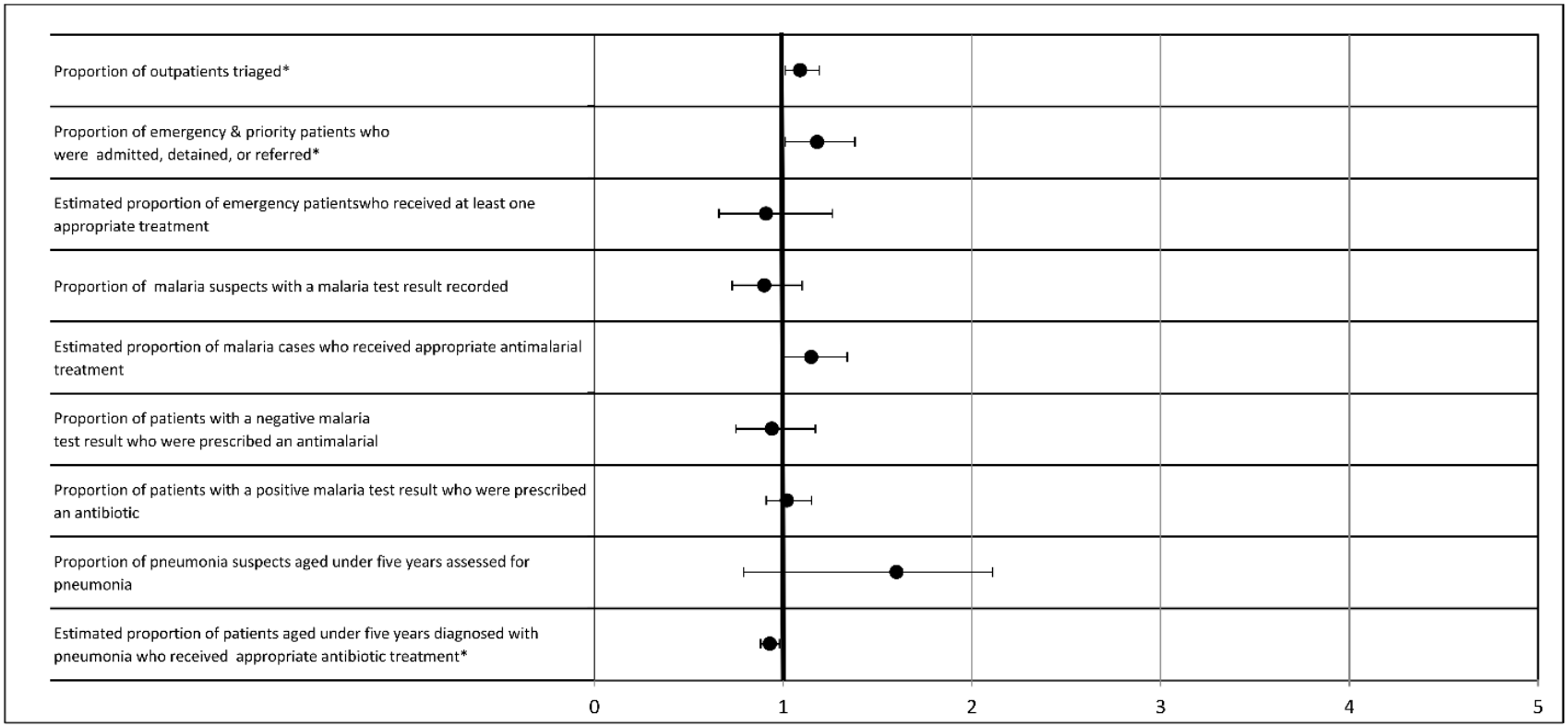
Difference-in-difference in improvements in arm B from baseline to after training and delayed OSS compared to arm A were sometimes large, but not statistically significantly for any of the nine indicators (Figure 4.3).

***Effect of OSS Extension in Arm A***

The relative risk of facility performance during extended OSS (time 3) was compared to performance during infectious disease training and OSS (time 1) (Figure 4.4). In the regression analysis, two emergency triage, assessment, and treatment indicators showed significant additional improvement: 1) outpatients triaged (Arm A: 86% vs. 95%, aRR=1.09, 99% CI=1.01, 1.19) and 2) emergency and priority patients who were admitted, detained, or referred (Arm A: 37% vs. 45%, aRR=1.22, 99% CI=1.01, 1.38) (Figure 4.4). The estimated proportion of patients aged under five years diagnosed with pneumonia who received an appropriate antibiotic treatment significantly declined during time 3 (59% vs. 53%, aRR: 0.93; 99%

CI=0.88, 0.98). The difference-in-difference across the other six indicators were small and not statistically significantly different from the training and immediate OSS period.

**Figure 4.4 Adjusted relative risk ratios assessing the effect of the extended OSS period on Arm A**




*p<0.01

This figure measures the additional effect of extended OSS in arm A by compares Time 3 in this arm, after the Integrated Management of Infectious Disease (IMID) training, the on-site support (OSS) educational outreach, and extended OSS to time 1, the period after IMID training and OSS.

## DISCUSSION

Despite the nine months between the infectious disease training program and implementation of on-site support, the combined effect of these interventions was similar to the sequential implementation, with both the delayed and immediate on-site support associated with improvement in four of nine indicators. While the magnitude of change tended to be smaller with delayed than with immediate on-site support, this difference was not significant for any of the nine indicators. Thus, educational outreach, in this case coupled with continuous quality improvement activities, held up to nine months after an initial training can still lead to improvement in health facility indicators.

The on-site support extension period showed significant improvement for two indicators (outpatients triaged and emergency and priority patients who were admitted, detained, or referred), a significant decrease in one indicator (patients aged under five years who received appropriate antibiotic treatment) and no significant change for the remaining six indicators. A reduced level of effort for on-site support, conducting visits every other month rather than every month, had heterogeneous effects during six months after the trial, but was effective in maintaining improvements made during the more intensive time period. This corroborates data from a pre/post study on malaria case management, in which on-going monthly or bi-monthly site visits led to sustained improvements in clinical performance up to one year after training.[30] Facility performance indicators at these sites continued to improve after the first year, reaching nearly perfect performance for malaria diagnostic testing and appropriate treatment after four years of implementation.[31]

This study adds new information about the effect of timing, duration, and frequency of educational outreach activities on facility performance. The delayed on-site support arm provided a rare opportunity to rigorously assess the timing of on-site support in relation to training. In most studies published on training and on-site support interventions, the on-site support immediately follows training. However, on a larger scale such well-timed interventions are not always possible, as program managers face competing priorities when scheduling interventions. Based on the findings presented, training program managers should be

encouraged that they can implement an educational outreach intervention up to nine months after training with statistically significant improvements in performance. These findings may also be useful for designing and implementing inter-professional and community-based education programs for pre-service health professionals, such as the Medical Education Partnership Initiative (MEPI).[32,33]

While the majority of indicators showed large improvements over time, five out of the nine indicators were still below 60% and one reverse coded indicator, patients with a positive malaria test who were prescribed an antibiotic remained above 40% at time 3, after several months of OSS visits. This is consistent with findings from other studies, in which post-intervention practice was often less than 50% of desired performance.[11] The median level of improvement in our study was 16% (range -1% to 59%), consistent with the review of educational outreach visits, which reported a median relative improvement in performance indicators of 21.0% (interquartile range 11% to 41%).[11] The majority of studies in this review were conducted in high resource settings and these results were achieved after one or two visits. Given the lower level of pre-service training and lack of infrastructure, staffing and support in limited resource settings, a longer duration and more concentrated effort may be required to achieve an effect similar to those found in high resource settings.[13]

We may have had unrealistic expectations for improvements in the nine facility performance indicators presented here and 23 indicators in Weaver et al.[13], even after including the additional six months of intervention in the extended OSS. Rather than trying to address a multitude of indicators at the same time, facilities could instead focus on one to four indicators until the desired level of performance is achieved before shifting the program's focus to other performance indicators.

A program review by the HealthCare Improvement Project assessed 27 collaborative quality improvement projects across 12 countries.[34] In pre/post analyses, these projects demonstrated an average of 50% improvement after one year and projects focused on one to seven quality of care indicators (an average of 3.75), usually within one focus area (i.e. maternal health, HIV, TB, malaria). The Joint Uganda Malaria

Program (JUMP), on which the IDCAP program was modeled, combined training with a malaria surveillance program that included on-site visits every one to two months. Selected sites improved two key malaria indicators to above 90% after four years of implementation.[31]

A longer intervention duration, which slowly integrates multiple diseases, may be a more effective method for improving quality of care. Yet, even the modest facility performance improvements observed during the IDCAP intervention may translate into significant changes in health outcomes at the population level. An epidemiological model of the combined effects of IMID training and on-site support in Phase 1 showed reduced malaria prevalence by over 16% (Ssebuliba et al., unpublished manuscript).

In Uganda, donor-funded NGOs are supporting the Ugandan Ministry of Health to conduct supervision, with the majority of these programs focusing on vertical programs, such as HIV, TB or malaria. Integrating OSS to cover multiple diseases and sequencing the focus of visits could reduce redundancies in disease-specific support visits, such as assessing infrastructure and stock issues, and reducing the additional staff time and transport expenses related with supporting multiple single-disease interventions. Currently, the Ugandan Ministry of Health is encouraging this type of integrated supervision across disease areas (Mbonye, personal communication). The design of IDCAP was based on the JUMP model, which has been successfully scaled in Uganda.[27] Based on the large effects of IMID and OSS on several indicators found in this study, further operational research is needed to determine whether a phased approach focused on improving a small set of related indicators and building in additional disease areas over a longer period of time would produce effect on an integrated set of facility performance indicators.

**Limitations**

Uptake of the intervention in the delayed OSS was lower than in the immediate on-site support, primarily due to the inclusion of a greater number of hospitals. This may have led to the smaller magnitude of change observed in the delayed OSS arm compared to the immediate on-site support. The sample size for this study was designed to detect a difference between arms at a five percent level of significance and may not be

sufficient to detect a difference-in-difference at the one percent level of significance comparing two arms before and during the training and on-site support interventions. The accuracy of the data were not validated. It is possible that patients meeting the denominator definitions (i.e. emergency patients, malaria suspects, pneumonia suspects) were present but were not recorded, which would lead to an under reporting of cases for these indicators. The "post" analysis period was the period during the implementation of on-site support, rather than after, which may have led to an underestimation of the effect of the intervention. The pre/post analysis components, to measure the effect of delayed on-site support on arm B and the effect of the on-site support extension period on arm A, did not control for other changes at the sites over the course of the intervention. Also, in this study we did not test maintenance of facility performance after discontinuation of OSS. Given that indicators in arm A showed no significant decline during January to February 2011, the two months when no OSS took place, it is possible that the facility performance at these sites would have been maintained without the additional bi-monthly OSS. Further research is needed to determine whether facility performance can be maintained in the absence of on-going educational outreach.

**Generalizability**

Eligibility criteria for IDCAP focused on health centers IV and comparable small hospitals in Uganda that met the inclusion criteria, thus these results would only be generalizable to these health facilities in Uganda. However, to the extent that these health facilities are similar to other primary care facilities throughout sub-Saharan Africa these results may inform the design and implementation of educational outreach in other settings.

## CONCLUSIONS

Educational outreach held up to nine months after training had statistically significant effects on facility performance. Bi-monthly educational outreach maintained gains made in facility performance, but incremental improvements were heterogeneous.

**Supporting Information**

S1 Table. CONSORT Checklist.

A table which presents the detailed CONSORT checklist, which includes the CONSORT extension for cluster trials.

https://doi.org/10.1371/journal.pone.0136966.s001

(PDF)

S1 Figure. Proportion of patients managed appropriately for all nine indicators by arm and time.

Raw proportions and sample sizes for each of the nine facility performance indicators presented by arm and time period.

https://doi.org/10.1371/journal.pone.0136966.s002

(PDF)

**Competing Interests**

Dr. Stephen Kinoti is currently employed by Fio Corporation and was previously employed by University Research Co. LLC. Dr. Kinoti's affiliations to these companies do not alter our adherence to Implementation Science policies on sharing data and materials. All other authors declare that they have no competing interests.

**Authors' contributions**

SN, MKM, SK, AR, MRW, and KSW conceived and designed the experiments. SZ performed the experiments. SMB, MKM, TR, and MRW analyzed the data: SMB, MKM, and MRW wrote the paper. RC and YM reviewed the manuscript to meet submission requirements: RC YM. All authors reviewed and approved final submission.

**Acknowledgements**

IDCAP was a collaboration among five organizations: Accordia Global Health Foundation, Ugandan Ministry of Health, Infectious Diseases Institute, International Training and Education Center on Health, and University Research Co. LLC. The authors would like to thank the IDCAP Steering Committee for guidance: Drs. Geoffrey Bisoborwa, Alex Coutinho, Beatrice Crahay, Warner Greene, King Holmes, Nigel Livesly, Fred Wabwire-Mangen, M. Rachad Massoud, Alex Opio, W. Michael Scheld, Gisela Schneider. The authors would also like to thank colleagues at the Ministry of Health. This work was supported through grant number 94298 to Accordia Global Health Foundation from the Bill & Melinda Gates Foundation. The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript. The findings and conclusions contained within the manuscript are those of the authors and do not necessarily reflect positions or policies of the Bill & Melinda Gates Foundation.

**REFERENCES**

1. World Health Organization. The World Health Report 2006: Working Together for Health: World Health Organization; 2006.

2. Bloom BS. Effects of continuing medical education on improving physician clinical care and patient health: a review of systematic reviews. Int J Technol Assess Health Care. 2005;21(3):380–385.

3. Davis D, Galbraith R. Continuing medical education effect on practice performance: effectiveness of continuing medical education: American College of Chest Physicians Evidence-Based Educational Guidelines. Chest. March 2009;135(3 Suppl):42S–48S. [PubMed: 19265075].

4. Forsetlund L, Bjørndal A, Rashidian A, et al. Continuing education meetings and workshops: effects on professional practice and health care outcomes. The Cochrane Collaboration. April 2009;2:CD003030. doi: 10.1002/14651858.CD003030.pub2.

5. Wayne W, Martin G. Service Delivery Indicators. Education and Health services in Uganda: Data for Results and Accountability: World Bank; 2013.

6. Naikoba S, Colebunders R, Van Geertruyden JP, et al. Design of a cluster randomized trial assessing integrated infectious diseases training and onsite support for mid-level practitioners in Uganda. International Journal of Care Pathways. 2012;16(152):doi: 10.1177/2040402613479342.

7. The President's Emergency Plan for AIDS Relief. Quality Strategy Phase I: Institutionalization of Countries' Ability to Improve HIV Clinical Programs: The President's Emergency Plan for AIDS Relief; 2014.

8. The U.S. President's Emergency Plan for AIDS Relief. Five-Year Strategy 2009.

9. Burlew R, Puckett A, Bailey R, Caffrey M, Brantley S. Assessing the relevance, efficiency, and sustainability of HIV/AIDS in-service training in Nigeria. Human Resources for Health. April 2014;12(20):doi:10.1186/1478-4491-12-20.

10. Lawn JE, Rohde J, Rifkin S, Were M. Alma-Ata 30 years on: revolutionary, relevant, and time to revitalise. Lancet. September 2008;372(9642):917-927.

11. O'Brien MA, Rogers S, Jamtvedt G, et al. Educational outreach visits: effects on professional practice (Review). The Cochrane Library. 2008(3).

12. Rubenstein L, Khodyakov D, Hempel S, et al. How can we recognize continuous quality improvement? International Journal for Quality in Health Care. 2014;26(1):6-15 doi:10.1093/intqhc/mzt085.

13. Weaver MR, Burnett SM, Crozier I, et al. Facility Performance Results for the Integrated Infectious Disease Capacity-Building Evaluation in Uganda: a Mixed Design Study with Pre/Post and Cluster Randomized Trial Components. PLoS ONE;9(8):e103017. doi:10.1371/journal.pone.0103017.

14. Fairall LR, Zwarenstein M, Bateman ED, et al. Effect of educational outreach to nurses on tuberculosis case detection and primary care of respiratory illness: pragmatic cluster randomized trial. British Medical Journal. November 2005;331(7519):750-754. doi: 10.1136/bmj.331.7519.750.

15. Fairall LR, Bachmann MO, Lombard C, et al. Task shifting of antiretroviral treatment from doctors to primary-care nurses in South Africa (STRETCH): a pragmatic, parallel, cluster-randomised trial. The Lancet. 2012;380(9845):889-898. doi: 10.1016/S0140-6736(12)60730-2.

16. Ferguson JTB, Peterson ED, Coombs LP, et al. Use of continuous quality improvement to increase use of process measures in patients undergoing coronary artery bypass graft surgery: a randomized control trial. Journal of the American Medical Association. 2003;290(1):49-56. doi:10.1001/jama.290.1.49.

17. Engels Y, van den Hombergh P, Mokkink H, van den Hoogen H, van den Bosch W, Grol R. The effects of a team-based continuous quality improvement intervention on the management of

primary care: a randomised controlled trial. British Journal of General Practice. 2006;56(531):781-787.

18. Ayieko P, Ntoburi S, Wagai J, et al. A Multifaceted Intervention to Implement Guidelines and Improve Admission Paediatric Care in Kenyan District Hospitals: A Cluster Randomised Trial. PLoS Med. Apr 2011;8(4): e1001018.

19. O'Malley G, Marseille E, Weaver MR. Cost-effectiveness analyses of training: a manager's guide. Human Resources for Health. May 2013;11(20):doi:10.1186/1478-4491-11-20.

20. Rowe AK, Onikpo F, Lama M, Osterholt DM, Rowe SY, Deming MS. A Multifaceted Intervention to Improve Health Worker Adherence to Integrated Management of Childhood Illness Guidelines in Benin. American Journal of Public Health. May 2009;99(5):837-846.

21. Rowe K, Osterholt DM, Kouame J, et al. Trends in health worker performance after implementing the Integrated Management of Childhood Illness strategy in Benin. Tropical Medicine and International Health. April 2012;17(4):438-446. doi:10.1111/j.1365-3156.2012.02976.x.

22. Imani PD, Jakech B, Kirunda I, et al. Effect of classroom training vs. on-site support on clinical practice in Uganda: A cluster randomized trial. BMC Pediatrics. Forthcoming.

23. Weaver MR, Crozier I, Eleku S, et al. Improving Facility Performance in Infectious Disease Care in Uganda: A Mixed Design Study with Pre/Post and Cluster Randomized Trial Components. PLoS One. December 2012;7(12):e51319. doi:10.1371/journal.pone.0051319.

24. Mbonye MK, Burnett SM, Burua A, et al. Effect of Integrated Capacity-Building Interventions on Malaria Case Management by Health Professionals in Uganda: A Mixed Design Study with Pre/Post and Cluster Randomized Trial Components. PLOS One. January 2014;9(1):e84945. doi:10.1371/journal.pone.0084945.

25. Government of Uganda, Ministry of Health. Health Sector Strategic Plan II, 2004/05-2009/10. 2004.

26. Miceli A, Sebuyira L, Crozier I, et al. Advances in Clinical Education: A Model for Infectious Disease Training for Mid-Level Practitioners in Uganda. International Journal of Infectious Diseases. Disease, 2012 (16): e708–e713 2012;16:e708–e713.

27. Ssekabira U, Bukirwa H, Hopkins H, et al. Improved malaria case management following integrated team-based training of health care workers in Uganda. American Journal of Tropical Medicine and Hygiene. 2008;79(5):826-33.

28. Quality Assurance Project (QAP) I, II, and III. URC. Available at: http://www.urc-chs.com/project?ProjectID=114. Accessed April 2, 2013.

29. BIPAI in Uganda. Baylor International Pediatric AIDS Initiative. Available at: http://www.bipai.org/uganda/. Accessed April 2, 2013.

30. Namagembe A, Ssekabira U, Weaver MR, et al. Improved clinical and laboratory skills after team-based, malaria case management training of health care professionals in Uganda. Malaria Journal. February 2012;11(44): doi:10.1186/1475-2875-11-44. http://www.malariajournal.com/content/11/1/44.

31. Sserwanga A, Harris JC, Kigozi R, Menon M, Bukirwa H, Gasasira A. Improved malaria case management through the implementation of a health facility-based sentinel site surveillance system in Uganda. PLoS One. 2011;6(e16316).

32. Frenk J, Chen L, Bhutta ZA, et al. Health professionals for a new century: transforming education to strengthen health systems in an interdependent world. The Lancet. December 2010;376(9756):1923-1958. doi: 10.1016/S0140-6736(10)61854-5.

33. Mariam DH, Sagay AS, Arubaku W, et al. Community-Based Education Programs in Africa: Faculty Experience Within the Medical Education Partnership Initiative (MEPI) Network. Acad Med. August 2014;89(8 Supplement):S50-4. doi: 10.1097/ACM.0000000000000330.

34. Franco LM, Marquez L, Ethier K, Balsara Z, Isenhower W. Results of Collaborative Improvement: Effects on Health Outcomes and Compliance with Evidence-based Standards in 27 Applications in 12 Countries. Collaborative Evaluation Series. Bethesda, MD: USAID Health Care Improvement Project, University Research Co., LLC (URC); 2009.

# Chapter 5:
# Effect Of TB/HIV Integration on TB/HIV Indicators in Rural Ugandan Health Facilities

**Effect of TB/HIV Integration on TB and HIV indicators in Rural Ugandan Health Facilities**

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Forthcoming in the Journal of Acquired Immune Deficiency Syndromes

**ABSTRACT**

**Background:** The World Health Organization recommends integrating services for patients co-infected with tuberculosis (TB) and HIV. We assessed the effect of TB/HIV integration on antiretroviral therapy (ART) initiation and TB treatment outcomes among TB/HIV-coinfected patients using data collected from 14 rural health facilities during two previous TB and HIV quality of care studies.

**Methods:** A facility was considered to have integrated TB/HIV services if patients with TB/HIV had combined treatment for both illnesses by 1 provider or care team at 1 treatment location. We analyzed the effect of integration by conducting a cross-sectional analysis of integrated and non-integrated facility periods comparing performance on ART initiation and TB treatment outcomes. We conducted logistic regression, with the patient as the unit of analysis, controlling for other intervention effects, adjusting for age and gender, and clustering by health facility.

