Task-Shifting and Task-Sharing Models of Antiretroviral Therapy Service Delivery and Adult Adherence to Antiretroviral Drugs in Tanzania, Uganda, and Zambia: A Mixed Method Study

by
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ABSTRACT

Background: Adherence to antiretroviral therapy (ART) underlies the success of HIV prevention and treatment. Significant research has focused on understanding how individual, interpersonal, community, and structural factors influence adherence. Few studies, however, have examined how models of care – the combinations of services together with task-shifting of responsibilities to different cadres of staff – may support patient adherence.

Methods: Manuscript 1 used cluster analysis and Delphi survey methods to identify task-shifting/task-sharing models of ART delivery among 19 routine ART programs in Tanzania, Uganda, and Zambia. Manuscript 2 used multivariable logistic regression to examine the association between task-shifting/task-sharing models of care and adherence. Adherence was measured by medication possession ratio (MPR) >90%. The analysis adjusted for clustering at the clinic level and adjusted for individual-level factors known to influence patient adherence. Manuscript 3 used a qualitative case study methodology with four purposively selected ART clinics in Uganda that represented unique task-shifting/task-sharing models of HIV care. Data collection included direct observations, analysis of documents and audio-visual materials, and 79 in-depth interviews with 39 ART providers and 40 ART clients. Cross-case analysis was then used to explore healthcare delivery factors that may facilitate patient adherence to ART.
**Results:** The cluster analysis identified three task-shifting/task-sharing models. The main differences across models were the availability of medical doctors, the scope of clinical responsibility assigned to nurses, and the use of lay health care workers. Patients in the doctor-led model were more likely than patients in the mixed-model (where doctors, clinical officers and nurses shared clinical responsibilities) to have incomplete adherence with an MPR <90% (adjusted relative risk (aRR): 1.60, 95% confidence interval (CI): 1.03, 2.48). Patients in the doctor-led model also showed a non-significant trend towards being more likely than patients in the task-shifted model (where doctors shifted clinical responsibilities to clinical officers and nurses) to have MPR<90% (aRR=1.58, 95% CI 0.88, 2.85%). There was no evidence of difference in MPR<90% between patients in the mixed-model and task-shifted model. The qualitative case study found longer antiretroviral drug refills, expert patients, and routine pill counts to be three programmatic factors supporting patient adherence.

**Conclusions:** The structure of ART service provision – including staffing patterns and the range of supportive services offered – can influence patient adherence. With increasing country ownership of ART programs in sub-Saharan Africa, the recommendation for immediate initiation of treatment for all people living with HIV, and the use of new models of care delivery such as differentiated care, it is important to continue to examine to effectively structure ART programs can be structured to support optimal patient adherence.
Thesis Committee: Caitlin Kennedy, Ph.D. (advisor), David Celentano, Ph.D. (chair), Julie Denison, Ph.D., Larry Chang, M.D., Joanne Katz, Ph.D. (alternate), Deanna Kerrigan, Ph.D. (alternate)
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For Molly Hope Onzuru Tsui

Be curious, kind, and do good. Always.
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<tr>
<td>3TC</td>
<td>Lamivudine</td>
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<tr>
<td>AIDS</td>
<td>Acquired Immune Deficiency Syndrome</td>
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<tr>
<td>aRR</td>
<td>Adjusted relative risk</td>
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<td>ART</td>
<td>Antiretroviral therapy</td>
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<td>ARV</td>
<td>Antiretroviral</td>
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<tr>
<td>AZT</td>
<td>Azidothymidine</td>
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<tr>
<td>CAGE</td>
<td>Cut, Annoyed, Guilty, Eye-Opener</td>
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<td>CD4</td>
<td>Cluster of differentiation 4</td>
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<td>CDC</td>
<td>Center for Disease Control and Prevention</td>
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<td>CE</td>
<td>Continuing education</td>
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<tr>
<td>CHW</td>
<td>Community health worker</td>
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<tr>
<td>CHV</td>
<td>Community health volunteer</td>
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<tr>
<td>CI</td>
<td>Confidence interval</td>
</tr>
<tr>
<td>CO</td>
<td>Clinical officer</td>
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<tr>
<td>CTX</td>
<td>Cotrimoxazole</td>
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<tr>
<td>D4T</td>
<td>Stavudine</td>
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<tr>
<td>DHS</td>
<td>Demographic and Health Survey</td>
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<tr>
<td>DO</td>
<td>Direct observation</td>
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<tr>
<td>E</td>
<td>Expected</td>
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<td>EFV</td>
<td>Efavirenz</td>
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<tr>
<td>FDC</td>
<td>Fixed dose combination</td>
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<td>FP</td>
<td>Family planning</td>
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<td>FTC</td>
<td>Emtricitabine</td>
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<td>HAART</td>
<td>Highly active antiretroviral therapy</td>
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<td>HIV</td>
<td>Human Immunodeficiency Virus</td>
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<td>HRH</td>
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<td>IMF</td>
<td>International Monetary Fund</td>
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<td>INH</td>
<td>Isoniazid prophylaxis</td>
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<td>IRB</td>
<td>Institutional review board</td>
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<td>km</td>
<td>Kilometer</td>
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<tr>
<td>Lab tech</td>
<td>Laboratory technician</td>
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<tr>
<td>LHW</td>
<td>Lay health worker</td>
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<tr>
<td>Ln</td>
<td>Logarithmic</td>
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<td>LTFU</td>
<td>Lost to follow up</td>
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<tr>
<td>Max</td>
<td>Maximum</td>
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<tr>
<td>MD</td>
<td>Medical doctor</td>
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<tr>
<td>Min</td>
<td>Minimum</td>
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<tr>
<td>MO</td>
<td>Medical officer</td>
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<tr>
<td>MOH</td>
<td>Ministry of Health</td>
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<tr>
<td>MPR</td>
<td>Mean possession ratio</td>
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Nat Ref  National referral
NGO  Non-governmental organization
NRNR  Non-profit non-religious
NVP  Nevirapine
O  Observed
OI  Opportunistic infection
OR  Odds ratios
PEP  Post exposure prophylaxis
PEPFAR  President’s Emergency Plan for AIDS Relief
Pharm Tech  Pharmacy technician
PHC  Primary health center
PLWHIV  People living with HIV
QUAL  Qualitative
QUAN  Quantitative
RCT  Randomized controlled trials
Ref  Referral
REF  Reference group
RLS  Resource limited settings
RMSEA  Root mean square error of approximation
RNA  Ribonucleic acid
ROC  Receiver operating characteristic
SEM  Social ecological model
SSA  Sub-Saharan Africa
STI  Sexually transmitted infection
T  Tanzania
TB  Tuberculosis
TDF  Tenofovir
TLC  Total lymphocyte count
U  Uganda
UNAIDS  United Nations Program on HIV/AIDS
VLT  Viral load testing
WBC  White blood cell count
WHO  World Health Organization
Z  Zambia
INTRODUCTION

BACKGROUND

HIV and AIDS in Tanzania, Uganda and Zambia

The world’s highest burden of HIV infections and AIDS-related mortality is in East and Southern Africa. This region is home to 6.2% the world’s population but over 50% of the global HIV burden. According to the most recent UNAIDS estimates, as of 2016, this region has 19.4 million people living with HIV and 790,000 new HIV infections – representing 43% of the global total of new HIV infections (UNAIDS, 2017b). Table 1 summarizes the estimates of the burden of HIV and AIDS in Tanzania, Uganda, and Zambia.

