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report

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THE UNIVERSITY of NORTH CAROLINA at CHAPEL HILL
PROJECT SOAR SUPPORTING OPERATIONAL AIDS RESEARCH

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Through operations research, Project SOAR will determine how best to address challenges and gaps that remain in the delivery of HIV and AIDS care and support, treatment, and prevention services. Project SOAR will produce a large, multifaceted body of high-quality evidence to guide the planning and implementation of HIV and AIDS programs and policies. Led by the Population Council, Project SOAR is implemented in collaboration with Avenir Health, Elizabeth Glaser Pediatric AIDS Foundation, Johns Hopkins University, Palladium, and The University of North Carolina.

The Population Council confronts critical health and development issues—from stopping the spread of HIV to improving reproductive health and ensuring that young people lead full and productive lives. Through biomedical, social science and public health research in about 50 countries, the Council works with our partners to deliver solutions that lead to more effective policies, programs, and technologies to improve lives worldwide. Established in 1952 and headquartered in New York, the Council is a nongovernmental, nonprofit organization with an international board of trustees.

The University of North Carolina Project-Malawi (UNC Project) is a collaboration between the University of North Carolina at Chapel Hill and the Malawi Ministry of Health with the mission to identify innovative, culturally acceptable, and affordable methods to improve the health of the people of Malawi, through research, capacity building, and clinical care.

Resource and implementing partners who made this study possible:

The **mothers2mothers** program aims to impact the health of mothers by putting them at the heart of improving reproductive, maternal, newborn, child, and adolescent health. The Mentor Mother Model empowers mothers living with HIV, through education and employment, as role models to help other women and their families access essential services and medical care.

The **Baylor** program strives to help children and families live healthy and fulfilled lives by providing high quality healthcare and empowering health professionals and communities in Southern Africa. Specifically, the Tingathe program focuses on using community health workers to improve PMTCT, EID, and pediatric HIV care and treatment services.

Dignitas International is a medical and research organization dedicated to improving health care for people facing a high burden of disease and unequal access to services. They are committed to working with patients, health workers, researchers and policymakers to tackle the barriers to health care. The expert client model focuses on greater involvement of people living with HIV in the delivery of health care.

The **Elizabeth Glaser Pediatric AIDS Foundation** (EGPAF) seeks to end global pediatric HIV/AIDS through prevention and treatment programs, research, and advocacy. Their vision is a world in which children and families live free from HIV/AIDS. EGPAF has an expert client component through which community members living with HIV and adhering to treatment volunteer at the health facility to support others living with HIV in their community.

Partners In Health strives to provide a preferential option for the poor in health care; and to achieve two overarching goals: to bring the benefits of modern medical science to those most in need of them and to serve as an antidote to despair. The organization hires and trains community health workers, who live in the communities where they work and are trusted community members, to help patients overcome obstacles to health care.

Improving PMTCT Outcomes for Mother-infant Pairs Through Community-facility Linkage: Results from a mixed methods study in Malawi

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All research-specific activities, including site assessments, sample data collection, data analyses, and results dissemination were led by investigators from University of North Carolina (UNC) Chapel Hill, UNC Project-Malawi, and the Malawi Ministry of Health.

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ACRONYMS

CFL	Community-facility linkage
CHW	Community health worker
DHMT	District Health Management Team
DHO	District Health Office
EID	Early infant diagnosis
FGD	Focus group discussion
HCW	Healthcare worker
HEI	Infant exposed to HIV
HSA	Health surveillance assistant
HTC	HIV testing and counseling
IDI	In-depth interview
m2m	mothers2mothers
MIP	Mother-infant pair
MOH	Ministry of Health
PBFW	Pregnant and breastfeeding women
PMTCT	Prevention of mother-to-child transmission of HIV
SOC	Standard of care
SSA	sub-Saharan Africa

EXECUTIVE SUMMARY

Despite the impressive maternal and child health gains generated by the Option B+ and test and start strategies in Malawi, including increased maternal access to antiretroviral therapy (ART) and decreased vertical transmission rates, client attrition from the prevention of mother-to-child transmission of HIV (PMTCT) care continuum threatens recent progress. As many as 15 percent of HIV-positive pregnant women do not start ART (Tenthani et al. 2014), and another 30 percent become lost to follow-up within 24 months of treatment initiation (Ministry of Health [MOH] 2018a). Similarly, high loss to follow-up is seen among infants exposed to HIV (HEIs) under 12 months of age and young children 12 to 24 months of age, with 14 percent and 24 percent loss to follow-up in these two age groups, respectively (MOH 2018a). Such mother-infant pair (MIP) drop-out from the PMTCT continuum has deleterious "downstream" effects and threatens Malawi's progress toward ambitious 95-95-95 targets.

To improve MIP care retention in Malawi, several PMTCT care delivery models have emerged to strengthen community-facility linkage (CFL), a concept defined as any "formalized connection between a health facility and the communities it serves to support improved health outcomes." Similar to other settings in sub-Saharan Africa (SSA), three models have been widely implemented to complement Malawi's National PMTCT Programme: 1) mentor mothers; 2) expert clients; and 3) community health workers (CHWs). While the rationale underpinning these models has been substantiated by evidence generated from general ART and PMTCT programs across SSA, a clear and rigorous description of each model, including characterization of supervisory structures, training, and relationships with clinical services, is currently unavailable. Equally important, the comparative impact of these models and their components on MIP care retention and other health outcomes have not been well characterized, particularly in the era of test and start.

In the USAID-funded Project SOAR "Maternal-Infant Retention Study" reported here, we have attempted to address these evidence gaps by rigorously characterizing these community-facility linkage models and comparing their impact against each other and the "traditional" standard of care (SOC) according to routinely collected health outcomes for MIPs, including maternal retention in care and viral suppression, and infant HIV-free survival. To this end, specific objectives of this study were to: (1) establish a clear typology for CFL models by describing the main components of, and patient and key stakeholder perspectives on, three such models in Malawi; (2) describe MIP health outcomes in each model, and compare outcomes across models; and (2a) examine associations between individual components of CFL models and MIP health outcomes, controlling for confounding.

METHODOLOGY

We sought to rigorously define and compare these CFL models with each other and a "traditional" SOC (i.e., facility-based PMTCT services delivered in the absence of CFL providers) using a mixed methods approach involving both quantitative and qualitative data collection.

For the quantitative component (addressing specific objectives 2 and 2a), we used an efficient two-stage cohort study design. In the first stage, we gathered individual-level routine medical record data for a full cohort of women and their HEI from PMTCT program referral or enrollment through the child's second birthday. We included all mothers and their HEIs who newly enrolled in or were newly HIV diagnosed and referred to the national PMTCT program from 1 July 2016 to 30 June 2017 across 30 randomly selected high-volume health facilities and their surrounding communities in five representative districts of Malawi (each health facility and the surrounding communities to which the facility was responsible for providing health services denotes one "facility catchment area" or "study site"). The study period of interest was chosen to align with Malawi's adoption of universal "test and treat," which became national policy on 1 April 2016 and reached stable implementation on 1 July 2016. In the second stage, we employed an epidemiological sampling method to prospectively ascertain MIP PMTCT program status (i.e., in care, stopped, transferred, died, or lost to follow-up), maternal viral load, and infant HIV status, and overcome the limitations traditionally associated with retrospective data (e.g., missing data, outcome misclassification). Applying this method, we randomly selected a nested sample of 832 MIPs from the full 2016 cohort of 2,589 MIPs. This "nested cohort" then completed a field survey including a questionnaire about their experiences with CFL models and services, underwent viral load testing, and had their children ages 12–24 months receive HIV testing. Such prospective data collection enabled us to confirm primary outcomes, fill in missing data, and efficiently make inferences about the comparative impact of different CFL service delivery models and their main components using routinely available data.

For the qualitative component (addressing specific objective 1), we conducted both rapid and in-depth site assessments at a purposive sample of 15 of our randomly selected study sites to ensure we captured a mix of facility catchment areas representative of the various geographic, demographic, and PMTCT programmatic contexts offering CFL models and SOC in Malawi. Rapid site assessments encompassed: 1) a structured CFL model survey looking at CFL model and health system inputs, resourcing, and operations; and 2) structured observations of clinic visits and of client interactions with expert clients, mentor mothers, CHWs, health surveillance assistants (HSAs), and other MOH healthcare workers (HCWs) in the models of interest. In-depth site assessments included CFL model surveys and structured observations as done with rapid assessments, but also incorporated: 3) focus group discussions (FGDs) with CFL providers and MOH HCWs; and 4) in-depth interviews (IDIs) with purposively selected key stakeholders, including members of District Health Management Teams (DHMT) and supervisors and managers of CFL programs. A final qualitative data collection activity for all sites was the completion of IDIs with 43 pregnant and breastfeeding women living with HIV sampled purposively from nested cohort participants to reflect a diversity of experiences with CFL models in study districts.

KEY FINDINGS

1. All CFL models incorporated: 1) long-term relationships and trust building that served as a platform for HIV education and behavior change communication to help engage and retain clients in HIV care and treatment; 2) counseling, psychosocial support, and facilitated linkage and navigation activities; and 3) a mix of facility-based and community-based activities. However, notably, expert clients and mentor mothers were explicitly recruited from among

people living with HIV and were identified as having a distinctive ability to connect with, and act as role models for, vulnerable clients, as opposed to CHWs who were not required to be living with HIV to join this cadre.

2. Across sampled study facilities, we noted widespread coverage of mentor mother, CHW, and expert client models in Malawi's national PMTCT program, collectively reaching an estimated 95 percent of MIPs.
3. In Malawi, the "traditional" SOC in which PMTCT services are exclusively facility-based and delivered by professional HCWs only (without involvement of lay health worker/CFL providers) was infrequently encountered at study sites. In its place, a new "enhanced" SOC seems to be emerging in which volunteer expert clients provide basic community outreach and peer support services to PMTCT clients. Expert clients often do so after receiving limited training and supervision from the MOH and with limited external resourcing from partner non-governmental organizations. Because of the small numbers of MIPs reporting no receipt of CFL model services, and the changing CFL model landscape in Malawi, quantitative results in this study focus on expert clients as the main comparator group reflecting an emerging and enhanced SOC.
4. Each CFL model had slight variations in major activities, staffing structures, and approaches to CFL provider remunerations: 1) The CHW model had the lowest overall client to CFL provider ratio for defaulter tracing and follow-up activities at approximately four clients per CHW, on average, and expert clients had the highest ratio at about 10 clients per expert client; 2) Expert clients had the most frequent routine contacts with MIPs at about four per quarter, with mentor mothers having the fewest at approximately three per quarter, on average; 3) The proportion of CFL providers who were formally employed in their roles varied by model, with all CHWs and mentor mothers considered full-time employees of their respective organizations and only 50 percent of expert clients considered employees of their affiliated organizations; however, almost all CFL model providers received some form of monthly remuneration for their activities. Overall, CFL models were more similar in these dimensions than they were different.
5. All stakeholders recommended scale-up of CFL models. However, MOH officials and CFL managers' recommendations were tempered with concerns and words of caution, noting resourcing challenges (particularly for supervision) and a need for careful workforce planning to ensure structural supports are in place and adequate for CFL model scale up.
6. Women receiving the CHW model were 1.13 (95% CI: 1.01, 1.26; p=0.04) times as likely to start ART during the six months after HIV diagnosis as those exposed to the expert client model.
7. Over the first two years after HIV diagnosis, the proportion of days pregnant and breastfeeding women living with HIV spent retained in care, on ART, and virally suppressed was 53.7 percent for the expert client only group, 68.1 percent for the CHWs only group, 58.7 percent for the mentor mothers only group, and 64.2 percent for women who received more than one model. Compared to women receiving the expert client model, women supported by CHWs spent significantly more days—14.3 percent (95% CI: 2.6%, 26.1%; p=0.02) more days in fact—in care, on ART, and virally suppressed.
8. Mothers living with HIV in CFL models spent more time in care, on ART, and virologically suppressed when: 1) CFL providers were individually assigned 30 or fewer MIPs to follow (8%;

95% CI: 3.7, 12.8); and 2) CFL providers made more frequent routine home visits to clients (i.e., more than 2 times per quarter) (5%; 95% CI: -9.1, 18.7).

9. Infants receiving the CHW and mentor mother models were 1.15 (95% CI: 0.80, 1.67) and 0.84 (95% CI: 0.50, 1.42) times as likely, respectively, to experience a composite poor outcome (i.e., encompassing documented positive HIV test result, lost to follow-up, or death) by one year of age than those supported by expert clients, although this result was not statistically significant.
10. While we could not reliably determine the final maternal-to-child transmission (MTCT) risk for all MIPs because of missing infant medical record data, we could make limited inferences based on early infant diagnosis (EID) testing data from the nested cohort. For this sub-group, we estimated the prevalence and prevalence ratio (PR) of vertical transmission at 18 months by CFL model as follows: expert client model (2.6%; PR: n/a [referent]); CHW model (3.1%; PR: 1.22, 95% CI: 0.45, 3.11); mentor mother model (0.98%; PR: 0.43, 95% CI: 0.22, 3.17); and ≥2 models (6.3%; PR: 2.43, 95% CI: 0.00, 22.39).

CONCLUSION AND RECOMMENDATIONS

1. All CFL models contributed to strengthening general and PMTCT-focused HIV service delivery for MIPs, and had reached approximately 95 percent of MIPs at the sampled sites.
2. We observed important differences in maternal and infant health outcomes by CFL model, with generally superior maternal outcomes seen in the CHW model and a possible trend toward better infant outcomes in the mentor mother model. Compared to women supported by expert clients, women receiving the CHW model were more likely to start ART during the first six months after HIV diagnosis and to spend more time in an optimal state of being retained on ART and virally suppressed. Compared to infants receiving the expert client model, infants who received the mentor mother model were less likely to experience a poor outcome.
3. Data from the nested cohort suggest that infants exposed to HIV who received any CFL model had lower prevalence of vertical transmission at 18 months than those who did not receive a CFL model, with this effect most pronounced for infants who received the mentor mother model.
4. Key components shared in common across CFL models such as the frequency of contact with MIPs and staffing ratios for CFL providers may explain, in part, the positive effects we observed. These essential components should be the focus of quality improvement efforts such that CFL models ensure their providers have a smaller caseload of clients and make more frequent and meaningful contacts with them.
5. Opportunities exist to develop an operational framework around an essential minimum package of CFL model services that can be delivered by governments and implementing partners. Such operational guidance can also provide important standards for the following key dimensions of CFL models: CFL provider employment and levels of remuneration; CFL provider supervisory structures and training requirements; maximum client to CFL provider staffing ratios; recommended frequency, timing, and location of client contacts; and reporting/accountability lines within the formal health system.