**Results:** From January 2012 to June 2014, 996 patients with TB were registered, 97% were tested for HIV and 404 (42%) were HIV positive. Excluding transfers, 296 patients were eligible for analysis with 117 and 179 from nonintegrated and integrated periods, respectively. Being treated in a facility with TB/HIV integration was associated with lower mortality [adjusted odds ratio (aOR)=0.38, 95% confidence interval (CI)=0.18 to 0.77], but there was no difference in the proportion initiating ART (aOR=1.34, 95% CI=0.40 to 4.47), with TB treatment success (aOR=1.43, 95% CI=0.73 to 2.82), lost to follow-up (aOR=1.64, 95% CI=0.53 to 5.04), or failure (aOR=1.21, 95% CI=0.34 to 4.32).

**Conclusion:** TB/HIV service integration was associated with lower mortality during TB treatment even in settings with suboptimal proportions of patients completing TB treatment and starting on ART.

**Key words:** tuberculosis/HIV co-infection, anti-retroviral therapy initiation, tuberculosis treatment outcomes, mortality, Africa, south of the Sahara, Uganda

## INTRODUCTION

Tuberculosis (TB) and HIV are among the top 10 causes of death in the world, resulting in nearly 2 million deaths in 2016.[1] People living with HIV are more vulnerable to TB infection and have a higher risk of mortality during TB treatment compared to HIV-negative patients. These vulnerabilities have led to TB becoming the leading cause of death among people living with HIV, accounting for 37 percent of all AIDS-associated deaths.[1,2] In 2012, the World Health Organization (WHO) released policy guidance on the implementation of collaborative TB/HIV activities, emphasizing the need to establish mechanisms for delivering integrated TB and HIV services, preferably at the same time and location.[3] One model to achieve TB/HIV integration is the "one-stop shop" approach where patients co-infected with TB and HIV are treated for both illnesses by 1 provider or care team during 1 visit at 1 treatment location.[4,5] In addition to colocation, the use of combined treatment plans, is another method for integrating care for HIV patients with multiple diagnoses.[6]

Several studies have demonstrated the effects of TB/HIV integration on TB treatment outcomes or HIV-related indicators [isoniazid preventive therapy, antiretroviral therapy (ART) uptake, time to initiation, mortality].[7–11] However, few have assessed both TB and HIV-related indicators in the same study, with fewer focusing on effects of integration on performance in rural health facilities.[4,12–14] This study used data from 2 evaluations of on-site support interventions conducted over 3 years in Uganda to determine whether TB treatment outcomes and ART initiation of TB/HIV-coinfected patients are associated with TB/HIV integration status at rural health facilities.

## METHODS

### Study Design

This was a cross-sectional, retrospective study using data collected from 14 health facilities enrolled in 2 quasiexperimental studies conducted between January 2012 to June 2014.[15,16] Each health facility was classified based on their TB/HIV integration status before and during the interventions in the previously

conducted studies. We compared integrated and nonintegrated facility periods to determine the effect of integration on the following indicators: ART initiation, TB treatment success, and mortality. The

TREND checklist is available in Table 1, Supplemental Digital Content, http://links.lww.com/QAI/B228.

**Setting, Participants, and Eligibility**

Fourteen rural health facilities that were part of the intervention arm for either the TB REACH or MENTORS program were included in this analysis.[15,16] Ten facilities received the TB REACH intervention and 5 received the MENTORS intervention as described below. One facility was included in both interventions, for a total of 14 facilities included in the analysis.

The health facilities were 13 health centers IV and 1 district hospital drawn from all regions of Uganda. Health Centers IV serve a catchment population of 100,000, providing outpatient and limited inpatient and surgical services for minor ailments, labor and delivery, and referral to district hospitals. During the interventions, they were the lowest level health facility at which ART and TB treatment initiation services were available. All TB patients coinfected with HIV and not transferred in or out of the health facility for TB treatment were included in the analysis.

**Description of interventions**

For TB REACH, a team comprised of a clinical officer, a laboratory technician and a data manager conducted on-site support visits for two days once per month over a 9-month period (from January to October 2012) (Table 5.1). These visits included multidisciplinary and cadre-specific clinical sessions covering key areas of TB diagnosis and case management.[15] For MENTORS, 2 clinical officers trained as mentors conducted visits to each facility for 1 day every 6 weeks, over a 9-month period from October 2013 to June 2014. These visits focused on providing one-on-one clinical mentorship on HIV and TB care for 4 clinical officers, registered nurses and registered midwives at each facility.[16] As part of these visits in both interventions, program staff also worked with health facility staff to integrate TB/HIV services. Key strategies to foster TB/HIV integration included conducting trainings on the management of TB/HIV-

coinfected patients, moving TB drugs into the HIV clinic, and modifying TB and HIV clinic schedules, so that clinics for both illnesses were held on the same day. To prevent nosocomial transmission, program staff helped to establish open air waiting areas and collaborated with health facility staff to develop systems to actively identify and separate coughing patients from other patients and fast track them through the patient care process.

**Table 5. 1 Timeline of interventions and guidelines**

<table>
<tr><td colspan="2" rowspan="2"></td><td colspan="4">2012</td><td colspan="4">2013</td><td colspan="4">2014</td></tr>
<tr><td>Jan-Mar</td><td>Apr-Jun</td><td>Jul-Sep</td><td>Oct-Dec</td><td>Jan-Mar</td><td>Apr-Jun</td><td>Jul-Sep</td><td>Oct-Dec</td><td>Jan-Mar</td><td>Apr-Jun</td><td>Jul-Sep</td><td>Oct-Dec</td></tr>
<tr><td rowspan="2">Data Collection</td><td>TB REACH</td><td colspan="3">Intervention Study Period:<br>Jan – Oct 2012</td><td colspan="3">Follow-up Period*:<br>Nov 2012-Jun 2013</td><td colspan="8"></td></tr>
<tr><td>MENTORS</td><td colspan="5"></td><td colspan="3">Baseline Study Period:<br>Jan-Sept 2013</td><td colspan="3">Intervention Study Period:<br>Oct 2013- Jun 2014</td><td colspan="2">Follow-up Period*:<br>Jul 2014-Mar 2015</td></tr>
<tr><td rowspan="2">Guidelines</td><td>ART</td><td colspan="8">Ending Nov 2013<br>CD4 count < 250 cells/mm3 or signs of stage 4 HIV:<br>initiate ART after 2 weeks of TB treatment<br>CD4 count was above 250 cells/mm3:<br>initiate ART after completion of TB treatment</td><td colspan="4">Starting Dec 2013<br>CD4 count < 50 cells/mm3:<br>initiate ART after 2 weeks of TB treatment<br>CD4 count > 50 cells/mm3:<br>initiate ART after 8 weeks of TB treatment</td></tr>
<tr><td>TB</td><td colspan="8">Ending Nov 2013<br>8-month regimen:<br>2 months HRZE, 6 months HE</td><td colspan="4">Starting Dec 2013<br>6-month regimen:<br>2 months HRZE, 4 months HR</td></tr>
</table>

*Outcomes for patients who started treatment during the intervention study period were collected during the follow-up period.

Abbreviations: Isoniazid (H), Rifampicin (R), Pyrazinamide (Z), Ethambutol (E)

**Study Outcomes and Definitions**

The primary outcomes for TB and HIV-coinfected patients were (1) the proportion who started on ART during TB treatment, the proportion who (2) were cured or completed, (3) died, (4), were lost to follow-up, or (5) had treatment failure during TB treatment. The outcome indicator definitions are presented in Table 5.2. The data source for all 5 indicators was the National Tuberculosis and Leprosy Program (NTLP) Unit Register of the participating facilities.

During the time of the interventions, the guidelines on when to initiate ART and TB treatment regimens for coinfected patients changed (Table 5.1). From 2009-2013, the recommended period to initiate ART ranged from starting after 2 weeks, if CD4 count was less than 250 cells/$mm^3$ or patient had signs of stage 4 HIV, to starting after TB treatment, if CD4 count was above 250 cells/$mm^3$.[17] In December 2013, the guidelines were changed to recommend starting patients on ART after 2 weeks, if the CD4 count was less than 50 cells/$mm^3$, or after 8 weeks, if it was greater than 50 cells/$mm^3$.[18] During the same period, , the guidelines for TB treatment changed from an 8-month to a 6-month treatment regimen for new adult cases. Both regimens include a 2-month initial phase of isoniazid, rifampicin, pyrazinamide and ethambutol. The 6-month treatment regimen had a continuation phase of 4 months of isoniazid and rifampicin, compared to a 6-month continuation phase of isoniazid and ethambutol under the 8-month regimen.

After implementation of the interventions, program managers who were involved in the TB REACH and MENTORS projects classified each health facility's TB/HIV integration status before (MENTORS) and during (MENTORS and TB REACH) the interventions. Although data on TB outcomes and ART initiation was available for MENTORS for both time points, it was not available before the TB REACH intervention. Thus, each facility contributed between 1 to 3 time points that were integrated or not (integration periods), depending on whether they were enrolled in the TB REACH intervention (9 facilities, 1 integration period), MENTORS intervention (4 facilities, 2 integration periods), or both (1 facility, 3 integration periods) – for a total of 20 integration periods.

**Table 5. 2 Indicator definitions**

| | Indicators | Definition |
|---|---|---|
| 1 | Proportion of TB and HIV co-infected patients started on ART | **Numerator:** Number of TB patients who have a positive HIV test result, excluding transfer-ins and transfer-outs who had an ART number recorded in the NLTP Unit Register at a date later than TB treatment initiation.<br><br>**Denominator:** Number of TB patients who have a positive HIV test result who were not started on ART prior to TB treatment initiation, excluding transfer-ins and transfer-outs. |
| 2 | Proportion of TB and HIV co-infected patients who were cured or completed TB treatment (out of all those with a treatment outcome recorded) | **Numerator:** Number recorded as either cured or completed TB treatment, excluding transfer-ins and transfer-outs<br><br>**Denominator:** Number of TB patients who have a positive HIV test result and treatment outcome recorded (cured or completed, died, lost to follow-up, or treatment failure), excluding transfer-ins and transfer-outs. |
| 3 | Proportion of TB and HIV co-infected patients who died during TB Treatment (out of all those with a treatment outcome recorded) | **Numerator:** Number recorded as died during TB treatment, irrespective of cause, excluding transfer-ins and transfer-outs<br><br>**Denominator:** Number of TB patients who have a positive HIV test result and treatment outcome recorded (cured or completed, died, lost to follow-up, or treatment failure), excluding transfer-ins and transfer-outs |
| 4 | Proportion of TB/HIV patients who **were lost to follow-up** during TB treatment | **Numerator:** Number recorded as lost to follow-up during TB treatment, excluding transfer-ins and transfer-outs<br><br>**Denominator:** Number of TB patients who have a positive HIV test result and treatment outcome recorded (cured or completed, died, lost to follow-up, or treatment failure), excluding transfer-ins and transfer-outs |
| 5 | Proportion of TB/HIV patients who **had TB treatment failure** | **Numerator:** Number recorded as experiencing TB treatment failure during TB treatment, excluding transfer-ins and transfer-outs<br><br>**Denominator:** Number of TB patients who have a positive HIV test result and treatment outcome recorded (cured or completed, died, lost to follow-up, or treatment failure), excluding transfer-ins and transfer-outs |

TB/HIV integration was defined as TB patients infected with HIV being treated for both TB and HIV by 1 provider or care team using a combined treatment plan during 1 visit at 1 treatment location. The combined treatment plan included treatments for both diagnoses and took into consideration drug interactions and side-effects, as well as scheduling drug refills to coincide on a single visit when possible. Program managers were blinded to the study outcomes but not to overall facility performance when classifying the health facilities.

**Sample Size**

The number of facilities was based on the samples required for testing the effect of the TB REACH and MENTORS interventions.[15,16] For TB REACH, the sample size was calculated to detect a 50% change, from 15% to 65% in proportion of presumptive TB cases with a sputum smear, with a power of 80% and 5% level of significance. For MENTORS, the sample size was calculated to detect a 10% absolute difference in knowledge on HIV case scenarios with 80% power at a 5% level of significance.

**Data Collection**

Facility-based data entrants entered routinely collected patient data into electronic replicas of the NTLP Unit register during each project. For TB REACH, data were collected during the intervention from January to October 2012. Data entry personnel returned to the facilities in June 2013 to collect data on TB treatment outcomes for all patients who started TB treatment between January and October 2012. Data was not available for TB treatment outcomes before TB REACH. For MENTORS, data for January to September 2013 was entered retrospectively before the start of the intervention in October 2013 to create the time point before the intervention. Data entry personnel also entered data from October 2013 to June 2014 to create the time point during intervention. Data entrants remained on-site from July 2014 to March 2015 after the intervention and collected TB treatment outcomes for all patients who started TB treatment between October 2013 and June 2014.

**Statistical Methods**

We analyzed the effect of integration by conducting a cross-sectional analysis assessing change in ART initiation, TB treatment outcomes (success, mortality, lost to follow-up, and treatment failure), by TB/HIV integration status. We conducted bivariate analyses to compare patient demographics for the integrated and non-integrated health facility periods, using Student's *t* tests for continuous and $\chi^2$ tests for categorical variables. Using the patient as the unit of analysis, we conducted logistic regression analysis with TB/HIV integration status as the independent variable, adjusting for age, sex, the introduction of the revised guidelines, and clustering by health facility. We controlled for other effects of the interventions and changes over time by including time (pre/post intervention) as a covariate. In addition to reporting the main effect of TB/HIV integration, we also report the effects of the change in guidelines on the outcomes. Sensitivity analyses were performed for the 4 TB outcomes, with 2 alternative assumptions about the missing observations: (1) all missing values were interpreted as either having the outcome (treatment success, death, lost to follow-up, or treatment failure) with a value of 1, or (2) not having the outcome and a value of 0. Data analysis was done using the statistical package Stata (version 14.2; StataCorp, College Station, TX).

**Ethics Statement**

Both studies were reviewed and approved by the Uganda National Council on Science and Technology. TB REACH was reviewed and approved by the Scientific Review Committee of the Infectious Diseases Institute and the Institutional Review Boards of Joint Clinical Research Center and Johns Hopkins University. MENTORS was reviewed and approved by the Institutional Review Boards of the Joint Clinical Research Center and the US Centers for Disease Control. The database used for analysis in this study did not contain identifying information on patients.

## RESULTS

### Characteristics of study population

For the 10 facilities included in TB REACH, 8 of the facilities were integrated after the intervention (Table 5.3). For the 5 facilities included in MENTORS, none were integrated before the intervention and three were integrated after intervention. Of the 20 TB/HIV integration periods assessed, health facilities were integrated in 11 (55%) periods, all occurring after intervention, and not integrated in 9 (45%) periods, 5 before intervention and 4 after intervention.

**Table 5. 3 Health facility integration periods**

| | Total | Not integrated | Integrated |
|---|---|---|---|
| **Number of health facility integration periods** | 20 | 9 (45.0%) | 11 (55.0%) |
| ***Prior to intervention*** | 5 | 5 (100.0%) | 0 (0.0%) |
| TB REACH | 0 | 0 (0.0%) | 0 (0.0%) |
| MENTORS | 5 | 5 (100.0%) | 0 (0.0%) |
| ***Post-intervention*** | 15 | 4 (26.7%) | 11 (73.3%) |
| TB REACH | 10 | 2 (20.0%) | 8 (80.0%) |
| MENTORS | 5 | 2 (40.0) | 3 (60.0) |

A total of 996 patients with TB were registered for TB treatment; 966 (97%) were tested for HIV, and 404 (42%) were HIV-positive. Of the 404 patients with TB/HIV, 108 were transferred-in or transferred-out during their TB treatment, leaving 296 eligible patients - 117 and 179 during nonintegration and integration periods, respectively. Of these 57.8% were men and the median age was 33 (interquartile range 26-40) (Table 5.4).

**Table 5. 4 Patient demographics**

| | Total | Not integrated | Integrated | p-value |
|---|---|---|---|---|
| **Total TB/HIV patients enrolled** | 296 | 117 | 179 | |
| Average number of TB/HIV patients, per facility | 15.6 | 14.6 | 16.3 | 0.806 |
| Sex; n (%) | | | | 0.735 |
| Male | 171 (57.8) | 69 (59.0) | 102 (57.0) | |
| Female | 125 (42.2) | 48 (41.0) | 77 (43.0) | |
| Age (years); median (IQR) | 33 (26, 40) | 34 (28, 43) | 33 (26, 39) | 0.182 |

**ART initiation**

Of the 296 patients with TB/HIV included in the study, 174 (58.8%) had not initiated ART before starting TB treatment and had their ART start date recorded when ART was initiated. In this subset of patients, the difference in the proportion initiated on ART during integration periods compared with during nonintegrated periods was not statistically significant {47.7% vs. 33.8%; adjusted odds ratio (aOR)=1.34 [95% confidence interval (CI): 0.40 to 4.47]} (Table 5.5). There was no effect of the change in guidelines on T5 ART initiation (see Table 2, Supplemental Digital Content, http://links.lww.com/QAI/B228).

**Table 5. 5 Descriptive statistics and regression results of the comparison of healthcare facilities by TB/HIV integration level, adjusted for age, gender, intervention effects and change in guidelines, and clustering by healthcare facility**

| | TB/HIV Integration Status | | | Regression Results | | | |
|---|---|---|---|---|---|---|---|
| | **Total** | **Not integrated** | **Integrated** | **OR (95% CI)** | **p-value** | **Adjusted OR (95% CI)** | **p-value** |
| **ART Indicator**[+] | | | | | | | |
| Proportion of TB/HIV patients started on ART | 38.5% (67/174) | 33.8% (24/71) | 47.7% (43/103) | 1.40 (0.33, 6.02) | 0.648 | 1.34 (0.40, 4.47) | 0.632 |
| **TB Indicators**[++] | | | | | | | |
| Proportion of TB/HIV patients with treatment success (completed or cured) | 54.5% (126/231) | 53.8% (49/91) | 55.0% (77/140) | 1.05 (0.47, 2.35) | 0.910 | 1.43 (0.73, 2.82) | 0.298 |
| Proportion of TB/HIV patients who died during TB treatment | 19.5% (45/231) | 27.5% (25/91) | 14.3% (20/140) | 0.44* (0.26, 0.73) | 0.002 | 0.38* (0.18, 0.77) | 0.008 |
| Proportion of TB/HIV patients who were lost to follow-up during TB treatment[+++] | 24.7% (57/231) | 17.6% (16/91) | 29.2% (41/140) | 1.94 (0.52, 7.30) | 0.326 | 1.64 (0.53, 5.04) | 0.386 |
| Proportion of TB/HIV patients who had TB treatment failure[+++] | 1.3% (3/231) | 1.10% (1/91) | 1.4% (2/140) | 1.30 (0.18, 9.58) | 0.794 | 1.21 (0.34, 4.32) | 0.774 |

* $p<0.01$

[+]Of the 296 in the sample, 122 (41.2%) were not included in the analysis: 84 (68.9%) were already on ART prior to starting TB treatment, and thus were not eligible, 38 (31.1%) were missing ART start date and were excluded because it was unclear whether they started ART before or after TB treatment. Those missing comprised 18 (20.2%) of the non-integrated time period and 20 (16.3%) of the integrated time period samples.

[++]Of the 296 in the sample, 65 (22.0%) had outcomes missing - 26 (22.2%) of the non-integrated time period and 39 (22.2%) of the integrated time periods samples.

[+++]Age was omitted in the final model for lost to follow-up due to collinearity. Age and time period were omitted in the model for TB treatment failure, due to collinearity.

**TB Treatment Outcomes**

Of the 296 patients included in the study, 231 (78.0%) had TB treatment outcomes recorded. A similar proportion of patients with TB/HIV were completed or cured in both arms, with 55.0% in the integration and 53.8% in the non-integration periods (aOR = 1.43; 95% CI: 0.73 to 2.82) (Table 5.5). There was a smaller proportion of patients with TB/HIV who died while on TB treatment during integrated facility periods (14.3%) compared with non-integrated facility periods (27.5%) (aOR = 0.44; 95% CI: 0.18 to 0.77). There were no differences in the patients lost to follow-up (29.2% vs. 17.6%; aOR = 1.64; 95% CI: 0.53 to 5.04) or the proportion with TB treatment failure (1.4% vs. 1.10%, aOR = 1.21; 95% CI: 0.34 to 4.32). There was no effect of the change in guidelines on any of the TB treatment outcomes (see Table 2,

Supplemental Digital Content, http://links.lww.com/QAI/B228).

In sensitivity analyses, we imputed the 38 cases with missing data for the 4 TB treatment outcomes as equal to zero or one. The direction and significance of the effect estimates were the same, with 1 exception. The effect of TB/HIV integration on mortality was not statistically significant when it was assumed that all patients with missing treatment outcomes had died (aRR = 0.48; 95% CI: 0.21 to 1.11).

To assess the contribution of ART initiation to mortality, we compared the proportion of patients who died by their ART status. The proportion who died was similar among those on and not on ART (20% vs. 23%, $\chi^2 = 0.0219$, $P = 0.882$).

**DISCUSSION**

Integration of TB and HIV services was associated with lower mortality in rural health facilities when compared with settings where TB and HIV services were not integrated. Integration of TB and HIV treatment services could lead to declines in mortality through several mechanisms, including ART initiation, earlier ART initiation, increased and earlier TB screening, and earlier initiation on TB treatment.[19–21] We found no evidence for an effect of TB/HIV integration on ART initiation and the proportion who died was similar among patients regardless of whether they were on ART. It is possible

that integration of services led to earlier ART initiation among those who were initiated on ART during TB treatment. We were unable to reliably assess time to ART initiation in this study because of the small number of patients (n = 62) in this group. Given the similar rates of survival regardless of ART initiation found in this study, mortality among those on ART could be due to late presentation with low CD4 counts. Several studies have documented higher mortality in the first few months of starting ART among patients with low CD4 counts.[22–24]

While data on the timeliness of TB treatment initiation were not available for this analysis, both Manabe & Zawedde et al. and Naikoba et al. reported an increase in TB screening among outpatients when assessing the effect of the TB REACH and MENTORS interventions, and Naikoba et al. also reported high rates of TB screening among patients with HIV.[15,16]

Through earlier identification of patients with TB and HIV, and earlier initiation on both TB treatment and ART, facilities offering integrated TB/HIV services could likely reduce mortality. During TB REACH and MENTORS, facility staff implemented several interventions to improve TB/HIV integration that may have improved TB screening and initiation among patients with HIV, such as taking more active measures to identify HIV patients with TB symptoms and moving TB drugs to the HIV clinic. At the same time, changes in national guidelines that recommended earlier initiation on treatment were also being implemented. Future studies on TB/HIV integration would benefit from further studying the components of TB/HIV integration to describe the pathways through which TB/HIV integration leads to reduction in mortality and which specific components of integration lead to the greatest improvement.