Table 1 2015 HIV and AIDS estimates in Tanzania, Uganda, and Zambia

<table>
<thead>
<tr>
<th>Country</th>
<th>HIV Prevalence among Adults 15-49 years</th>
<th>Number of People Living with HIV (all ages)</th>
<th>Number of AIDS-Related Deaths</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tanzania</td>
<td>4.7% (4.2% - 5.3%)</td>
<td>1,400,000 (1,200,000 - 1,600,000)</td>
<td>36,000 (29,000 - 42,000)</td>
</tr>
<tr>
<td>Uganda</td>
<td>7.1% (6.6% - 7.7%)</td>
<td>1,500,000 (1,300,000 - 1,600,000)</td>
<td>28,000 (22,000 - 35,000)</td>
</tr>
<tr>
<td>Zambia</td>
<td>12.9% (12.3% - 13.4%)</td>
<td>1,200,000 (1,200,000 - 1,300,000)</td>
<td>20,000 (16,000 - 24,000)</td>
</tr>
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</table>

While there has been substantial progress in providing antiretroviral therapy (ART) to people living with HIV, treatment access remains limited in many countries, including the region hardest hit of HIV. According to the most recent 2016 estimates, HIV treatment is available to only 60% of those who need it in East and Southern Africa – about 11.7 million people (UNAIDS, 2017b). Using 2013 WHO treatment guidelines to
estimate ART coverage, treatment access ranges from 53% in Tanzania, 57% in Uganda, to 63% in Zambia in 2015\(^1\) (Table 2) (UNAIDS, 2016) and ART coverage is estimated to have increased to 62% in Tanzania, 65% in Zambia, and 67% in Uganda in 2016\(^2\) (UNAIDS, 2017a).

Table 2 2015 Estimated percentage of women and men aged 15 years and older living with HIV receiving antiretroviral therapy in Tanzania, Uganda, and Zambia

<table>
<thead>
<tr>
<th>Country</th>
<th>Reported Number of Adults on ART in 2015</th>
<th>2015 Estimated ART Coverage Using 2013 WHO Treatment Guidelines</th>
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<tbody>
<tr>
<td></td>
<td></td>
<td>Among Females and Males</td>
</tr>
<tr>
<td>Tanzania</td>
<td>688,604</td>
<td>53% (47% - 60%)</td>
</tr>
<tr>
<td>Uganda</td>
<td>774,904</td>
<td>57% (52% - 62%)</td>
</tr>
<tr>
<td>Zambia</td>
<td>706,743</td>
<td>63% (59% - 67%)</td>
</tr>
</tbody>
</table>

Limited ART access is one cause of delayed treatment initiation for people living with HIV and can have serious health implications (Hoffmann et al., 2013). Early HIV treatment initiation is especially important to achieving viral control and slowing the progressive destruction of the immune system (Hocqueloux et al., 2013). It is also important for realizing the full HIV prevention benefits of treatment particularly for people in sero-discordant partnerships (M. S. Cohen et al., 2013).

\(^1\) In 2012, ART coverage among people with HIV infection eligible for ART according to the 2010 WHO guidelines ranged from 61% in Tanzania, 64% in Uganda, to 79% in Zambia (UNAIDS, 2013). In contrast, ART coverage among people with HIV infection eligible for ART according to the 2013 WHO guidelines ranged from 53% in Tanzania, 57% in Uganda, to 63% in Zambia (UNAIDS, 2016). The 2016 UNAIDS Gap Report ART coverage estimates are lower compared to estimates from the 2013 UNAIDS Report because estimates are based on the 2013 WHO treatment guidelines which expanded for ART for people with a CD4 count of 500 or less. The 2013 UNAIDS Report on the Global AIDS Epidemic ART coverage estimates were based on the 2010 WHO treatment guideline which recommended ART for people with a CD4 count of 350 or less.

\(^2\) HIV prevalence, number of people living with HIV, number of AIDS death, number of people on ART, and disaggregated data by sex by country were not available in the 2017 UNAIDS progress report. Therefore, 2015 country specific data were used for table 1 and table 2.
Human Resources for Health Crisis

The human resource for health crisis is a major factor limiting expansion of HIV treatment in sub-Saharan Africa (Holmes et al., 2014; Walsh, Ndubani, Simbaya, Dicker, & Brugha, 2010; WHO, 2006b). The crisis has limited the number of people who can initiate ART and the capacity of existing programs to keep patients retained in care and adhering to treatment. Efforts to scale-up ART, while successful, have exposed and potentially exacerbated pre-existing weaknesses of the health systems in the region (Chen et al., 2004; Holmes et al., 2014). The shortcomings of the health workforce in Africa is highlighted again in the recent Ebola outbreak in Western Africa (Sidibé & Campbell, 2015). Specifically, inadequate numbers and an imbalanced distribution of health workers are major constraints to expanding ART services and achieving universal access to HIV care and treatment, especially in rural areas.

Inadequate Numbers of Health Workers - Africa has just 3% of the global health workforce yet it accounts for 24% of the global burden of disease (WHO, UNAIDS, & UNICEF, 2010). There are not enough doctors, nurses, pharmacists, and other health cadres to meet existing primary health care needs, let alone expand ART services. Tanzania with 3 doctors, nurses, and midwives per 10,000 population, Uganda with 14 doctors, nurses, and midwives per 10,000 population, and Zambia with 8 doctors, nurses, and midwives per 10,000 population, all fall below the WHO’s critical threshold of 23 doctors, nurses, and midwives per 10,000 population to meet a country’s basic primary health care needs (WHO, 2010). The WHO estimates that adequate provision of ART in resource constrained settings requires, at minimum, one or two doctors, up to seven nurses, about three pharmacy staff, and a wide range of community health workers
per 1,000 people (Hirschhorn, Oguda, Fullem, Dreesch, & Wilson, 2006). However, the number of health workers providing ART services is far from the required minimum. According to the latest available figures from 2004\(^3\), the number of people living with HIV per doctor is 2164 in Tanzania, 397 in Uganda, and 1216 in Zambia, and the number of people living with HIV per nurse is 117 in Tanzania, 75 in Uganda, and 37 in Zambia (Samb et al., 2007). The number of health workers in these three countries is in sharp contrast to the United States and the United Kingdom where there are nearly two doctors and ten nurses per person living with HIV (Samb et al., 2007).

One cause of the shortage of trained health workers is an inadequate training of new health professionals (Chen et al., 2004; Crisp & Chen, 2014a, 2014b; Haddart & Picazo, 2003). In many African countries, governments provide medical and nursing education on limited budgets, resulting in inadequate support to invest in the development of new health professionals (Haddart & Picazo, 2003). WHO estimates that the current educational system produces only 10% of the health professionals needed in African countries (WHO, 2006a). To scale up training of health professionals, WHO recommends combining public financial support with private investment and scaling up the number of students attending both public and private institutions (WHO, 2013). Notably, WHO emphasized the need to prioritize limited public financial resources on where the public health needs are. Investments need to be targeted where it will achieve the “highest impact on the quantity, quality, and relevance of health workers” so national governments should invest where there are “skill-mix imbalances in the health sector”. This may mean

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\(^3\) No new data are available on health workforce per people living with HIV. The 2010 figures do not disaggregate the combined workforce of doctors, nurses, and midwives.
investing in midwives and nurses for a cost-effective public health approach (WHO, 2013).

According to some development professionals, the chronic underinvestment of human resources for health in sub-Saharan Africa is in response to the Structural Adjustment Programs instituted by the International Monetary Fund (IMF) and the World Bank (Liese & Dussault, 2004). The Structural Adjustment Programs are conditional neoliberal economic policies that countries must uphold if they want to borrow money from the IMF and the World Bank. Structural Adjustment Programs sought to control public wages and reduce public expenditures. The health workforce, along with other civil servants, was perceived as a drain and burden on the national budget rather than as an asset for poverty reduction (Liese & Dussault, 2004). As a result of the Structural Adjustment Programs instituted in the late 1980’s and early 1990’s in countries such as Tanzania, Uganda, and Zambia, budgetary stringencies limited governments’ ability to train, attract, retain, and maintain the morale of professional health workers. The health workforce stagnated and declined during this time. In Tanzania and Uganda, civil service reform reduced the numbers of trained healthcare providers through enforcement of early retirement, voluntary departure, and retrenchment (Haddart & Picazo, 2003; JLI, 2004). In Zambia, the freezing and reduction of public service salaries through public sector reform led to an exodus of health workers from government service to private or non-governmental organization health projects which had better working conditions and more reliably paid positions (Haddart & Picazo, 2003; JLI, 2004).