6. Further research is needed to describe CFL model cost-effectiveness, characterize the sustainability and maintenance of CFL models, and identify strategies for optimal integration and accountability of CFL models within public health systems in Malawi and elsewhere across SSA.

INTRODUCTION

Universal test and treat (UTT) for pregnant and breastfeeding women (PBFW), first introduced as the "Option B+" strategy in Malawi, has saved countless maternal lives and averted thousands of pediatric HIV infections throughout sub-Saharan Africa (SSA) (Schouten et al. 2011; UNAIDS 2016). In the first year of implementation in Malawi, Option B+ increased maternal antiretroviral therapy (ART) uptake by over 700 percent (Chimbwandira et al. 2013; Tenthani et al. 2014). However, despite impressive maternal and child health gains generated by the UTT strategy in Malawi, client attrition from the prevention of the mother-to-child transmission of HIV (PMTCT) care continuum threatens recent progress. As many as 15 percent of HIV-positive pregnant women do not start ART (Tenthani et al. 2014), and another 26 percent become lost to follow-up within 12 months of treatment initiation (Malawi Ministry of Health [MOH] 2018a). Similarly, high loss to follow-up is seen among infants exposed to HIV (HEIs) and young children, with 14 percent and 24 percent out of care by 12 and 24 months of age, respectively (MOH 2018a). Such mother-infant pair (MIP) drop-out from the PMTCT continuum has deleterious "downstream" effects, as failure to deliver quality PMTCT services—including HIV diagnosis, treatment, and care for mother and infant—leads to higher vertical transmission rates and worse clinical outcomes for HIV-positive mothers and HEIs alike (Barker, Mphatse, and Rollins 2011). Taken together, the effects of client loss from the PMTCT continuum may undermine Malawi's progress toward UNAIDS-endorsed 95-95-95 targets (Government of Malawi [GoM] 2015).

Interrupting the PMTCT care continuum at multiple points are a variety of psychosocial, health system, and structural barriers. These barriers encompass lack of social support (Ware et al. 2009), fragmented social networks (Merten et al. 2010), gender inequality (Falnes et al. 2011), infrequent male partner involvement (Cataldo et al. 2017), internalized and enacted HIV stigma (Merten et al. 2010; Cataldo et al. 2017; O'Gorman, Nyirenda and Theobald 2010), high travel and opportunity costs for accessing facility-based HIV services (Posse et al. 2008), and limited counseling to facilitate acceptance of a new HIV diagnosis (Cataldo et al. 2017), among other barriers (Busza et al. 2012).

To mitigate these barriers and improve MIP care retention in Malawi, several models have emerged to engage MIPs and strengthen community-facility linkage (CFL), a concept defined as any "formalized connection between a health facility and the communities it serves to support improved health outcomes" (UNICEF 2015). Similar to other SSA settings, three models have been widely implemented to complement the National PMTCT Program and enhance the historical standard of care (SOC) in Malawi, which has traditionally involved a cadre of Ministry of Health (MOH) professional health workers, known as health surveillance assistants (HSAs), moving between clinics and decentralized "health posts" to enact a broad array of public health activities, including supporting PMTCT clients through health talks and tracing of those who have disengaged from care.

In contrast, the three most common CFL models in Malawi—1) mentor mothers, 2) expert clients; and 3) community health workers (CHWs) (Keehn and Karfakis 2014)—mostly or exclusively have a PMTCT focus and offer intensive psychosocial support to PMTCT clients. Mentor mothers

and expert clients are types of peer health workers—women and men living with HIV who offer longitudinal health education and psychosocial support, often via peer group meetings, to PMTCT clients (Wouters et al. 2012). CHWs are community-based health workers who provide clients with psychosocial support, promote medication and appointment attendance, accompany clients to health facilities for clinic visits, and support the services provided by other, often facility-based, health workers (Wouters et al. 2012). To varying degrees, all three models are thought to mobilize their respective CFL "provider"—i.e., the mentor mother, expert clients, or CHW—to trace PBFW living with HIV and HEIs who fall out of care, and encourage these women and infants to return to the clinic by phone contact or by targeted home visits in the community.

While data regarding the impact of these cadres are still emerging, programs involving lay health workers have demonstrated early promise for improving maternal HIV prevention knowledge and uptake of such PMTCT services as HIV testing and counseling, ART, and early infant HIV diagnosis (Marcos, Phelps, and Bachman 2012). For instance, the Baylor Tingathe CHW program has catalyzed improvements in ART uptake (uptake of other ARV prophylactic regimens prior to Option B+ introduction), facility-based delivery, infant PMTCT prophylaxis, and early infant diagnosis (EID) testing (Kim et al. 2012). Similarly, the Partners In Health CHWs serve as health educators; accompany patients with HIV, TB, and other maladies to the health facilities; and strengthen linkages for patients to the formal health system, including for PMTCT services (Admon et al. 2013). In Uganda, the mentor mother model improved 12-month ART retention for HIV-positive m2m-supported facilities compared to clinics without m2m services (91% vs. 64%, respectively) (Zikusooka et al. 2015). In South Africa, the presence of mentor mothers yielded favorable results on process indicators for HIV status disclosure, clinic attendance, and safe breastfeeding practices (Keehn and Karfakis 2014). While the expert clients are a newer cadre of CFL providers, they undertake tasks ranging from providing psychosocial support and leading community-based support groups (Herce et al. 2015) to offering facility-based counseling and vital sign measurement (Tenthani et al. 2014) and tracing HIV-infected women who disengage from care in their communities.

Overall, PMTCT programs involving CHWs, mentor mothers, and expert clients each may take different approaches to engage MIPs, link facilities and communities, and reach populations of women who may not otherwise seek PMTCT services (Marcos, Phelps, and Bachman 2012). Yet despite their promise, limited evidence rigorously describes these models, the unique and shared characteristics of each model, and the impact that they and their components have on important joint PMTCT outcomes for mothers and their infants under routine program conditions in SSA. Moreover, a clear understanding of each model's major activities and defining features, including levels of CFL provider remuneration, frequency of client contacts, supervisory structures and training, provider-to-client ratios, and relationship with clients and the formal health system, is similarly lacking (Marcos, Phelps, and Bachman 2012). Finally, how and to what extent these components, both individually and collectively as part of CFL models, impact MIP care retention and joint health outcomes has not been well characterized, particularly in the era of test and start, and against UNAIDS established 95-95-95 benchmarks. Therefore, to bridge these knowledge gaps, identify the essential elements of CFL models, and, ultimately, improve combined outcomes for HIV-infected pregnant women and their infants in an integrated PMTCT continuum, rigorous impact evaluation and characterization of CFL models is urgently needed (Marcos, Phelps, and Bachman 2012; McNairy et al. 2015).

In the USAID-funded Project SOAR "Maternal-Infant Retention Study" reported here, we have attempted to address these evidence gaps by rigorously characterizing these community-facility linkage models and comparing their impact against each other and the "traditional" SOC according to routinely collected health outcomes for MIPs, including maternal retention in care and viral suppression, and infant HIV-free survival.

METHODOLOGY

OBJECTIVES

Our research objectives were to:

1. Establish a clear typology for CFL models by describing the main components of, and key stakeholder experiences of and perspectives with, three common approaches in Malawi.
2. Describe MIP health outcomes in three CFL models, and compare outcomes across models and versus the SOC using an epidemiologic sampling strategy.
    a. Examine associations between individual components of CFL models and MIP health outcomes, controlling for confounding.

STUDY SETTING & DESIGN

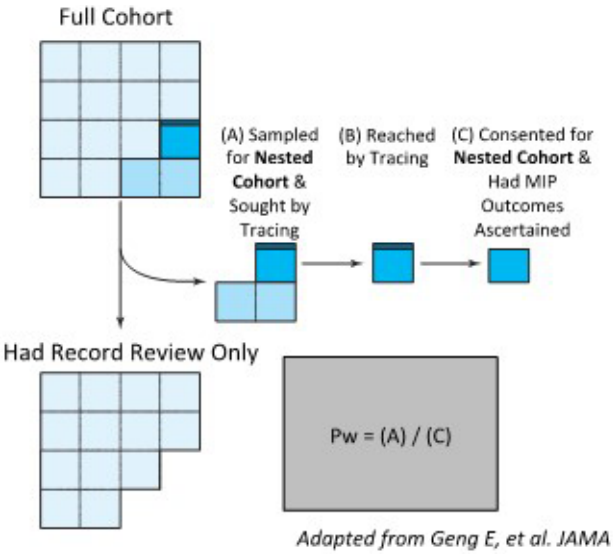
The study setting included five districts representative of Malawi, with a diversity of partner- and government-supported PMTCT programming. The five districts, encompassing Lilongwe, Mzimba North, Mzimba South, Salima, and Zomba were purposively selected to: reflect the breadth of Malawi's demography; include diverse urban, peri-urban, and rural catchment areas; and capture the major CFL models of interest with as little "contamination" of multiple CFL models operating in the same district as possible. Within each district we used electronic MOH integrated HIV data to select 50–100 percent of all "high volume" sites/catchment areas—defined as ≥30 PBFW newly diagnosed with HIV infection in the catchment area within the last year[1]—for field-based data collection. In practice, this resulted in us visiting all eligible high-volume sites in 4 of the 5 study districts (i.e., 22 total) and a 50 percent random sample of eligible sites (i.e., 8 of 16) in the last study district due to operational constraints. We confirmed the presence of CFL models of interest or SOC active in each of the 30 selected facility catchment areas during the period of interest through a programmatic mapping exercise conducted with CFL program managers and MOH District Health Offices (DHOs). During this exercise and prior to study data collection, we realized that the "traditional" SOC in which no lay or peer CFL cadres operated at a site were no longer in existence by the time of study implementation. After conferring with the Study Advisory Committee, expert clients were felt to represent an "enhanced" SOC in the current national PMTCT/ART program in Malawi and were used as the referent group for between model analyses (see Data Analysis below).

At all sampled facility catchment sites within each district, we aimed to rigorously define and compare three widely adopted models for CFL with each other and the SOC using a mixed methods approach involving both quantitative and qualitative data collection. For the quantitative

[1]Calculated based on the quarterly data for new PMTCT enrollees at ANC and maternity between July 2016 and June 2017. This data is published on the Malawi MOH website.

component, we used an efficient sampling-based cohort design (**Figure 1**). First, we constructed a retrospective cohort of all HIV-infected women who entered the national PMTCT program and received CFL services or the SOC in our 30 randomly selected facility catchment areas between 1 July 2016 and 30 June 2017. Next, we selected a random sample of women from our full cohort to undergo a field survey involving administration of a study questionnaire and measurement of biomarkers to create a "nested cohort."

Figure 1 Sampling full cohort to develop nested cohort



Adapted from Geng E, et al. JAMA 2008.

For the qualitative component, we conducted both rapid and in-depth site assessments (**Appendix Table 2**) at a purposive sample of 15 of our study sites to better understand the CFL models, their associated activities, and the effects in facilities and communities from a health system perspective. Rapid site assessments included: 1) a structured CFL model survey; and 2) structured observations of clinic visits and of client interactions with expert clients, mentor mothers, CHWs, HSAs, and other MOH healthcare workers. In-depth site assessments involved CFL model surveys and structured observations (1 & 2) as well as: 3) focus group discussions with CFL providers and MOH HCWs; and 4) in-depth interviews with purposively selected key stakeholders, including DHMT members and supervisors/managers of CFL programs.

DATA COLLECTION METHODS

At each of the 30 study sites, we began data collection by reviewing existing MOH and CFL program data, and constructing a full cohort including all women who met the following eligibility criteria:

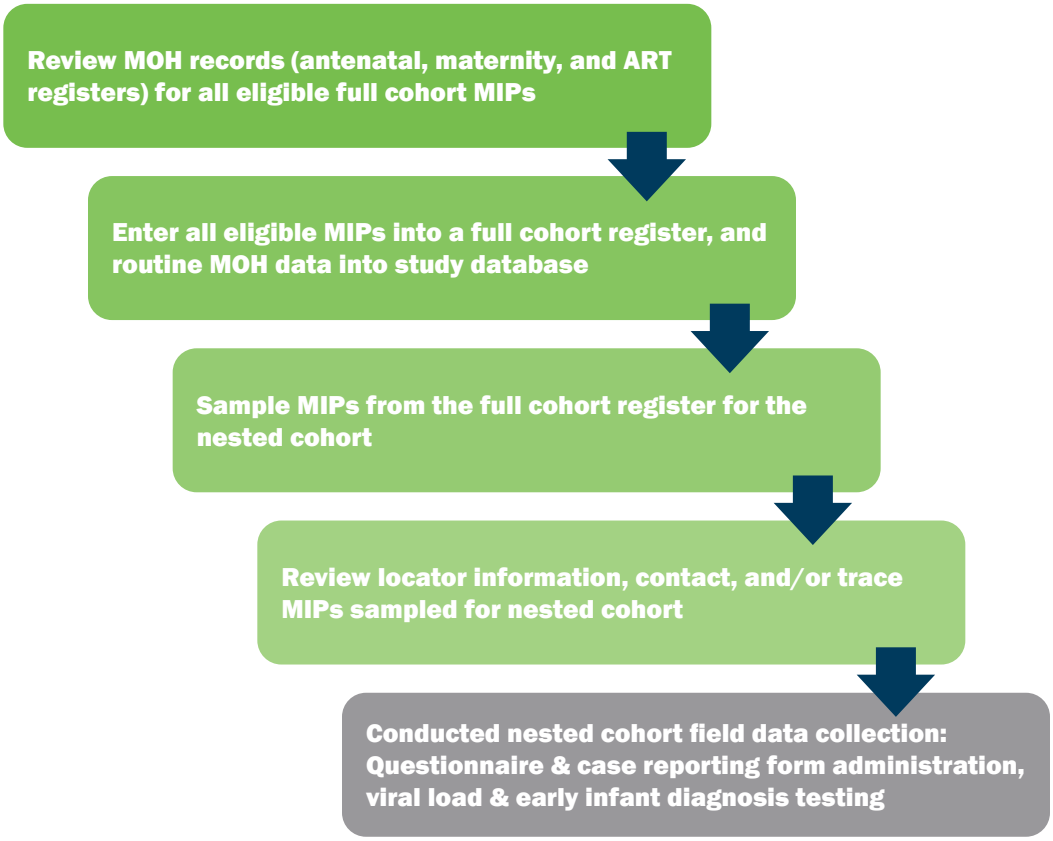
1. Newly diagnosed or had documented evidence of HIV infection between 1 July 2016 and 30 June 2017.
2. Documented referral to or enrollment in Malawi's PMTCT/ART program.
3. Pregnant (at any gestational age) or breastfeeding at the time of HIV diagnosis/positive HIV status identification.
4. ≥16 years of age at the time of PMTCT referral/enrollment.
5. Received an antenatal, maternity, or PMTCT service at a facility catchment area served by a CFL model of interest or SOC.