Overall, the proportion of patients with TB/HIV initiated on ART during TB treatment (38.5%) and who were successfully treated for TB (54.5%) were low in this study, and the proportion of those who died was high (19.5%). Even during the integration periods, which had lower mortality than non-integration periods, 14.3% of patients died during TB treatment. These results suggest a lower level of quality of care than seen in several other studies of TB/HIV integration.[12,13,25–27] Three of these 5 similar studies were performed in urban areas and most assessed outcomes 2 years after integration. This longer follow-up period may have

allowed TB/HIV integration to become better established in these facilities and resulted in a greater proportion of patients with TB benefitting from the TB/HIV integration throughout their full treatment period. The outcomes in this study were assessed in rural facilities during the period when TB/HIV integration was implemented and followed for 9 months. Some of the patients included in this analysis started their treatment before the TB/HIV integration which usually occurred a few months into the projects, and thus may have only partially benefitted from the TB/HIV integration during their treatment. This may have reduced our ability to assess the full effects of TB/HIV integration on our outcome indicators and resulted in lower overall performance.

Given the benefits of TB/HIV integration, as cited in this study and in others, TB/HIV integration should be further supported, particularly in areas with high burden of TB and HIV coinfection. In Uganda, the Ministry of Health is already supporting a country-wide approach to improving TB/HIV integration in all health facilities.[28,29] Operationally, there are many challenges to integrating TB and HIV services, and rural facilities require special consideration.[5] Nurses and clinical officers are also less likely to have received regular training on updated guidelines for TB and HIV treatment than medical officers and physicians, and may be more reluctant to initiate ART due to fear of drug interactions and immune reconstitution syndrome.[30] Regular supportive supervision can effectively improve the clinical skills of mid-level practitioners in providing HIV and TB care. Both the TB REACH and MENTORS studies helped to improve the quality of care over 9-month interventions, when compared with control facilities, while also improving TB/HIV integration.[15,16]

This study used existing datasets from two operational research interventions to draw conclusions regarding the effects of TB/HIV integration in rural settings. The NTLP Unit Register was a key data source for both interventions. The use of this standardized government register facilitated the analysis across the 2 projects. Both interventions also employed facility-based data entrants to review and verify the data as it was entered. Although these data were of higher quality than routine health register data, there were still gaps in the data quality that affected the analysis. For example, sensitivity analyses were conducted to address missing data

for TB outcomes. In addition, as this study was a secondary analysis, some data that would have been useful, such as CD4 count and World Health Organization clinical stage, were not collected for both interventions and thus could not be analyzed. This analysis was also limited to the sample size for the 2 interventions and may not have been large enough to show a difference in the intended outcomes. Future research should be powered with an adequate sample size. However, this analysis did allow us to gain further insight into TB/HIV integration in rural health facilities at little additional cost. Operational studies should collect data using existing national registers and make anonymized data publicly available for further analysis, taking into account best practices in responsible, ethical data sharing.[31,32] This is particularly important for low-resource settings where funding for operations research is limited to avoid waste and unnecessary duplication and to accelerate advancements in program implementation.[33]

Our study had several limitations that should be considered when interpreting the findings. First, this was a cross-sectional study and was not randomized. Differences in mortality could have been influenced by factors other than the TB/HIV integration, including the effect of the 2 interventions (TB REACH and MENTORS), changes in ART guidelines during the study period, or other factors related to TB and HIV care and treatment, such as resources and infrastructure. Also, the TB/HIV integration status of the control facilities that did not receive the TB REACH and MENTORS interventions were not available so we were not able to use these facilities in the analysis. We attempted to control for the effects of these interventions and guidelines changes by using covariates to account for the time before and after the intervention and the change in guidelines as covariates in the model. We were unable to control for CD4 count, a main factor in determining timing of ART initiation for patients with TB in both the previous and revised ART guidelines, as our data source was the NTLP Unit Register. Future research could link patient records across NTLP and ART registers. Second, eligibility criteria focused on subdistrict referral facilities within rural Uganda engaged in 2 TB and HIV interventions. However, to the extent that these facilities are similar to health facilities throughout sub-Saharan Africa, these results would be generalizable to TB/HIV integration in other rural settings. Third, program managers familiar with the 2

interventions classified each facility's integration status based on their knowledge of the facility. Although they did not have access to the results by facility for these study outcomes, they may have been familiar with which facilities had higher performance in general, and it is possible they could have been biased in classifying higher performing sites as being more integrated. Finally, the effect of TB/HIV integration on mortality was not robust in sensitivity analyses when missing data on the TB treatment outcome was assumed to mean that the patient had died. However, this sensitivity analysis had a much higher proportion of deaths than seen in other studies.

## CONCLUSION

TB/HIV service integration was associated with lower mortality on TB treatment even in a setting with suboptimal proportions completing TB treatment and starting on ART.

**Conflicts of Interest and Source of Funding:** TB REACH was supported by a grant from the Stop TB Partnership through grant number T9-370-114UGA from the Canadian International Development Agency. MENTORS was made possible by the support from the US President's Emergency Plan for AIDS Relief through cooperative agreement 1U01GH000527 from the US Centers for Disease Control and Prevention, Division of Global HIV/AIDS. Salary support for research to YCM and SZM was provided by Fogarty International Center, National Institutes for Health (grant #D43TW009771: HIV co-infections in Uganda: TB, Cryptococcus, and Viral Hepatitis). The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript. The findings and conclusions contained within the manuscript are those of the authors and do not necessarily reflect positions or policies of the funders. The authors declare no conflict of interest.

## ACKNOWLEDGEMENTS

**Acknowledgments:** We gratefully acknowledge the TB REACH team and Dr. Sarah Naikoba, Dr. Dan Senjovu Kaggwa, and Mr. Pallen Mugabe of the MENTORS team for sharing the MENTORS program data. We are also grateful to the health center staff who participated in these two interventions, as well as the program staff who supported the health facilities to integrate TB and HIV services.

**Author contributions.** YCM, SZM, SMB and SMH designed the study. SZM, the TB REACH team and the MENTORS teams gathered the data. SMB, SZM, SMH and YCM designed the analysis, interpreted the data and drafted the manuscript. All authors read and approved the final manuscript.

**REFERENCES**

1. UNAIDS. *Ending AIDS: Progress towards the 90-90-90 Targets*. Geneva, Switzerland: UN Joint Programme on HIV/AIDS (UNAIDS); 2017. http://www.unaids.org/sites/default/files/media_asset/Global_AIDS_update_2017_en.pdf. Accessed December 2, 2017.

2. WHO. *Global Tuberculosis Report 2017*.; 2017. doi:WHO/HTM/TB/2017.23.

3. World Health Organization. WHO policy on collaborative TB/HIV activities. Guidelines for national programmes and other stakeholders. *World Heal Organ Doc*. 2012;WHO/HTM/TB:1-34. doi:23586124.

4. Hermans SM, Castelnuovo B, Katabira C, et al. Integration of HIV and TB services results in improved TB treatment outcomes and earlier, prioritized ART initiation in a large urban HIV clinic in Uganda. *JAIDS J Acquir Immune Defic Syndr*. 2012;60(June 2012):1-14. doi:10.1097/QAI.0b013e318251aeb4.Integration.

5. Legido-Quigley H, Montgomery CM, Khan P, et al. Integrating tuberculosis and HIV services in low- and middle-income countries: A systematic review. *Trop Med Int Heal*. 2013;18(2):199-211. doi:10.1111/tmi.12029.

6. Weaver MR, Conover CJ, Proescholdbell RJ, et al. Cost-effectiveness analysis of integrated care for people with HIV, chronic mental illness and substance abuse disorders. *J Ment Health Policy Econ*. 2009;12(1):33-46. http://www.who.int/hiv/pub/guidelines/uganda_tb.pdf?ua=1.

7. Ansa GA, Walley JD, Siddiqi K, Wei X. Assessing the impact of TB/HIV services integration on TB treatment outcomes and their relevance in TB/HIV monitoring in Ghana. *Infect Dis Poverty*. 2012;1(1):13. doi:10.1186/2049-9957-1-13.

8. Patel MR, Nana M, Yotebieng M, Tabala M, Behets F, Van Rie A. Delayed antiretroviral therapy

despite integrated treatment for tuberculosis and HIV infection. *Int J Tuberc Lung Dis*. 2014;18(6):694-699. doi:10.5588/ijtld.13.0807.

9. Suthar AB, Rutherford GW, Horvath T, Doherty MC, Negussie EK. Improving antiretroviral therapy scale-up and effectiveness through service integration and decentralization. *AIDS*. 2014;28:S175-S185. doi:10.1097/QAD.0000000000000259.

10. Ledibane TD, Motlhanke SC, Rose A, Kruger WH, Ledibane NRT, Claassens MM. Antiretroviral treatment among co-infected tuberculosis patients in integrated and non-integrated facilities. *Public Heal Action*. 2015;5(2):112-115. doi:10.5588/pha.14.0099.

11. Kaplan R, Caldwell J, Bekker LG, et al. Integration of TB and ART services fails to improve TB treatment outcomes: Comparison of ART/TB primary healthcare services in Cape Town, South Africa. *South African Med J*. 2014;104(3):204-209. doi:10.7196/SAMJ.7696.

12. Schulz SA, Draper HR, Naidoo P. A comparative study of tuberculosis patients initiated on ART and receiving different models of TB-HIV care. *Int J Tuberc Lung Dis*. 2013;17(12):1558-1563. doi:10.5588/ijtld.13.0247.

13. Owiti P, Zachariah R, Bissell K, et al. Integrating tuberculosis and HIV services in rural Kenya: uptake and outcomes. *Public Heal Action*. 2015;5(1):36-44. doi:10.5588/pha.14.0092.

14. Galagan S, Jed S, Sumitani J, et al. Improving TB and HIV treatment monitoring in South Africa: Evaluation of an advanced TB/HIV course for health care workers. *Open Forum Infect Dis*. 2016:ofw248. doi:10.1093/ofid/ofw248.

15. Manabe YC, Zawedde-Muyanja S, Burnett SM, Mugabe F, Naikoba S, Coutinho A. Rapid Improvement in Passive Tuberculosis Case Detection and Tuberculosis Treatment Outcomes After Implementation of a Bundled Laboratory Diagnostic and On-Site Training Intervention Targeting Mid-Level Providers. *Open Forum Infect Dis*. 2015;2(Suppl 1):1-8. doi:10.1093/o.

16. Naikoba S, Senjovu KD, Mugabe P, et al. Improved HIV and TB Knowledge and Competence among Mid-level Providers in a Cluster-Randomized Trial of One-on-One Mentorship for Task Shifting. *J Acquir Immune Defic Syndr*. 2017;75(5):e120-e127. doi:10.1097/QAI.0000000000001378.

17. Uganda Ministry of Health. *National Antiretroviral Treatment Guidelines for Adults, Adolescents, and Children, 3rd Edition*.; 2009. http://library.health.go.ug/publications/service-delivery-diseases-control-prevention-communicable-diseases/hivaids/national-3. Accessed March 2, 2018.

18. Uganda Ministry of Health. *Addendum to the National Antiretroviral Treatment Guidelines*.; 2013. https://aidsfree.usaid.gov/sites/default/files/tx_uganda_add_to_art_2013.pdf. Accessed March 2, 2018.

19. Onyango DO, Yuen CM, Cain KP, Ngari F, Masini EO, Borgdorff MW. Reduction of HIV-associated excess mortality by antiretroviral treatment among tuberculosis patients in Kenya. *PLoS One*. 2017;12(11):1-13. doi:10.1371/journal.pone.0188235.

20. Agbor AA, Bigna JJR, Billong SC, et al. Factors associated with death during tuberculosis treatment of patients co-infected with HIV at the Yaoundé Central Hospital, Cameroon: An 8-year hospital-based retrospective cohort study (2006-2013). *PLoS One*. 2014;9(12):1-22. doi:10.1371/journal.pone.0115211.

21. Naidoo K, Baxter C, Abdool Karim SS. When to start antiretroviral therapy during tuberculosis treatment. *Curr Opin Infect Dis*. 2014;26(1):35-42. doi:10.1097/QCO.0b013e32835ba8f9.When.

22. Gupta A, Nadkarni G, Yang W-T, et al. Early Mortality in Adults Initiating Antiretroviral Therapy (ART) in Low- and Middle-Income Countries (LMIC): A Systematic Review and Meta-Analysis. *PLoS One*. 2011;6(12):e28691. doi:10.1371/journal.pone.0028691.

23. Walker AS, Prendergast AJ, Mugyenyi P, et al. Mortality in the year following antiretroviral therapy

initiation in HIV-infected adults and children in Uganda and Zimbabwe. *Clin Infect Dis*. 2012;55(12):1707-1718. doi:10.1093/cid/cis797.

24. Boulle A, Schomaker M, May MT, et al. Mortality in Patients with HIV-1 Infection Starting Antiretroviral Therapy in South Africa, Europe, or North America: A Collaborative Analysis of Prospective Studies. *PLoS Med*. 2014;11(9). doi:10.1371/journal.pmed.1001718.

25. Ndagijimana A, Rugigana E, Uwizeye CB, Ntaganira J. One-stop TB-HIV services evaluation in Rwanda: comparison of the 2001-2005 and 2006-2010 cohorts. *Public Heal Action*. 2015;5(4):209-213. doi:10.5588/pha.15.0093.

26. Louwagie G, Girdler-Brown B, Odendaal R, Rossouw T, Johnson S, Van der Walt M. Missed opportunities for accessing HIV care among Tshwane tuberculosis patients under different models of care. *Int J Tuberc Lung Dis*. 2012;16(8):1052-1058. doi:10.5588/ijtld.11.0753.

27. Van Rie A, Patel MR, Nana M, et al. Integration and Task Shifting for TB/HIV Care and Treatment in Highly Resource-Scarce Settings: One Size May Not Fit All. *J Acquir Immune Defic Syndr*. 2014;65(3):e110-e117. doi:10.1097/01.qai.0000434954.65620.f3.

28. National Tuberculosis and Leprosy Program. *Quality Improvement Manual for TB Care Services*. Entebbe, Uganda; 2017. http://library.health.go.ug/publications/service-delivery-diseases-control-prevention-communicable-diseases/tuberculosis/quali-6. Accessed March 2, 2018.

29. Management Sciences for Health. *One-Stop Shop for TB/HIV Services: A Model for Increasing Antiretroviral Therapy Uptake in Uganda*.; 2017. https://www.msh.org/resources/one-stop-shop-for-tbhiv-services-a-model-for-increasing-antiretroviral-therapy-uptake-in. Accessed March 2, 2018.

30. Loveday M, Zweigenthal V. TB and HIV integration: obstacles and possible solutions to implementation in South Africa. *Trop Med Int Heal*. 2011;16(4):431-438. doi:10.1111/j.1365-

3156.2010.02721.x.

31. Parker M, Bull S. Sharing Public Health Research Data: Toward the Development of Ethical Data-Sharing Practice in Low- and Middle-Income Settings. *J Empir Res Hum Res Ethics*. 2015;10(3):217-224. doi:10.1177/1556264615593494.

32. Rani M, Buckley BS. Systematic archiving and access to health research data: rationale, current status and way forward. *Bull World Health Organ*. 2012;90(12):932-939. doi:10.2471/BLT.12.105908.

**S1 Table. TREND checklist**

| PAPER SECTION and topic | Item | Descriptor | Reported on Page No. |
|---|---|---|---|
| ***TITLE & ABSTRACT*** | | | |
| | 1a | Information on how units were allocated to interventions | Abstract - methods |
| | 1b | Structured abstract recommended | Abstract |
| | 1c | Information on target population or study sample | Title/Abstract |
| ***INTRODUCTION*** | | | |
| Background & Objectives | 2a | Scientific background and explanation of rationale | Background |
| | 2b | Theories used in designing behavioral interventions | Not applicable |
| ***METHODS*** | | | |
| Participants | 3a | Eligibility criteria for participants, including criteria at different levels in recruitment/sampling plan (e.g., cities, clinics, subjects) | Setting, Participants and Eligibility |
| | 3b | Method of recruitment (e.g., referral, self-selection), including the sampling method if a systematic sampling plan was implemented | Setting, Participants and Eligibility |
| | 3c | Recruitment setting | Setting, Participants and Eligibility |
| | 3d | Settings and locations where the data were collected | Setting, Participants and Eligibility |
| Interventions | 4 | Details of the interventions intended for each study condition and how and when they were actually administered, specifically including: | - |
| | 4a | Content: what was given? | Project Description, Manabe [13] Naikoba [14] |
| | 4b | Delivery method: how was the content given? | Project Description, Manabe [13] Naikoba [14] |
| | 4c | Unit of delivery: how were the subjects grouped during delivery? | Project Description, Manabe [13] Naikoba [14] |
| | 4d | Deliverer: who delivered the intervention? | Project Description, Manabe [13] Naikoba [14] |
| | 4e | Setting: where was the intervention delivered? | Setting, Participants and Eligibility |

| PAPER SECTION and topic | Item | Descriptor | Reported on Page No. |
|---|---|---|---|
| | 4f | Exposure quantity and duration: how many sessions or episodes or events were intended to be delivered? How long were they intended to last? | Project Description, Manabe [13] Naikoba [14] |
| | 4g | Setting: where was the intervention delivered? | Project Description, Manabe [13] Naikoba [14] |
| | 4h | Time span: how long was it intended to take to deliver the intervention to each unit? | Project Description, Manabe [13] Naikoba [14] |
| | 4i | Activities to increase compliance or adherence (e.g., incentives) | Project Description, Manabe [13] Naikoba [14] |
| Objectives | 5 | Specific objectives and hypotheses | Study Design |
| Outcomes | 6a | Clearly defined primary and secondary outcome measures | Outcomes |
| | 6b | Methods used to collect data and any methods used to enhance the quality of measurements | Data collection |
| | 6c | Information on validated instruments such as psychometric and biometric properties | Not applicable |
| Sample size | 7a | How sample size was determined and, when applicable, explanation of any interim analyses and stopping rules | Sample Size Manabe [13] Naikoba [14] |
| Assignment Method | 8a | Unit of assignment (the unit being assigned to study condition, e.g., individual, group, community) | Study Design |
| | 8b | Method used to assign units to study conditions, including details of any restriction (e.g., blocking, stratification, minimization) | Study Design |
| | 8c | Inclusion of aspects employed to help minimize potential bias induced due to non-randomization (e.g., matching) | Setting, Participants and Eligibility |
| Blinding (masking) | 9 | Whether or not participants, those administering the interventions, and those assessing the outcomes were blinded to study condition assignment; if so, statement regarding how the blinding was accomplished and how it was assessed. | Outcomes |
| Unit of Analysis | 10a | Description of the smallest unit that is being analyzed to assess intervention effects (e.g., individual, group, or community) | Statistical Methods |

| PAPER SECTION and topic | Item | Descriptor | Reported on Page No. |
|---|---|---|---|
| | 10b | If the unit of analysis differs from the unit of assignment, the analytical method used to account for this (e.g., adjusting the standard error estimates by the design effect or using multilevel analysis) | Statistical Methods |
| Statistical Methods | 11a | Statistical methods used to compare study groups for primary methods outcome(s), including complex methods of correlated data | Statistical Methods |
| | 11b | Statistical methods used for additional analyses, such as a subgroup analyses and adjusted analysis | Statistical Methods |
| | 11c | Methods for imputing missing data, if used | Not applicable |
| | 11d | Statistical software or programs used | Statistical Methods |
| ***RESULTS*** | | | |
| Participant flow | 12 | Flow of participants through each stage of the study: enrollment, assignment, allocation, and intervention exposure, follow-up, analysis (a diagram is strongly recommended) | Characteristics of study population |
| | 12a | Enrollment: the numbers of participants screened for eligibility, found to be eligible or not eligible, declined to be enrolled, and enrolled in the study | Characteristics of study population |
| | 12b | Assignment: the numbers of participants assigned to a study condition | Characteristics of study population |
| | 12c | Allocation and intervention exposure: the number of participants assigned to each study condition and the number of participants who received each intervention | Characteristics of study population |
| | 12d | Follow-up: the number of participants who completed the follow-up or did not complete the follow-up (i.e., lost to follow-up), by study condition | TB Outcomes; ART initiation |
| | 12e | Analysis: the number of participants included in or excluded from the main analysis, by study condition | TB Outcomes; ART initiation |
| | 12f | Description of protocol deviations from study as planned, along with reasons | Not applicable |
| | 12g | Enrollment: the numbers of participants screened for eligibility, found to be eligible or not eligible, declined to be enrolled, and enrolled in the study | Characteristics of study population, Figure 5.1, Manabe, Naikoba |
| Recruitment | 12 | Dates defining the periods of recruitment and follow-up. | Study Design |
| Baseline data | 14a | Baseline demographic and clinical characteristics of participants in each study condition | Table 5.3 patient demographics |
| | 14b | Baseline characteristics for each study condition relevant to specific disease prevention research | Not applicable |
| | 14c | Baseline comparisons of those lost to follow-up and those retained, overall and by study condition | Not applicable |

| PAPER SECTION and topic | Item | Descriptor | Reported on Page No. |
|---|---|---|---|
| | 14d | Comparison between study population at baseline and target population of interest | Not applicable |
| Baseline equivalence | 15 | Data on study group equivalence at baseline and statistical methods used to control for baseline differences | Table 5.3. Patient demographics |
| Numbers analyzed | 16a | Number of participants (denominator) included in each analysis for each study condition, particularly when the denominators change for different outcomes; statement of the results in absolute numbers when feasible | Outcomes, Figure 5.1 |
| | 16b | Indication of whether the analysis strategy was "intention to treat" or, if not, description of how non-compliers were treated in the analyses | Not applicable |
| Outcomes and Estimation | 17a | For each primary and secondary outcome, a summary of results for each estimation study condition, and the estimated effect size and a confidence interval to indicate the precision | TB outcomes, ART initiation, Table 5.4 Descriptive Statistics and Regression Results |
| | 17b | Inclusion of null and negative findings | TB outcomes, ART initiation Table 5.4 Descriptive Statistics and Regression Results |
| | 17c | Inclusion of results from testing pre-specified causal pathways through which the intervention was intended to operate, if any | Not applicable |
| Ancillary analyses | 18 | Summary of other analyses performed, including subgroup or restricted analyses, indicating which are pre-specified or exploratory | Study Design |
| Adverse events | 19 | Summary of all important adverse events or unintended effects in each study condition (including summary measures, effect size estimates, and confidence intervals) | Not applicable |
| ***DISCUSSION*** | | | |
| Interpretation | 20a | Interpretation of the results, taking into account study hypotheses, sources of potential bias, imprecision of measures, multiplicative analyses, and other limitations or weaknesses of the study | Discussion, Limitations |
| | 20b | Discussion of results taking into account the mechanism by which the intervention was intended to work (causal pathways) or alternative mechanisms or explanations | Discussion |
| | 20c | Discussion of the success of and barriers to implementing the intervention, fidelity of implementation | Discussion |
| | 20d | Discussion of research, programmatic, or policy implications | Discussion |

| PAPER SECTION and topic | Item | Descriptor | Reported on Page No. |
|---|---|---|---|
| Generalizability | 21 | Generalizability (external validity) of the trial findings, taking into account the study population, the characteristics of the intervention, length of follow-up, incentives, compliance rates, specific sites/settings involved in the study, and other contextual issues | Discussion |
| Overall Evidence | 22 | General interpretation of the results in the context of current evidence and current theory | Discussion |

**S2 Table. Effect of Guideline Changes on TB and HIV outcomes**

| | | Guideline Change | | Regression Results | |
|---|---|---|---|---|---|
| | **Total** | **Before** | **After** | **Adjusted OR (95% CI)** | **p-value** |
| **ART Indicator** | | | | | |
| Proportion of TB/HIV patients started on ART | 38.5% (67/174) | 40.3% (58/144) | 30.0% (9/30) | 0.70 (0.84, 5.99) | 0.753 |
| **TB Indicators** | | | | | |
| Proportion of TB/HIV patients with treatment success (completed or cured) | 54.5% (126/231) | 52.7% (106/201) | 66.7% (20/30) | 2.34 (0.68, 8.06) | 0.179 |
| Proportion of TB/HIV patients who died during TB treatment | 19.5% (45/231) | 18.4% (37/201) | 26.7% (8/30) | 0.95 (0.22, 4.17) | 0.946 |
| Proportion of TB/HIV patients who were lost to follow-up during TB treatment[+] | 24.7% (57/231) | 27.9% (56/201) | 3.33% (1/30) | 0.11 (0.01, 1.49) | 0.097 |
| Proportion of TB/HIV patients who had TB treatment failure[+] | 1.3% (3/231) | 1.32% (2/201) | 3.33% (1/30) | 5.00 (0.85, 29.48) | 0.075 |

[+]Age was omitted in the final model for lost to follow-up due to collinearity. Age and time period were omitted in the model for TB treatment failure, due to collinearity.