**Imbalanced Distribution of Health Workers** - Geographic disparity of health workers is another problem compounding the human resources for health crisis in sub-
Saharan Africa. In many African countries, health professionals are grossly concentrated in urban areas compared to rural areas (Crisp & Chen, 2014a, 2014b). In Uganda, some 70% of medical doctors and 40% of nurses and midwives are based in urban areas where only 12% of the population reside; this implies that many rural facilities are staffed by untrained or less skilled health workers (Uganda MoH, 2007). The urban-rural disparity is even worse in Zambia where less than half of all health workers and less than 25% medical doctors live and work in rural areas where over two-thirds of Zambians reside (Brugha et al., 2010).

Studies suggest that health professionals migrate from rural to urban areas because of better earning potential, working conditions (e.g., availability of electricity, running water, medical supplies, drugs, stationary, availability of professional camaraderie, and higher probability of promotions), and living conditions (e.g., housing, schooling for children, leisure activities) (Chen et al., 2004; Crisp & Chen, 2014a, 2014b; Dussault & Franceschini, 2006; Liese & Dussault, 2004; WHO et al., 2010). This problem is exacerbated in contexts where there is a heavy burden of HIV and AIDS. Health workers leave rural postings for urban ones, reporting they feel burned out from a high workload providing outpatient services to HIV positive patients (Brugha et al., 2010; Chen et al., 2004).

In addition to an imbalanced internal migration of health workers, international migration of health workers is also a problem. A “carousel effect” has been observed whereby highly trained health workers out-migrate to more affluent countries, such as physicians from Zimbabwe, Botswana, Malawi, and other African countries emigrating to work in South Africa, and South African physicians emigrating to work in remote regions...
in the United Kingdom, the United States, and Canada (Chen et al., 2004; Crisp & Chen, 2014a, 2014b; Liese & Dussault, 2004). The most common reasons cited for emigration are a lack of job opportunities, low wages, poor working conditions, and a lack of continuing education and training (Liese & Dussault, 2004).

A Public Health Approach to HIV Care and Treatment

In response to the scarcity of doctors and nurses and limited health systems infrastructure with laboratory, procurement, and supply-chain management in many resource-constrained countries, the WHO recommended a “public health approach” to enable scale-up of provision of HIV care and treatment services (Gilks et al., 2006). Strategies of the “public health approach” stand in contrast to an individualized treatment model common in high-income countries, which is characterized by specialist physician management and advanced laboratory monitoring of HIV positive patients. Several strategies developed to maximize accessibility of quality ART services at the population level include: the use of standardized and simplified treatment protocols to enable a lower cadre of health workers to deliver ART (e.g., focusing on the “four S’s”: start drug treatment, substitute for toxicity, switch after treatment failure, and stop), free ARV drugs at the point of service delivery, and decentralized implementation of treatment from tertiary or specialist facilities to primary level facilities in health districts (Gilks et al., 2006). WHO advocated sharing of clinical management of HIV patients teams and suggested that treatment teams be led by a few doctors with the bulk of the team made up of nurses, clinical officers, and trained lay health workers (Gilks et al., 2006).
Task-Shifting Rationale, History, and Effectiveness in ART Service Delivery

Within the public health model, task-shifting has emerged as an important approach to scaling-up ART services in sub-Saharan Africa. It is defined as the rational redistribution of tasks among the health workforce team - usually from more to less specialized health cadres (e.g., from doctors to nurses, from nurses to community or lay health workers) (WHO, 2006b).

**Rationale** - The primary rationale of task-shifting is to rapidly extend quality HIV services at a lower cost by relying on cadres of health worker who can be trained more quickly and cost less to employ (Callaghan, Ford, & Schneider, 2010; Fulton et al., 2011; Zachariah et al., 2009). For example, it takes on average six years of pre-service education to produce a doctor compared to three years of pre-service education to produce a clinical officer or medical assistant in Kenya, Tanzania, Malawi, and Zambia (Dovlo, 2004).

Further, ART programs employing mainly non-physician clinicians, such as nurses instead of doctors, and pharmacy technicians instead of pharmacists, cost less to run. A study modelling the cost implications of using different types of health workers to provide follow-up care for HIV patients in Uganda found substantial cost-saving opportunities: using nurses instead of physicians could save $1.51 million annually and using pharmacy workers instead of pharmacists could save $4.07 million annually (Babigumira et al., 2011). Another study compared the costs of treatment programs managed by doctors versus primary healthcare nurses and found that nurse-managed
programs could save 11% of the cost of a physician-managed program with no significant differences in treatment outcomes, such as mortality and loss to follow-up (Long et al., 2011). Authors of a systematic review of 34 studies on task-shifting of health services to community health workers in low- and middle-income countries concluded that there was “substantial evidence” for health systems cost-saving: 30 of the 34 studies found evidence of a reduction in health costs either to the health system or to the patient and the other four studies had mixed impacts (Seidman & Atun, 2017). Notably, the authors emphasized the need to measure efficiency alongside cost-effectiveness because although wages for a lower-skilled worker will almost always be lower than for a higher-skilled worker, cost-savings may not be guaranteed because a lower-skilled worker may operate less efficiently (Seidman & Atun, 2017).

**History** - The concept of task-shifting is not new in public health. It has been implemented throughout history as a pragmatic response to a shortage of health workers. Prior to the recent resurgence of interest on “task-shifting” to expand HIV-related services in sub-Saharan Africa, the redistribution of tasks among the health workforce team was known as “task substitution” or “intra-cadre skills delegation” (Dovlo, 2004; Samb et al., 2007).

**Creating new cadres of health workers** - Some of the earliest examples of task-shifting in Africa date back to the early 20th century when auxiliary or paraprofessional cadres of health workers, such as medical assistants and auxiliary nurse midwives, were created to provide medical care in colonized countries (Lehmann, Van Damme, Barten, & Sanders, 2009). For example, Uganda pioneered one of the first cadres of non-physician clinicians called “licentiates” in 1918 who carried out diagnosis and management of basic
communicable diseases and are now currently known as “clinical officers” (Dambisya & Matinhure, 2012). These auxiliary health workers formed the backbone of a nascent health system in the post-independence era in the 1950’s and 1960’s by staffing rural health centers and district hospitals and making up for the scarcity or absence of health professionals, such as doctors, nurses, and pharmacists.

Programs to train lay personnel as community health workers (CHWs) or community health volunteers (CHVs) proliferated in the 1960s to 1980s. CHWs and CHVs were tasked to provide health education and promote preventive health practices (e.g., childhood vaccination, hand-washing) at the household level in rural and poor populations. The potential capacity and acceptance of CHWs in the health service delivery was influenced by global attention to the Barefoot Doctor approach to primary health care in China and increased awareness on the failure of the Western “missionary” model of health care (e.g., physician-centered, tertiary level care based in hospitals) to meet basic health needs in developing countries. The Declaration of the Primary Health Care at Alma-Ata, Kazakhstan in 1978 explicitly defined a role for CHWs with Article VII.7 stating “primary health care … relies, at local and referral levels, on health workers, including physicians, nurses, midwives, auxiliaries, and community workers as applicable, as well as traditional practitioners as needed, suitably trained socially and technically to work as a health team and to respond to the expressed health needs of the community” (International Conference on Primary Health Care, 1978). CHWs have been used to extend a variety of health services from surveillance and monitoring of pregnant mothers, to health promotions of oral rehydration therapy and hand-washing, to directly
observed therapy for tuberculosis, and distribution of pre-packed medicines for home-based treatment of uncomplicated fevers in children (Haines et al., 2007).

**Extending scope of practice to existing cadres of health workers** - In addition to the creation of new cadres of health workers, task-shifting may involve extending the scope of practice of an existing health worker with additional training and at times with the aid of an innovative technology. For example, the West Africa Post-Graduate Medical College offers specialty practical diploma course in psychiatry, ophthalmology, otorhinolaryngology, and anesthesia to enable general practicing physicians to undertake enhanced roles in these areas (Dovlo, 2004). In another example, registered midwives in South Africa were trained and certified in the late 1990’s to use manual vacuum aspiration kits and perform abortion services in primary care settings (Dickson-Tetteh & Billings, 2002). More recently, some non-governmental organizations have trained CHWs to use Uniject, a prefilled injection system, to deliver Depo-Provera for birth control (H. M. Burke, Mueller, Packer, et al., 2014; H. M. Burke, Mueller, Perry, et al., 2014; Cover, Blanton, Ndiaye, Walugembe, & Lamontagne, 2014).