In the first stage of data collection, we gathered individual-level MOH data on each woman and her infant from PMTCT enrollment through the child's second birthday (**Figure 2**). Specifically, we focused data collection on: HIV testing history; 6-, 12-, and 24-month post-ART initiation maternal

program status (e.g., alive in care, transferred out, stopped ART, died, and lost to follow-up); 6- and 24-month maternal viral load (timing per national guidelines); exposed-infant first HIV-1 DNA PCR result (from 6 weeks of age per national guidelines); 12- and 24-month HEI program status (e.g., alive in care, transferred out, stopped ART, died, and lost to follow-up); and 12- and 24-month HEI HIV serostatus (timing of rapid testing per national guidelines). We entered all available full cohort data abstracted from routine paper and electronic MOH records—including the Baobob[2] electronic medical record, adult and pediatric ART cards, HIE cards, ART registers, HIV care clinic (HCC) registers (for HEIs), maternity registers, and HIV viral load and DNA PCR testing registers—into a secure Access database (Redmond, Washington, USA).

In the second stage of data collection (**Figure 2**), all women who met eligibility criteria for the full cohort were eligible for sampling and inclusion in the nested cohort, regardless of their ART status in the national program (i.e., regardless of whether they were known to be active and in care, had never established care, had "defaulted" or were categorized as lost to follow-up to the national PMTCT program). From the full cohort data (first stage), we sampled MIPs (**Appendix Table 1**) at each study site to obtain outcomes on a nested cohort of representative women and their infants (i.e., MIPs). For MIPs that were sampled and we were able to reach (through routine clinic appointments, community outreach, in-person tracing, or telephone tracing) and enroll into

Figure 2 Overview of steps in developing full and nested cohorts



[2]The Baobob electronic medical record is a national, CDC/PEPFAR-funded electronic system that captures individual-level HIV program, clinical, pharmacy, and laboratory data for patients enrolled in Malawi's National HIV Program.

the nested cohort, we administrated a field survey. The field survey involved collecting real-time data using a detailed tablet-based questionnaire about their experiences with CFL models and services, and conducting VL testing (for mothers) and HIV testing (DNA PCR testing for infants ≤12 months and rapid testing for young children >12 months) on their child of interest for the study. We attempted to enroll at least 30 participants per site (**Appendix Table 1**).

For the qualitative data component, in-depth and rapid site assessment sites (**Appendix Table 2**) were purposively selected to ensure a demographic mix of clinics (i.e., in all regions of Malawi—Northern, Central, and Southern), a variety of CFL models, including the SOC, and an assortment of facility types (i.e., district hospital, community hospital, and health center—rural or urban). At all sites, we first completed a pre-coded CFL Model Survey using key informants, who were CFL model site supervisors (or similar) or MOH facility/clinic department in-charges (or designees), and were generally familiar with HIV, PMTCT, and/or health services available in the facility catchment area. Next, we completed structured observations, which involved directly observing encounters between MIPs and HCWs, as well as between MIPs and CFL providers, and generally observing the flow and dynamics of service delivery activities in facilities and the surrounding communities (**Appendix Table 3**). We then transcribed the observations into research memos.

At in-depth site assessments only, we then proceeded to *also* conduct FGDs with: 1) MOH professional healthcare workers (e.g., clinical officers and nurses); 2) MOH lay healthcare workers (e.g., HSAs and clinic attendants); and 3) CFL providers (**Appendix Table 3**). We recruited FGD participants based on cadre and availability, as invitations were open to all relevant professional and lay staff in and around the facility, and FGDs were capped at a maximum of eight participants. We also interviewed purposively selected MIPs from the nested cohort to further explore maternal perceptions, experiences, and satisfaction with CFL models and services, including with their key components, and how these services have affected their longitudinal engagement with, and retention in, the national ART/PMTCT program. Thirdly, we conducted managerial IDIs with DHMT members (or designee), CFL site-level supervisors (or equivalent), and district-, regional-, or national-level CFL program managers (or similar). All FGDs and IDIs followed a semi-structured question guide. We trained FGD and IDI moderators on FGD and IDI procedures, and they recorded each interview with audio recorders for translation and transcription following the FGDs and IDIs.

ETHICAL REVIEW

The Malawi National Health Sciences Research Committee (UNCPM #21708), the University of North Carolina at Chapel Hill Institutional Review Board (#17-1114), Brigham & Women's Hospital (Reliance Agreement #17-1114), James Cook University (HREC #1812), and all associated regulatory bodies reviewed and approved the study protocol, all consent forms, and all data collection tools, CRFs, and guides. All study procedures were conducted in strict compliance with the United States and Malawian ethical standards regarding research on human participants and strictly followed international guidelines for Human Subjects Protection and Good Clinical Practice. All nested cohort participants and in-depth interview participants provided written informed consent. All focus group discussion, structured observation, and CFL model survey respondents provided verbal informed consent. For illiterate participants, researchers engaged an impartial third-party witness to advocate for the participant.

DATA ANALYSIS

Part 1—Qualitative

We used thematic analysis and combined an inductive and deductive approach. To identify major and minor themes that explain those patterns, we followed the following process: a) familiarization through careful reading of transcripts and research memos, noting emergent themes; b) performing open coding in which codes are created based on identified themes, and codes are assigned to specific sections of transcripts, with double-coding conducted on a sample of data to promote inter-coder reliability; c) developing a codebook; d) performing data reduction in which inventory was taken in relation to each given code, capturing the variation or richness of each theme and noting differences between individual or among subgroups; e) data display using matrices and tables; and f) interpretation of data by searching for relationships among themes or concepts identified and developing diagrams in order to map out relationships in the data. Two investigators reviewed all qualitative data, independently identified emergent themes, and conferred to agree upon final coding and findings. All analyses were done in NVivo (QSR International, Australia, Version 12).

Part 2—Quantitative

This analysis involved descriptive statistics and comparison of key maternal and infant outcomes by CFL model exposure as reported by the health facility. We calculated descriptive statistics for full and nested demographic characteristics, CFL model exposure, and routine record outcomes. To determine CFL model exposure for MIPs in the full cohort, we used responses from a MIP questionnaire examining CFL model services received by nested cohort participants. For full cohort MIPs enrolled into the nested cohort, we used the CFL model they reported receiving during the period of interest to indicate their CFL model exposure. For women not enrolled into the nested cohort, we imputed CFL model exposure based on the CFL model most frequently cited by nested cohort participants as providing services at the study site during the period of interest. We defined our primary outcome, maternal retention in care, as the proportion of mothers alive and in care at 12 and 24 months post-ART initiation among all eligible women at the start of the cohort. We report crude HEI mortality at 12 and 24 months as part of our survival analysis. We looked for differences in time to ART initiation across CFL models using the Aalen-Johansen estimator to account for the competing event of death. We compared the effects of CFL models on outcomes of interest by calculating cumulative incidence of DNA PCR testing (infants only), ART initiation (women only), and loss to follow-up in the ART program (mothers and infants). We produced survival curves showing the proportion of infants alive, in care, and not diagnosed with HIV by CFL model. For all between-model comparisons, we used “expert clients” as the referent group owing to the fact that the “traditional” SOC in which no lay or peer cadres operated at a site were essentially non-existent by the time of study implementation and this was the most commonly encountered model at study sites, particularly at sites with limited to no NGO support. After conferring with the Study Advisory Committee, expert clients were felt to represent an “enhanced SOC” in the current national PMTCT/ART program in Malawi.

We estimated the ultimate indicator of CFL model performance on maternal health by creating a novel “longitudinal maternal suppression metric.” This metric summarized the percent of days

over the two years following HIV diagnosis that women spent in HIV care, on ART, and virologically suppressed, and was then compared across CFL models. The percent of time suppressed was estimated by averaging the product of the probability of being retained on treatment (i.e., after starting ART and prior to, or without, becoming lost to follow-up) at any given timepoint and the probability of being virally suppressed, given one was on ART. The probability of being on treatment at time *t* was calculated as the cumulative incidence of ART initiation minus the cumulative incidence of lost to follow-up. The probability of viral suppression given one was on ART was estimated at each timepoint using a two-stage procedure that made use of both the VL data abstracted from the routine medical record *and* the VL measurements obtained by the study team of the nested cohort. First, we estimated the probability of having a study-obtained VL at each timepoint, given that a patient did not have a routine VL documented in the medical record. Then, we assigned routinely collected viral loads a weight of one and study-obtained viral loads a weight defined by the inverse probability that a patient had a study-obtained VL at that timepoint. In the weighted VL data, we modeled the probability of viral suppression at each timepoint using a flexible logistic regression model. In this model, we conservatively assumed that the first 30 days on ART were all unsuppressed. After the first 30 days, we allowed the probability of suppression to vary flexibly over time by modeling time since HIV diagnosis using penalized b-splines.

All of the comparisons accounted for confounding by health facility level using inverse probability weighting, which helps to standardize the distribution of the exposure within levels of a potential confounder (**Appendix Figure 1**). When applied to a model of the association between the exposure and an outcome of interest, these weights create a "pseudo-population" of individuals in which the exposure is unassociated with the potential confounder. The exposure distribution within each level of the potential confounder is the same as the overall exposure distribution in the study population. In our inverse probability weighting, the weights are stabilized by the overall exposure probability so that the number of individuals in each level of the potential confounder remains the same (**Appendix Figure 1**).

KEY QUALITATIVE FINDINGS

MAJOR CHARACTERISTICS OF THREE CFL MODELS

In this section, we characterize the main features of the three major CFL models examined in the study (**Table 1** and **Table 2**).

CHWs—A snap shot

CHWs are men or women who may or may not be HIV-positive. Typically, CHWs have a higher level of education (2–4 years of secondary school + qualifying exams) compared to expert clients or mentor mothers. CHWs are required to live within the communities, so that they are "embedded" and accessible community members. CHWs are formal paid employees, and, in this study, were trained to focus on HIV programming and supervised by the Baylor Tingathe CHW program (**Table 1**).

CHWs work in both clinic and community settings (**Table 2**). In the community, CHWs are mobile, visiting clients in their homes or other settings, and they do not have any restrictions on the distances traveled.

Expert clients—A snap shot

Expert clients are men or women who are living with HIV, are (at least nominally) virally suppressed, and are open to others about their HIV status. They must be confident and willing to discuss their own experiences with HIV and ART in both support group and one-on-one settings. There is no age requirement. Expert clients tend to be volunteers who receive a monthly stipend, and could be affiliated with either the MOH or an NGO. They usually receive an initial training of about two weeks. Subsequent supervision and mentorship were highly variable depending on the availability of NGO support.

Expert clients work in both clinic and community settings (**Table 2**). While expert clients are technically supposed to be based in both the ART and ANC departments in clinics, interview and observational data suggest that for various reasons (space, staff dynamics, and relative time demand), expert clients are usually based in ART departments and visit ANC on an as needed basis. Expert clients can visit clients in their homes or other settings in the community.

Mentor mothers—A snap shot

Mentor mothers are women living with HIV who have been through the PMTCT cascade themselves. In order to be a mentor mother, the women need to have disclosed their HIV status and be open to talking about living with HIV and living positively with others. Mentor mothers are formally interviewed and considered mothers2mothers (m2m) paid employees. They undergo a two-week intensive training workshop covering the MOH HIV guidelines and all MOH tools and m2m tools.

Table 1 CFL overview by model

	Parent NGOs	Eligibility to be a CFL provider*	Community involvement	Sex	HIV status & disclosure	PMTCT cascade experience	Recruitment process	Training provided**	Paid or volunteer***	Job enablers
CHWs	Baylor Tingathe Program	All required to have 2–4 years of secondary school + qualifying exams	Required to live within the communities	Male + female	No HIV status requirement	N/A	Advert + interview process	✓	100% are considered employees, a handful of CHWs are not paid but receive other in kind benefits; average monthly salary is ~120 USD	Some but not all receive a uniform, bicycle, and airtime
Expert clients	mothers2mothers; Lighthouse; Partners in Hope—Project Equip; EGPAF; some volunteers through MOH	Some said no education requirement; others said 2 years of secondary school + exam is required	No requirement, but usually from the areas around the facility	Male + female	All are HIV-positive & are open to discussing their status	Not required	Differs by organization—some recruit from within facilities or communities	✓	50% are considered employees & are paid; average monthly salary is ~60 USD	Some but not all receive a uniform, bicycle, food pack, and airtime
Mentor mothers	mothers2mothers	All required to have 2–4 years of secondary school + exams	No requirement, but usually from the areas around the facility	female	All are HIV-positive & have disclosed to at least one person	Completed PMTCT cascade	Advert + interview process	✓	All are paid employees of m2m; average monthly salary is ~50 USD	Uniform, airtime, food
No CFL model (i.e., standard of care/health surveillance assistants)	MOH	All required to have 4 years of secondary school + exam	Work and live within the same catchment areas	Male + female	No HIV status requirement	N/A	Centrally recruited government paid cadre (HSAs)	✓	All are considered paid employees	Uniform and bicycle

*In Malawi, the Junior Certificate of Education (JCE) is the examination taken midway through secondary school (after 2 years of secondary school); and the Malawi School Certificate of Education (MSCE) is the final examination at secondary school level in Malawi (after 4 years of secondary school).

**All models reported receiving formal introductory training before starting CFL activities (n=23); and all receive training on the national HIV guidelines (n=23).

***Employee was defined as receiving a salary at regular intervals; salaries are calculated based on the averages reported in Malawi Kwacha.

Table 2 CFL activities by model*

	Focus population	Work setting	Mobility + distance traveled	Routine home visits	Routine home visit frequency**	Back to care tracing	Back to care tracer ratio***	Provide HTS services	Conduct EID testing	Disclosure counseling****
CHWs	All people living with HIV, with a focus on women and children	Health facility + community	No restrictions on distances traveled; some have bicycles to improve their reach & efficiency	✓	3.4 per quarter	✓	1 CHW per 4 clients	✓–	✓	✓
Expert clients	All people living with HIV, with a focus on women and children	Health facility + community	No restrictions on distances traveled	✓–	4.7 per quarter	✓–	1 expert client per 10 clients	✓–	✖	✓–
Mentor mothers	Pregnant mothers living with HIV, breastfeeding mothers living with HIV, and HEIs, and children living with HIV	Health facility + community However, more of the focus is in the facility; some sites have community-based mentor mothers	Facility-based mentor mothers are restricted to a 5 kilometer radius from the facility	✓	3 per quarter	✓	1 mentor mother per 5 clients	✓–	✖	✓
Standard of care	All people within their catchment areas	Health facility + community HSAs often work out of community-based health posts	No restrictions on distances traveled	✓	4 per quarter	✓	1 HSA per 4 clients	✓	✓	✓

*On this table, a "✓–" refers to <100% reporting on the CFL model survey, while "✓" refers to 100%; and "✖" refers to 0% reporting on the survey.