# Chapter 6:
# Introduction and Evaluation of an Electronic Tool for Improved Data Quality and Data Use During Malaria Case Management Supportive Supervision

**Introduction and evaluation of an electronic tool for improved data quality and data use during malaria case management supportive supervision**

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Forthcoming in the American Journal of Tropical Medicine and Hygiene

**ABSTRACT**

Although on-site supervision programs are implemented in many countries to assess and improve the quality of care, few publications have described the use of electronic tools during health facility supervision. The President's Malaria Initiative (PMI)-funded MalariaCare project developed the MalariaCare Electronic Data System (EDS), a custom-built, open-source, Java-based, Android application that links to District Health Information Software (DHIS2) for data storage and visualization. The EDS was used during supervision visits at 4,951 health facilities across 7 countries in Africa. The introduction of the EDS led to dramatic improvements in both completeness and timeliness of data on the quality of care provided for febrile patients. EDS improved data completeness by 47 percentage points (42% to 89%) on average when compared with paper-based data collection. The average time from data submission to a final data analysis product dropped from over 5 months to one month. With more complete and timely data available, Ministry of Health and National Malaria Control Program (NMCP) staff could more effectively plan corrective actions and promptly allocate resources, ultimately leading to several improvements in the quality of malaria case management. While government staff used supervision data during MalariaCare-supported lessons learned workshops to develop plans that led to improvements in quality of care, data use outside of these workshops have been limited. Additional efforts are required to institutionalize use of supervision data within ministries of health and NMCPs.

**Key Words:** malaria, supervision, mobile health, quality assurance

## INTRODUCTION

In recent years, the use of mobile health tools designed to support health workers and improve the quality of care has rapidly expanded.[1–3] Within health worker capacity building, much of the evidence building has been in the design and implementation of electronic tools to support health workers at the point of care.[4,5] In contrast, few publications have described the use of such tools by supervisors during on-site supportive supervision at health facilities.

At the same time, there is increasing interest in using routinely collected data to assess current practices, guide decision-making, and assess the impact of interventions designed to improve quality of care.[6] To date, the main sources of information on health care quality have typically come from periodic health facility surveys, such as the World Health Organization (WHO)'s Service Availability and Readiness Assessments (SARA) tool, the Demographic Health Survey's Service Provision Assessments (SPA), and the World Bank's Service Delivery Indicators (SDI) reports.[7–9] Although valuable sources of information, these assessments are conducted infrequently, are expensive, and data collected may not be sufficient to inform localized programmatic decision-making due to national-level sampling strategies. With many countries implementing on-site supervision programs to assess and improve the quality of care, data collected during supervision visits could offer timely insight into key challenges that health facilities are facing. Use of electronic tools for health surveys and routine health register information data collection has improved data completeness and reduced time to when data can be reviewed.[10] In its third year of implementation, the President's Malaria Initiative (PMI)-funded MalariaCare project developed the MalariaCare Electronic Data System (EDS), an electronic tool to guide on-site supportive supervision of malaria case management, which could enable ministries of health to take advantage of this under-utilized data source by providing complete and timely quality assurance data for decision-making at multiple levels of the health system.

Between 2012 and 2017, MalariaCare worked in 17 countries to support national malaria control programs (NMCPs) in designing and implementing a case management quality assurance system to

improve the diagnosis and treatment of malaria and other febrile illnesses. A key component of the quality assurance system was outreach training and supportive supervision (OTSS) to monitor and improve performance of health facilities, which was implemented in selected facilities within 9 of the 17 countries based on the needs and requests of NMCPs. During OTSS, a team of at least 2 government staff, usually clinical and laboratory supervisors, visited health facilities to observe and assess the quality of case management for febrile illnesses and to provide mentorship. At the end of each OTSS visit, which usually takes one day or less, the supervision team provided feedback, either verbally or in writing, to health facility staff based on their findings, and they collaboratively developed an action plan for the health facility staff to improve the quality of care. A full description of the OTSS intervention can be found in Eliades et al.[11] To help supervisors collect standardized information and better assess health facility performance in case management over time, MalariaCare introduced an OTSS checklist that is completed by supervisors during their visit, and programmed the checklist into the EDS, which also contained additional features designed to guide supervisors in providing mentorship during the OTSS visit. In this analysis of programmatic data we describe the process of implementing the EDS, its outcomes related to data quality and data use, and the comparative costs of using the paper checklist versus EDS for data entry.

## MATERIALS AND METHODS

**Program setting and population.** From September 2015 to June 2016, MalariaCare began EDS implementation in 7 of the 9 countries where MalariaCare supported NMCPs to conduct OTSS: Ghana, Kenya, Malawi, Mali, Mozambique, Tanzania, and Zambia. In May 2017, the Democratic Republic of the Congo began using the EDS, but only as a database for entry of data from paper-based checklists.[11] Within each country, ministries of health selected both public and private facilities within regions or provinces agreed upon by the ministry and USAID mission for OTSS visits.

**Program description.** Prior to the introduction of the EDS, supervisors in each country used paper checklists when conducting OTSS visits. Following each set of visits to targeted facilities within a defined time period (or "round"), the completed paper checklists were sent to a central location for data entry.

***EDS application and content development.*** MalariaCare's EDS is a custom-built, open source, Java-based, Android application that links to District Health Information Software (DHIS2) for data storage and visualization. The EDS was adapted from Population Services International's (PSI's) Health Network Quality Improvement System, which is used to assess and improve the quality of health service provision in the private sector.[12] The EDS application is compatible with Android versions 4.0.3 and up, and is licensed for open source use.[13] The interface is optimized for use on a 7-inch Android tablet, but has been used on phones and smaller screens with no reported loss of functionality. The supervisors completed assessments offline during their OTSS visit using the EDS application. Completed assessments were then automatically uploaded to a DHIS2 password-protected website designed specifically for the EDS once a network connection was established. The DHIS2 server was also configured as a Hypertext Transfer Protocol Secure (HTTPS) site, which also encrypts data during transmission between the EDS and the DHIS2 server.

MalariaCare developed checklist questions based on current national malaria case management guidelines and existing national malaria supervision checklists, when available. Drafts of the paper checklists were reviewed by the NMCP staff and field-tested in each country, and minor country-specific modifications were made where necessary. The OTSS checklist was then programmed into the EDS application, and a second round of field-testing was conducted in each country to solicit feedback from supervisors on the design of the application and to test its functionality.

The final content for MalariaCare's EDS checklist includes 6 core modules: 1) *microscopy observation*, where supervisors observe laboratory staff preparing, staining, and reading microscopy slides; 2) *malaria rapid diagnostic test* (*RDT) observation*, where supervisors observe health workers conducting RDTs; 3) *clinical observation*, where supervisors observe health workers conducting consultations with febrile patients; 4) *adherence*, a review of health facility registers to assess adherence to testing and treatment protocols; 5) *general OTSS*, an assessment of human resources, commodities, and infrastructure;

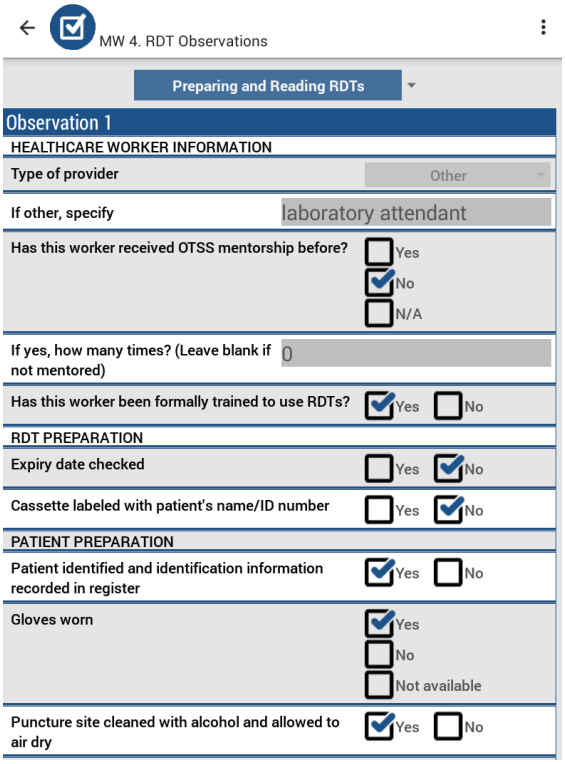
and 6) *feedback and action plans*, where supervisors record the top problems identified during the visit and action plans to address them.

Content within the EDS application can be modified through the DHIS2 interface, so that modules can be added or changed as needed to include other aspects of malaria case management or other diseases or topics entirely. In some countries, additional modules were developed during the program to address country-specific requests, including modules on pharmacy and logistics, HMIS data quality assessments, severe malaria, and malaria in pregnancy. The EDS is structured so that each module can be submitted to the EDS DHIS2 website independently, and supervision teams can work simultaneously with each supervisor submitting her/his assigned module(s). Figure 6.1 provides screenshots of the EDS application; Figure 6.2 summarizes its key features.

**Figure 6.1 Screenshots of the EDS application**

**1a) Data entry screen for RDT observation module**

**1b) Performance summary page**



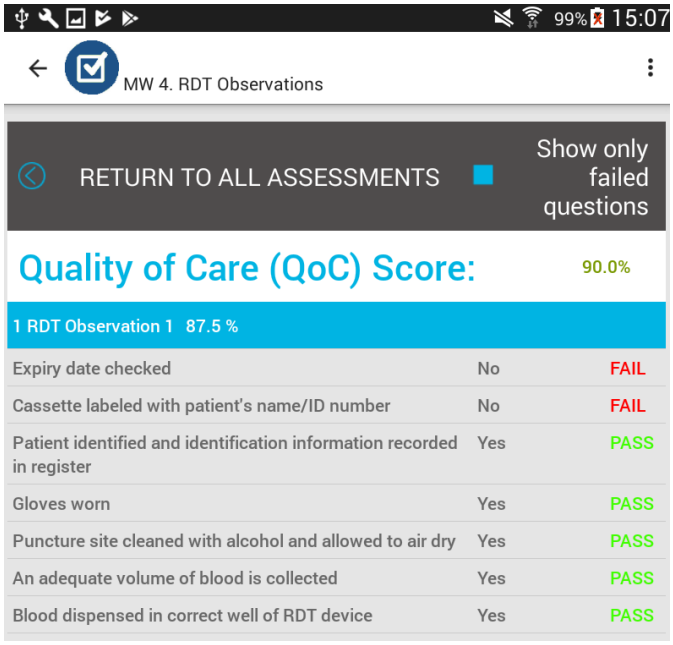



**Figure 6. 2 Key features of the MalariaCare EDS**

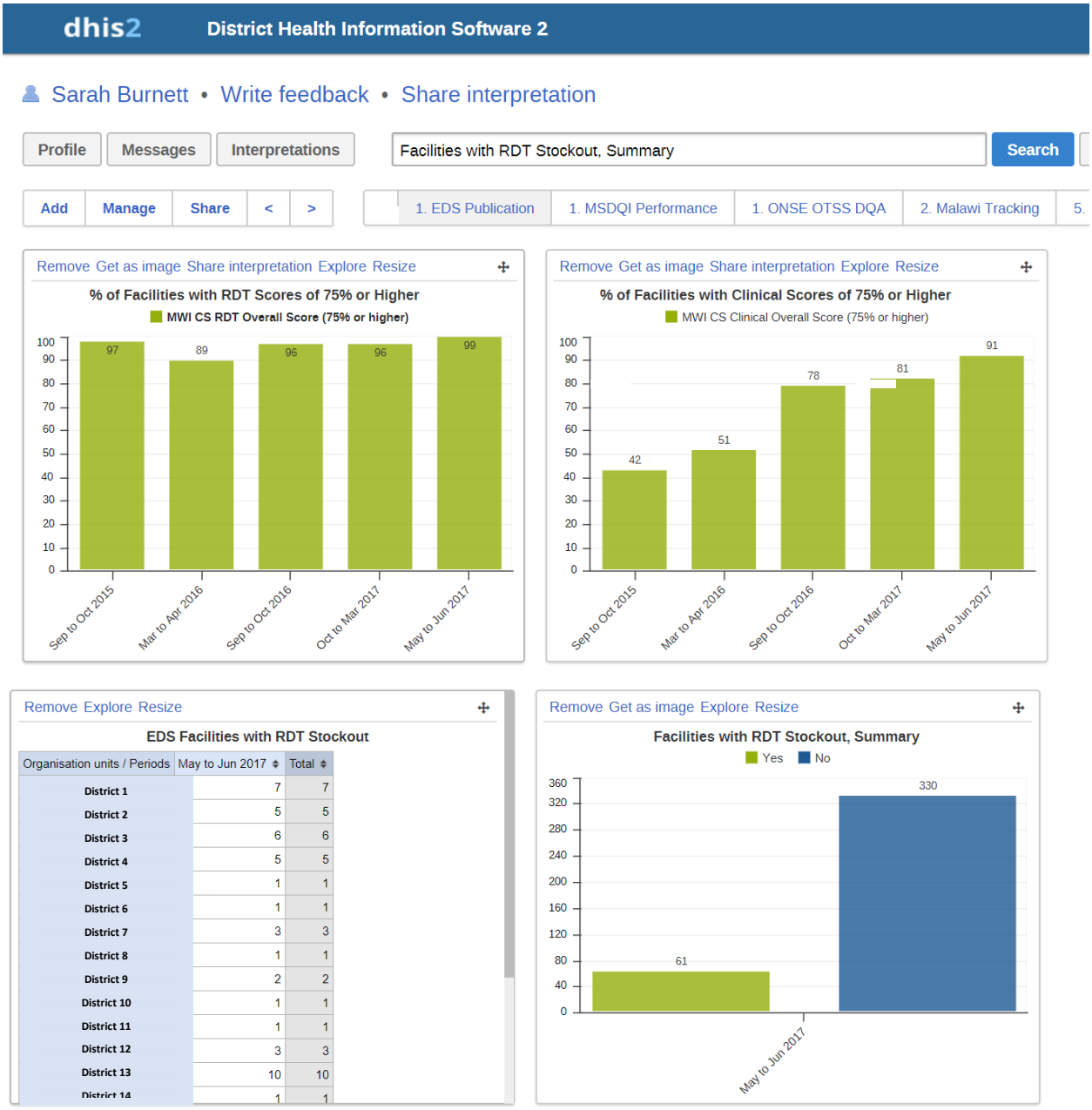
- **Multi-user functionality:** Each module can be completed separately and simultaneously by different supervisors to promote team-based supervision.
- **Automatic saving:** Data are automatically saved and backed up on the tablet, as soon as they are entered.
- **Completeness monitoring:** The percentage of completed items is tracked for each module, allowing supervisors to monitor whether they have missed any steps.
- **Automatic scoring:** After completing an observation, supervisors can review summary scores to help assess each health care worker's performance.
- **Feedback support:** Performance summary page highlights items that health workers missed to help supervisors focus their attention on these critical items (see Figure 1b).
- **Automatic data submission:** Once a supervisor marks a module as complete, it automatically sends to the EDS DHIS2 website whenever an internet connection is established.
- **Improved data availability:** Once submitted, data is immediately available in the online EDS DHIS2 website for review of individual submissions and dashboards are updated within 24 hours.
- **Review of previous visit:** The most recently submitted assessments for all facilities assigned to each supervisor are available for review when the supervisor logs in to the application.

***EDS DHIS2 website.*** The data collected in the EDS application was sent to the EDS DHIS2 website for data storage and visualization. DHIS2 is an open source software used for the health management information system (HMIS) in 60 countries at the time of publication; however, the EDS DHIS2 website is separate from national HMIS DHIS2 websites and has been configured for use with the EDS application.14 It was designed separately so as not to interfere with national HMIS DHIS2 websites during EDS testing and scaling, but with the intention for future integration of the EDS and HMIS data, at the discretion of a country's MOH.

After a checklist was submitted to the EDS DHIS2 website, the individual checklist data were available for immediate review while graphs and dashboards were automatically updated with the checklist content within 24 hours. From this website, government and program staff with access rights could review the data. Working with NMCPs, MalariaCare developed dashboards for the national, regional, and district levels to summarize and track key indicators. The EDS DHIS2 website allowed data users to modify visualizations, including graphs and tables, to drill down to identify specific districts or health facilities with poor performance, and to identify specific skills that needed to be strengthened across health facilities.

Using the dashboards, national, regional, and district malaria coordinators monitored the implementation of supervision, assessed progress, and identified key areas of focus—whether individual districts and health facilities or specific competency areas that needed to be addressed. With this information, NMCPs could then direct interventions and resources where they were needed most, and cost-effectively improve the quality of malaria case management. Figure 6.3 provides an example of an EDS DHIS2 dashboard.

**Figure 6.3 EDS DHIS2 dashboard**



***Training.*** To support the implementation of the MalariaCare EDS, 2 training packages were developed. The EDS end user training was a 3-day training package that trained supervisors to use an electronic tablet and to use the EDS application to complete the OTSS checklist and provide mentoring during an OTSS visit. The training included a health facility visit to give supervisors practical experience. The EDS data user training was a 3-day training package to train district, regional, and national level decision-makers to create new graphs and dashboards within the EDS DHIS2 website, interpret the findings and track performance, share the results in a district or regional report, and use that data to guide action planning. Following this training, key government staff were coached in using the EDS data to guide action planning during lessons learned workshops (LLWs), which were regional forums held after OTSS rounds to discuss key trends and develop regional- and district-level quality assurance action plans.

Analysis of implementation data. The purpose of introducing the EDS was to improve both supervision data quality and data use, and ultimately, to improve the quality of case management of febrile illnesses. The combined effects of OTSS and EDS on the quality of malaria case management are presented in Eliades et al., Alombah et al., and Martin et al.[15–17] The outcomes presented here focus on the effect of the EDS on data quality and data use.

We measured data quality by documenting data completeness and timeliness from the last paper-based visit, first EDS visit, and most recent EDS visit for each health facility. We defined completeness as the proportion of health facilities visited with sufficient data to calculate each of the project's 6 key health facility performance indicators. Three of the health facility indicators (RDT, microscopy, and clinical observations) required at least one complete observation to calculate a score. The other 3 health facility performance indicators (testing prior to treatment, adherence to negative test results, and adherence to positive test results) required register reviews and data from at least half of the recommended sample (either 5 or 10 patient records depending on the indicator) to calculate a score. A health facility was considered "visited" if a paper checklist was submitted, or if at least one EDS module was submitted to the EDS DHIS2 website.

Timeliness was measured as the number of days between the last OTSS visit for a group of health facilities visited during a set of OTSS rounds to the date when the first analysis with cleaned data was produced. Timeliness was then further divided into timeliness for 1) data submission, the number of days between the last round of OTSS visits and the date when all available data were entered or appeared in the EDS DHIS2 website; and 2) data analysis, the number of days between data entry completion and the presentation of the first analysis with cleaned data.

The comparative cost of data entry using a paper checklist versus EDS was also analyzed. The costs of data entry per health facility visit for the last paper round was calculated from the total costs of printing the paper checklists and the costs of person-time for data entry divided by the total number of health facilities visited. EDS costs included the costs of the tablets and accessories (including allowances for 5% replacement per year for loss and breakage), airtime for sending data, and web hosting costs for the EDS DHIS2 (assuming a separate website for each country). For EDS, the one-time cost of purchasing the tablets was depreciated over the 4-year life expectancy of the tablet, by using the straight-line depreciation method. To estimate the average number of visits per tablet per round, the number of health facilities visited during the most recent round was divided by the total number of tablets used by supervisors. Airtime costs per tablet per round were divided by the number of visits per tablet per round to calculate the airtime costs per visit. The depreciated cost of the tablets per year and the recurring annual costs of airtime and web hosting were then divided by the number of health facility visits within a year (based on the total number of health facilities visited per round and the number of rounds per year). An informal assessment was done to collect specific examples of district, regional, and national staff using EDS data to improve the quality of malaria case management. We did not assess any differences in data use between the paper-based checklist and EDS.

**RESULTS**

In the 7 countries where the EDS was fully implemented, all supervisors who participated in the MalariaCare-supported OTSS visits were trained in the use of EDS for supervision as part of their

supervisor training. From September 2015, when roll-out of the EDS started, through September 2017, a total of 1,686 supervisors were trained (Table 6.1). The supervision teams ranged from 2 to 4 members, depending on the country, and each team visited between 6 and 11 facilities on average per round of visits. A total of 11,396 OTSS visits were conducted using the EDS at 4,951 health facilities.