Overall, examples of task-shifting can be summarized into two main categories: 1) extension in the scope of practice of existing health worker cadres (e.g., training midwives in rural areas to undertake delivery-related tasks normally undertaken by medical doctors); and 2) creation of new auxiliary cadres of health workers to substitute the work of health professionals (e.g., training clinical officers or medical assistants to carry out diagnosis and management of primary health care needs in rural settings) (Dovlo, 2004; McPake & Mensah, 2008; Philips, Zachariah, & Venis, 2008; Samb et al., 2007).
In some instances, task-shifting is formalized with written endorsements by the Ministry of Health in policies and changes to laws to accommodate the new roles of health workers. For example, laws were changed in South Africa and Zambia to allow nurses and midwives to take on new abortion-related tasks (Dovlo, 2004). Often, task-shifting is practiced informally in response to the day-to-day reality of healthcare needs and the chronic scarcity of health workers. For example, nurses in Ghana regularly take on delivery of babies with breeched presentations and perform episiotomies in the absence of physicians even though these tasks are considered more technically complex and the responsibility of medical doctors (Dovlo, 2004).

**Task-Shifting in ART Service Delivery** - The most commonly cited forms of task-shifting of ART services are the use of non-physician clinicians, such as clinical officers, health officers, and nurses to determine ART eligibility, prescribe ART regimens, and provide clinical monitoring of HIV patients. These clinical aspects of task-shifting have been reported in countries such as Botswana (Monyatsi et al., 2012), Ethiopia (Assefa et al., 2012), Kenya (Naikoba et al., 2017), Lesotho (M. S. Cohen et al., 2013), Malawi (Bemelmans et al., 2010), Mozambique (Brentlinger et al., 2010a; Sherr et al., 2009), Rwanda (Shumbusho et al., 2009b), South Africa (Davies, Homfray, & Venables, 2013; de Wet, Wouters, & Engelbrecht, 2011; Fairall et al., 2012; Georgeu et al., 2012; Green et al., 2014; Grimsrud, Kaplan, Bekker, & Myer, 2014; Long et al., 2011; Mitchell et al., 2012; Sanne et al., 2010), Swaziland (Mavhandu-Mudzusi, Sandy, & Hettema, 2017), and Uganda. In Kenya and Uganda, small projects have piloted the utilization of trained persons living with HIV (also known as “peer health workers”) to provide home-based clinical monitoring of HIV patients with the aid of mobile
technologies, such as pre-programmed personal digital assistants and mobile phones (Chang et al., 2010; Selke et al., 2010; Wools-Kaloustian et al., 2009).

Task-shifting also involves the delegation of non-clinical aspects of ART services. A commonly documented example is task-shifting clinic-based adherence counselling from nurses to community health workers in Ethiopia (Assefa et al., 2012), expert patients living with HIV in Uganda (Chang et al., 2010; Dambisya & Matinhure, 2012), and trained community volunteers known as “adherence support workers” in Zambia (Torpey et al., 2008). In Ethiopia and Uganda, lay health workers, including both HIV-positive and HIV-negative community volunteers, were trained to engage in community-based counselling and support of ART patients and tracing of defaulted patients who have consecutively missed multiple clinical monitoring appointments or ARV drug refill appointments (Alamo et al., 2012; Assefa et al., 2012). In Tanzania, community health workers were trained to deliver ART and provide adherence and family planning counselling to clinically stable patients in their homes (Geldsetzer et al., 2017).

In addition, some ART sites in Ethiopia, Lesotho, Malawi, South Africa, and Uganda have reported task-shifting of administrative or clerical work to expert patients and community health workers working at the ART clinic in order relieve nurses of the burden of necessary but menial tasks. These tasks included retrieving or archiving patient files, registering patients, and guiding patients through clinic flow (de Wet et al., 2011; Landes et al., 2017; Mwai et al., 2013; Rasschaert et al., 2011).

**Impact on Access** - Task-shifting is hypothesized to expand access to HIV treatment by making ART service delivery more efficient. This involves reducing bottlenecks in ART initiation by allowing nurses or clinical officers to assess ART
eligibility and prescribe ART regimens in order to reduce the workload for doctors and allow them to focus on managing patients with more complicated needs (Callaghan et al., 2010). Multiple studies have documented the impact of non-physician-managed care on patient access to ART treatment. Non-physician-led ART prescription and clinical monitoring of stable patients have been correlated with an increase in patient enrolment of existing HIV care and treatment programs in Lesotho (M. S. Cohen et al., 2013), Malawi (Bemelmans et al., 2010), South Africa (Bedelu, Ford, Hilderbrand, & Reuter, 2007a), Botswana, Swaziland, and Uganda (Emdin & Millson, 2012). It also has enabled the decentralization of ART services to rural clinics in Cameroon (Loubiere et al., 2009), Malawi (Nkhata et al., 2016), Mozambique (Sherr et al., 2009), Uganda (Nkhata et al., 2016), Zambia (Morris et al., 2009), and Zimbabwe (Nkhata et al., 2016).

Evidence on how task-shifting affects patient wait times prior to ART initiation is mixed. Some studies found nurse-managed care improved clinic efficiency. For example, two studies found that nurses in task-shifting prevented the development of waitlists in South Africa (Emdin & Millson, 2012) and Haiti (Ivers et al., 2011). Two other studies found that task-shifting reduced clinic time in Nigeria (Emdin & Millson, 2012). In contrast, several studies have found that nurse-managed care did not improve efficiency. In Uganda, nurses on average spent twice the amount of time with each patient compared to doctors (Wanyenze et al., 2010). In South Africa, nurse-managed care increased clinic wait times, with one study reporting a decrease in the number of patients initiated on ART (Zachariah et al., 2009) and another study finding no significant reduction in mortality of wait-listed patients (Fairall et al., 2012).
Impact on Safety and Effectiveness - There is a growing and consistent body of evidence on comparable standard of care and effectiveness of task-shifted ART services. The findings of these studies are described in greater detail here.

Comparable Standard of Care: Three studies in Botswana, Mozambique, and Uganda have compared the clinical performance of task-shifted cadres of health workers, such as nurses and non-physician clinicians, to that of physicians. All three studies found no significant differences in performance of ART related tasks between the task-shifted health workers and the physicians. The nurse prescribers in Botswana were found to correctly document clinically relevant variables, such as pill counts, chief compliant, physical exam, laboratory testing, and WHO staging 96% of the time (Monyatsi et al., 2012). Non-physician clinicians (tecnicos de medecina) in Mozambique were observed to have comparable clinical performance to national norms of physicians in correctly assigning a WHO stage and management of cotrimoxazole, ART, opportunistic infection, and adverse drug reaction (Brentlinger et al., 2010b). Both nurses and clinical officers in Uganda demonstrated a high level of agreement with physicians in clinical decision-making to initiate a patient on ART (Vasan et al., 2009). Overall, these studies indicate that if non-physician cadres of health workers are adequately trained and supervised, they are capable of providing comparable standards of care to physician cadres.