**Reported as the average number of home visits a CFL provider offers a client each quarter.

***Calculated as average number of clients one CFL provider traces for back to care services each month.

****General disclosure support, as data on the specifics was not collected.

Mentor mothers carried out activities in both facilities and communities and may carry a distinct "facility" or "community" designation depending on where they primarily focus activities (**Table 2**). In facilities, mentor mothers tend to be based and have an office within the antenatal department, which is a distinguishing feature compared to CHWs and expert clients. Facility-based mentor mothers interact with all women coming for their first antenatal visit regardless of their HIV test result, as they provide pre- and post-testing support to all women. While facility-based mentor mothers conduct home visits within a five-kilometer radius, some sites also have community-based mentor mothers, who work predominately in the communities surrounding the health facilities. The two types of mentor mothers work together, have linkage registers, and have monthly meetings to ensure clients from the community are linked to the facility and vice versa.

SUMMARY—Major characteristics of three CFL models

- All models incorporated longitudinal, task-shifted communication built on a trusting relationship as a key strategy to help engage and retain clients in HIV care and treatment
- All models incorporated information and education, counseling, psychosocial support, and facility linkage and navigation activities.
- Although with differing emphasis, all models involved some combination of facility-based and community-based activities.
- Mentor mothers had an explicit focus and somewhat unique mandate for being based at the ANC and helping women navigate queues for receiving antenatal care.
- Allowing for the different financial profile of the "umbrella" NGOs, there were few meaningful distinctions in conceptual approach or strategies of the models with one exception.
- Expert clients and mentor mothers were explicitly recruited from among people living with HIV, who were identified as having a distinctive ability to connect with and act as role models to vulnerable clients.

STAKEHOLDER EXPERIENCES AND PERSPECTIVES

Using a health systems heuristic (Scott, George, and Ved 2019) we consider evidence on the stakeholder experiences and perspectives first in relation to program inputs, and secondly in relation to program governance (**Appendix Figure 2**).

Program inputs

Drawing on the work of Scott et al., we consider stakeholder experiences and perspectives in relation to the following program inputs: i) recruitment and training; ii) supplies; iii) support and monitoring; iv) role clarity; and v) record keeping.

i) Recruitment and training

Recruitment processes were to a great degree contingent on the partner NGO, rather than the model itself. At one end of the spectrum, Baylor CHW targeted more highly educated individuals, while expert client recruitment focused less on formal educational attainment and more on personal resilience, suppressed viral load status, and capacity for communication as the *de facto*

counselor. Several key stakeholders noted the importance of adopting a targeted recruitment approach, even for volunteer models, since the work conducted by CFL providers at the intersection of community-clinic was high stakes.

All three CFL Models provided initial training for their CFL providers, although to different degrees (Table 1). Of the models reviewed, Baylor-CHWs (quarterly or need-dependent), mentor mothers (quarterly or bi-annually), and some expert clients (ad hoc) reported ever having received follow-up training. While some NGO-supported expert client models offered refresher trainings, others (including some NGO-supported) expert client models reported lack of follow-up training as both technically challenging and professionally demotivating, as they felt underprepared and underappreciated in their work.

> *"Organizations keep changing. The organization that we are now working under, they just told us the rules of our work and what we are supposed to be doing. We really wish that we would probably go for a refresher, so that we can add on the knowledge that we have. As you know, the country keeps changing and the things we know are still the same old.*
>
> —Zomba, Expert client

District-level officials commented that the differentiated approach to training—often influenced by NGO budgets—was problematic in efforts to harmonize and coordinate clinic-based activities with cohorts who had differing levels of competency.

ii) Supplies

Of the three models, Baylor-CHWs reported being most comprehensively resourced to carry out both their clinic and community-based tasks, including having program-specific registers and data collection tools and NGO-financed purpose-built office space at one site. Mentor mothers also generally reported being well resourced, including receiving phone credit that facilitated their tracing work, uniforms that aided their identification in the clinics, and structured diaries and registers to follow-up on their clients. Some mentor mothers noted, however, that they did not receive adequate or any support for transportation costs.

> *"Transportation, it is very far to get to the where the clients and we don't have bikes. [The Partner] has only given transportation for tracing for one month, so we exhausted that. The new office bearers told us that they did not get a hand over [regarding] transportation, so it's really a challenge. [But] they supply us with pens and registers I cannot lie.*
>
> —Zomba, Mentor mother

Expert clients reported more varied experiences. Some described receiving resources to carry out their work, but most—even those who had signed formal contracts of employment—noted that they often paid out of pocket for transport or phone credit. Some mentioned lack of uniforms, although others noted that uniforms may actually inhibit tracing in cases where clients were fearful of being publicly identified. Generally, expert clients did not report receiving the same kinds of program-specific data collection tools and registers that CHWs and mentor mothers noted.

iii) Support and monitoring

Approaches to supervision varied significantly among the three models. Baylor-CHWs received substantial on-site supervision, with a supervisor and assistant supervisor responsible for coordinating the activities and helping resolve issues of all site CHWs.

> *"We have an immediate supervisor who supervises us almost on [a] daily basis. Every morning, we have a meeting where we share responsibilities. If it is follow-ups, [we go over] who should we target and what should we do there?*
>
> —Lilongwe, Baylor-CHW

Both mentor mothers and Baylor-CHW described NGO-specific data collection tools that helped them monitor progress against set targets. Mentor mothers in Lilongwe described having a site coordinator, who assigned day-to-day tasks and provided routine monitoring and supervision. By contrast, expert clients across various sites and NGOs, reported differing levels of on-site supervision. Those under m2m and EGPAF reported receiving rotating support, typically via a rotating team that visited clinics on a roster. Expert clients not currently affiliated with an NGO, however, had no formal supervision and fell loosely under the MOH ANC or ART department in-charge at the clinic where they worked.

> *"I can say that some are more organized [and better] resourced [while others] only have a district focal person and they could rely on the Ministry of Health staff and the HSAs and the support groups [...]. So, that is the difference.*
>
> —Salima, DHO officer

iv) Role clarity

Baylor-CHW supervisors are responsible for planning and coordinating activities in an integrated manner, including helping draft monthly work plans that named and placed staff in different places according to clinic priorities. Roles were clear from the outset. Mentor mothers and expert clients recruited by NGOs described similar approaches. However, expert clients trained by an NGO but working under government supervision described less clarity in relation to their duties, as one individual noted:

> *"There is no proper procedure as to how many women we look after, or how many defaulters [...] we look [for] in the register [...] we consider where the people we have found are coming from and we check who [among us] comes from that area.*
>
> —Lilongwe, Expert client

v) CFL record keeping

All CFL providers working under NGO supervision reported data collection as part of their routine duties, although variations existed. Baylor CHWs and mentor mothers described having monthly targets and monitoring their own progress toward those targets. Expert clients more often reported collecting data that informed routine clinic DHIS reporting, including updated information about the health and "lost to care/treatment interruption" status of mothers and

infants. Baylor CHWs and mentor mothers had their own data collection tools, which presented both challenges and opportunities. In some cases, DHO officials expressed concern about lack of harmonization (and implied duplication) in data collection, as one stakeholder from Lilongwe noted below:

> *"Yeah, the challenges are there [laughs]. You know these people are being supported by different NGOs [that] have their own reporting system. So the most challenging thing is they don't have standard tools [...]. So as a District, we don't have one tool that all these people should be using, so that maybe if we are capturing the data, it should be standardized data. Yeah?*
>
> —Lilongwe, DHO officer

Conversely, others noted that NGO data could contribute to effective monitoring and to improving the District Health Office's ability to make decisions:

> *"mothers2mothers has got a comprehensive model [...] I am thinking so because I look at their monitoring and evaluation system the M & E tools that they have, they are quite comprehensive they able to capture good data. And so it can easily inform our decisions.*
>
> —Mzimba North, DHO officer

Where CFL providers helped to document client outcomes on MOH treatment cards and contributed to record keeping and filing, they were described as directly strengthening clinic functions.

SUMMARY—CFL model program inputs

Recruitment & training

- **Recruitment approaches are critical**: No matter what skills are targeted, taking the time to get the right people is important to the success of any CFL models.
- The opportunity cost of not recruiting carefully is substantial, reducing efficiency and potentially damaging already vulnerable clinic-client relationships.
- **Training is important**: Competency is critical to both the quality and "value-add" in a human resource constrained environment.
- **Follow-up training is equally important**: Though costly, where provided, the motivational and technical advantages of providing training were repeatedly highlighted.

Resourcing

- **Adequate resourcing**, including for supplies such as registers/diaries, phones, phone credit, and transportation, strengthen CFL providers' capacity and motivation to perform.
- In the absence of adequate resourcing, individual providers may (are likely to) deviate from expected/standard operating procedures.

Support and monitoring

- Supervision models ranged from non-existent to daily oversight, depending on the NGO.
- **Supervision and monitoring improved role clarity**, aided professional development capacity, and enhanced providers' motivation to perform.
- Improved supervision was also associated with stronger routine monitoring and evaluation/data collection.
- However, **CFL providers clearly demonstrated capacity to self-organize** and operate independently with minimal supervision, especially in relation to community-based activities.
- "Top-heavy" supervisory **models that encourage micro-management may not be appropriate** for community-oriented services.

Role clarity

- **Clear roles and responsibilities assist** with self-efficacy, monitoring, and ultimately improved integration.
- Government-supervised CFL providers in this study reported lack of clarity in their role, but also demonstrated substantial personal initiative, often drawing on training/experience gained in NGO supported roles.

Record keeping

- Where adequately trained, **CFL record keeping helped providers** track and monitor performance and informed program and District decision making.
- **Non-alignment of NGO indicators with MOH indicators** and the burden of data collection that new (donor-mandated) indicators imposed on MOH staff were **ongoing concerns**.

Program governance

Contemporary health systems literature increasingly acknowledges that governance of health programs needs to be understood not simply as the formal rules and enabling infrastructure, but as the network of relationships and (informal) practical norms that arise from constant interaction among policy makers, managers, service providers, and clients.

We consider stakeholder experiences and perspectives in relation to the following relationships indicative of CFL program governance: i) CFL-district relationships; ii) CFL-community relationships; iii) financing and sustainability; and iv) Scale-up.

1) CFL—district relationships

CFL managers from all three models and DHMT officials interviewed for this study described a similar process of engagement between NGO partners and the District counterparts. First, District Health Officers and sometimes District Executive Committees were approached by NGO/CFL program representatives, who were subsequently invited to sit on some form of District partner coordinating committees and, under District guidance, mutual priorities were discussed and duplication of effort avoided. As part of this arrangement, relationships between District and NGO officials were described as mostly cordial. However, some District stakeholders described concerns. First, they noted frustrations with the way NGOs often cherry picked already well performing sites or focused programs on issues that the District felt were well-served already.

> *"[Partner 1] was in twelve facilities. And these twelve facilities are amongst the top performing in the district. The challenge is that when [Partner 2] came to take over from [Partner 1]—of course the donor interest - that they were also going into the [same] twelve facilities. So the question that we were asking is: 'aren't these twelve graduating from this support?' [...] So in terms of coordination at district level, it is quite a challenge because partners come with their interest, [and] it's not easy to come to a compromise and work for a common goal.*
>
> —Mzimba North, DHO

These tensions also reflected an underlying power dynamic between District officials, whose authority and permissions were required for NGOs to operate at a given site, and NGO officials who were often better resourced than the DHO and had powerful lobbyists for their issue of interest. Reflecting on the way these power dynamics affected NGO-government relationships, and the need to improve at least perceptions of aligning with MOH priorities, one CFL program manager described their CFL provider recruitment process as such:

> *"So once they have applied, we shortlist together with the facility staff and then we conduct the interviews with mothers2mothers staff together with the MOH staff, for the sake of transparency.*
>
> —Lilongwe, CFL manager

ii) CFL—community relationships

Embeddedness of the CFL models in the community was largely achieved through the development of trusting interpersonal relationships with individual clients or small groups of clients (e.g., support groups), rather than through formal approaches to community leadership or community forums. Responsiveness to requests by community members to provide advice or counseling or referrals were described as the most common expression of that trust.

> *We have created a lot of relationships in the villages. When someone is sick, we receive information that we should go till the person is well, and we are happy because of that.*
>
> —Lilongwe, Expert client

Several expert clients and mentor mothers described occasionally liaising with Traditional Leaders to assist them in locating a specific client. However, most respondents described how they did not specifically routinely involve community leadership or community structures due to concerns about confidentiality breaches.

iii) Financing and sustainability

Although to varying degrees, almost all stakeholders interviewed across the three CFL models in this study recognized that their activities were associated with substantial set-up and maintenance costs. Most respondents identified substantial ongoing costs in the need to salary (or at least provide in-kind incentives for) CFL providers, as well as deliver a minimum level of site-supervision (**Appendix Table 4**). Other key costs included transport, whether purchase of vehicles and fuel, bicycles, or public transport reimbursements; training and refresher training; stationery and uniforms; and periodic group review and planning meetings.

Almost all high-level respondents (professional health workers, CFL managers, and district officials) expressed doubt that the government could absorb such costs given existing material and human resource constraints experienced within the health system. Yet, donor funded programs were also identified as sub-optimal. In all study sites, there were stakeholders who raised concerns about short-term project financing and CFL model sustainability. Many clearly identified the negative impact that multiple, rolling NGO programs had on provider engagement and motivation and service consistency and coherence.