**Table 6.1 Number of visits conducted using EDS**

| Country | Number of supervisors trained in EDS* | Number of unique health facilities visited | Number of visits conducted | Number of visit rounds with EDS | Average number of visits per facility using EDS |
|---|---|---|---|---|---|
| Country 1 | 685 | 1,973 | 4,524 | 4 | 2.29 |
| Country 2 | 178 | 935 | 2,314 | 4 | 2.47 |
| Country 3 | 315 | 1,227 | 1,875 | 5 | 1.53 |
| Country 4 | 113 | 413 | 1,418 | 5 | 3.43 |
| Country 5 | 121 | 144 | 431 | 4 | 1.86 |
| Country 6 | 68 | 102 | 418 | 8 | 4.10 |
| Country 7 | 187 | 157 | 416 | 3 | 2.65 |
| **Total** | **1,669** | **4,951** | **11,396** | **33** | **2.27** |

*Number of supervisors trained in EDS includes supervisors MalariaCare trained for other partner organizations, while the number of health facilities and visits includes MalariaCare-supported facilities alone.

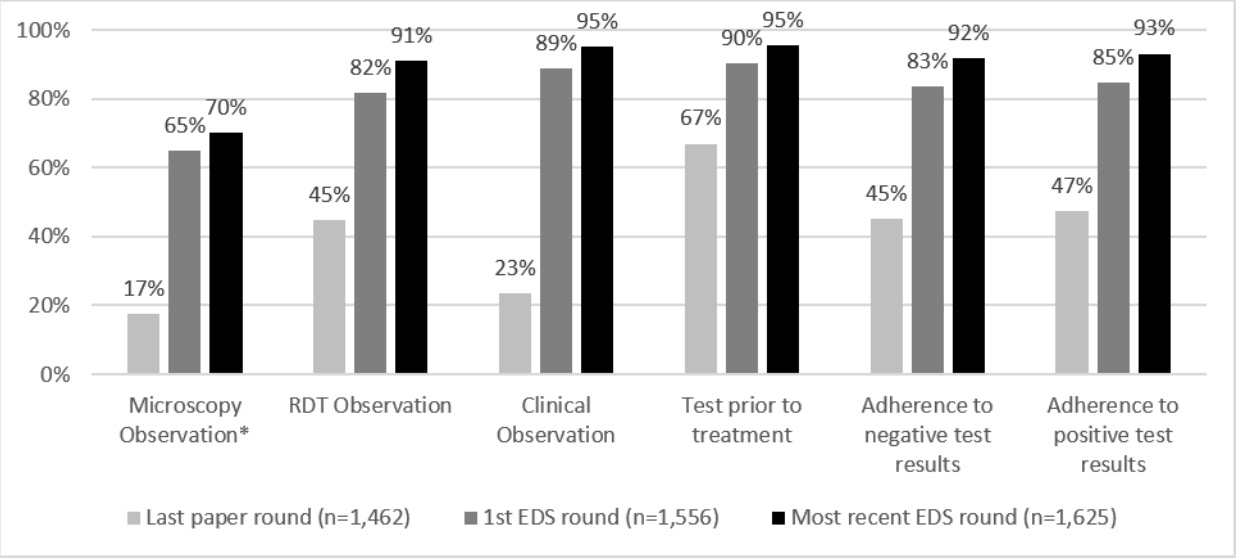
**Data quality: completeness and timeliness**

***Completeness.*** For 5 of the 7 EDS countries (Kenya, Mali, Mozambique, Tanzania, and Zambia), we compared data completeness for the last round using a paper checklist, the first round using EDS, and the most recent round using EDS. In Ghana and Malawi, the last round with a paper checklist had a different number of questions and thus was not comparable.

From the last round with a paper checklist to the first visit using the EDS, a dramatic improvement was observed in the percentage of facilities with complete scores, with an average improvement of 40 percentage points across the 6 areas, and 5 of the 6 competency areas demonstrating greater than 80 percent completeness (Figure 6.4). The first EDS visit to most recent EDS visit also showed an incremental improvement, with an average 7 percentage point increase, and 5 of the 6 competency areas greater than 90 percent complete.

Despite improvement, completeness for microscopy scores lagged behind, with only 70% of scores completed. In later visits, we added a question to the checklist asking supervisors to include the reason why they were unable to complete an observation. During the most recent visit, 11% of supervisors reported not being able to do a microscopy observation due to lack of staff (6%), stock-outs of supplies (2%), a power outage (2%), or a microscopy test not being ordered (1%); 2% of RDT scores and 1% of clinical score were missing for similar reasons.

**Figure 4. Percentage of health facilities with complete scores, by competency area**




***Timeliness.*** Table 6.2 reports the mean, median, and range of the number of days it took for program staff from each country to verify that supervisors had submitted data for all completed visits to the EDS DHIS2 website from one round of supervision, to clean and analyze the data following submission, and the total number of days from last OTSS visit to first data analysis. The number of days required for verifying data submissions fell from an average of 84.4 days with the paper checklist to 16.9 in the most recent EDS round, an 80% decrease. With the paper checklists, the time to data submission was affected by the time required to transport and enter the paper checklists. During the use of the EDS, the time to data submission was affected by connectivity challenges and, early in the process, challenges in staff learning to use the system. For example, making sure that airtime was loaded, that the mobile data function in the

tablets was turned on for submission, and that program staff were able to monitor the submissions in on a daily or weekly basis and follow-up with supervisors, as needed. The numbers of days required for cleaning the data and producing a final analysis fell from an average of 73.1 days to 12.6, an 83% decrease. In total, the time from submission and analysis to data being available for decision-making dropped from an average of 5 months post-visit to less than one month.

As illustrated in Table 6.2, even with the EDS, clean, usable data were not automatically available in "real-time." Program staff still needed to follow up with supervisors to ensure that visits were being completed and that the findings of those visits were documented through data submissions. Moreover, some data cleaning, due to supervisor error in completing the checklist and/or duplicate submissions, was required.

**Table 6.2 Number of days from the end of OTSS round until analysis shared**

| | ***Number of days: Mean (median [range])*** | | |
|---|---|---|---|
| **Visit** | **Data submission** | **Analysis** | **Total** |
| Last paper visit (n = 2,380) | 84.4 (91.0 [15.0-166.0]) | 73.1 (54.0 [3.0-216.0]) | 157.6 (145.0 [74.0-364.0]) |
| First EDS visit (n = 3,333) | 27.5 (20.0 [0.0-121.0]) | 19.8 (16.0[0.0-71.0]) | 47.3 (27.0 [20.0-146.0]) |
| Most recent EDS visit (n = 3,105) | 16.9 (11.5 [1.0-79.0]) | 12.6 (11.0 [1.0-30.0]) | 29.4 (28.0 [6.0-80.0]) |

***EDS field implementation issues.*** Over the course of the project, MalariaCare made several modifications to the EDS application and implementation processes to address key challenges faced by personnel in the field. Significant issues are summarized below.

***Sending completed checklist data.*** The initial version of EDS required the supervisor to have an internet connection and press a button to send a module from the tablet. This proved frustrating, requiring the supervisor to repeatedly check for internet connectivity and/or wake up at inconvenient hours to try to send during times of lower network traffic. Supervisors would also press the send button repeatedly, which resulted in duplicate submissions to the EDS DHIS2 website. To address this problem, a subsequent version of the EDS application allowed the supervisor to simply mark a module as complete, and the tablet would automatically push the data to the server once it detected an available network signal.

***User names and passwords.*** In order to ensure that the appropriate checklists and health facilities appeared in the EDS application, supervisors were required to enter a user name and password. However, due to the infrequency of OTSS visits (every 3 months or fewer), supervisors often forgot these. One solution instituted in some countries was to introduce just one user account per district, while adding a space for supervisors to write in their name within each module. While this reduced the ability to track individual supervisor actions, ultimately this was seen by MalariaCare and NMCP staff as a more practical option, as supervisors who could not access their application would not be able to use the tool to guide mentoring or document their supervision visit.

***Reviewing results.*** Two EDS application improvements were made for reviewing data at the supervisor-level. First, a performance summary page was added so that supervisors, after marking the module as complete, could easily identify the missed items and discuss with health facility staff (see Figure 6.1b). Second, a feature was added so that supervisors could review the previous visit's results, even when conducted by a different supervisor using another tablet. This was particularly useful for the feedback and action plan module, which required supervisor teams to review the top issues during the previous visit.

***Content and application updates.*** Through its connection with DHIS2, each time the supervisors logged into the application, the content was updated to reflect the latest version of the checklist, ensuring that old checklist versions were removed from circulation prior to the next use. MalariaCare also uploaded the EDS application to the Google Play Store, which allows changes in the EDS application features to update when connected to the internet, rather than requiring the program staff and supervisors to uninstall the old version and install a new one. During the project, we disabled the auto-syncing of applications to reduce inadvertent data usage. When a new version of the EDS application was released, program staff would either update the tablets centrally or inform supervisors to update their tablets to the latest version.

**Data use.** With EDS, dramatic improvements in data completeness and timeliness allowed for the timely use of OTSS data to inform decision-making during the MalariaCare project. The most critical opportunity for timely data use is at the health facility during OTSS visits, where supervisors can provide direct feedback to health workers immediately after observing the quality of care. Using the EDS, supervisors had rapidly available scores for each competency area, as well as a performance summary page which helped them to focus on key gaps and provide targeted mentorship. Supervisors reported that they found these aspects of the EDS to be a major advantage over the previous paper-based checklist, stating that it allowed them to better direct the feedback they provided to health care workers and helped to guide their action planning sessions.

To further support data use by health managers at the district, regional, and national levels, data user training was conducted after at least one round of OTSS with the EDS. This training included key national malaria case management and monitoring and evaluation staff, and malaria focal persons and health information officers at the regional or district levels. In some cases, regional/district managers of health services were included for at least part of the training. A total of 535 staff were trained in data use, with the numbers trained ranging from 10 to 301 per country. On average, one to 5 government staff per region/district implementing OTSS participated in the data use training sessions. Following the data use trainings, MalariaCare supported trained staff to update their dashboards based on the most recent round of

OTSS and develop presentations, which were then shared during the LLWs. These data provided the basis for developing regional and district-wide action plans to address key gaps. Below we present a series of case use scenarios that highlight key examples of data use in MalariaCare-supported countries.

**Targeting low performing facilities for additional intervention.** Within the MalariaCare program, the EDS also enabled better targeting of program resources. For example, in Zambia, financial constraints required MalariaCare to select OTSS facilities where performance during the previous visit was low; this would not have been possible to analyze in time without the EDS. Similarly, in Malawi, facilities that scored low on the management of severe malaria were selected to participate in an additional clinical mentoring intervention designed to improve management of severe inpatient cases.

**Increasing assessments for severe disease.** During the LLW after the first OTSS round using EDS in country 4, district malaria focal persons and supervisors reviewed the results of the clinical management indicators and found that checking for signs of severe disease for febrile outpatients was only 49%. Supervisors then decided to visit health facilities in between official OTSS visits to further educate clinical providers; by the last visit during the project, performance on this indicator rose to 82%.

**Integrating OTSS and HMIS data to reduce RDT stock-outs and improve testing rates.** At an LLW in country 3, a regional malaria focal person presented the HMIS data on the proportion of malaria cases confirmed along with the EDS data that indicated 34% of facilities reporting a sustained RDT stock-out during OTSS. Using this data, the focal person was then able to garner the support of regional and district council leadership who followed up with district health staff. The malaria-focused technical teams from the region and district councils also met with each district to discuss the reasons for poor performance at certain health facilities, and then to conduct additional problem-solving visits. Key strategies utilized were: training health facility staff on completing RDT stock forms, redistributing RDT stock between health facilities within districts, and reinforcing the importance of testing all patients prior to treatment. By the last OTSS visit during the project, RDT stock-out rates dropped to 12% while test confirmation rates rose from 89% to 97%.

Despite these positive examples, widespread and routine use of the EDS dashboards by government staff remains a challenge. Review and use of data has largely occurred only with MalariaCare prompting and support, such as during LLWs. When asked why data was not used more often outside of the LLWs, several of those trained in data use said they forgot how to use the EDS DHIS2 website, and that they did not have regular internet access.

**Costs.** A common concern when replacing a paper-based system with an electronic system is the relative cost. To better understand the costs associated with implementing the EDS, data entry costs for the paper checklists and the EDS were compared. For the paper-based data entry, costs included printing and data entrant consultant fees. For the EDS, costs included a one-time purchase of tablets and accessories (cases and screen protectors), spread over a life expectancy of 4 years, and operating costs including annual server hosting and maintenance (assuming independent servers for each country) and airtime. Table 3 presents the average costs per visit for paper-based and EDS data entry. The total data entry cost per visit ranged from US$2.42–$17.17 for the paper checklist, and US$7.86–$31.29 for the EDS. Per visit, the EDS was usually more expensive than paper. Five of the 7 countries were between US$0.16–$28.04 more expensive. In 2 countries (country 3, country 6) the EDS was between $1.15-$2.99 less expensive. For the EDS, the one-time costs of tablet purchase ranged from 26% to 75% of the total data entry cost per visit, with the operating costs making up the remainder.

**Table 6.3 Average cost of data entry per facility visit, paper-based checklist vs. EDS**

| | Country | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | **1** | **2** | **3** | **4** | **5** | **6** | **7** | **Average** |
| **Cost drivers** | | | | | | | | |
| Number of health facilities visited, latest round | 1181 | 782 | 480 | 402 | 144 | 72 | 120 | 454 |
| Number of rounds per year | 2 | 3 | 2 | 2 | 2 | 4 | 2 | 2.43 |
| Number of tablets | 448 | 150 | 129 | 98 | 38 | 16 | 48 | 132 |
| Number of tablets per supervision team | 4 | 2 | 2 | 2 | 2 | 2 | 2 | 2.28 |
| Average number of facilities visited per tablet per round | 2.64 | 5.21 | 3.72 | 4.10 | 3.79 | 4.50 | 2.50 | 3.78 |
| Cost per tablet, with accessories (US$) | $189 | $211 | $165 | $190 | $599 | $265 | $165 | $255 |
| **Costs of data entry per facility visit (US$)** | | | | | | | | |
| EDS | $11.98 | $7.18 | $8.90 | $10.42 | $31.29 | $14.17 | $23.19 | $15.31 |
| One-time tablet purchase, as a proportion of data entry costs | 75% | 47% | 62% | 56% | 63% | 26% | 36% | 52% |
| Paper checklist | $2.42 | $7.02 | $10.05 | $8.20 | $3.25 | $17.17 | $5.42 | $7.65 |
| **Cost difference** | **$9.56** | **$0.16** | **($1.15)** | **$2.23** | **$28.04** | **($2.99)** | **$17.78** | **$7.66** |

EDS costs per visit were lower when a greater number of health facilities were reached with a lower number of tablets. For example, in country 2, where a total of 150 supervisors in teams of 2 visited 782 health facilities with 3 rounds per year (2,346 health facility visits), average EDS costs were only US$7.86 per visit. While a similar number of health facility visits were done per year in country 1 (2,362 visits conducted over 2 rounds involving 1,181 health facilities), supervisors travel in teams of 4 and each supervisor has a tablet. This requires twice the number of tablets per visit, and increases costs to nearly double, at US$13.77 per visit. In country 7, costs were relatively high due to the smaller number of health facilities and the large number of active supervisors. In that program, while 8 regional supervisors visited 5 facilities each, at the district level supervisors would visit 2 health facilities per district per round. However, in one country with a lower number of health facilities (country 6) the EDS costs were lower than paper-based data entry. This was due to the comparatively higher cost paid for paper-based data entry, which was done by program staff due to the low number of paper checklists. Regular program staff compensation is higher than it is for temporary data entry personnel with the qualifications required for this work. In countries with a higher volume of paper checklists for entry, lower-cost data entry consultants were used. Finally, in countries that conducted more visits per tablet per round (country 2, country 6), the one-time costs accounted for a lower proportion of the total data entry costs.

In 4 countries, tablets and accessories such as cases and screen protectors were bulk purchased from the United States and shipped, which kept unit costs between US$165 and US$211. In country 5 and country 6, where tablets were purchased locally and in lower volume, the cost per tablet was much higher at US$599 and US$265, respectively. The tablets in country 5 were also a more advanced model, which was recommended for purchase based on a reported lack of reliability in lower level models used for previous projects in-country. This, in addition to the lower number of facilities covered in country 5, led to a significantly higher cost per visit for EDS when compared with other countries. In country 3, which combined the lowest tablet cost and a larger scale program, EDS was less expensive than paper-based data entry. In countries with a greater number of tablets needed per facility visit (country 1) or where tablets

were more expensive (country 5), the one-time costs accounted for a higher proportion of the total data entry costs.

## DISCUSSION

The MalariaCare project experienced dramatic improvements in data completeness and timeliness immediately after the introduction of an electronic tool to guide on-site supportive supervision. Data completeness using the paper-based checklists varied by indicator but was low overall. To our knowledge, no other studies have evaluated data completeness and timeliness of national supportive supervision programs at this scale. Studies that evaluated completeness of national HMIS data during early DHIS2 implementation, which requires paper-based data management at the facility level, found similar rates of completion, at 36% in Uganda and 26.5% in Kenya.[10,18]

Several features of the EDS are likely to have directly contributed to these improvements: automated remote data submission, which reduced time to submission and opportunities for data loss; remote monitoring of data submissions through the EDS DHIS2 dashboards, which allowed centrally based program managers to quickly follow up on missing submissions; and automated scoring and performance summaries, which increased immediate usability of the data and may have further motivated supervisors to complete the checklist.

With increased availability of scores, including during facility visits, and a significant reduction in the time needed to have a full, analyzed dataset available for use, data could more effectively be used for decision-making: supervisors were able to provide more targeted feedback during supervision visits, government and MalariaCare program staff could better utilize limited resources by targeting poorly performing facilities, and district, regional, and national staff began using EDS data to drive measurable improvements in quality of care. Across country programs where OTSS was implemented using EDS, MalariaCare has observed improvements in each of the project's 6 key indicators (RDT, microscopy and clinical performance, testing prior to treatment, and adherence to positive and negative test results).[15–17]

Comparing only the operational costs for data entry, EDS tended to be more expensive per visit than using a paper checklist, with cost differentials ranging from between US$0.16 USD and US$28.04 per visit for 5 of the 7 countries. The EDS operational costs were lower when it was used at scale—when there were a greater number of health facilities over a greater number of visits, when health facilities were visited by fewer supervisors, and when tablets were purchased in bulk. Given the demonstrated benefits of using the EDS, in terms of data timeliness and completeness and increased data use which has led to improved case management, we believe that EDS is worth the additional cost in countries where large-scale supportive supervision is planned. Further implementation research should be done to compare the cost-effectiveness of electronic systems for supportive supervision, like the EDS, and paper-based systems. If such systems enable better and more timely feedback and program modification, as described with the EDS, it may lead to greater improvements in case management practices and, ultimately, reduced morbidity.

The EDS could also reduce overall health care costs by helping to systematically target facilities for supervision or allowing supervisors and managers to target specific areas of weakness. With average costs between US$44 and US$333 per OTSS visit, it is financially difficult for government programs to reach every facility for a supervision visit 2–4 times per year, as WHO and many governments currently recommend.[11,19] Use of EDS data could help to better target follow-up visits to low-performing facilities, thus achieving higher quality at a lower cost for governments and donors. Using supervision data to target specific interventions, such as equipment purchases, stock distribution, or additional capacity building efforts could also decrease costs to the health system while improving quality of care. The EDS also supports the management of large-scale supervision programs through the ability to modify content as guidelines are updated or country needs change, and with automated updates pushed to the tablets, which ensures that old versions of checklists are quickly and easily removed from circulation.

Our cost analysis did not include EDS development costs or the costs of information technology support staff required to ensure smooth operation of the system. MalariaCare was able to build upon existing software developed by PSI and leverage its position as a global project to develop one application that

worked across 8 countries. With its open-source status, and the ability to adapt content for any topic or disease as needed, the EDS also has the potential to be used across multiple disease programs, which could further reduce costs across programs to obtain a more complete picture of the total costs involved in the implementation and use of the EDS.

The EDS provides more localized and timely data than have been available through periodic national health facility surveys. With improved access to supervision data, district, regional, and national staff have better information to drive decision-making and can incorporate quality improvement into routine management systems. Government staff used supervision data during MalariaCare-supported events to develop plans that led to improvements in quality of care. However, outside of these events there has been limited use of the EDS DHIS2 dashboards for data use. This is not surprising, given that establishing habits for data use takes time and the OTSS data use efforts are still in their early stages. In most countries, only one to 3 OTSS visits have taken place since the EDS data use training was implemented.

Use of supportive supervision data beyond the supervisor level must be institutionalized within the NMCP and health management system. Steps should be taken to provide a strong operating environment for use and interpretation of the EDS dashboards. Job descriptions for key personnel at the national, regional, and district levels and routine reporting templates should be revised to include the analysis and use of supportive supervision data. Supervision data should be analyzed and shared during existing district and regional health department meetings. Following these review meetings, accountability structures for ensuring the implementation of quality assurance action plans within district and regional health management teams need to be strengthened or established. Within these structures, OTSS and HMIS data, as well as other data sources such as routine stock data and/or community interventions, should be integrated to provide a full picture of malaria case management with each locality.

While the organizational changes proposed above will help to create a sustainable data use culture for supervision data, simple technical modifications to address barriers in the use of the EDS application and the EDS DHIS2 website could further improve data quality and data use and allow more time to focus

on quality assurance efforts. For example, the EDS application could be improved by reducing the time required to log in and restricting data submissions unless the modules are complete. The somewhat complex DHIS2 visualization environment could also be simplified and tailored further for supervision data. Finally, internet access must be available at the time of data collection, analysis, and reporting, whether through provision of airtime or mobile internet access devices, NMCPs supplementing district internet allowances, or shifting data analysis to HMIS officers who tend to have more consistent access to a computer and internet than malaria focal persons.

## CONCLUSION

The introduction of an electronic tool for supervision led to dramatic improvements in both data completeness and timeliness of data on the quality of care provided for febrile patients and supported Ministry of Health and NMCP staff in their decision-making process for planning corrective actions and promptly allocating resources. Additional efforts are required to institutionalize use of supervision data within ministries of health and NMCPs.

**Acknowledgments:** The authors of this study acknowledge the contributions of government and project staff in all 7 countries who were the principal actors implementing the project.