Treatment Effectiveness: Clinical outcomes of non-physician prescription and clinical monitoring of ART patients have been evaluated in Ethiopia, Lesotho, Kenya, Uganda, Rwanda, and South Africa. The majority of effectiveness studies have utilized retrospective cohort analysis to examine outcomes such as mortality, viral load, CD4 cell count, adherence, retention, and loss to follow-up among ART patients (Alamo et al.,
2012; Assefa et al., 2012; Babigumira et al., 2011; Bedelu, Ford, Hilderbrand, & Reuter, 2007b; Bemelmans et al., 2010; Brennan et al., 2011; Chang et al., 2009; R. Cohen et al., 2009; Ivers et al., 2011; Loubiere et al., 2009; Shumbusho et al., 2009a). These studies were typically conducted in a rural, decentralized ART site that is primarily managed by clinical officers and nurses (Assefa et al., 2012; Bemelmans et al., 2010; Brennan et al., 2011; R. Cohen et al., 2009; Loubiere et al., 2009; Shumbusho et al., 2009a). Some studies specifically documented the role of lay or community-based health workers in supporting task-shifting of clinical ART services (Alamo et al., 2012; Bedelu et al., 2007b; Chang et al., 2009; Ivers et al., 2011; Wools-Kaloustian et al., 2009). Overall, trends in study findings indicate no evidence of a statistical difference in outcome indicators, such as mortality, virologic failure, CD4 cell count (proxy of immunologic response), change in Karnofsky score or WHO stage (measures of HIV disease progression) in patients managed by non-physicians compared to physicians (Assefa et al., 2012; Bemelmans et al., 2010; Brennan et al., 2011; R. Cohen et al., 2009; Shumbusho et al., 2009a). These results suggest that nurses and clinical officers can effectively and safely prescribe ART and provide clinical management of patients when given appropriate training and support.

While most effectiveness studies are observational in nature, there have been five randomized controlled trials (RCTs) that assessed the effectiveness of task-shifting of ART services on clinical outcomes, such as mortality and virologic failure. Three of the RCTs examined the effectiveness of nurse-based HIV care and treatment: trials by Sanne and colleagues and Kiweewa and colleagues compared nurse versus doctor clinical management of HIV patients already initiated on ART, while a trial by Fairall and
colleagues assessed the effectiveness of providing additional training and supervision for nurses to prescribe ART and to clinically manage HIV patients. All three studies indicate that trained nurses are capable of providing effective HIV care and treatment resulting in comparable virologic and immunologic outcomes in patients compared to doctor-centered care (Fairall et al., 2012; Kiweewa et al., 2013; Sanne et al., 2010). Two of the RCTs examined the effectiveness of lay health workers in providing home-based clinical monitoring HIV patients in Uganda and Kenya. In both of these studies, lay health workers performed monthly home visits and clinical monitoring of HIV patients with the aid of a checklist and patients receiving home-based HIV care were compared to those who received facility-based HIV care (Jaffar et al., 2009; Selke et al., 2010). Results indicate that treatment outcomes, such as viral load and CD4 cell counts, are comparable in patients receiving task-shifted home-based care compared to patients receiving facility-based care.

A systematic review based on six effectiveness studies came to a similar conclusion that non-inferiority of patient outcomes was achieved with task-shifting from doctors to nurses, and from health professionals to mid-level cadres or lay health workers. However, the study authors also cautioned that most of the studies were underpowered to detect any statistical differences (Mdege, Chindove, & Ali, 2013). A Cochrane Review of ten studies set in Africa, including four RCTs, found high quality evidence of no difference in mortality at one year in nurse-initiated and followed-up HIV therapy, and moderate quality evidence of lower rates of losses of follow-up at one year. Overall, the Cochrane Review authors concluded that there were moderate quality evidence that task-
shifting responsibility from doctors to trained and supported nurses does not reduce ART patients’ quality of care (Kredo, Adeniyi, Bateganya, & Pienaar, 2014).

**Adherence to Antiretroviral Drugs**

**Importance of ARV Drug Adherence** - The efficacy of HIV treatment relies on patients’ sustained adherence to ARV drugs. High levels of adherence are required for suppressing the virus, especially as incomplete adherence and early treatment discontinuation are among the strongest predictors of virologic failure, drug resistance, and mortality among people living with HIV (Lucas, 2005). Many studies suggest that at least 95% adherence to ARV drugs is needed to achieve optimal viral load suppression, but studies on more potent ART regimens suggest that it is possible to achieve clinical outcomes with lower levels of adherence (70%) (Bangsberg et al., 2006).

Treatment failure has serious individual and public health consequences in resource-limited settings. In many countries in sub-Saharan Africa, ART regimen options remain limited to a single non-nucleoside reverse transcriptase inhibitor based first line regimen, followed by a single protease inhibitor based second line regimen. Individuals with treatment failure need to switch from first to second line regimens, where access is limited and may be available only at urban referral centers. Treatment failure may also lead to the possible spread of strains of drug resistant virus in the community and have serious cost implications for national health system and donor programs given the expensive cost of second line regimens (Barnighausen et al., 2011; Boyd & Cooper, 2007; Eholie et al., 2007).
Adherence Rates in Sub-Saharan Africa - Most literature points to a high level of adherence among ART patients in sub-Saharan Africa compared to patients in the United States and Europe. According to a 2006 meta-analysis of adherence, 77% of ART patients in sub-Saharan Africa achieved adequate levels of adherence (95% CI: 68%-85%) and these rates are comparable to, or better than, those in resource-rich countries (Mills, Nachega, Buchan, et al., 2006). However, these promising data should be interpreted with caution, as adherence estimates were drawn mainly from self-reported data which are prone to over-estimation, and that study populations may not be representative of most ART patients receiving treatment in the region. In addition, patients in the meta-analysis were mostly in early stages of treatment and may have been highly motivated to adherence to ART and not yet developed long-term adverse effects of therapy that can lead to non-adherence (Mills, Nachega, Buchan, et al., 2006). Also, most patients studied were in early treatment programs receiving substantial external technical and financial support, and participants enrolled in pilot studies, cohort studies, or therapeutic trials may have benefited from more extensive programming to support high standards of patient follow-up and adherence behaviors (Eholie et al., 2007; Gill, Hamer, Simon, Thea, & Sabin, 2005). Furthermore, these patients started ART before WHO recommended Test and Treat so patients were likely to have been required to attend at least three or more pre-ART initiation counselling sessions and to bring a treatment buddy to these sessions; they may also have been physically ill prior to ART initiation, given lower CD4 count cut-offs for ART initiation at the time of the studies, which may have motivated adherence.
Longitudinal observational studies of patients not enrolled in therapeutic trials have found that ART adherence rates decline over time (Amberbir, Woldemichael, Getachew, Girma, & Deribe, 2008; Etard et al., 2007; Laurent et al., 2002). In Ethiopia, adherence (defined as a composite measure of self-reported missed doses and non-adherence to drug scheduling and dietary instructions) declined from 79% at baseline to 76% at 3 month follow-up (Amberbir et al., 2008). In Senegal, 88% of patients self-reported adherence levels ≥80% at baseline and the trend of decline in adherence over 18 months was statistically significant (OR 0.92, 95% CI: 0.87-0.97, p<0.002) (Laurent et al., 2002). A seven year follow-up of another cohort of adult ART patients in Senegal found a 14% decrease in the proportion of patients with adherence ≥95% from the first year since ART initiation (87%, 95% CI: 85.0-88.8%) to the seventh year of follow-up (73%, 95% CI: 69.0-77.5%); most of the decrease in adherence levels occurred within the first two years of ART initiation (Etard et al., 2007).

Determinants of Non-Adherence in Sub-Saharan Africa - Determinants of non-adherence to ARV drugs vary by study populations and study design (cross-sectional vs. longitudinal). In sub-Saharan Africa, determinants of non-adherence to ARV drugs can be grouped into patient factors, medication regimen, disease characteristics, patient-provider relationship, and the clinical setting.