> *Yeah, I think the challenge is [...] when the funding is not adequate, the project phases out and compromises the delivery of health services.*
>
> —Salima, DHO

> *Once partners are not there, sustainability becomes a challenge.*
>
> —Mzimba North, DHO

iv) Scale-up

The value placed on the CFL models by District officials, professional and lay health workers, and clients cannot be over emphasized. Recommendations to scale-up CFL models to other clinics and nationally were unequivocal, with the most common recommendation to scale-up expert clients. Perceptions of the relative versatility of expert clients were important, as were considerations of their work in the community, which many respondents felt required skills and relationships not found among existing MOH staff. Nonetheless, recommendations to scale-up were also tempered with concerns and words of caution. Many identified the manifest resourcing challenges relating to scale-up, as briefly outlined in the previous section. Others provided a more analytical perspective, reflecting on the structural and institutional challenges posed by ensuring

national or even District-wide coverage of CFL providers, and the health workforce planning implications that would go with it:

> *"Scale-up? Yes. Carefully. Yes, I would do it. But I would emphasize that you should do it carefully. If it's not done carefully I think there might be challenges.*
>
> —Zomba, DHO

> *"Mmh, but ah expert clients are a good model but [...] if you are to implement it I think you need a good analysis before you think of going out fully fledged. Because there are issues to do with how many expert clients do you need in a catchment population. I have seen mothers2mothers producing results when they are only probably two of them at a facility.*
>
> —Mzimba South, DHO

SUMMARY—CFL model program governances

CFL—district relationships

- DHO stewardship of health services is well acknowledged by NGO partners.
- However, the organizational (donor-driven) priorities of NGOs still dominate decisions about CFL implementation, including site selection and CFL provider recruitment.
- Sometimes these NGO priorities undermine DHO efforts to strengthen service quality or service coverage equitably by "cherry picking" high performing sites or staff.
- The burden of NGO coordination—including for expanded CFL coverage—is a substantial strain on already limited DHO human resource capacity.

CFL—community relationships

- Embeddedness in the community was largely achieved through the development of trusting interpersonal relationships between individual CFL providers and individual clients or small groups (e.g., support groups), rather than through formal approaches to community leadership or community forums.
- Responsiveness to requests by community members to provide advice, counseling, and referrals were described as the most common expression of that trust.

Financing and sustainability

- All three CFL models involve set-up and maintenance costs associated with training, supervision, and resources for CFL providers.
- GoM is unlikely to be able to absorb such costs given existing health system resource constraints.
- However, front-line stakeholders stressed that short-term, donor-funded programs were also sub-optimal, increasing the difficulties of program overlap and negatively impacting provider engagement and motivation and service consistency and coherence.

Scale-up

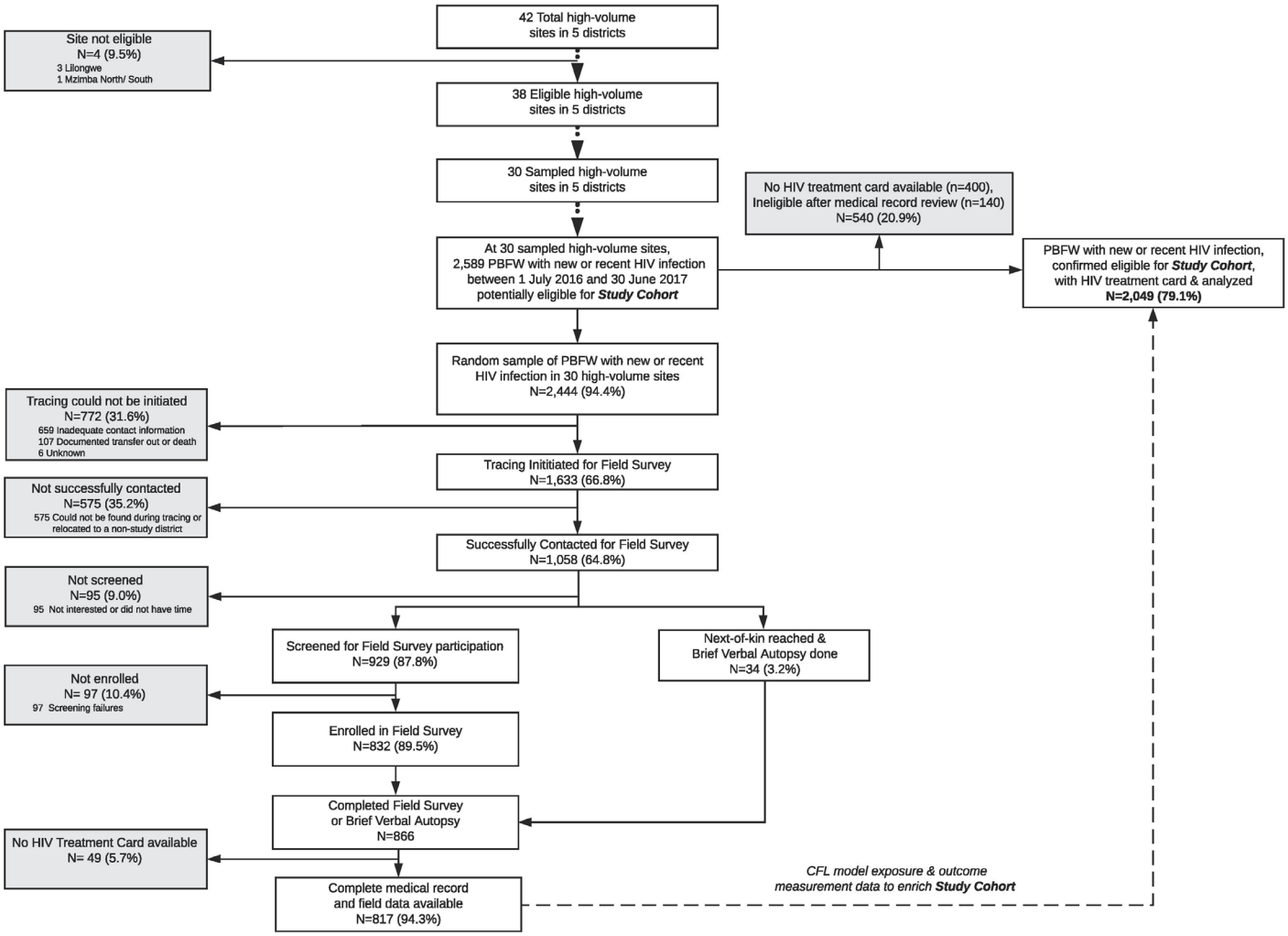
- All stakeholders recommended scale-up of CFL models, with the most common recommendation to scale up the expert client model.
- However, MOH officials and CFL managers recommendations were tempered with concerns and words of caution, noting manifest resourcing challenges (particularly for supervision) and a need for careful workforce planning to ensure structural supports are in place and adequate.

KEY QUANTITATIVE FINDINGS

PARTICIPANT FLOW

Figure 3 depicts the flow of participants from the full and the nested cohorts, including the steps of record review, participant sampling, tracing, successful contact, screening, and consent and enrollment.

Figure 3 Participant flow through the study.



CHARACTERISTICS OF THE FULL AND NESTED COHORTS

There were 2,049 women included in the full cohort with an available HIV treatment card, 866 of whom had an outcome ascertained through verbal autopsy (n=34) or enrollment into the nested

cohort (n=832) between 15 January 2018 and 31 May 2019, and 817 with a complete medical record available for analysis. The following table (**Table 2**) describes the demographic features of the full cohort and the nested cohort. Overall, most women in the full cohort were between 18 and 24 years of age, living in Lilongwe District, receiving health services from a MOH Health Centre, and enrolled as WHO Stage 1 (i.e., during pregnancy and breastfeeding). The distributions of the main demographic variables were similar between the full and nested cohorts, suggesting that our sampling strategy was effective and that women enrolled in the nested cohort were generally representative of women in the full cohort.

Table 2 Characteristics of 2,049 women enrolled in the national PMTCT program at 30 sampled facilities in Lilongwe, Mzimba North, Mzimba South, Salima, and Zomba districts in Malawi between 1 July 2016 and 30 June 2017 and characteristics of the subset of 817 women enrolled in the nested cohort.

Characteristics	Study population (i.e., Full cohort) N = 2,049		Sample of study population (i.e., Nested cohort) N = 817	
	n	%[c]	n	%
Age, years				
<18	83	5.2	33	4.5
18–24	698	38.5	265	36.0
25–29	450	24.8	182	24.7
30–34	379	21.5	173	23.5
≥35	178	10.0	83	11.3
Missing[a]	261		81	
District				
Lilongwe	767	29.8	212	26.0
Mzimba (North plus South)	400	15.5	163	20.0
Salima	353	13.7	241	29.5
Zomba	529	41.0	201	24.6
Facility type/level				
Government primary health centre	1,255	62.2	452	55.3
Government rural/community hospital	64	2.5	28	3.4
Government district hospital	274	10.6	150	18.4
Christian Health Association of Malawi (CHAM) facility	456	24.7	187	22.9
WHO Stage				
1	1,897	99.8	767	99.6
2	4	0.2	3	0.4
Missing[a]	148		47	
CFL model received[b]				
Expert clients	778	38.0	277	33.9
Community health workers	640	31.2	286	35.0
Mentor mothers	345	16.8	154	18.8
≥2 CFL models	192	9.4	51	6.2
No CFL model	94	4.6	49	6.0
Missing[a]				

[a]Missing data were not included in the denominator for calculation of percentages for characteristics of interest;

[b]Based on participant self-report, where available, and single imputation based on distribution of nested cohort participant responses for women not enrolled in the nested cohort.

[c]Percentages for age, district, facility type/level, and WHO Stage are weighted to account for variation in site sampling across districts.

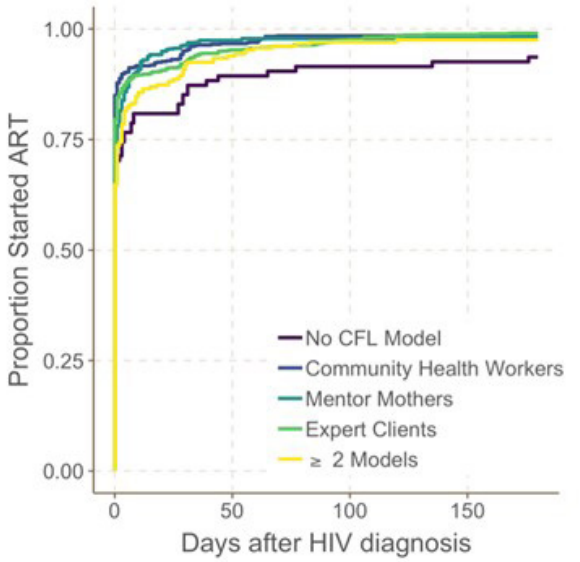
CFL, Community facility linkage; WHO, World Health Organization

Most facilities reported offering at least one CFL model, with the majority of women seeking care at a facility that reported offering a single model (86%) (Table 2). Based on data from the full cohort, an estimated 38 percent of women in the full cohort received expert clients services alone. Similarly, an estimated 31 percent of women received CHW services alone and 17 percent received mentor mother services alone. An estimated 9 percent of pregnant, breastfeeding, and/or post-partum women living with HIV received ≥2 CFL models. Participants in the nested cohort were slightly more likely to report receiving no CFL model (i.e., the traditional SOC, 6%) and less likely to report receiving services from more than one CFL model (6.2%). Relatively few participants in both the full cohort and nested cohort reported receiving no CFL model (i.e., no CHWs, mentor mothers, or expert clients).

MATERNAL OUTCOMES IN THE FULL AND NESTED COHORTS

We documented maternal outcomes in the national PMTCT/ART program according to MOH definitions of: Alive on ART, Transferred Out, Died, and Lost to Follow-up (MOH 2018b). Of women with complete MOH treatment records (i.e., ART treatment cards) in the full (n=2,049) and nested (n=817) cohorts, almost all started ART within one year of HIV diagnosis (**Table 3**). Time to ART initiation was uniformly short (**Figure 4**). Over 90 percent of women started ART within one day of HIV diagnosis, reflecting adoption of the Option B+ and "Test and Start" policies.

Figure 4 Proportion of women starting ART by CFL model over 6 months of follow-up



At 12 months, the majority of women were alive on ART. In the full cohort the proportion Alive on ART was 65 percent and in the nested cohort this proportion was 76 percent. The proportion of women lost to follow-up was higher in the full cohort (24%) compared to the nested cohort (16%). Additionally, mortality at 12 months was higher in the nested cohort (2%) compared to the full cohort (0.9%) due to the known underreporting of mortality in routine data collection systems that was addressed through the sampling strategy used to enroll the nested cohort (Holmes et al. 2018). When combining routine and study-initiated records for determining outcomes in the nested cohort, the proportion alive on ART at one year stayed essentially the same at 76 percent, but mortality increased to 3 percent.

Table 3 12-month outcomes measured in routine data among 2,049 women enrolled in PMTCT programs at 30 randomly selected facilities in Lilongwe, Mzimba North, Mzimba South, Salima, and Zomba districts in Malawi between 1 July 2016 and 30 June 2017 and followed for up to 3 years, limited to those with complete ART treatment records.

Outcome	Full cohort*		Nested cohort	
	n	%	n	%
Started ART within 12 months of HIV diagnosis	2,031	99.1	814	99.6
Routinely recorded outcomes at 12 months after HIV diagnosis				
Alive on ART	1,331	65.0	620	75.9
Lost to follow-up	491	24.0	131	16.0
Transferred out	180	8.8	37	4.5
Dead	19	0.9	17	2.1
Alive and never started ART	18	0.9	10	1.2
Alive, in care, but stopped ART	10	0.5	2	0.2
Integrating study-recorded deaths and records of ART program outcomes at 12 months after HIV diagnosis				
Alive on ART			617	75.5
Lost to follow-up			133[a]	16.3
Transferred out			31	3.8
Dead			24[b]	2.9
Alive and never started ART			10	1.2
Alive, in care, but stopped ART			2	0.2

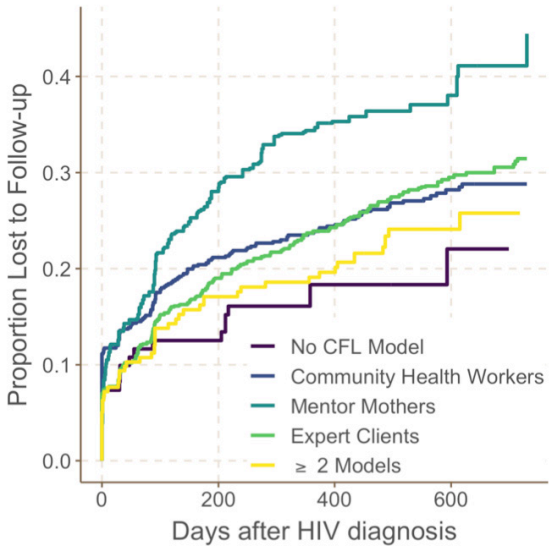
*Excludes 400 women without an ART card found

[a]Excludes people identified as lost (at 1 year after HIV dx) by routine records but reporting being in care at 1 year, and includes additional people not identified as lost through routine records but who reported that they had not had a clinic visit in the 6 months prior to the survey

[b]Includes deaths identified through tracing

Maternal loss to follow-up by 24 months after HIV diagnosis was significantly higher among women who received mentor mother services compared to other models, implying worse retention in care for this model (**Figure 5**). PBFW who received mentor mother services were 1.45 times (95% CI: 1.14, 1.84) as likely as PBFW who received the expert client model to be lost to follow-up by 24 months (p=0.003) (**Table 4**). Maternal loss to follow-up by 24 months after HIV diagnosis was lower among women who received ≥2 CFL models, implying better retention in care when mothers receive services from ≥2 models over the PMTCT cascade. Indeed, PBFW who received services from ≥2 models were 0.82 times (95% CI: 0.59, 1.14) as likely as PBFW who

Figure 5 Proportions of mothers lost to follow-up by days after HIV diagnosis and CFL model



received the expert client model to be lost to follow-up by 24 months. This association was not statistically significant (p=0.23).