**Financial support:** Financial support was provided by the United States President's Malaria Initiative under the terms of Cooperative Agreement AID-OAA-A-12-00057.

**Disclosures:** None.

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**REFERENCES**

1. Aranda-Jan CB, Mohutsiwa-Dibe N, Loukanova S. Systematic review on what works, what does not work and why of implementation of mobile health (mHealth) projects in Africa. *BMC Public Health*. 2014;14(1):188. doi:10.1186/1471-2458-14-188.

2. Tomlinson M, Rotheram-Borus MJ, Swartz L, Tsai AC. Scaling Up mHealth: Where Is the Evidence? *PLoS Med*. 2013;10(2):1-5. doi:10.1371/journal.pmed.1001382.

3. Hall CS, Fottrell E, Wilkinson S, Byass P. Assessing the impact of mHealth interventions in low- and middle-income countries - what has been shown to work? *Glob Health Action*. 2014;7(1):1-12. doi:10.3402/gha.v7.25606.

4. Amoakoh-Coleman M, Borgstein AB-J, Sondaal SF, et al. Effectiveness of mHealth Interventions Targeting Health Care Workers to Improve Pregnancy Outcomes in Low- and Middle-Income Countries: A Systematic Review. *J Med Internet Res*. 2016;18(8):e226. doi:10.2196/jmir.5533.

5. Agarwal S, Perry HB, Long LA, Labrique AB. Evidence on feasibility and effective use of mHealth strategies by frontline health workers in developing countries: Systematic review. *Trop Med Int Heal*. 2015;20(8):1003-1014. doi:10.1111/tmi.12525.

6. Ashton RA, Bennett A, Yukich J, Bhattarai A, Keating J, Eisele TP. Methodological Considerations for Use of Routine Health Information System Data to Evaluate Malaria Program Impact in an Era of Declining Malaria Transmission. 2017;97(Suppl 3):46-57. doi:10.4269/ajtmh.16-0734.

7. World Health Organization (WHO). *Service Availability and Readiness Assessment (SARA): An Annual Monitoring System for Service Delivery: Reference Manual, Version 2.2.*; 2015.

8. ICF International. The DHS Program - Service Provision Assessments (SPA). https://dhsprogram.com/What-We-Do/Survey-Types/SPA.cfm. Accessed October 11, 2017.

9. World Bank. Service Delivery Indicators. 2018.

10. Kiberu VM, Matovu JK, Makumbi F, Kyozira C, Mukooyo E, Wanyenze RK. Strengthening district-based health reporting through the district health management information software system: The Ugandan experience. *BMC Med Inform Decis Mak*. 2014;14(1):40. doi:10.1186/1472-6947-14-40.

11. Eliades MJ, Alombah F, Wun J, et al. Operational considerations and costs of malaria case management supportive supervision. *Am J Trop Med Hyg*. 2018;#(#):#-#.

12. Population Services International. Quality Improvement within Social Franchise Networks » DHIS in action. https://mis.psi.org/where-is-hnqis/?lang=en. Accessed October 11, 2017.

13. EyeSeeTea. MalariaCare Electronic Data System (EDS) Application Source Code. 2017. https://github.com/EyeSeeTea/EDSApp.

14. University of Oslo. DHIS2 Overview | DHIS2. https://www.dhis2.org/overview. Accessed October 11, 2017.

15. Eliades MJ, Wun J, Burnett SM, et al. Effect of supportive supervision on performance of malaria rapid diagnostic tests in sub-Saharan Africa. *Am J Trop Med Hyg*. 2018;#(#):#-#.

16. Alombah F, Eliades MJ, Wun J, et al. Effect of supportive supervision on malaria microscopy competencies in sub-Saharan Africa. *Am J Trop Med Hyg*. 2018:#-#.

17. Martin T, Eliades MJ, Wun J, et al. Effect of supportive supervision on competency of febrile case management in sub-Saharan Africa. *Am J Trop Med Hyg*. 2018;#(#):#-#.

18. Githinji S, Oyando R, Malinga J, et al. Completeness of malaria indicator data reporting via the District Health Information Software 2 in Kenya, 2011-2015. *Malar J*. 2017;16(1):1-11. doi:10.1186/s12936-017-1973-y.

19. World Health Organization (WHO). Malaria Microscopy Quality Assurance Manual - Ver. 2.

# Chapter 7:

# Discussion

## 7.1 SUMMARY OF RESULTS

This dissertation addressed the following main research questions: 1) does on-site support (OSS) alone, without other interventions, improve health workers' skills? 2) is training plus OSS more effective than training alone? 3) does the time period between training and OSS have an impact on the effect of the interventions? 4) does implementing structural/facility-based changes during OSS, such as integration of services, improve quality of care? and 5) are electronic tools effective in improving data quality and data use as part of supervision programs?

Reviews of interventions to improve the quality of care at health facilities have noted that existing research lacks high-quality rigorous trials and those that compare interventions to each other, rather than to a non-intervention control group alone.[1–6] Through the IDCAP, TB REACH and MENTORS studies, which were randomized cluster-control trials and quasi-experimental studies, we sought to address some of the limitations found in previous research. As part of IDCAP, we conducted one of the first rigorous studies to document the effect of OSS on laboratory practice. We found that OSS alone improved laboratory technicians' ability to correctly conduct HIV, TB, and malaria laboratory tests, by 18% to 29% per test (Chapter 2). Although there are few studies of the effects of supervision alone on laboratory practice, these findings are similar to studies in Ghana, Nigeria and the multi-country MalariaCare program, which all showed significant improvement in one more of these three tests following supervision.[7–9] By comparing clinicians' performance in managing patients living with HIV, we found that training plus OSS was more effective at improving clinical practices (Chapter 3). Trainees who received both training and OSS showed greater improvement than those who received training alone in five of six clinical consultation tasks, with increases ranging from 23% to 69% by task. The finding that combining multiple interventions to improve quality of care is more effective than a single approach has been corroborated for pediatric care from the IDCAP study, as well as by several reviews.[2,5,10,11] We also assessed the effectiveness of training and OSS to improve overall health facility performance as documented through patient records – comparing facilities where staff received OSS immediately following training to facilities where staff received OSS nine months

later. We found that OSS held up to nine months after an initial training was as effective in improving health facility indicators as OSS held immediately post-training (Chapter 4). In addition, six months of bi-monthly educational outreach, following monthly visits over nine months, effectively maintained facility performance gains but had only a limited effect in continuing to improve health facility performance.

By combining datasets from the TB REACH and MENTORS studies, both follow-on projects to IDCAP, we found that integrating TB and HIV services, as a component of an OSS intervention can reduce mortality (Chapter 5). Therefore, adding systemic change efforts, such as reorganization of services to include OSS may be an effective approach for improving quality of care. However, as part of this study we did not systematically assess why some health facilities were successful in integrating services while others were not. As Dr. Donald Berwick, former President and Chief Executive Officer of the Institute for Healthcare Improvement notes, this type of qualitative, local knowledge, which is often lost in randomized trials, provides a deeper understanding of how the context influences processes and outcomes, and contributes to greater programmatic learning which accelerates the path to better outcomes.[6]

Finally, using information collected during the implementation of the large-scale, multi-country MalariaCare project, we assessed the effect of an electronic tool used during OSS on data quality and data use to improve the quality of malaria case management (Chapter 6). While not a randomized trial, this program assessment found that use of the tool improved data completeness by 47 percentage points, reduced data processing time from over 5 months to one month and led to several documented cases of improved case management. In addition, we also presented data on the relative costs of the previous paper-based data entry compared to the electronic tool. The electronic tool was more expensive per facility visit than the paper-based system. Further research is needed to determine whether the increase in costs may be justified by the improvements in program implementation.

The chapters presented as a part of this dissertation were drawn from four projects (IDCAP, TB REACH, MENTORS and MalariaCare). Through the IDCAP-related papers included in this dissertation, and other IDCAP publications, there is evidence that health worker capacity building interventions can be effectively

integrated across disease areas to simultaneously improve provider practice and facility performance. Burnett et al.[12] demonstrated that OSS alone could improve laboratory practice for tests across three diseases. Imani et al.[13] and Burnett et al.[14] demonstrated that IDCAP's training and OSS improved clinical practices for managing childhood illness, as well as patients living with HIV.

The IDCAP interventions were more effective in improving indicators related to emergency triage, assessment and treatment (ETAT) and malaria.[15–17] For HIV, TB and pneumonia, there was less consistent improvement across arms or no improvement, depending on the indicator.[15–17] There are several reasons why the ETAT and malaria indicators may have improved over others. First, they were the focus of the first two OSS sessions, so there was more time to introduce improvements during the nine-month intervention. Second, they were more likely to be chosen as a focus of quality improvement activities by health facility quality improvement teams. Third, they may be easier indicators to improve as they focus on addressing acute conditions rather than chronic illnesses. Although pneumonia is an acute illness, its lower prevalence and the lack of a diagnostic test may have led to the relative lower levels of improvement in this area. Another possibility is that a combination of these factors were at play. Health facility staff may have chosen ETAT and malaria for their CQI indicators because they were presented earlier on in OSS. The program designers placed these sessions earlier because they hypothesized that health facility staff could more rapidly improve acute illness outcomes.

IDCAP may have been too ambitious in attempting to improve a total of 23 facility performance indicators with nine visits over nine months. Among the six indicators that improved in Weaver et al., there was an average improvement of 24 percentage points, and average final performance among these indicators ranged from 16% to 86%, with several indicators below the desired level for high quality care.[15] Among the nine indicators followed in the extended intervention arm, which received training and 12 OSS visits over 15 months, only two indicators reached above 80%.[16] The increased visits effectively maintained performance in the extended intervention arm (Chapter 4), but did little to further support facilities to reach proficiency in performance.

A program review of 27 collaborative quality improvement projects across 12 LMICs found that the projects focused on one to seven quality of care indicators over a year, usually within one disease or topic area (i.e. maternal health, HIV, TB, malaria).[18] Average improvement was 50 percentage points and 76% of the indicators evaluated across these projects reached at least 90%, even though more than half had baseline levels at 50% or below. With one-third of the indicators or less, these collaborative quality improvement projects achieved a greater level of improvement. Programs may be able to see more dramatic improvement if they focus on a few key indicators in one topic area over a period of time.

In part to address the lack of improvement in TB and HIV indicators, the IDCAP follow-on interventions, TB REACH and MENTORS, focused specifically on these two diseases. TB REACH used a similar OSS model as IDCAP, with two-day visits that included multidisciplinary training, cadre-specific clinical training and data-driven continuous quality improvement sessions. These visits were held monthly in the first three months and then bimonthly for the next six months of the intervention, for a total of six visits per facility. The intervention differed from IDCAP in two respects: it focused only on TB and TB/HIV indicators, and it included provision of FM and Xpert MTB/RIF diagnostics with a two-day training and support for its use. This was important because an increased number of sputa to screen was anticipated as a result of the training intervention, so a faster, more efficient smear technique would allow more testing in the same time period. This intervention assessed change in seven health facility performance indicators and saw improvement in four. Indicators that significantly improved showed an average improvement of approximately 50 percentage points. Still only one indicator that significantly improved reached at least 80% by the end of the project.

TB REACH focused on one topic area and one-third of the indicators assessed in IDCAP. Just over half of the indicators significantly improved and improved at double the average improvement under IDCAP. Given this comparison, there may be a trade-off in the number of indicators and the magnitude of change. While IDCAP improved a greater number of indicators, seven compared to four in TB REACH, the average improvement was smaller, at 24 percentage points. While a useful heuristic, this rough comparison should

be interpreted with caution. While these two studies shared some indicators, not all indicators and topic areas were the same.

The MENTORS study focused on eight HIV and TB management indicators. Rather than the multi-part OSS intervention, MENTORS visited health facilities for five days, once every six weeks, over a nine-month period to provide one-on-one mentoring for four MLP at each health facility. The goal was for each mentee to receive eight hours of mentoring per visit over the six visits. Of the eight facility performance indicators, five significantly improved, and of those that improved the average improvement was 10 percentage points.[19] The MENTORS program improved knowledge and competence, as demonstrated by mean changes of 13.4 and 27.8 percentage points, respectively.

However, lower levels of improvement were seen in facility performance when compared to the TB REACH program, which monitored a similar number of indicators. This could be due to the difference in the two interventions – TB REACH combined on-site training, clinical and lab cadre-specific break-out sessions, and quality improvement with improved, rapid laboratory diagnostics, whereas MENTORS focused on one-on-one mentoring for four clinical staff. It may also be due to the difference in topic areas and indicators used in the interventions. As malaria indicators seemed easier to improve during IDCAP, it may be that TB indicators, TB REACH's topic area, may be easier to improve than the HIV indicators that were the predominant focus of the MENTORS study. However, Franco et al. found the time required to reach at least 80% performance among the improvement projects they assessed was independent of topic area (maternal child health, HIV and TB) and more closely related to the level of performance at baseline.[18] The quality of care field may benefit from more studies and more rigorous analysis of the potential differences in assessing times to achieving proficiency in specific indicators. This could be useful to program planners in setting realistic targets and expectations.

In addition, quality of care study comparisons are hampered by differences in the indicators used to measure quality.[6,20] While there is good consensus on meaningful outcome measures, process indicators are less standardized. Many indicators reported in studies are restricted to individual projects, and not indicators

that are routinely reported throughout the entire health system. This, along with lack of open access to research datasets, limits the ability of researchers to compare their results across studies. While some indicators differed across the IDCAP, TB REACH and MENTORS projects, due to the objectives of the studies, they all used standard Ministry of Health registers for TB and HIV indicators. This enabled the secondary analysis of TB/HIV integration in the TB REACH and MENTORS projects in Chapter 5. Wherever possible, quality of care research should seek to use national data sources and indicators and/or indicators used in globally recognized surveys, such as those from the Service Delivery Indicators (SDI), Service Availability and Readiness Assessment (SARA), Service Provision Assessment (SPA), and Demographic Health Surveys. When gaps are found for specific diseases or areas of interest, process indicators should be validated to determine their relation to their proximate health outcomes. IDCAP, TB REACH and MENTORS were research studies reaching between 5-36 health facilities with relatively intense interventions, in that they involved health facility visits conducted over 2-5 days, once a month or every other month, with mobile teams of 2-4 members. Under MalariaCare, which was PMI's flagship case management program and a main implementer of OSS for malaria in nine SSA countries, most health facilities received two to four visits per year, or one visit every three to six months. In order to operate at scale, the program also used government employees, trained as supervisors over a 3-5 day training, rather than a mixed program staff and government employee team. These supervision visits focused on the case management of malaria and other febrile illnesses and did not assess quality of care for other infectious diseases.

The primary outcomes tracked by the MalariaCare project were changes in quality of care as assessed through direct observation of health workers. Using this metric, an analysis across MalariaCare-supported countries demonstrated improvements of 5.9%, 3.6% and 6.3% from the first to the third visit for rapid diagnostic testing, microscopy and clinical management, respectively.[9,21,22] Notably, these effect sizes are smaller than the clinical observation effect sizes for IDCAP and MENTORS, which is not surprising given the lower intensity of the intervention and the fact that the health workers assessed were a convenience

sample of those at the health facility that day, rather than follow-up of individual health workers over time.[13,14,19] Data on health facility performance, as measured through malaria diagnosis and treatment practices recorded in health facility registers, was not assessed during MalariaCare. Data quality assurance and comprehensive register reviews were outside of the project's mandate.

The MalariaCare project provides an example of an OSS program for a single disease operating "at scale", reaching over 5,600 health facilities across 9 countries with supportive supervision visits over the life of the project.[23] However, even under this large, PMI-funded global cooperative agreement, only 13% of health facilities on average per country were reached with a health facility visit at least once a year, due to the high cost per visit and the large number of health facilities.[24] A cost analysis under MalariaCare found the transport and per diem costs for one-day visits for teams with 2-4 members ranged from $44 to $333 per visit, depending upon the country.[23] Given the cost of OSS interventions and the time and intensity it takes to produce results, we consider some promising approaches as to how these interventions could be more cost-effectively implemented to improve quality of care across infectious diseases at scale below.

## 7.2 ON-SITE SUPPORT: THE WAY FORWARD

### 7.2.1 Try New Models of Integration to Reach Economies of Scale

One potential method of increasing reach would be to integrate OSS across multiple diseases. In this way rather than having visits for individual diseases, multiple diseases could be addressed during a single visit. In many countries several disease-specific OSS schemes are implemented simultaneously through vertical HIV, TB and malaria programs as a result of donor funding mandates. This results in common health facility indicators, such as health facility infrastructure, staffing levels and drug stocks being assessed during each visit. This information is often kept within each program and not shared. This was one of the key arguments behind the testing of the IDCAP program – that addressing multiple diseases in one visit may be more cost-effective.

Integration of OSS across diseases would also be a way to address the common concern that disease-specific interventions may be inadvertently skewing resources towards one disease rather than supporting the health system as a whole. This has been a particular concern for HIV quality of care interventions, given the complexity of managing HIV cases and the vast resources that have flowed through HIV programs in recent years. One large longitudinal study assessed the effects of the President's Emergency Plan for AIDS Relief (PEPFAR) on health systems strengthening in Uganda.[25] This study associated the counts of total patients on ART within each district with service volumes for non-HIV care. Districts with a higher number of patients on ART had fewer outpatient visits for children aged 4 and younger, fewer TB sputum tests conducted, and fewer deliveries within the facility. At the same time, the rate of maternal deaths in districts with more ART patients was 13% lower than in districts with few ART patients, although this finding was not statistically significant. A smaller study in Uganda among six urban clinics found that PEPFAR-funded HIV programs led to improvements in both HIV and non-HIV related services.[26] Another study from Kenya found that facilities that provided antiretroviral therapy had better quality prenatal and postnatal care.[27] In Rwanda, researchers found that ART service provision led to declines in non-HIV service utilization, but the study did not assess the effects on quality of care.[28] Together these findings imply that efforts to improve HIV services may reduce patient volume but increase the quality of care for areas outside of HIV.

Another study that assessed changes in maternal and child health indicators in Zambia from 1990 to 2010 found that rapid scale-up of vertical malaria prevention programs was accompanied by stagnation or decline in 'horizontal' routine health services, such as polio immunization and skilled birth attendance.[29] A similar study in Uganda did not show the same pattern.[30] While ownership and use of insecticide treated nets and use of ACTs to treat malaria cases increased from 1990 to 2010, initial antenatal care visits and skilled birth attendance also increased over the same period. Areas that stalled were those that required multiple contacts with the health system - four or more antenatal care visits, three doses of oral polio vaccine, and two doses of intermittent preventive therapy during pregnancy. These findings are similar to those found in the interventions described in this dissertation in two ways. First, as shown with the lower levels of

improvement in HIV and TB care during IDCAP, conditions and treatments that require multiple contacts with the health system are likely to be more difficult to change. Second, comparing the IDCAP and TB REACH facility performance results revealed that there may be a trade-off when integrating programs across multiple diseases. Substantial improvement in one or two diseases may come at the cost of making little to no improvement in others. If too many diseases and indicators are included as part of an intervention, there may be only modest improvement across any one indicator.

One approach to address these trade-offs is to implement a 'structured integration' OSS model, where facility visits are integrated across multiple disease areas and health facilities sequentially work to improve indicators over time. In this model, health facilities would work to improve the quality of care for one to two diseases and one to four indicators at a given time. The initial indicators for each health facility could be chosen using several different methods, such as: poor baseline performance, the relative patient load for the disease at the health facility, morbidity or mortality, the interest of the health facility staff, district, region or national goals, or a system of randomization so that a certain proportion of health facilities are working on a given indicator at each time. After the desired level of performance is achieved, additional diseases or indicators could be added, while programs continue to monitor the initial areas of improvement to ensure they do not decline.

Another potential approach would be to implement a 'diagonal' OSS model in which a set of highly cost-effective interventions are implemented on a large scale and are overlaid on top of strongly supported facility- and community-based health systems.[31] In terms of OSS, this could mean routine health systems supervision visits during which data on health facility infrastructure, staffing levels, data quality assurance and drug stocks are assessed along with a few key sentinel indicators for each vertical program. This information would then be shared with the vertical disease programs, through a standardized dashboard. Disease programs could use this information, in addition to the routine HMIS data to monitor facility performance. Using the dashboard as a guide, facilities could then be selectively targeted for additional disease-specific visits based on factors similar to those described for the structured integration approach. In

an era of vertical disease programs, where nearly 36% of development assistance for health is directed to the three diseases of HIV, TB and malaria, integration of OSS may be challenging.[32] Three major sources for health funding in SSA are the Global Fund to Fight HIV, TB and Malaria (the Global Fund), PEPFAR, and PMI. Each of these programs fund large-scale health worker OSS programs focused on single diseases. While donors recognize the need for more cost-effective interventions and further integration, there are tensions in their implementation. Vertical program donors may be reluctant to endorse an integrated OSS model, which may require them to reduce the focus of the intervention on their priority disease. By their very nature, infectious diseases require consistent control and treatment efforts so that gains made in lowering morbidity and mortality are not lost. However, currently health facilities are not being consistently reached by existing OSS models and new methods must be sought.

Before implementing any new OSS models, additional research should be conducted to better understand the current supervision landscape within countries. While there are several thought pieces on how integration may best be achieved, there is a lack of literature describing how health system staff experience current OSS efforts through multiple vertical programs and what systems they think would best support them to improve the quality of care.[33–35] Several studies have interviewed health systems staff to describe the effects of vertical programs on health services, but did not provide constructive recommendations as to how health systems could benefit from vertical programs or how systems and individual program approaches could be effectively integrated based on staff recommendations.[36–38] Interviews could also be done with Ministries of Health, national programs and donors to constructively develop and build support for an integrated model that meets the needs of various stakeholders.

### 7.2.2 Collect and Scale Learning

Another method to accelerate the impact of OSS is to systematically collect lessons learned from individual improvement efforts and share them across health facilities. The Institute for Healthcare Improvement (IHI) has long championed learning collaboratives as a method for making breakthrough improvements in quality

of care while reducing costs.[39] IHI's model of Breakthrough Series Collaboratives are "short-term (6- to 15-month) learning system[s] that bring together a large number of teams from hospitals or clinics to seek improvement in a focused topic area."[39] Each health facility sends a team of at least three people to attend two-day learning sessions during which team members are provided guidance on methods for improving performance, share methods and results from their improvement activities, and collectively reflect on lessons learned. This system provides access to both experts and peers as a source of social support and encouragement for continuing improvement efforts.