Patient factors that have been examined for their relationship with adherence include socio-demographic characteristics (e.g., age, gender, race/ethnicity, marital status, income/ household wealth, and education), cognitive characteristic (e.g., forgetfulness) and psychosocial characteristics (e.g., depression, psychiatric co-morbidity, alcohol or drug use, social support, knowledge and attitudes about HIV, including stigma and self-
Socio-demographic variables have not been shown to be associated with non-adherence in sub-Saharan Africa (Mills, Nachega, Bangsberg, et al., 2006). However, there is a growing recognition that psychosocial factors, such as untreated depression (Cerutti et al., 2016; Fonsah et al., 2017; Heestermans, Browne, Aitken, Vervoort, & Klipestein-Grobusch, 2016; Kim et al., 2017; Shubber et al., 2016; Smith Fawzi et al., 2016), alcohol use (Kekwaletswe & Morojele, 2014; Lyimo et al., 2014; Morojele, Kekwaletswe, & Nkosi, 2014; Negash & Ehlers, 2013), stigma, and self-efficacy play important roles in mediating non-adherence (Ammassari et al., 2002; Chesney, Morin, & Sherr, 2000; Mills, Nachega, Bangsberg, et al., 2006). Notably, stigma is associated with not disclosing one’s HIV status to loved ones and frequent treatment interruptions because taking ARV medications is a hidden behavior (Katz et al., 2013; Mills, Nachega, Bangsberg, et al., 2006). Stigma is also associated with low social support because it keeps people living with HIV from accessing spousal and/or family support to help overcome obstacles to care and treatment adherence (Ammassari et al., 2002; Katz et al., 2013; Ware et al., 2009).

Medication regimen factors include type of ARV drugs, side effects, number of daily pills, daily dosage, and food requirements necessary to take the medication (Katz et al., 2013; Mills, Nachega, Bangsberg, et al., 2006). Patients taking protease inhibitor regimens tend to have lower adherence because these regimens are associated with more side effects, complicated dosing schedules, and dietary restrictions (Ickovics & Meade, 2002). Patients’ knowledge and beliefs about the efficacy of ART treatment also affect adherence (Ammassari et al., 2002; Thielman et al., 2014).
Disease characteristics such as HIV related symptoms, opportunistic infections, low CD4 cell counts, and number of hospitalizations have been associated with decreasing adherence (Ickovics & Meade, 2002; Mills, Nachega, Bangsberg, et al., 2006).

Patient-provider relationship can motivate or discourage patients to adhere to ARV medications. Important factors examined include trust in the provider, perceptions of competence, communication style, and inclusion of patient in decision-making (Katz et al., 2013). For example, compassionate providers can develop bonds of trust and empower patients to overcome stigma associated with taking medicines (Katz et al., 2013).

Clinical setting, including factors such as confidentiality, ease of scheduling appointments, transportation, family centered care, has not been examined as much as the other factors but these components of health services are believed to moderate the impact of access-related barriers on retention to care and ART adherence (Katz et al., 2013; Lamb, El-Sadr, Geng, & Nash, 2012; Mills, Nachega, Bangsberg, et al., 2006; Rosen, Fox, & Gill, 2007).

Clinical Practice to Promote Adherence - Strategies to support adherence within clinical services in Tanzania, Uganda, and Zambia have changed in recent years. In the past, clinical services were often structured to promote adherence behaviors in patients initiating ART. First, patients eligible for ART were required to attend three sessions of pre-treatment counselling with a trained adherence counsellor. Now, the number of preparedness counselling sessions are at the discretion of the counsellor as it is recognized that patients who completed the three sessions for pre-ART counselling had significant delays from ART eligibility to initiation, compared to those who received
counselling at the time of ART initiation, and they often received no benefits from the additional visits (Siedner et al., 2012). The counselling content has remained focused primarily on the biomedical needs of the patient (e.g., educating patients on the importance of adherence and implications of resistance, recognizing side effects) and on promoting habitual adherence behavior (e.g., tailoring medication behavior to patients’ daily activities, including the use of behavioral cues, such as taking medications at meals or prayer times, and reminder aides, such as using a radio program or mobile phone alarm clock (FHI, 2007). Second, patients were strongly encouraged (or, in some settings, required) to nominate a treatment supporter (buddy) to attend pre-treatment counselling sessions with them. The role of the treatment supporter is to encourage patients to take medications as prescribed and to keep clinic appointments (Stubbs, Micek, Pfeiffer, Montoya, & Gloyd, 2009). This is no longer required as programs have found that many patients randomly select strangers to stand in as a treatment buddy, or patients to delay ART initiation because they are unwilling to disclose their HIV status (Kulkarni et al., 2016). Programs continue to follow-up newly initiated ART patients more frequently. For example, patients who have just started on ART are seen by a clinical provider and an adherence counsellor every two weeks until stable (e.g., no adverse response to the ART regimen) and then followed-up every four weeks until they have completed six months of treatment. Stable patients who have been on ART for longer than six months are followed-up every one to three months and their adherence is assessed at each appointment by an expert patient, nurse, or counsellor, who asks the patient to provide a 3-day recall of missed treatment doses (or another adherence measure). Counselling is provided for patients who report being non-adherent to their ARV drugs.
There are a few limitations to existing clinical practices to support patient adherence. First, fewer efforts have focused on supporting the adherence needs of long-term ART patients - a population that is continually increasing in number. ART-experienced patients are in need of support as evidenced by declining rates of adherence in patients over time (Amberbir et al., 2008; Etard et al., 2007; Laurent et al., 2002). Second, existing clinic-based strategies to promote adherence are narrowly focused on educating patients on their biomedical needs and on developing habitual medication-taking behaviors (Campbell & Cornish, 2010; Campbell, Gibbs, Maimane, & Nair, 2008; Mills, Lester, & Ford, 2012). While there is some recognition of the importance of social support in medication adherence, particularly for patients newly initiating ART who are encouraged (or required in some ART programs) to identify a treatment supporter, programs to support adherence for patients on long-term care and treatment are lacking.

**Non-Clinical Factors Supporting Adherence** - Literature on ART adherence in sub-Saharan Africa emphasizes the importance of patient-nominated treatment supporters (informal caregivers not trained, paid, or supported by the ART program who are identified by HIV patients) to promote medication adherence in the home environment. Studies have found patients with treatment supporters have significantly higher levels of ART adherence than patients without treatment supporters (Barnighausen et al., 2011; Igumbor, Scheepers, Ebrahim, Jason, & Grimwood, 2011; Kunutsor et al., 2011; Mugusi et al., 2009; Nachega et al., 2006).

Treatment supporters help patients to maintain adherence to ART in very practical ways. They remind patients to take their ARV medications and attend clinic appointments, and they also provide significant emotional and instrumental support. In
Tanzania, treatment supporters are found to encourage HIV status disclosure and restore hope in the patient, and combat stigma in the community (O'Laughlin, Wyatt, Kaaya, Bangsberg, & Ware, 2011). In South Africa, treatment supporters help patients cope psychologically by listening and being compassionate, and providing instrumental support, such as offering food, money, or transport when needed (Nachega et al., 2006). Similarly, another study in Uganda and Tanzania found that treatment supporters provide important material support, including seeking loans on behalf of the patient to ensure funds to pay for adequate nutrition or transport to the clinic (Ware et al., 2009).

However, existing treatment supporters generally do not receive adequate training or support for their role in caregiving and helping patients take their medications as prescribed. Studies have found HIV caregivers are at risk of emotional and physical burnout and weakening household economies (Akintola, 2008, 2010; Campbell et al., 2008; Lindsey, Hirschfeld, & Tlou, 2003). There is a need to mitigate these risks in order to sustain treatment supporters in providing long-term care to ART patients.

STUDY SETTING

The parent study for this dissertation, titled “Adult ART retention and adherence in Tanzania, Uganda, and Zambia”, was a quantitative research project designed to characterize levels and identify factors related to retention and adherence among HIV positive adult patients in 19 diverse ART clinics in Tanzania, Uganda, and Zambia. The ART Study was composed of two separate protocols, one on program retention (Koole et al., 2014) and the other on ARV drug adherence (Denison et al., 2015). Data were drawn from the adherence study, which was a cross-sectional survey of 4,500 ART patients and
their clinic-based providers. Adherence was assessed by various measures, including patient and provider report of adherence and drug possession ratio calculated from pharmacy refill records. Clinical data were also abstracted from the patient medical chart (clinical, laboratory, and pharmacy records) and linked to the patient and provider interview data. A one-time semi-structured interview with 19 ART clinic managers was conducted to collect information on the clinic’s program characteristics and augment individual patient data collected for the retention and adherence studies.