Table 4 Hazard ratios, 95% CIs, and p-values comparing rate of loss to follow-up among participants receiving each model as determined by routine data among 2,049 women enrolled in PMTCT programs at 30 randomly selected facilities in Lilongwe, Mzimba North, Mzimba South, Salima, and Zomba districts in Malawi between 1 July 2016 and 30 June 2017, followed out to 3 years and limited to those with complete HIV treatment records. All results adjusted by inverse probability weighting to account for confounding by facility type/level.

Model	Adjusted Hazard Ratio	95% CI	p-value
Expert clients only *(Referent)*	1	—	—
CHWs only	0.98	0.79, 1.23	0.89
Mentor mothers only	1.45	1.14, 1.84	0.003
≥2 models	0.82	0.59, 1.14	0.23
No CFL model	0.68	0.42, 1.11	0.12

For the next step in the maternal HIV care cascade, viral suppression among those on ART, women who received CFL services from CHWs only and ≥2 models spent a higher proportion of days over a 24-month follow-up period in care, on ART, and virally suppressed compared to the expert client only group (**Table 5**). Over the first two years after HIV diagnosis, the proportion of days spent retained in care, on ART, and virally suppressed was 54 percent for the expert client only group, 68 percent for the CHWs only, 59 percent for mentor mothers only, and 64 percent for women who received ≥2 models. Women exposed to the CHW model spent 14.3 percent more time suppressed on ART, on average, compared to women exposed to expert clients only (95% confidence interval: 2.6%, 26.1%; p=0.02).

Table 5 Estimated probabilities of ART initiation, retention in care, and viral suppression* over 24 months after HIV diagnosis among 2,049 women diagnosed with HIV during pregnancy or breast feeding at 30 randomly sampled facilities in Lilongwe, Mzimba North, Mzimba South, Salima, and Zomba districts in Malawi between 1 July 2016 and 30 June 2017 and followed for up to 3 years, WEIGHTED to account for confounding by facility type, limited to those with a complete treatment record

Model	Proportion of days in care & suppressed* over 24 months %	Difference in proportion of days in care and suppressed over 24 months %	95% CI	p-value
Expert clients only *(Referent)*	53.7	—	—	—
CHWs only	68.1	14.3	2.6, 26.1	0.02
Mentor mothers only	58.7	4.9	-6.7, 16.6	0.42
≥2 models	64.2	10.4	-12.0, 32.9	0.37

*This table uses viral load data from both full and nested cohorts, where viral load data from the nested cohort are up-weighted to represent all members of the full cohort missing VL data.

INFANT OUTCOMES IN THE FULL AND NESTED COHORTS

Among HEIs with complete early infant diagnosis (EID) testing documentation, the proportion who received testing (as ascertained by a documented DNA PCR result on the infant follow-up card) within the first 100 days of life was generally above 80 percent in all cases and for all models (**Figure 6**). Among HEIs with complete EID documentation, a higher proportion exposed to ≥2 CFL models had received a DNA PCR test for HIV-1 than HEIs exposed to the expert client model.

HEIs exposed to ≥ 2 models were 1.44 times as likely to undergo DNA PCR testing by six months as HEIs exposed to expert clients only (**Table 6**).

Figure 6 Proportion of infants with a routinely collected PCR test result by model, among 1,326 HIV-exposed infants

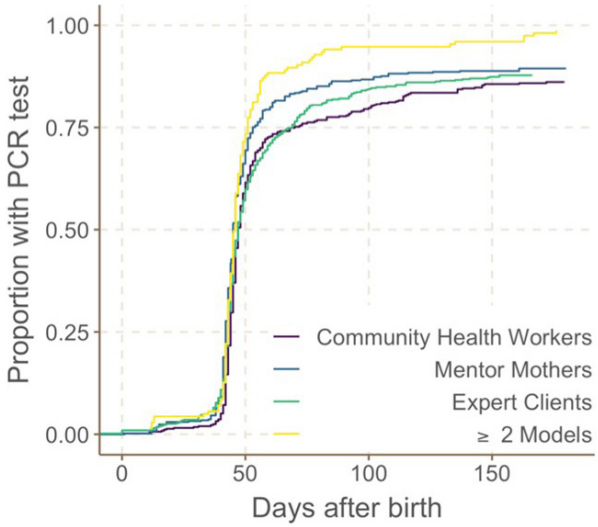


Table 6 Proportion of HIV-exposed infants with PCR testing by 6 months by CFL model exposure (to support Figure 6)

Model	Proportion with PCR testing by 6 months		
Facility-reported exposure to:	1-year risk	Adjusted Hazard Ratio*	95% CI
Expert clients only	88.0	—	—
CHWs only	86.4	0.96	0.82, 1.12
Mentor mothers only	89.5	1.24	1.01, 1.52
≥2 models	98.7	1.44	1.20, 1.74

*Adjusted using inverse probability weighting for facility type/level.

On average, HEIs completed a median duration of 524 days (Interquartile range [IQR]: 390-686) in follow-up. Most of the HIV-exposed infants in the full cohort (72%) and nested cohort (67%) were in care at 12 months, while 11 percent in the full cohort and 7 percent in the nested cohort were lost from care (**Table 7**). Four infants were diagnosed with HIV infection by the study, with two observed to have started ART and two others documented to have been linked to care. An additional 33 infants in the full cohort were known to be HIV-infected, of whom 29 (88%) were known to be alive, in care, and on ART. Few infants were confirmed to be HIV-free by 12 months (179, 12%) owing to continued breast-feeding exposure and follow-up in the MOH HIV-exposed infant cohort.

Table 7 Last known status among infants in the nested and full cohorts at up to 12 months of follow-up

Last known status, up to 12 months of follow-up*	Nested cohort N=847		Full cohort N=1,549	
	n	%	n	%
Established HIV-infected				
In care	17	2.0	29	1.9
Died	0	0.0	1	0.1
Defaulted	1	0.1	2	0.1
Transferred out	0	0.0	1	0.1
Established HIV-free				
Discharged	3	0.4	7	0.5
Alive, missing follow-up card	172	20.3	172	11.1
Established HIV-infected, diagnosed by study				
In care	2	0.2	2	0.1
Newly linked, missing follow-up card	2	0.2	2	0.1
HIV-exposed, HIV status not established				
In care	571	67.4	1,117	72.1
Died, documented in routine record	6	0.7	8	0.5
Died, ascertained by study	9	1.1	9	0.6
Defaulted	56	6.6	174	11.2
Transferred out	8	0.9	25	1.6

*On average, infants were followed 524 days (IQR 390–686). 469 infants from the nested cohort and 890 infants from the full cohort were administratively censored, i.e., not followed for the full period of 1 year. Of all infants who were administratively censored, the median duration of follow-up was 403 days (IQR 323–480).

Twelve-month risk of loss to follow-up was highest among HIV-exposed infants of mothers reporting receipt of the CHW model (**Table 8**). Indeed, the adjusted hazard of loss to follow-up among these HEIs was 1.15 times as high as HEIs that received expert client services only, although this result was not statistically significant.

Table 8 12-month risk of lost to follow-up among HIV-exposed infants by CFL model

Model	n	12-month risk	Adjusted Hazard Ratio*	95% CI
Overall	1,260	12.2	—	—
Expert clients *only*	512	11.8	1	—
CHWs *only*	386	14.5	0.15	0.80, 1.67
Mentor mothers *only*	234	7.1	0.84	0.50, 1.42
≥2 Models	128	4.5	1.08	0.29, 4.11

*Weighted to account for confounding by facility type + sensitivity analysis to account for switch of CFL model exposure in Mzimba in January 2018.

The percentage of HEIs diagnosed with HIV by 18 months in the nested cohort only was below 7 percent in all cases. An 18-month time point was used, as it allowed for observation of infants who tested late (according to MOH guidelines) for the 12-month milestone HIV status ascertainment (i.e., from 12 through 18 months of age), but at a time that is still biologically meaningful for estimating vertical transmission. The proportion of infants found to have HIV infection was highest for infants who received ≥2 CFL models at 6 percent and lowest for MIPs who were exposed to the mentor mother model (0.98%) (**Table 9**). MIPs exposed to the mentor mother model were 0.43 times as likely as MIPs exposed to the expert client model to experience vertical HIV transmission. However, none of the observed effects was statistically significant.

Table 9 Proportion of infants diagnosed with HIV in the nested cohort by 18 months, by model, weighted to account for confounding by age at testing and facility type (N=822).

Model	%	Prevalence ratio (95% CI)
Expert clients *only*	2.6	Referent
CHWs *only*	3.1	1.22 (0.45, 3.11)
Mentor mothers *only*	0.98	0.43 (0.22, 3.17)
≥2 Models	6.3	2.43 (0.00, 22.39)

CFL MODEL COMPONENTS

We examined the association between CFL model components and maternal viral suppression over the first two years of follow-up post-HIV diagnosis to identify essential CFL services that may be driving the maternal outcomes observed (**Table 10**). The difference in percentage of days suppressed for mothers was higher when: 1) CFL providers were individually assigned less than 30 MIPs to follow, and 2) when CFL providers offered routine home visits to check on their clients more than two times per quarter.

Table 10 Comparison of proportion of days alive, on ART, and virally suppressed over a 2-year period following HIV diagnosis by component service, among pregnant and breastfeeding women living with HIV (N=2,049).

Model component	n*	Average time spent in care, on ART, and virologically suppressed during the first two years after HIV diagnosis		
		% days suppressed	Difference in % days suppressed	95% CI
CFL providers formally employed by parent organization				
No	754	63.9	0	NA
Yes	698	59.7	-4.2	-11.2, 2.8
CFL providers accompany clients to their clinic visit				
No	509	61.4	0	NA
Yes	943	61.9	0.6	-4.9, 6.1
Individuals CFL providers responsible for (i.e., caseload)				
>30 patients	669	56.0	0	NA
≤30 patients	395	64.2	8.2	3.7, 12.8
Reported frequency of routine CFL provider home visits				
1–2 times per quarter	158	55.2	0	NA
>2 times per quarter	768	60.0	4.8	-9.1, 18.7
Initiates tracing				
After 1 week of a missed clinic visit	611	62.0	0	NA
Within 1 week of a missed clinic visit	841	61.2	-0.7	-7.2, 5.7

*Numbers not summing to 2,049 reflect missing data for the model component of interest.

DISCUSSION

In summary, we conducted a large, mixed methods comparative evaluation of common CFL models—expert clients, mentor mothers, and CHWs—operating under routine programmatic conditions in 30 facilities and their surrounding communities in five districts of Malawi. In so doing, we reviewed individual-level medical records for over 2,000 MIPs, and enriched those routine data with field survey data collected on a nested cohort randomly selected from among all study MIPs. Based on a comparative and integrated analysis of both the qualitative and quantitative results, it is evident that CFL models contribute to strengthening HIV service delivery for mothers and infants along the entire PMTCT continuum. CFL models help to improve clinical service function, coverage, and quality, and provide additional human resource capacity to a badly under-resourced health system.

Virtually all districts and facilities we studied had some form of CFL provider model operating, making comparisons between CFL models and a strictly "traditional" SOC unfeasible for our primary outcome of interest, 12-month retention in care. That being the case, 12-month retention in care was found to be comparable for study mothers (65%, corrects to 71% if transfer outs are removed in our calculation as done by MOH for reporting retention) and infants (84% when looking at HEI, not HIV-diagnosed only) to that reported contemperaneously by the national PMTCT program for Malawi overall (74% and 83% for mothers and infants, respectively). This suggests that our purposively selected study districts and randomly selected study sites were largely representative of Malawi's national PMCTCT program as a whole.

To enable outcome comparisons between MIPs receiving different CFL models, we selected the expert client model as the "reference" model in our quantitative analyses because it was the most commonly encountered model in study districts and because it tended to receive less resourcing from implementing partners. Our qualitative findings corroborate this observation, suggesting that the expert client model was the model most likely to be integrated into government structures and to receive oversight from DHOs. In this way, implementation of the expert client model may represent a new "enhanced" SOC for PMTCT in Malawi.

Looking at the first steps of the PMTCT cascade, our time to event analysis shows that the CHW model was associated with slightly higher, and the mentor mother model slightly lower, rates of maternal ART initiation compared to the expert client model. These differences notwithstanding, most women, across all CFL models, initiated ART within seven days of their HIV diagnosis, consistent with WHO guidelines for rapid ART start and the Test and Treat Guidelines in Malawi (MOH 2018b) newly adopted during the study observation period. Differences in CFL model effects became more apparent when assessing loss to follow-up over a 24-month follow-up period. Based on our time to event analysis, loss to follow-up was highest for mothers who received the mentor mother model and lowest for mothers who received ≥2 models and no CFL model. These differential effects in loss to follow-up were most frequently observed during the first six months after HIV diagnosis when PMTCT clients are thought to be at the highest risk to disengage from care.

Sustaining ART and achieving viral suppression are important next steps in the PMTCT cascade and the ultimate goals of the second and third 95s. We attempted to estimate the amount of time women spent in care, on ART, and virally suppressed in the CFL models we examined using a novel "longitudinal maternal suppression metric." In comparison to women receiving services from the expert client model, exposure to the CHW model was associated with PBFW spending significantly more days—14 percent more—over two years following HIV diagnosis in an optimal state of retention on ART with viral suppression. One possible explanation for this finding based on our qualitative results is that expert clients often work without implementing partner support. As a result, there may be fewer resources to support their training, supervision, and documentation of their activities in comparison to CHWs in which implementing partners provide resources and oversight. It is also likely that the better staffing ratio for CHWs (for activities like "defaulter" tracing) may have had an effect or that there may have been positive contributions to the PMTCT program made by CHWs who pass between facilities and communities to support service delivery in a variety of settings such as the antenatal clinic, ART clinic, and laboratory. In addition, the statistically non-significant trend observed of clients who received mentor mother support spending less time in care, on ART, and suppressed may reflect the greater focus of mentor mothers on providing facility-based support during the period of interest, which has since changed to encompass a more balanced blend of both community- and facility-level responsibilities. A trend toward modestly improved 24-month retention in care with community-based over facility-based maternal support was observed in the PURE Malawi trail (Phiri 2017).