To bring these efforts to scale, IHI then developed a revised model implemented in waves.[40] In the first wave, experts spend a greater amount of time with a few facilities to rigorously develop and test improvement ideas and record the outcomes of the tests – what works, what doesn't and why. The successful improvements are then compiled into a "change package," which is shared with a greater number of health facilities in later waves. In their review of quality improvement collaboratives, Franco et al. found that systematically transferring learning from earlier to later waves using this method dropped the time to reaching performance levels of 80% in half.[18] Due to the high cost of bringing together staff from every health facility, in Ghana the 'Project Fives Alive!' team further modified the wave method to rapidly reach scale.[41] In Wave 1, quality improvement teams were formed at the health facility level. In Wave 2 teams were formed at the sub-district level with all health centers and health posts contributing members to one sub-district team. Hospitals still formed their own teams during this wave due to their higher patient volume. After spending 15 months in the 27 Wave 1 health facilities to develop strong change packages, the project was then able to rapidly scale up to over 800 facilities in Wave 2, which was implemented over the remaining four years of the project. In addition to achieving improvements in the range of 6 to 11 percentage points across a series of maternal and child health indicators, the study also demonstrated a 20% reduction in under-five mortality.[41] During Wave 2, health facilities received site visits from district staff every 8-10 weeks.[42] This study used quasi-experimental design using time series data, a method commonly used for

quality improvement evaluations. The few randomized control trials that have tested the effects of quality improvement initiatives have found more modest improvements.[43,44]

### 7.2.3 Use Integrated Data Sources as Part of Routine Program Management

The proposed OSS models and the documentation and sharing of improvement efforts require high quality data that is routinely used to guide program interventions. OSS programs often use checklists to structure the visit and provide a standardized method for supervisors to assess health facilities and record key findings.[4] The increasing availability of electronic tools makes it easier not only for supervisors to use this information during their visits but also for managers at the district, regional and national levels to routinely review this information. As described in Chapter 6, with electronic OSS tools, such as the MalariaCare EDS, program managers have the ability to integrate OSS data with routine health management information system (HMIS) data and stock data to obtain a fuller picture of quality of care within each health facility. By triangulating these data sources, program managers can identify which facilities are struggling to provide high quality HIV, TB or malaria care and drill down to determine whether issues are predominantly due to infrastructure (stock, staffing, equipment), knowledge and skills, or facility management. Based on these assessments, managers can then recommend appropriate interventions to address key barriers.

In addition to the collection of OSS data, OSS visits could also be utilized to improve the HMIS data quality. These indicators are critical for both disease surveillance and for routinely assessing quality of care. HMIS data are also a potentially rich source of data for evaluation of interventions and to assess the long term progress of disease programs, but have been underused due to data quality concerns.[45] During OSS visits, supervisors could conduct HMIS data quality assessments and provide feedback to staff. Supervisors could also orient health facility staff to key HMIS indicators and support them in using these indicators to track their progress. A simple wall chart may be an effective method to help staff to visualize data and inform decision making.[46]

Improving data quality is often one of the first steps in the quality improvement process. As IDCAP, TB REACH and MENTORS were research studies, they employed data entry staff for each site to transcribe data from registers, as well as data supervisors who visited health facilities on a monthly or bi-monthly basis to further assess and improve data quality. While this was necessary to produce high quality data for research purposes, many health systems currently either cannot afford or do not prioritize this level of data quality assurance on a routine basis. Under the MalariaCare program, HMIS data quality was not part of the program mandate, and thus was not an explicit focus of the intervention in most countries.

Routine data reviews, connecting HMIS, OSS, stock and any other relevant data sources, should be conducted at the health facility as well as at district, regional and national level meetings. In many countries, data review meetings are already occurring for either health systems, specific disease areas, or both.[47,48] In IDCAP, TB REACH, and MalariaCare, learning sessions were held to review the data collected by the project, at the facility and district or regional levels.[15,23] In many programs, data reviews often focus on HMIS data when it is available.[49] Rarely is systematically-collected OSS data reviewed to help identify and address gaps in quality. The availability of electronic tools designed for OSS will increase access and better enable managers to use this data to guide decision making. However, OSS data is likely to suffer the same issues as HMIS data in terms of both data quality and use. Steps will need to be taken to ensure that OSS tools and analysis and reporting processes are streamlined, data quality audits are systematically conducted, and relevant staff are supported in using data for decision-making.[50]

Support from national governments and donors is critical to the use of the data for improving quality of care. It is the role of national government to define quality standards and develop systems to monitor progress towards standards, holding health facilities accountable for their results. National governments should engage staff at each level of health system to routinely use data to assess progress and develop and implement actions to improve the quality of care where needed. In support of this role, national governments are increasingly developing national healthcare quality strategies that provide outcome-oriented goals based on national health priorities and describe the national structures required at each level of health system.[51–

[54] National infectious disease programs should work with these centralized quality units to ensure a coordinated approach to improving quality that matches national health priorities.

Donors also have a role in fostering a culture of quality and data use. Donors can help strengthen and support quality and data systems. For example, PEPFAR and other donors, through their support of national governments and HIV-implementing partners, catalyzed the development of HIV-specific quality improvement initiatives. These initiatives then led to the development of the national quality improvement strategies described above.[55] Strengthening national data systems helps maintain consistency in quality improvement and OSS interventions over time in an uncertain funding environment where many donor-supported projects last from one to five years. Donors can also use these strengthened quality and data systems to support regular data review and hold governments and implementing partners accountable for their progress towards agreed upon targets.

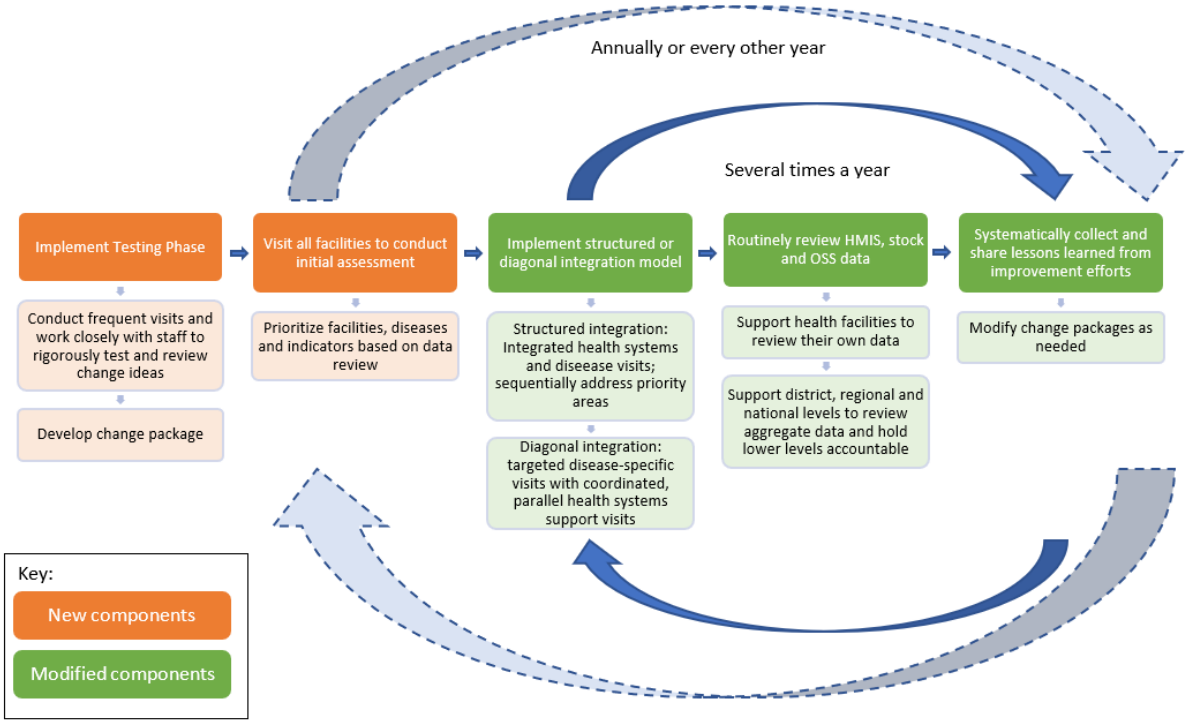
## 7.3 RECOMMENDATIONS

This dissertation provides practical guidance to governments, donors and partners as they design and implement training and OSS interventions for infectious diseases in SSA and proposes new methods to accelerate improvements in health worker performance.

Specific recommendations based on these study findings are as follows: OSS interventions alone can be effective in improving practice, however there is an added benefit of combining training with OSS; if OSS cannot be held immediately following training, OSS provided up to nine months later is still effective; integration of services done as part of OSS can improve quality of care, and electronic tools used to guide OSS tend to be more expensive than paper checklists, but improve data completeness, timeliness, and likely data use. A further analysis of the multiple interventions and a comparison of their outcomes, along with literature from similar studies, led to development of a proposed new approach for OSS integration, as seen in Figure 7.1 below. Figure 7.1 modifies components that existed to varying levels within the four studied

projects and adds new components based on promising approaches from the literature review. Below we describe each of the new and modified components within this approach.

**Figure 7.1 Proposed approach for integrated OSS**




### 7.3.1 Implementing Testing Phase

Prior to scaling OSS visits, programs should choose a small set of facilities (10-30) to work with closely to rigorously develop and test change ideas. Those ideas that are successful, and that produce the greatest change with the least amount of additional effort, should then be collated into a change package that can be rapidly scaled.

### 7.3.2 Visit all facilities, prioritize for future visits.

When scaling, all facilities should be visited at least once annually or every other year, as resources are available, with a broad assessment tool that assesses health systems, as well as 1-2 sentinel indicators for each disease area. Using data from this visit, along with routine health facility data, facilities can be prioritized for future visits.

### 7.3.4 Implement integrated supervision model

After selecting facilities, programs should implement integrated supervision visits, using either the 'structured' or 'diagonal' supervision model. With either model, programs should ask health facilities to focus only on one to four indicators within one topic area at a time. As these improve others can be added, while continuing to monitor those that have already improved. Programs may be able to see more dramatic improvement if they focus on a few key indicators in one topic area.

### 7.3.5 Routinely review HMIS, stock and OSS data

To assess current quality of care and to identify possible barriers to high quality care, multiple data sources including routine HMIS, stock and OSS data, should be regularly reviewed together at district-wide health meetings. The selected indicators for reviews should be based on national data systems and considered priorities by governments and donors. To improve data quality, data quality assurance exercises should be conducted during facility visits and summaries of data quality should be presented at reviews. Regional, district and health facility staff should also be supported to develop their capacity to routinely review their own data. Higher-level government staff and donors should hold health facilities accountable for improving the quality of care to meet national standards.

### 7.3.6 Systematically collect and share lessons learned

As the OSS is scaled, new solutions may be developed that should be incorporated into change packages and shared with facilities across regions and districts. These additions to the change package should be systematically collected during OSS visits, shared as part of data review meetings, and documented. As part of this process, programs should also track the level of effort and time required to achieve proficiency to better understand and set expectations for the time required for improvements, and to compare the relative effectiveness of each intervention.

## 7.4 FUTURE RESEARCH PERSPECTIVES

Based on the work in this dissertation, we propose conducting two future research studies. First, to address the gap in literature describing the current supervision landscape within countries, we propose conducting a descriptive research project with quantitative and qualitative components to better understand how national staff in infectious disease programs and central quality units within Ministries of Health; district staff, including managers, program coordinators and supervisors; and health facility staff experience multiple vertical supervision programs. The project would also interview donors of health systems and vertical disease programs. The purpose of this research would be to a) describe how supervision is currently taking place across multiple disease programs, b) identify opportunities for cross-program synergies, c) identify barriers to integration and potential solutions based on Ministry of Health staff and donor experience. The findings of this research would then further inform the design integrated supervision programs.

Following this research, we propose conducting a cluster, randomized control trial to compare existing largely vertical supervision structures with the proposed diagonal supervision model. A third arm, with another model of integration, would further allow us to make head-to-head comparisons of integration methods. This study would be designed to assess the relative impact of each type of program on facility performance indicators across infectious diseases (HIV, TB, malaria), as well as maternal and child health indicators. The study would also include a cost-effectiveness analysis to compare the changes in facility performance in relation to the relative costs of each program, and, where possible, use modeling to estimate each program's effects on changes on incidence, prevalence and mortality.

Additional future research questions are as follows:

1. What methods of integrating OSS interventions provide the greatest impact on quality of care in the shortest period of time and at the lowest cost?

   a. Do programs see greater improvement if they focus on fewer diseases or indicators at any one time?
   b. Is structured or diagonal OSS more effective than multiple vertical programs that are not integrated?
   c. How many visits are required over what time period to reach high standards of care?
2. Does integration and review of OSS, stock and HMIS data accelerate improvements over review of HMIS data alone?
3. Does the development and dissemination of change packages accelerate improvements?
4. What is the effect of specific disease or indicators on the time required to achieve a high standard of quality of care?
   a. Do some diseases or indicators take longer to improve on average? If so what factors impact the time required?
5. Does MOH and donor focus on specific indicators lead to greater improvements in quality of care?
6. How long are improvements made during OSS visits maintained? What is the relative impact of various factors on maintenance?

## 7.5 CONCLUSION

The research in this dissertation provides practical guidance to governments, donors and partners as they design and implement training and OSS interventions for infectious diseases in sub-Saharan Africa and adds to the existing literature on methods for improving health worker performance. Specific recommendations based on these findings include: OSS interventions alone can be effective in improving practice, however there is an added benefit of combining training with OSS; if OSS cannot be held immediately following training, OSS provided up to nine months later is still effective; integration of services done as part of OSS can improve quality of care, and electronics tools used to guide OSS tend to be more expensive than paper checklists, but improve data completeness, timeliness, and likely data use.

Programs should implement supervision models that are integrated across infectious diseases, incorporate routine data reviews, and that systematically collect and scale learning.

**REFERENCES**

1. Bosch-Capblanch X, Liaqat S, Garner P. Managerial supervision to improve primary health care in low- and middle-income countries. *Cochrane Database Syst Rev*. 2011;9(9):CD006413. doi:10.1002/14651858.CD006413.pub2.

2. O'Brien MA, Rogers S, Jamtvedt G, Oxman Andrew D, Odgaard-Jensen J, Kristoffersen Doris T. Educational outreach visits: effects on professional practice and health care outcomes. *Cochrane Database Syst Rev*. 2007;4(3).

3. Ivers NM, Grimshaw JM, Jamtvedt G, et al. Growing Literature, Stagnant Science? Systematic Review, Meta-Regression and Cumulative Analysis of Audit and Feedback Interventions in Health Care. *J Gen Intern Med*. 2014;29(11):1534-1541. doi:10.1007/s11606-014-2913-y.

4. Vasan A, Mabey DC, Chaudhri S, Brown Epstein H-A, Lawn SD. Support and performance improvement for primary health care workers in low- and middle-income countries: a scoping review of intervention design and methods. *Health Policy Plan*. 2016;(November 2016):czw144. doi:10.1093/heapol/czw144.

5. Wu S, Roychowdhury I, Khan M. Evaluations of training programs to improve human resource capacity for HIV, malaria, and TB control: A systematic scoping review of methods applied and outcomes assessed. *Trop Med Health*. 2017;45(1):1-11. doi:10.1186/s41182-017-0056-7.

6. Buckley GJ, Pittluck RE, Board on Global Health, Institute of Medicine, The National Academies of Sciences, Engineering and M. *Improving Quality of Care in Low- and Middle-Income Countries*. Washington, DC: The National Academies Press; 2015. doi:10.17226/21736.

7. Bates I, Bekoe V, Asamoa-Adu A. Improving the accuracy of malaria-related laboratory tests in Ghana. *Malar J*. 2004;3:38. doi:10.1186/1475-2875-3-38.

8. Sarkinfada F, Aliyu Y, Chavasse C, Bates I. Impact of introducing integrated quality assessment

for tuberculosis and malaria microscopy in Kano, Nigeria. *J Infect Dev Ctries*. 2009;3(1):20-27. doi:10.3855/jidc.101.

9. Alombah F, Eliades MJ, Wun J, et al. Effect of supportive supervision on malaria microscopy competencies in sub-Saharan Africa. *Am J Trop Med Hyg*. 2018:#-#.

10. Ssebuliba DM, Pretorius C, Burnett SM, et al. Evaluating the impact of two training interventions to improve diagnosis and case-management of malaria and pneumonia in Uganda. *Epidemiol Infect*. 2017;145(1):194-207. doi:10.1017/S0950268816002107.

11. Ivers N, Jamtvedt G, Flottorp S, et al. Audit and feedback : effects on professional practice and healthcare outcomes ( Review ) SUMMARY OF FINDINGS FOR THE MAIN COMPARISON. *Cochrane database Syst Rev*. 2012;6(6):CD000259. doi:10.1002/14651858.CD000259.pub3.

12. Burnett SM, Mbonye MK, Martin R, et al. Effect of on-site support on laboratory practice for human immunodeficiency virus, tuberculosis, and malaria testing. *Am J Clin Pathol*. 2016;146(4):469-477. doi:10.1093/ajcp/aqw138.

13. Imani P, Jakech B, Kirunda I, Mbonye MK, Naikoba S, Weaver MR. Effect of integrated infectious disease training and on-site support on the management of childhood illnesses in Uganda: A cluster randomized trial. *BMC Pediatr*. 2015;15(1):1-14. doi:10.1186/s12887-015-0410-z.

14. Burnett SM, Mubiru N, Imani P, et al. Synergistic impact of training followed by on-site support on HIV clinical practice: A mixed design study in Uganda with pre/post and cluster randomized trial components. *J Acquir Immune Defic Syndr*. 2018. doi:10.1097/QAI.0000000000001630.

15. Weaver MR, Burnett SM, Crozier I, et al. Improving facility performance in infectious disease care in Uganda: A mixed design study with pre/post and cluster randomized trial components. *PLoS One*. 2014;9(8). doi:10.1371/journal.pone.0103017.

16. Burnett SM, Mbonye MK, Naikoba S, et al. Effect of educational outreach timing and duration on facility performance for infectious disease care in Uganda: A trial with pre-post and cluster randomized controlled components. *PLoS One*. 2015;10(9):1-17. doi:10.1371/journal.pone.0136966.

17. Mbonye MK, Burnett SM, Naikoba S, et al. Effectiveness of educational outreach in infectious diseases management: a cluster randomized trial in Uganda. *BMC Public Health*. 2016;16(1):714. doi:10.1186/s12889-016-3375-4.

18. Franco LM; Marquez L; Ethier K; Balsara Z; Isenhower W. Results of collaborative improvement: Effects on health outcomes and compliance with evidence-based standards in 27 applications in 12 countries. *Univ Res Co*. 2009;(December). http://www.popline.org/node/209398.

19. Naikoba S, Senjovu KD, Mugabe P, et al. Improved HIV and TB Knowledge and Competence among Mid-level Providers in a Cluster-Randomized Trial of One-on-One Mentorship for Task Shifting. *J Acquir Immune Defic Syndr*. 2017;75(5):e120-e127. doi:10.1097/QAI.0000000000001378.

20. Akachi Y, Kruk ME. Quality of care: measuring a neglected driver of improved health. *Bull World Health Organ*. 2017;(December 2016):465-472. doi:10.2471/BLT.16.180190.

21. Eliades MJ, Wun J, Burnett SM, et al. Effect of supportive supervision on performance of malaria rapid diagnostic tests in sub-Saharan Africa. *Am J Trop Med Hyg*. 2018;#(#):#-#.

22. Martin T, Eliades MJ, Wun J, et al. Effect of supportive supervision on competency of febrile case management in sub-Saharan Africa. *Am J Trop Med Hyg*. 2018;#(#):#-#.

23. Eliades MJ, Alombah F, Wun J, et al. Perspectives on implementation considerations and costs of malaria case management supportive supervision. *Am J Trop Med Hyg*. 2018;#(#):#-#.

24. MalariaCare. *Universal Diagnosis and Treatment to Improve Maternal and Child Health: Project*

*Year 4 Annual Report*.; 2017.

25. Luboga SA, Stover B, Lim TW, et al. Did PEPFAR investments result in health system strengthening? A retrospective longitudinal study measuring non-HIV health service utilization at the district level. *Health Policy Plan*. 2016;31(7):897-909. doi:10.1093/heapol/czw009.

26. Matsubayashi T, Manabe YC, Etonu A, et al. The effects of an HIV project on HIV and non-HIV services at local government clinics in urban Kampala. *BMC Int Health Hum Rights*. 2011;11(SUPPL. 1):S9. doi:10.1186/1472-698X-11-S1-S9.

27. Kruk ME, Jakubowski A, Rabkin M, et al. Association between HIV programs and quality of maternal health inputs and processes in Kenya. *Am J Public Health*. 2015;105:S207-S210. doi:10.2105/AJPH.2014.302511.

28. Price JE, Asuka Leslie J, Welsh M, Binagwaho A. Integrating HIV clinical services into primary health care in Rwanda: a measure of quantitative effects. *AIDS Care*. 2009;21(5):608-614. doi:10.1080/09540120802310957.

29. Colson KE, Dwyer-Lindgren L, Achoki T, et al. Benchmarking health system performance across districts in Zambia: A systematic analysis of levels and trends in key maternal and child health interventions from 1990 to 2010. *BMC Med*. 2015;13(1):1-14. doi:10.1186/s12916-015-0308-5.

30. Roberts DA, Ng M, Ikilezi G, et al. Benchmarking health system performance across regions in Uganda: A systematic analysis of levels and trends in key maternal and child health interventions, 1990-2011. *BMC Med*. 2015;13(1):1-16. doi:10.1186/s12916-015-0518-x.

31. Sepúlveda J, Bustreo F, Tapia R, et al. Improvement of child survival in Mexico: the diagonal approach. *Lancet*. 2006;368(9551):2017-2027. doi:10.1016/S0140-6736(06)69569-X.

32. Institute for Health Metrics and Evaluation (IHME). *Financing Global Health Visualization*. Seattle, WA: University of Washington; 2017.

33. Harries AD, Jensen PM, Zachariah R, Rusen ID, Enarson DA. How health systems in sub-Saharan Africa can benefit from tuberculosis and other infectious disease programmes. *Int J Tuberc Lung Dis*. 2009;13(10):1194-1199.

34. Elzinga G. Bulletin of the World Health Organization Vertical – horizontal synergy of the health workforce. 2015;(1):11-13.

35. Pierre-Louis M, Soucat A, Damme W Van, Pirard M, Assefa Y, Olmen J Van. *How Can Disease Control Program Contribute to Health System Strengthening in Sub-Saharan Africa : A Concept Note for Engaging in the Global Debates on Health Systems Strengthening*.; 2010. http://documents.worldbank.org/curated/en/2010/06/16565484/can-disease-control-program-contribute-health-system-strengthening-sub-saharan-africa-concept-note-engaging-global-debates-health-systems-strengthening.