Manuscripts one and two present both quantitative secondary data analyses drawing upon the infrastructure and data of the ART parent study. First, the infrastructure of the ART Study was leveraged by adding an additional data collection component on task-shifting of ART services to the survey for ART clinic managers. The additional survey components collected information on the types of health service tasks that were shifted to different cadres of health personnel (e.g., registration, triage, ART initial prescription, ART monitoring and management, clinical services, referral services, ART dispensing at the HIV clinic, ARV drug adherence counselling, phlebotomy, follow-up on missed appointments and defaulters, and medical records management); who was originally responsible for the task and who it was shifted to (e.g., from doctors and specialized physicians to non-physician clinician (level I), from non-physician clinical officers to nurses and midwives (type II), from nurses and midwives to nursing assistants and community health workers, including people living with HIV (type III), and patient self-management (type IV)); duration of task-shifting (how long has the change been practiced); and whether there were pre-service training, in-service training or support, and formal standard operating procedures to guide the implementation of task-shifting.
Second, I leveraged the data of the ART Study by merging and analyzing the clinic-based task-shifting data with the adherence data of the ART patients.

Manuscript three presents original qualitative data, including direct observations, in-depth interviews, and archival document collection, from four ART clinics in Uganda. These four clinics were purposively selected from among the parent ART study. These clinics were located in diverse locales: two in Kampala – one in Kawempe Division (4 km to the city’s central business district) and another in Nakawa Division (10 km to the city’s central business district), one in Mityana (77 km west of Kampala), and another in Mbarara (290 km southwest of Kampala). Details of each of the four study settings are described in detail under “case description”.

THEORETICAL FOUNDATIONS

Theoretical Perspective: Social Ecological Model

The theoretical perspective of this study is grounded in social ecological models (SEM). SEM are characterized by 1) multilevel characterization of the factors that influence health that include and go beyond the individual, and 2) the idea of “reciprocal causation” where the environment influences individual behaviors and individuals also influence and create the environment in which they live (McLeroy, Bibeau, Steckler, & Glanz, 1988; Sallis & Owen, 2002).

SEM are distinct from commonly used behavioral change theories (e.g., Health Belief Model, Theory of Reasoned Action and Theory of Planned Behavior, Stages of Change), which come from a psychological tradition and emphasize the process of
individual decision-making regarding behaviors (e.g., perceived risk, susceptibility) (Sallis & Owen, 2002). This approach can be limiting and lead to victim blaming by attributing unhealthy behaviors to ignorance and unwillingness on the part of individuals to change (McLeroy et al., 1988; Sweat & Denison, 1995). Bandura’s Social Cognitive Theory (1986), which also comes from a psychological tradition, examines the interaction of individuals, environments, and behavior. Although this theory recognizes environmental influence on behavior, the social context is acknowledged primarily in the extent that it influences individual beliefs (e.g., attitude development and assessment is equated with the social environment) (N. J. Burke, Joseph, Pasick, & Barker, 2009). Further, more macro or super-structural-levels of influence, such as social, organizational, historical, political, and cultural forces, on the individual are not fully explored and these factors are often treated as background variables only (N. J. Burke et al., 2009).

**Theoretical Perspective: Social Support**

SEM provide a useful framework for examining multiple levels of influence and the context shaping shapes task-shifting of ART services, which in turn, shape and interacts with patient adherence behavior. The ecological perspective acknowledges the idea of reciprocal determinism - that the environment influences the individual and the individuals influence the environment. However, the ecological perspective is limited in providing guidance on the *mechanisms* in which these individuals and their environment interact.
Social support is one of the main mechanisms describing the ways individuals and their social environments interact with each other. Social support is defined as “aid and assistance exchanged through social relationships and interpersonal interactions” (Heaney & Israel, 2002). According to (House, 1981), social support can be categorized into four main types: 1) emotional support (expressions of empathy, love, trust, and caring), 2) instrumental support (tangible aid and service), 3) informational support (advice, suggestions, and information), and 4) appraisal support (information that is useful for self-evaluation) (Heaney & Israel, 2002). There are numerous mechanisms through which social support is hypothesized to influence physical and mental health. (Berkman & Glass, 2000) hypothesize that social support can have a direct effect on health by meeting basic human needs, such as needs “for companionship, intimacy, a sense of belonging, and reassurance of one’s worth as a person” and improving an individual’s sense of well-being and health (Heaney & Israel, 2002). Another hypothesis (Berkman, Glass, Brissette, & Seeman, 2000; Israel, 1982) is that social support can indirectly influence health by enhancing an individual’s social coping resources (e.g., self-efficacy/ problem solving abilities, access to new contacts and information, perceived control) and/or community resources (e.g., community empowerment and community competence). Individual- and community-level resources act as a protective buffer and can mitigate negative effects of stressors on health by influencing the frequency and duration of exposure to stressors (Heaney & Israel, 2002).

Social support can be provided naturally or informally (e.g., family, neighbors, and friends) or formally (e.g., health care workers). It is likely that these different types of individuals also provide different amounts and types of social support. Typically, family
members are more likely to provide long-term emotional and instrumental help (e.g., family members raising children orphaned by AIDS) (Campbell & Cornish, 2010; Campbell et al., 2008), while neighbors and friends are more likely to provide short-term aide (e.g., giving or loaning money for a patient to travel to a clinic for ARV drug refills or clinical monitoring appointments) (Ware et al., 2009). Healthcare workers are more likely to provide informational help in medical settings (e.g., an adherence counsellor teaches a patient the consequences of non-adherence).

Social support is a relevant theoretical concept for the work presented here with task-shifting of ART services hypothesized to shape the amount and type of social support experienced by ART patients, which may influence adherence behavior. Based on my observations of ART clinics and its services, task-shifting of ART services has increased community involvement in HIV care and treatment in at least two ways: 1) using expert patients and other lay cadres of health workers in adherence counselling and support, patient tracing, and managing client flow; and 2) developing greater linkages with the community through collaborations with local churches/ faith-based groups, employers, and livelihood generating groups to provide nutritional support, income-generating opportunities, and general help for individuals and families who are having a hard time. Task-shifting of ART services has created linkages and increased overlapping networks of people who offer formal and informal social support. These individuals who span the formal and informal social support, such as expert patients, may be better positioned to facilitate ongoing community problem identification and problem solving. Also, expert patients may provide support for patient adherence compared to social workers, nurses and doctors because they share the lived experience of living with HIV in
general, maintaining daily adherence to medications and more, and they may be able to offer more helpful advice to patients newly initiated onto ART or to those who are experiencing treatment fatigue (Chang et al., 2010). Patients may also have better perceptions of the advice and support they are getting from expert patients.

Task-shifting tends to occur with a cascade of many other changes in the ART service delivery system. These changes in service delivery also change the environment in which patients experience social support. Examples of changes in service delivery models include ART clinics bringing services closer to the community through satellite clinics (e.g., travelling teams of health providers who rotate through satellite clinics), community-based distribution of ARV drugs (e.g., lay or professional health workers refilling ARV drugs in the village), and increased lengths of ARV drug refill (e.g., getting two to three months of ARV drugs instead of monthly refills). These strategies help individuals and community members mitigate poverty, a significant environmental stressor, because they make treatment access easier through reduced physical distance to the clinic, reduced travel time and cost, and reduced frequency of travel to the clinic.

Conceptual Framework

Given the importance of creating environments to enhance patient social support towards adherence, these theoretical ideas have been blended together to provide a framework for examining the relationship between task-shifted ART services and patient adherence to ARV drugs (Figure 1). Under each level on the figure are listed the factors that are important in shaping adherence based on empirical evidence from published
literature, the primary analysis from the ART Study, and my own hypotheses grounded in reflections on SEM.

The conceptual framework reflects the multi-level approach of this dissertation, which examines factors beyond the individual level. The context is an important part of this framework and is divided into five levels: super-structural, structural, environment, relational, and individual.

Super-structural: This is the most distal level of influence on individual behavior and represents macrosocial and macropolitical forces. These forces include: a) economic underdevelopment (Chen et al., 2004); b) gender norms that shape delegation of health tasks and recognition of select health cadres (George, 2008); c) the role of colonialism, civil service system, and Structural Adjustment Programs on shaping health services (Liese & Dussault, 2004); and d) the role of politics and donor funding for HIV care and treatment programs (Brugha et al., 2010; Iliff, 2006). While the ART Study does not have measures on these large-scale forces, some super-structural factors are considered in manuscript 3.