Results for HEIs regarding the comparative effects of CFL model exposure were more mixed, in part due to the smaller sample size, more missing routine infant records, and fewer observed events of interest, including loss to follow-up events and HIV acquisition via vertical transmission. However, receipt of more than one CFL model was associated with more favorable uptake of EID testing by 100 days of age. The estimated risk of HEI loss to follow-up by 12 months of age was lowest for those exposed to mentor mothers only compared to expert clients only; however, this finding should be interpreted with caution as the 95% confidence intervals were wide. The percentage of infants diagnosed with HIV by 18 months in the nested cohort was below 7 percent for all CFL models. The lowest percentage observed was among HEIs exposed to the mentor mother model. MIPs receiving mentor mother services had 0.43 times as many vertical transmission events as MIPs receiving support from expert clients. However, due to the relatively few vertical transmission events observed and resultant estimate imprecision, the possible superiority of the mentor mother should be interpreted with caution.

Notably, mothers and infants who received ≥2 models often had comparatively better results across most of the joint mother-infant continuum of care (McNairy et al. 2015). This observation requires further study, and may be explained by these women being more actively engaged in their own health care and "shopping" for services, or reflect the overall better staffing and health system resourcing and functioning at sites that could accommodate more than one implementing partner, who thus could offer more than one CFL model.

Mothers reported receiving different component services across the three CFL models studied. Looking at the association between distinct CFL model components and maternal viral suppression over two years suggests that certain components may be driving the maternal-infant outcomes observed. Indeed, a few components such as more frequent home visits or better CFL provider to patient staffing ratios were all associated with higher maternal retention and viral load

suppression. These findings reflect components that involve more frequent and intensive CFL provider-client contact and greater resourcing of the CFL model and require further study.

These results align with our qualitative findings and the drivers of CFL model effects that we identified across 56 in-depth interviews, 30 structured observations, and 30 focus group discussions. As a result of interactions with CFL providers, client interviewees and CFL provider focus group participants described how long-term relationships were built between MIPs and CFL providers, and how that trust enabled CFL providers to guide clients in their care along the PMTCT cascade, provide them with advice on adherence, and bring MIPs who had disengaged from care back into care. Specifically, through exposure to CFL providers who act as role models, clients gain knowledge about adhering to treatment, strategies for disclosing their HIV status to partners and family members, and guidance to navigate service delivery points at health facilities. Mothers thus gain self-efficacy to "not lose heart" from an HIV diagnosis and to stay in care despite the many multi-level obstacles they face. Home visits and client accompaniment may be essential and pragmatic means to further a client's trust in a CFL provider and strengthen the bonds of community-facility linkage. The service components identified in the quantitative analysis and corroborated by our qualitative findings may suggest an "essential package" of CFL services that can be adopted and implemented by governments, with the support of implementing partners, but remain agnostic about model or parent implementing organization.

Our findings fill an important gap in the literature on the effects of CFL models on maternal and infant HIV outcomes in routine PMTCT program settings in the treat all era. Prior studies examining the effects of CFL models on PMTCT outcomes before the treat all era have demonstrated their positive general effects on improving maternal HIV prevention knowledge and uptake of PMTCT services such as HIV testing and counseling, ART, and early infant HIV diagnosis (Marcos, Phelps, and Bachman 2012). More CFL model-specific research has described the contributions of a comprehensive psychosocial support program involving CHWs in ensuring high 24-month retention in a general community-based ART program in Rwanda (Rich et al. 2012). Data on mentor mothers from Uganda found superior 12-month ART retention and rates of infant positivity at 18 months in facilities where the m2m program was active compared to facilities without m2m programming available (Zikusooka et al. 2015). More recently, the PURE cluster randomized trial from Malawi demonstrated the superior effects of facility- and community-based peer support models (approximating the expert client and mentor mother models, respectively) versus the traditional SOC on ART uptake and 24-month retention in care (Phiri 2017). However, the CHW model was notably not included in the study, nor was the study reflective of routine program conditions with the intervention assigned by investigators.

Irrespective of the individual-level positive effects of CFL programs highlighted by our quantitative results, our qualitative findings suggest that in order for CFL programs to be maximally impactful, scalable, and sustainable, CFL programs require adequate investments in provider capacity building, supervision, and remuneration, as well as appropriate program governance at district and health facility levels and integration within the larger health system. These findings align with previous descriptive studies of general CFL programs from various low- and middle-income country settings, suggesting that levels of CFL provider remuneration, frequency of client contacts, staffing ratios, supervisory structures and training, and relationships with clients and the formal health system are likely essential for CFL program performance (Marcos, Phelps, and Bachman 2012).

LIMITATIONS

When this study was initially designed, we planned to use a "traditional" SOC exposure in which no CFL provider services were available at sites to assess the individual effects of each model. However, due to a rapidly evolving and improving PMTCT programming landscape in Malawi, there were low numbers of facilities and clients reporting no availability of CFL providers or models, and, thus, we could not estimate maternal and infant health outcomes for a traditional SOC in most cases. To help mitigate against this limitation, we used the expert client model as the referent group for quantitative analyses, since that has increasingly become a government-supported, and in some cases independent, CFL model. In this way, expert clients may be considered the new "enhanced" SOC. We also fell short of enrolling our pre-specified sample size of 1,200 MIPs for our nested cohort due to challenges with the time, resources, and logistics necessary for locating, tracing, and enrolling mobile clients with often incomplete contact information and infrequent contact with health facilities due to multi-month scripting.

While using routine records allowed us to collect important outcomes and vital status in the national ART program for a higher number of MIPs in the full cohort, there were various limitations associated with the use of routine MOH data. First, we had challenges finding complete mother-infant pair routine records at some facility sites, which disproportionately affected HEI follow-up records, so it was not possible to create matched mother and infant records in many cases. Even in cases where both mother and infant records were located, records were incomplete for some key outcomes such as viral load result and infant HIV test results. Although we were able to account for missing data through weighting and imputation, these missing data limited the precision of our effect size estimates. Finally, although we used exhaustive tracing procedures to ensure we enrolled a nested cohort that was representative of all MIPs in the full cohort, potentially differential missing contact information among those lost to follow-up may have meant we over-sampled MIPs more likely to have had contact with the health system.

Lastly, we suspect some reporting bias on the CFL model survey regarding services offered and number of providers present. While we did our best to try to mitigate that bias by having study staff do direct observation and verification of staffing and service delivery components, we note that some services and components of CFL models may have been reported but not actually available in reality. In terms of the qualitative data, we also note the possibility of recall bias during in-depth interviews when MIPs were asked about their CFL providers. In some cases, mothers had to be reminded of who the CFL providers were, requiring qualitative research assistants to probe about CFL providers by their individual characteristics (e.g., what they wear).

CONCLUSIONS & RECOMMENDATIONS

CONCLUSIONS

CFL models in Malawi are contributing to improved service function and client outcomes for PBFW living with HIV and their infants/young children. CFL models had widespread coverage in the national PMTCT program in our selected sites in Malawi, reaching most MIPs. Expert clients were the most commonly encountered model and may represent a new "enhanced" SOC for PMTCT programming in Malawi. We observed near universal and rapid ART initiation by six months after HIV diagnosis for PMTCT clients across all CFL models, and significantly superior retention on treatment and viral suppression for mothers receiving CHW services compared to women receiving services from expert clients. Similarly, we estimated a trend toward improved DNA PCR testing uptake at six months of age for HEIs who received services from ≥2 CFL models and the mentor mother model compared to HEIs who were supported by expert clients. Finally, the mentor mother model was observed to have lower 18-month vertical transmission than the expert client model, with the lowest prevalence of MTCT by 18 months.

Individual "core" components of CFL models appear to be having an effect on maternal retention in care and viral suppression over two years, suggesting that certain aspects of CFL model services may be driving the maternal-infant outcomes observed. A few components merit further study as especially promising drivers of effects, including more favorable CFL provider to patient ratios and more frequent contacts/home visits occurring between providers and patients. These findings speak to the possibility of identifying instrumental CFL model services that can form the basis for an "essential package" of CFL services endorsed by governments and funding agencies.

Findings from our qualitative research point to two key mechanisms or drivers of the effects observed. First, as service extenders, CFL providers are improving the coverage and reach of clinical services in a health system that historically and to-date struggles with human resource shortages. In clinics with well-integrated CFL programs, professional and lay health workers all praised the extended coverage and efficiency that CFL providers brought to their services and commented on their own improved work experience and motivation as a result. Clients similarly described improved access to and understanding of care services. A second critical mechanism driving CFL impact was their long-term relationship and trust building, providing a form of intermediary care—combining education, counseling, advice and referral—that extends beyond static clinic-based services.

Notwithstanding these contributions, our findings signal potential trouble areas warranting greater attention from policy makers and funders to avoid programming pitfalls and to ensure the continued success of CFL models in Malawi and the region. First, when district and facility-level oversight, integration within the health system, and resources are limited, CFL program impact

may be adversely affected. For instance, suboptimal governance arrangements at all levels—community, facility, and district—undermine CFL program planning and support. The primary local governance structure in Malawi—DHOs—are already overwhelmed with managing routine clinical operations and providing input on various NGO programming in each district, so there is often limited capacity for DHOs to also meaningfully coordinate CFL activities within the district. Second, NGOs often enter a District or a health facility with their own set of priorities, which are often donor-driven and may not align with the MOH national and district-level priorities. As a result, CFL providers can easily become "instruments of intervention," whose job descriptions and expected roles change as program scope and funding evolve. If there is not adequate training or support during transitions between supervising NGOs or to DHOs, the program can suffer or end prematurely. Third, inconsistent sources of CFL program funding challenge the sustainability and short-term and long-term impact of CFL programs. There are times when a program is set up and operational, and then funding is cut, which makes service delivery and consistency difficult. Fourth, we found evidence of still disparate governance arrangements, and a lack of coordinated planning (to date) to sustainably support and protect this important cadre of health workers. Notable among interviewee's descriptions of CFL operations was an instrumental attitude toward CFL providers themselves, best illustrated in descriptions of the abrupt "handing back" or "transfer" of CFL providers to other organizations as a result of rolling project funding cycles and changing donor priorities. The study findings show that, just as with any cadre of health worker, not everyone can be an effective CFL provider, with evidence in some sites of competitive recruitment for the same high-performing CFL providers. Yet a clear risk emerging from these short-term cycles, and abrupt transfers is the potential for disillusion, frustration, and weakened performance due to lack of job security, inconsistent conditions, and related confusion. Lastly, the lack of national normative guidance or an operational framework for the implementation of CFL programs, including the training, mentoring, and remuneration of CFL providers, often causes misalignment of MOH and partner programming priorities in Malawi. As a result of the above challenges, there may be missed opportunities to realize the full potential of CFL programs for improving PMTCT outcomes for mothers and infants impacted by HIV/AIDS.

RECOMMENDATIONS

1. All CFL models studied contributed to strengthening HIV service delivery for mothers and infants beyond historical notions of a "traditional" SOC and merit further investment to support maternal retention in care and infant HIV-free survival.
2. Individual "core" components shared in common across CFL models may explain the positive effects observed and can form the basis for advancing an essential minimal package of CFL model services. Such core components should include mechanisms for increasing the ratio of CFL providers to clients and the frequency of their interactions with CFL model beneficiaries.
3. Opportunities exist to develop an operational framework around an essential minimal package of CFL model services that can be delivered by governments and implementing partners. Such operational guidance should address the following key dimensions of CFL models: formal CFL provider employment and levels of remuneration; CFL provider supervisory structures and training requirements; maximum client to CFL provider staffing ratios; recommended frequency, timing, and location of client contacts; and reporting/accountability lines within the formal health system.

4. While a body of evidence is coalescing around CFL models, further research is needed to describe CFL model cost-effectiveness, characterize the sustainability and maintenance of CFL models, and identify strategies for optimal integration and accountability of CFL models within public health systems in Malawi and elsewhere in sub-Saharan Africa.

REFERENCES

Admon, Andrew et al. 2013. "Assessing and improving data quality from community health workers: a successful intervention in Neno, Malawi," *Public Health Action* 3(1): 56–59. doi: 10.5588/pha.12.0071

Barker, Pierre, Wendy Mphatse and Nigel Rollins. 2011. "Antiretroviral drugs in the cupboard are not enough: the impact of health systems' performance on mother-to-child transmission of HIV," *Journal of Acquired Immune Deficiency Syndromes* 56(2): e45–48. doi: 10.1097/QAI.0b013e3181fdbf20

Busza, Joana et al. 2012. "Community-based approaches for prevention of mother to child transmission in resource-poor settings: a social ecological review," *Journal of International AIDS Society* 15(Suppl 2): 17373. doi: 10.7448/IAS.15.4.17373

Cataldo, Fabian et al. 2017. "Exploring the experiences of women and health care workers in the context of PMTCT Option B Plus in Malawi," *Journal of Acquired Immune Deficiency Syndromes* 74(5): 517–522. doi: 10.1097/QAI.0000000000001273

Chimbwandira, Frank et al. 2013 "Impact of an innovative approach to prevent mother-to-child transmission of HIV—Malawi, July 2011–September 2012," *MMWR Morbidity and Mortality Weekly Report* 62(8): 148–151.

Falnes, Eli Fjeld et al. 2011. "'It is her responsibility': partner involvement in prevention of mother to child transmission of HIV programmes, northern Tanzania," *Journal of the International AIDS Society* 14: 21. doi: 10.1186/1758-2652-14-21

Government of Malawi. 2015. "Malawi AIDS response progress report 2015." Lilongwe: Government of Malawi.

Herce, Michael et al. 2015. "Supporting Option B+ scale up and strengthening the prevention of mother-to-child transmission cascade in central Malawi: results from a serial cross-sectional study," *BMC Infectious Diseases* 15: 328. doi: 10.1186/s12879-015-1065-y

Holmes, Charles et al. 2018. "Estimated mortality on HIV treatment among active patients and patients lost to follow-up in 4 provinces of Zambia: Findings from a multistage sampling-based survey," *PLoS Medicine* 15(1): e1002489. doi: 10.1371/journal.pmed.1002489

Keehn, Emily and Julie Karfakis. 2014. "Current practices to improve uptake, retention, and adherence to Option B+ in Malawi." Lilongwe: mothers2mothers.