36. Keugoung B, Macq J, Buvé A, Meli J, Criel B. The interface between health systems and vertical programmes in Francophone Africa: the managers' perceptions. *Trop Med Int Heal*. 2011;16(4):478-485. doi:10.1111/j.1365-3156.2010.02716.x.

37. Lohman N, Hagopian A, Luboga SA, et al. District Health Officer Perceptions of PEPFAR's Influence on the Health System in Uganda, 2005-2011. *Int J Heal Policy Manag*. 2016;6(2):83-95. doi:10.15171/ijhpm.2016.98.

38. Doherty T, Besada D, Goga A, Daviaud E, Rohde S, Raphaely N. "If donors woke up tomorrow and said we can't fund you, what would we do?" A health system dynamics analysis of implementation of PMTCT option B+ in Uganda. *Global Health*. 2017;13(1):1-11. doi:10.1186/s12992-017-0272-2.

39. Institute for Healthcare Improvement. The Breakthrough Series. *Innovation*. 2003:1-20.

40. Massoud M, Nielsen G, Nolan K, Nolan T, Schall M, Sevin C. A Framework for Spread: From

Local Improvements to System-wide Change. *IHI Innov Ser white Pap*. 2006:1. doi:www.ihi.org.

41. Singh K, Brodish P, Speizer I, et al. Can a quality improvement project impact maternal and child health outcomes at scale in northern Ghana? *Heal Res Policy Syst*. 2016;14(1). doi:10.1186/s12961-016-0115-2.

42. Sodzi-Tettey S, Twum N, Mobisson-Etuk L, Macy L, Roessner J, Baker P. Lessons Learned from Ghana's Project Fives Alive! A practical guide for designing and executing large-scale improvement initiatives. 2015. http://www.ihi.org/resources/Pages/Publications/ProjectFivesAliveLessonsLearnedGuide.aspx.

43. Schouten LMT, Hulscher MEJL, Everdingen JJE v., Huijsman R, Grol RPTM. Evidence for the impact of quality improvement collaboratives: systematic review. *Bmj*. 2008;336(7659):1491-1494. doi:10.1136/bmj.39570.749884.BE.

44. Waiswa P, Manzi F, Mbaruku G, et al. Effects of the EQUIP quasi-experimental study testing a collaborative quality improvement approach for maternal and newborn health care in Tanzania and Uganda. *Implement Sci*. 2017;12(1):1-18. doi:10.1186/s13012-017-0604-x.

45. Ashton RA, Bennett A, Yukich J, Bhattarai A, Keating J, Eisele TP. Methodological Considerations for Use of Routine Health Information System Data to Evaluate Malaria Program Impact in an Era of Declining Malaria Transmission. 2017;97(Suppl 3):46-57. doi:10.4269/ajtmh.16-0734.

46. Hazel E, Chimbalanga E, Chimuna T, et al. Using Data to Improve Programs: Assessment of a Data Quality and Use Intervention Package for Integrated Community Case Management in Malawi. *Glob Heal Sci Pract*. 2017;5:355-366.

47. MEASURE Evaluation. *Surveillance Data Review Meetings in Malaria-Endemic Counties in Kenya*.; 2017.

48. do Nascimento N, Barker C, Brodsky I. Where is the evidence? The use of routinely-collected patient data to retain adults on antiretroviral treatment in low and middle income countries–a state of the evidence review. *AIDS Care - Psychol Socio-Medical Asp AIDS/HIV*. 2018;30(3):267-277. doi:10.1080/09540121.2017.1381330.

49. Wickremasinghe D, Hashmi IE, Schellenberg J, Avan BI. District decision-making for health in low-income settings: A systematic literature review. *Health Policy Plan*. 2016;31:ii12-ii24. doi:10.1093/heapol/czv124.

50. Gloyd S, Wagenaar BH, Woelk GB, Kalibala S. Opportunities and challenges in conducting secondary analysis of HIV programmes using data from routine health information systems and personal health information. *J Int AIDS Soc*. 2016;19(Suppl 4):1-6. doi:10.7448/IAS.19.5.20847.

51. The Federal Democratic Republic of Ethiopia Ministry of Health. *Ethiopian National Health Care Quality Strategy: Transforming the Quality of Health Care in Ethiopia, 2016-2020*.; 2016. https://www.medbox.org/ethiopian-national-health-care-quality.../download.pdf. Accessed May 4, 2018.

52. The United Republic of Tanzania Ministry of Health and Social Welfare. *National Health and Social Welfare Quality Improvement Strategic Plan (2013-2018)*.; 2013.

53. Ghana Ministry of Health. *Ghana National Healthcare Quality Strategy (2017-2021)*.; 2016. http://www.moh.gov.gh/wp-content/uploads/2017/06/National20Quality20Strategy20Ghana.pdf.

54. World Health Organization. *National Quality Policy and Strategy: WHO Meeting Report*. Geneva, Switzerland: Geneva; 2017.

55. Mwidunda PE, Eliakimu E. Creating a national culture of quality: the Tanzania experience. *AIDS*. 2015;29(Supp 2):S175-177. doi:10.1097/QAD.0000000000000714.

# Dedication and Acknowledgements

## Dedication

*This work is dedicated to primary health care workers, especially those on the frontlines in often difficult working conditions throughout sub-Saharan Africa. Your continued efforts to provide high quality care have resulted in dramatic reductions in disease burden and saved millions of lives.*

*I look forward to continuing this journey with you and working to save many more.*

## Acknowledgements

I would like to thank Prof. Dr. Robert Colebunders for acting as my PhD promoter at the University of Antwerp and for supporting my registration. Your guidance in navigating the program and your quick, direct feedback pushed me to keep moving forward and provided a pathway to completion.

My sincere gratitude goes to Prof. Dr. Marcia R. Weaver for your continuous support throughout my academic and professional career. This dissertation would not have been possible without your mentoring and encouragement over the past 13 years. From the first time that I called you as a first year master's student asking about conducting evaluation work in international health, you have always been positive, supportive, and patient. Throughout our time working together you've provided countless opportunities for me to grow as a young evaluator and researcher and provided me with a strong training in conducting rigorous research, both by teaching and by example. I would not be the researcher I am today without your mentorship.

To Prof. Dr. Yukari Manabe, thank you for asking the tough questions. You helped me step back and look at the big picture, focusing on the impact, rather than getting too caught up in the details. Our discussions always reminded me to think a bit more critically about what factors really make the difference in improving health.

To my colleagues in research:

Dr. Martin Mbonye, I feel so fortunate to have had you go before me in the PhD process. Our conversations over the years and your dissertation work provided a basis that I used to plan and execute my own. Thank you also for the moral support you provided through your skype check-in calls.

Dr. Sabine Hermans and Dr. Stella Muyanja-Zawedde, thank you for your support on the TB/HIV integration manuscript. Sabine, your repeated review of the analysis plans and results, and openness in exploring questions with me, strengthened my understanding of epidemiology and analysis. Stella, this paper would not have been possible without your in-depth knowledge of the program and your always rapid response to my multiple rounds of questions to clarify one point or another.

Dr. Peace Imani and Dr. Nobert Mubiru, thank you for paving the way for the IDCAP HIV clinical observations manuscript. Peace, thank you for all of your efforts in ensuring a clean dataset ready for final analysis, and for providing an example with your work in the under-five population. Norbert, thank you for all your initial work on structuring the manuscript.

To the various organizations and teams I've worked with over the years that developed my research interests and provided a platform from which to conduct this work:

Thank you to the M&E team led by Dr. Gabrielle O'Malley and the Botswana country program led by Dr. Baz Semo at I-TECH. As my first position out of graduate school this is where my interest in building health care worker capacity to improve services for infectious disease programs began. The opportunity to work closely with the STI, TB and HIV units in Botswana on clinical mentoring programs in a supportive growth environment provided the foundation on which my research interests were built.

To Accordia Global Health Foundation and Kelly S. Willis, thank you for the opportunity to work on IDCAP project and the opportunity to further develop my research skills. This was a rare opportunity to focus completely on a large, complex, rigorous research study.

To the IDI training team, which housed the IDCAP, MENTORS and TB REACH programs, especially Dr. Sarah Naikoba, Dr. Dan Kaggwa Senjovu, Pallen Mugabe and Timothy Rubashembusya. Thank you for your continued support of my research efforts and for sharing program data.

To the MalariaCare program staff at PATH: To Molly Robertson, thank you for your work in providing the vision for the M&E team and being the original architect of the Malaria Electronic Data System. Without the foundation that you set, and your continued guidance as both a colleague and friend, we could not have accomplished so much in such a short amount of time. To my M&E team, Jolene Wun, Illah Evance and Kelly Davis, thank you for your tireless work on the EDS. Your commitment to getting the work done on time and at quality has made this system the success that it is today. To Paul Hamilton, thank you for the amazing growth opportunity and trusting me to lead the work of the M&E team.

To my long-time friend, Madonna Ramp, our long conversations and debates detailing the connections in fostering excellence in teachers in the United States and health care workers in sub-Saharan Africa were an inspiration. I am so grateful that we were able to share the challenges and triumphs of our doctoral journey.

To my partner, Abel Kerevel, thank you for your countless reviews, proofreads and edits, for being so understanding on all the nights and weekends when I retreated to the study, and for painting the study yellow, especially the second time when the first shade wasn't quite right.

Finally, I would like to thank my parents, Ken and Helen Burnett. Dad, thank you for reminding me to always "get an A today", to aspire to excellence while taking it a day at a time, knowing that success only comes through continued, dedicated hard work. Mom, your example of working full-time at a demanding job while finishing graduate school has inspired and encouraged me more than you know. Your love and support have enabled me to pursue my research and my professional career in developing systems and tools to improve the quality of care for infectious diseases.

# Curriculum Vitae

**Sarah M. Burnett, MPH, MPA**
Monitoring, Evaluation, and Learning Officer
PATH

## CAREER SUMMARY

Ms. Burnett has over 10 years of experience in global health care worker capacity building, mobile health technology, and operations research. She as a passion for demonstrating programmatic improvement and fostering continuous learning, and is experienced in all aspects of program implementation, from workplan writing, to providing on-the-ground and remote technical assistance, to ensuring that data is used to guide decision-making. Ms. Burnett is an enthusiastic collaborator with experience in team management and M&E capacity building.

As the M&E Team Lead for the USAID-funded MalariaCare project, Ms. Burnett led the M&E work in 17 countries, including an operations research study evaluating whether and how providing integrated community case management training and supportive supervision to private drug shop owners could improve the quality of integrated case management for children. Prior to PATH, she managed the technical assistance of projects for Accordia Global Health Foundation and was a Quality Improvement Advisor for I-TECH. She has a combined MPH and MPA from the University of Washington.

## PROFESSIONAL EXPERIENCE

**PATH, Washington, DC, USA** **03/2018 to present**
Sr. Data Analyst/Monitoring, Evaluation, and Learning Officer

Conducts key stakeholder consultations regarding data use practices

Accesses, compiles, cleans, analyzes and visualizes data to inform for vector control decision making in assigned project countries.

Plans and co-leads national data use workshops to build capacity in data access and use for vector control strategy and planning. decision-making.

Contributes to global dissemination of project learning and products including case study documents, presentations, and peer-reviewed publications.

Provides M&E guidance and technical assistance to ongoing projects at PATH, and contributes to M&E sections for proposal development

**PATH, Washington, DC, USA** **03/2015 to 02/2018**
Monitoring and Evaluation Team Lead/Capacity Building Officer, MalariaCare

Led monitoring and evaluation for a 17-country, US President's Malaria Initiative-funded malaria case management global cooperative agreement.

Supervised project M&E staff including data collection and reporting processes which resulted in improved productivity.

Led the strategy, roll-out and transition of a tablet-based electronic supervision tool connected to DHIS2 for data visualization and use by National Malaria Control Programs across seven countries; system used by over 1,600 regional and district supervisors

Identified and developed quasi-experimental evaluation designs and led data analyses; collaborated with program staff to review results and redesign programs based on evidence.

Technical Lead for an operations research project in Nigeria to assess the ability of drug shop workers to diagnose and treat common childhood illnesses; led the revision of data collection tools, oversight of field data collection teams, data analysis, and report writing.

**Accordia Global Health Foundation, Washington, DC, USA** **01/2010 to 02/2015**
Senior Research & Data Manager

Managed technical assistance projects for a clinical mentoring implementation science program in Uganda and a malaria case management operations research collaboration between two Nigerian universities.

Managed a data management and analysis staff of eight for the $12.6M Bill and Melinda Gates Foundation-funded Integrated Infectious Disease Capacity Building Evaluation (IDCAP) initiative, ensuring data quality assurance and timely completion of all data processing and analysis.

Analyzed over 1 million patient records for IDCAP, the first randomized control trial assessing the impact of on-site supervision on an integrated disease management for malaria, pneumonia, TB and HIV in Uganda.

Contributed to program development and study designs for multiple project proposals in Malawi, Nigeria and Uganda.

**International Training and Education Center for Health, Seattle, WA** **7/2007 to 12/2010**

Quality Improvement Advisor,

Worked collaboratively with the Botswana National STI and TB Programmes to develop data collection tools and a database to evaluate their clinical mentoring programs.

Developed curriculum and conducted trainings in data collection, data quality and data management for district M&E Officers in Botswana.

Provided monitoring and evaluation technical assistance for PEPFAR-funded programs in Botswana and India, including development of logical frameworks, monitoring and evaluation plans and reporting against PEPFAR indicators.

Drafted evaluation protocols for over 10 evaluation studies, including drafting data collection tools and data analysis plans.

Adapted standard operating procedures for data auditing and mentored staff in data management which resulted in a hand-over of data audit and reporting duties.

## EDUCATION

MPH, Social and Behavioral Sciences, University of Washington, Seattle, WA, 2007

MPA, University of Washington, Seattle, WA, 2007

BS, Psychology, Michigan State University, East Lansing, MI, 2003

## PROFESSIONAL AFFILIATIONS

Member, Roll Back Malaria Monitoring and Evaluation Reference Group, 10/2015 to present

Member, American Evaluation Association, 2/2015 to present

## COUNTRY EXPERIENCE

Botswana, India, Kenya, Malawi, Mozambique, Tanzania, Nigeria, Uganda

## LANGUAGES

English

## TECHNICAL SKILLS

Stata, Tableau, DHIS 2, SurveyCTO, EpiInfo, Atlas.ti, Microsoft Office Suite

## PUBLICATIONS

**Burnett SM**, Wun J, Evance I, et al. *Introduction and evaluation of an electronic tool for improved data quality and data use during malaria case management supportive supervision.* Am J Trop Med Hyg. [In Press]

Eliades MJ, Alombah F, Wun J, **Burnett SM**, et al. *Operational considerations and costs of malaria case management supportive supervision.* Am J Trop Med Hyg. [In Press]

Eliades MJ, Wun J, **Burnett SM**, et al. *Effect of supportive supervision on performance of malaria rapid diagnostic tests in sub-Saharan Africa.* Am J Trop Med Hyg. [In Press]

Alombah F, Eliades MJ, Wun J, **Burnett SM**, et al. *Effect of supportive supervision on malaria microscopy competencies in sub-Saharan Africa.* Am J Trop Med Hyg. [In Press]

**Burnett SM**, Zawedde-Muyanja S, Hermans SM, Weaver MR, et al. *Effect of TB/HIV Integration on TB and HIV indicators in Rural Ugandan Health Facilities.* J Acquir Immune Defic Syndr; [In Press]

**Burnett SM**, Mubiru N, Imani P, et al. *Synergistic impact of training followed by on-site support on HIV clinical practice: A mixed-design study in Uganda with pre/post and cluster randomized trial components.* J Acquir Immune Defic Syndr; 2018; 77(5) : 605-611.

Ssebuliba DM, Pretorius C, **Burnett SM**, et al. *Evaluating the impact of two training interventions to improve diagnosis and case-management of malaria and pneumonia in Uganda*. Epidemiol Infect. 2017;145(1):194-207. doi:10.1017/S0950268816002107; 2017

**Burnett SM**, Mbonye MK, Martin R, et al. *Effect of On-Site Support on Laboratory Practice for Human Immunodeficiency Virus, Tuberculosis, and Malaria Testing*. Am J Clin Pathol; 146(4):469-477. doi:10.1093/ajcp/aqw138; 2016

Mbonye MK, **Burnett SM**, Naikoba S, et al. *Effectiveness of educational outreach in infectious diseases management: a cluster randomized trial in Uganda.* BMC Public Health. 2016;16(1):714. doi:10.1186/s12889-016-3375-4.

**Burnett SM**, Mbonye MK, Naikoba S, et al. *Effect of educational outreach timing and duration on facility performance for infectious disease care in Uganda: A trial with pre-post and cluster randomized controlled components.* PLoS One. 2015;10(9):1-17. doi:10.1371/journal.pone.0136966.

Manabe YC, Zawedde-Muyanja S, **Burnett SM**, et al. *Rapid improvement in passive tuberculosis case detection and tuberculosis treatment outcomes after implementation of a bundled laboratory diagnostic and on-site training intervention Targeting mid-level providers.* Open Forum Infect Dis. 2015;2(Suppl 1):1-8. doi:10.1093/o.

Mbonye MK, **Burnett SM**, Naikoba S, et al. *Malaria care in infants aged under six months in Uganda: An area of unmet needs!* PLoS One. 2015;10(4):1-20. doi:10.1371/journal.pone.0123283.

Mbonye MK, **Burnett SM**, Colebunders R, et al. *Disease diagnosis in primary care in Uganda.* BMC Fam Pract. 2014;15(1):165. doi:10.1186/1471-2296-15-165.

Weaver MR, **Burnett SM**, Crozier I, et al. *Facility performance results for the Integrated Infectious Disease Capacity-Building Evaluation in Uganda: a mixed design study with Pre/Post and Cluster Randomized Trial Components.* PLoS One. 2014;9(8). doi:10.1371/journal.pone.0103017.

Means AR, Weaver MR, **Burnett SM**, et al. *Correlates of Inappropriate Prescription of Antibiotics to Patients with Malaria in Uganda.* PLoS One. 2014;9(2):1-7. doi:10.1371/journal.pone.0090179.

Mbonye MK, **Burnett SM**, Burua A, et al. *Effect of Integrated Capacity-Building Interventions on Malaria Case Management by Health Professionals in Uganda: A Mixed Design Study with Pre/Post and Cluster Randomized Trial Components.* PLoS One. 2014;9(1). doi:10.1371/journal.pone.0084945.

Ledikwe JH, Reason LL, **Burnett SM**, et al. *Establishing a Monitoring and Evaluation Health Workforce: Innovation for Low and Middle-Income Countries.* Hum Resour Health. 2013;11(1):35. doi:10.1186/1478-4491-11-35.

Namagembe A, Ssekabira U, Weaver MR, Blum N, **Burnett SM**, et al. *Improved clinical and laboratory skills after team-based, malaria case management training of health care professionals in Uganda.* Malar J. 2012;11(1):44. doi:10.1186/1475-2875-11-44.

**Burnett SM**, Weaver MR, Mody-Pan PN, et al. *Evaluation of an Intervention to Increase HIV Testing Among Youth in Manzini, Swaziland: A Randomized Control Trial.* J Adolesc Heal. 2011;48(5):507-513. doi:10.1016/j.jadohealth.2010.08.015.

## PRESENTATIONS

**Burnett SM.** *MalariaCare's Electronic Data System: An electronic system to support data collection and data use for quality improvement*. Presentation at the 66th Annual Meeting of the American Society of Tropical Medicine and Hygiene, Baltimore, Maryland. November 2017.

Chahale T, Onditi S, Onyando B, Dena R, Evance I, **Burnett SM**. *Improving adherence to the Kenya National Malaria Diagnosis and Treatment Guidelines: An outreach, training and supportive supervision (OTSS) approach in Vihiga County, Western Kenya*. Poster at the 66th Annual Meeting of the American Society of Tropical Medicine and Hygiene, Baltimore, Maryland. November 2017.

**Burnett SM**, Clark T, Amajor O, et al. *Improving quality of care for common childhood illness among private drug vendors in Ebonyi State, Nigeria*. Poster presented the 65th Annual Meeting of the American Society of Tropical Medicine and Hygiene; Atlanta, Georgia. November 2016

Tesha G, **Burnett SM**, Chacky F, et al. *Improving quality of malaria rapid diagnostic testing and test adherence through enhanced quality assurance in Tanzania*. Poster presented the 65th Annual Meeting of the American Society of Tropical Medicine and Hygiene, Atlanta, Georgia. November 2016.

Carnahan E, Desmond M, **Burnett SM**. *Evaluation Design in Real World Settings: The Case of Private Sector Fever Management in Nigeria*. Presented at the American Evaluation Association Conference; Atlanta, Georgia. October 2016.

Mbonye KM, Van geertruyden JP, **Burnett SM**, et al. Trusting Malaria Test Results: Fever and young age predicts inappropriate malaria treatment in Uganda. Presentation at 8th European Congress on Tropical Medicine and International Health Copenhagen, Denmark. September 2013.

Mbonye KM, **Burnett SM**, Naikoba S, et al., Improvement in diagnostic based malaria treatment after Integrated Capacity Building Interventions implementation in Uganda; a before-after and cluster randomized controlled study. Presentation at East, Central and Southern Africa Health Community Directors' Joint Consultative Committee and Best Practices Forum, Arusha, Tanzania. August 2013.

**Burnett SM**, Mbonye MK, Naikoba S, et al. Improvement in facility-based quality of care after an integrated infectious diseases capacity building intervention in Uganda: a before-after and cluster randomized controlled study. Poster at Consortium of Universities for Global Health Conference, Washington, DC. March 2013.

Mbonye M, Asiimwe J, **Burnett SM**, et al. Impact of On-Site Support on the Management of Malaria: a Randomized Controlled Trial. Poster at the 38th Annual International Conference on Global Health, Washington, DC. June 2011.

Kinoti SN, **Burnett SM**, Kirunda I, et al. Impact of Integrated Management of Infectious Diseases (IMID) training and Onsite Support (OSS) on Emergency Triage, Assessment and Treatment (ETAT) of seriously ill patients in Uganda: A randomized controlled trial. Presentation at the 54th ECSA Health Ministers' Conference, Mombasa, Kenya. November 2011.

Mudiayi TK, **Burnett SM**, Sejamitlwa A, et al. Evaluation of Tuberculosis Mentoring Programme: Using the Mentoring, Support and Supervisory Visit Tool. Presentation at the 2nd South African TB Conference. June 2010.