Kim, Maria et al. 2012. "The Tingathe programme: a pilot intervention using community health workers to a create a continuum of care in the prevention of mother to child transmission of HIV (PMTCT) cascade of services in Malawi," *Journal of International AIDS Society* 15: 17389. doi: 10.7448/IAS.15.4.17389

Malawi Ministry of Health. 2018a. "Integrated HIV program report July–August 2018." Lilongwe: Malawi Ministry of Health.

Malawi Ministry of Health. 2018b. "Malawi clinic HIV guidelines." Lilongwe: Malawi Ministry of Health.

Marcos, Tabsera, Benjamin R. Phelps and Gretchen Bachman. 2012. "Community strategies that improve care and retention along the prevention of mother-to-child transmission of HIV cascade: a review," *Journal of the International AIDS Society* 15: 17394. doi: 10.7448/IAS.15.4.17394

McNairy, Magaret L. et al. 2015. "Mother and child both matter: reconceptualizing the prevention of mother-to-child transmission care continuum," *Current Opinion in HIV and AIDS* 10(6): 403–410. doi: 10.1097/COH.0000000000000199

Merten, Sonja et al. 2010. "Patient-reported barriers and drivers of adherence to antiretrovirals in sub-Saharan Africa: a meta-ethnography," *Tropical Medicine & International Health: TM & IH* 15: 16–33. doi: 10.1111/j.1365-3156.2010.02510.x

O'Gorman, Deidre, Lot J. Nyirenda and Sally J. Theobald. 2010. "Prevention of mother-to-child transmission of HIV infection: views and perceptions about swallowing nevirapine in rural Lilongwe, Malawi," *BMC Public Health* 10: 354. doi: 10.1186/1471-2458-10-354

Posse, Mariana et al. 2008. “Barriers to access to antiretroviral treatment in developing countries: a review,” *Tropical Medicine & International Health: TM & IH* 13(7): 904–913. doi: 10.1111/j.1365-3156.2008.02091.x

Phiri, Sam et al. 2017. “Impact of facility- and community-based peer support models on maternal uptake and retention in Malawi’s Option B+ HIV prevention of mother-to-child transmission porgram: A 3-arm cluster randomized controlled trial (PURE Malawi),” *Journal of Acquired Immune Deficiency Syndromes* 75(Suppl 2): S140–S148. doi: 10.1097/QAI.0000000000001357

Rich, ML et al. 2012. “Excellent clinical outcomes and high retention in care among adults in a community-based HIV treatment program in rural Rwanda,” *Journal of Acquired Immune Deficiency Syndromes* 59(3): e35–42. doi: 10.1097/QAI.0b013e31824476c4

Schouten, Erik et al. 2011. “Prevention of mother-to-child transmission of HIV and the health-related Millennium Development Goals: time for a public health approach,” *The Lancet* 378(9787): 282–284. doi: 10.1016/S0140-6736(10)62303-3

Scott, Kerry, Asha S. George and Rajani R. Ved. 2019. “Taking stock of 10 years of published research on the ASHA programme” examining India’s national community health worker programme from a health systems perspective,” *Health Research Policy and Systems* 17: 29. doi: 10.1186/s12961-019-0427-0

Tenthani, Lyson et al. 2014. “Retention in care under universal antiretroviral therapy for HIV-infected pregnant and breastfeeding women (‘Option B+’) in Malawi,” *AIDS* 28(4): 589–598. doi: 10.1097/QAD.0000000000000143

UNAIDS. 2016. “On the fast track to an AIDS-Free generation,” Geneva: UNAIDS.

UNICEF. 2015. “Community-facility linkages to support the scale up of lifelong treatment for pregnant and breastfeeding women living with HIV,” New York: UNICEF.

Ware, Norma et al. 2009. “Explaining adherence success in sub-Saharan Africa: an ethnographic study,” *PLoS Medicine* 6(1): e11. doi: 10.1371/journal.pmed.1000011

Wouters, Edwin et al. 2012. “Impact of community-based support services on antiretroviral treatment programme delivery and outcomes in resource-limited countries: a synthetic review,” *BMC Health Services Research* 12: 194. doi: 10.1186/1472-6963-12-194

Zikusooka, Charlotte et al. 2015. “Summary: External evaluation and cost-benefit analysis of mothers2mothers’ Mentor Mother Programme in Uganda as implemented under the STAR-EC Program in Uganda.” Cape Town: Department of Programmes and Technical Support, mothers2mothers.

APPENDIX

Appendix Table 1 Nested cohort sampling frames

Site number	Number of MIPs potentially eligible for study cohort after initial medical record review	Site-level sampling fraction for field survey	Number sampled	Number recruited, contacted, and completing field survey
LL-01	75	100%	75	32
LL-02	324	100%*	243	47
LL-03	15	100%	15	9
LL-04	28	100%	28	11
LL-05	76	100%	76	26
LL-06	60	100%	60	16
LL-07	58	100%	58	19
LL-08	31	100%	31	10
LL-09	6	100%	6	3
LL-10	122	100%	122	31
LL-11	307	100%	307	38
MZ-01	196	100%	196	46
MZ-02	54	100%	54	31
MZ-03	41	100%	41	19
MZ-04	20	100%	20	9
MZ-05	87	100%	87	32
MZ-06	38	100%	38	23
SA-01	36	100%	36	17
SA-02	37	100%	37	23
SA-03	228	100%	228	114
SA-04	52	100%	52	41
SA-05	61	100%	61	38
ZA-01	99	100%	99	33
ZA-02	74	100%	74	35
ZA-03	84	100%	84	29
ZA-04	127	75%	93	29
ZA-05	122	75%	92	28
ZA-06	38	100%	38	21
ZA-07	62	100%	62	15
ZA-08	31	100%	31	7
Total	2,589	94%	2,444	832

*Initially sampled at 75%, but then changed to 100% because of low enrollment into field survey

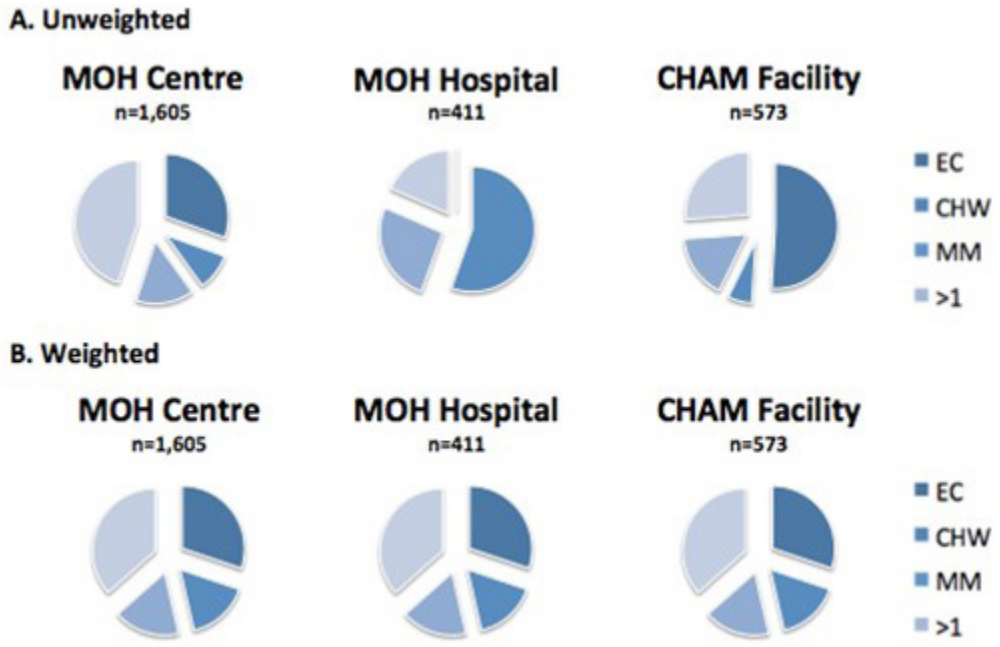
MIPs, mother-infant pairs; LL, Lilongwe; MZ, Mzimba North/South; SA, Salima; ZA, Zomba.

Appendix Table 2 Overview of qualitative data

Type of site assessment	Site assessment components					
	CFL model survey	Private structured observation	Public structured observation	Focus group discussions	MIP IDIs	Managerial and stakeholder IDIs
Rapid	X	X	X			
In-depth	X	X	X	X	X	X

Appendix Figure 1 Full cohort inverse probability weighting used for the quantitative analysis

Distribution of CFL model types by facility type for women in the full cohort (N=2,589)



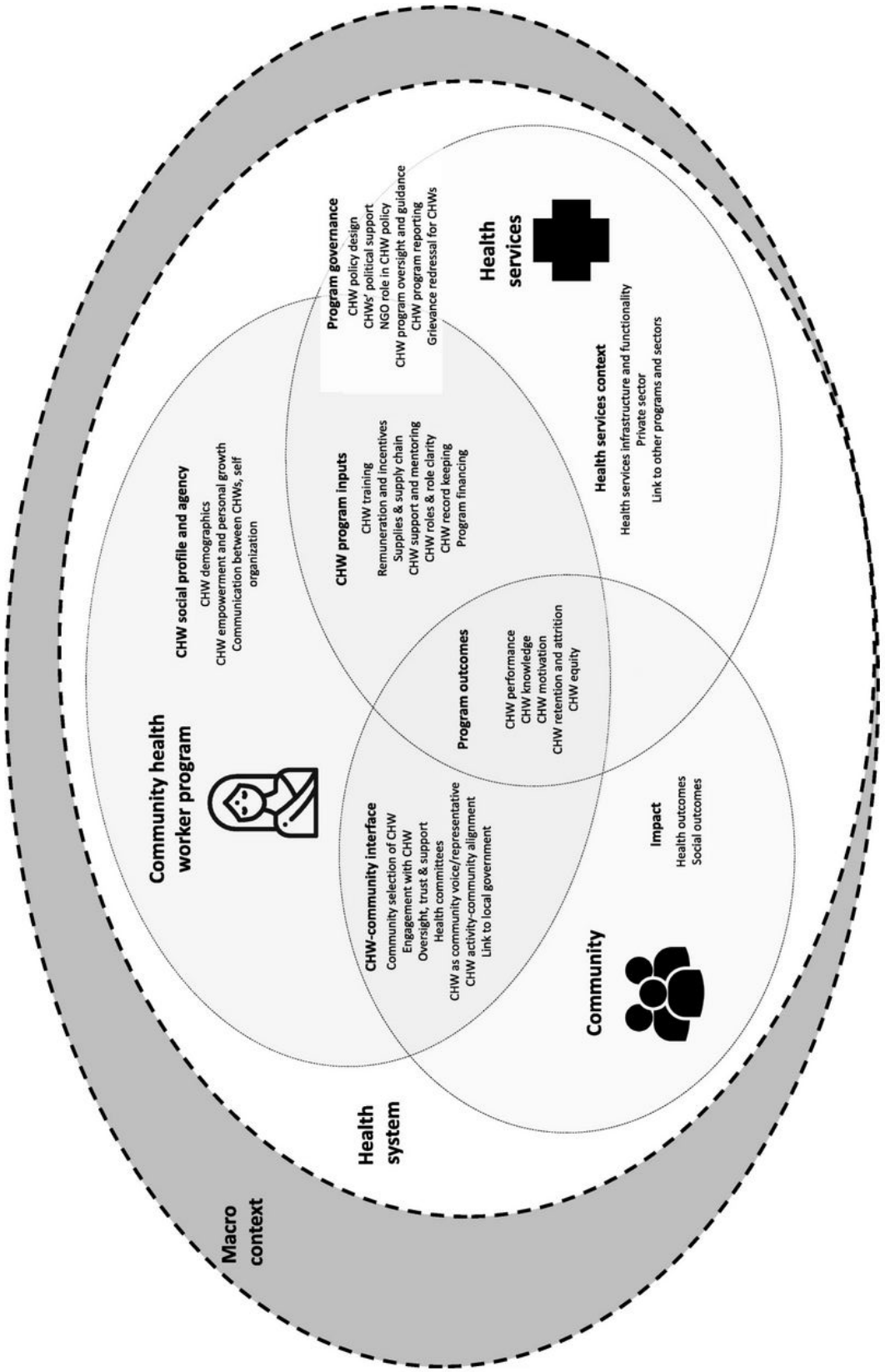
Appendix Table 3 Summary of qualitative data collection by site and type

Type of assessment	Region	Site	Focus group CFL workers* (participants)	Focus group professional HCW (participants)	Focus group lay HCW** (participants)	In-depth stakeholder interview	Semi-structured interview w/ mothers	Observations	CFL model survey
In depth	Central	Kawale	3 (17)	1 (8)	1 (5)	8	6	2	1
		Khombedza	1 (6)	1 (5)	1 (8)		6	2	1
		Salima Hospital	1 (6)	1 (4)	1 (4)		6	2	1
	Northern	Mitundu	2 (10)	1 (4)	1 (4)	2	5	2	1
		Mzuzu	1 (8)	1 (6)	1 (6)		6	2	1
		Namikango	2 (11)	1 (5)	1 (5)		4	2	1
	Southern	Pirimiti	2 (10)	1 (5)	1 (6)	3	6	2	1
		Zomba City	2 (7)	1 (8)	1 (5)		4	2	1
Rapid	Central	A25 HC	—	—	—	—	—	2	1
		Chitedze HC	—	—	—	—	—	2	1
		Daeyang Luke	—	—	—	—	—	2	1
		Mchoka	—	—	—	—	—	2	1
		Ndaula	—	—	—	—	—	2	1
	Northern	Mzimba	—	—	—	—	—	2	1
	Southern	Ngwelero	—	—	—	—	—	2	1
Total activities			14	8	8	13	43	30	15
Total people involved			75	45	43	13	43	—	

*Some facilities had more than one CFL program operating on site; where this was the case, a separate focus group was conducted with the CFL workers/providers of each program.

**Lay HCW primarily included health surveillance assistants (HSAs) but occasionally also MOH-hired counselors and clerical staff.

Appendix Figure 2 Conceptual framework of intersection between community health worker programs, community and health service domains (Scott et al. 2019)



Appendix Table 4 Illustrative list of nongovernment partners mentioned by key stakeholders in selected study districts*

District	Named PMTCT health-sector partners
Mzuzu	EGPAF Lighthouse UNICEF World Vision JH LISAP (Livingstonia Synod AIDS Program)
Salima	Baylor GHI Riders for Health Feed the Children
Mzimba	Lighthouse EGPAF World Vision Gro-home Global Hope Ministries LISAP UNICEF

*This list is not comprehensive and is intended to be indicative of the number of partners in each district contributing to PMTCT related activities.

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