Structural: This level, between the super-structural and environmental levels, highlights the importance of the health system, the legal, regulatory, and professional rules and policies that shape the ART clinics’ staffing patterns and services, as well as teaching institutions and the private sector in shaping the creation and demand for health professionals (Anand & Barnighausen, 2012). For example, the health system determines the staffing patterns of different levels of health facility (e.g., numbers and types of cadres) and the kinds of health services available (e.g., many primary health care clinics do not have laboratory testing capacity). National and professional bodies (e.g., medicine,
nursing, pharmacy) and training institutions define the scopes of work formally recognized at each level of health facility (Anand & Barnighausen, 2012). All of this, in turn, shapes the kinds of task-shifting strategies implemented at the ART clinics. While the ART Study did not assess variables at the structural level, they are explored in manuscript 3.

**Environment:** The environment refers to the “space” that shapes and is shaped by the experiences of ART patients, their caregivers, and treatment team. This includes the ART clinic and its programmatic components, as well as the wider community where the patient population and clinic resides. It is hypothesized that task-shifting of ART service delivery influences the amount and kinds of social support ART patients experience. For example, task-shifted ART services have increased or enhanced relational linkages between patients, community, and the clinic, particularly with the involvement of expert patients, patient-nominated treatment supporters, and lay health workers. This influence of the ART program on adherence is examined in manuscripts 2 and 3.

**Relational:** This is the proximate level to individual behavior and is situated between the environment and individual levels. The relational level refers to interpersonal relationships that may create social support systems for ART patients, including relationships with family members, friends, peers also living with HIV, clinic staff, community health workers, expert patients, and patient-nominated treatment supporters. As the literature review describes, these relations provide emotional and practical support to ART patients, which are often related adherence success in sub-Saharan Africa (Nachega et al., 2006; O'Laughlin et al., 2011; Ware et al., 2009). Manuscript 2 accounts for interpersonal characteristics by examining the relationship between model of care and
adherence while adjusting for the role of social support – feeling cared for and receiving instrumental help. Manuscript 3 further explores aspects of social support provided by expert patients.

Social Ecological Model: How Task-Shifted ART Services Influence ART Adherence in Uganda

Figure 1 Conceptual Framework - Social Ecological Model How Task-Shifted ART Services Influences ART Adherence in Uganda

Note: The influence of task-shifting on ART adherence is depicted in the yellow translucent circle between the environmental and relational levels.

Individual: This is the most basic unit of influence on behavior. Manuscript 2 accounts for individual characteristics by examining age, sex, and marital status, as well as the role of economic vulnerability on adherence, assessed by the Demographic and
Health Survey household wealth index and by average cost and average time used to reach their clinic.

Clinical characteristics believed to influence individual adherence behavior include pre-ART CD4 cell count, duration on ART, HIV symptoms, and CAGE, 4-questions screening for alcohol abuse. Evidence suggests that patient adherence declines over time on treatment. Patients’ ART regimen and the number of pills they have to take daily are also important considerations because of potential side effects and pill burden.

Adherence has also been associated with high levels of HIV stigma and non-disclosure resulting in patients not being able to take medications as prescribed (e.g., at meal times), or seek help to keep drug refill or clinical appointments (Katz et al., 2013). Manuscript 2 includes the Internalized HIV Stigma Scale and measures of HIV status disclosure from the ART Study. Depression is also associated with low adherence (Mills, Nachega, Bangsberg, et al., 2006). Manuscript 2 also includes the Hopkins Symptoms Checklist depression subscale (HSCL-15).

**DISSERTATION OUTLINE**

In this dissertation, I examine the relationship between task-shifting/task-sharing models of service delivery and patient adherence to antiretroviral therapy, and then conduct case studies on four ART programs in Uganda to see how program-level factors may influence or interact with patient adherence. Manuscript one presents the cluster analysis and Delphi survey results of three task-shifting/task-sharing models using data from 18 routine HIV care and treatment programs in Tanzania, Uganda, and Zambia. Manuscript two presents cluster level analysis results of the relationship between task-
shifting/task-sharing models of care and adherence. The analysis defines adherence using medication possession ratio of ART. This analysis also adjusts for individual-level factors found to influence patient adherence. Manuscript three presents a multiple case study of four ART clinics, where each clinic was purposefully selected to represent a unique task-shifting/task-sharing model of care in different contexts in Uganda. Manuscript three also explores the healthcare delivery factors facilitating patient adherence to ART. Results from these three manuscripts are summarized in the conclusions, which recap the overall findings from all three manuscripts, interpret these findings in light of existing literature and program priorities, and present recommendations for researchers, program planners, and policy-makers.

REFERENCES


trial in Dar es Salaam, Tanzania. *BMC Health Serv Res, 17*(1), 160. doi:10.1186/s12913-017-2032-7


Holmes, C., Pillay, Y., Mwango, A., Perriens, J., Ball, A., Barreneche, O.,... Doherty, M. C. (2014). Health systems implications of the 2013 WHO consolidated antiretroviral guidelines and


Siedner, M. J., Lankowski, A., Haberer, J. E., Kembabazi, A., Emenyonu, N., Tsai, A. C., . . . Bangsberg, D. R. (2012). Rethinking the "pre" in pre-therapy counseling: no benefit of
additional visits prior to therapy on adherence or viremia in Ugandans initiating ARVs. *PloS One, 7*(6), e39894. doi:10.1371/journal.pone.0039894


METHODS

SEQUENTIAL EXPLANATORY MIXED METHODS DESIGN

The overall research goal was to identify effective models of task-shifting and task-sharing that support the high levels of ARV drug adherence necessary to optimize treatment outcomes among patients on antiretroviral therapy in Tanzania, Uganda, and Zambia. The study utilized a sequential explanatory mixed methods design with a quantitative phase followed by a qualitative phase (Figure 2). In the first phase, quantitative methods were employed to identify different models of task-shifting and to create a measure of task-shifted ART models. The relationship of task-shifted ART models and ARV drug adherence, using a medication possession ratio, was then examined. In the second phase, qualitative data were collected to help explain and build upon the initial quantitative results on how a task-shifted ART model influences or interacts with patient ARV drug adherence.

Figure 2 Sequential explanatory mixed methods
Quantitative and qualitative data were “mixed” in two different ways. First, cases for the qualitative study were theoretically sampled based on the various task-shifted ART profiles each clinic represents (Figure 3 stage 2). Second, quantitative and qualitative data were synthesized by using the qualitative phase to elaborate, enhance, illustrate, and clarify results from the quantitative phase (Figure 3 stage 3).

**Figure 3 Selection of quantitative results to follow-up on qualitatively**

**Phase I: Quantitative Component**

The first aim sought to describe the task-shifting strategies used in ART service delivery models and their contextual factors in 19 diverse ART programs in Tanzania, Uganda, and Zambia. Cluster analysis and the Delphi survey were employed to achieve this aim.

**CLUSTER ANALYSIS**

Cluster analysis was performed to identify how task-shifting variables grouped together and create profiles of task-shifted ART models. Cluster analysis is a “statistical
method of proportioning a sample into homogeneous classes to produce an operational
classification” (p.555) (Burns & Burns, 2008). It is an exploratory data reduction
technique used to classify a large amount of information into smaller, more manageable
groupings or ‘clusters’. The analytic process began with each case (ART clinic) as a
separate cluster and then it combined the clusters sequentially – reducing the number of
clusters at each step until only one cluster is left. Clusters were formed by maximizing
dissimilarity between groups. A hierarchical tree diagram (also called a dendrogram in
SAS) was produced to visualize the linkage points. Once an optimal number of clusters
was determined, a new categorical variable was generated and it provided the cluster
memberships of each case in the sample. Descriptive statistics, including bivariate tests,
were conducted to describe and examine whether classifying variables were significantly
different between groups.

Cluster analysis was an appropriate method because it did not rely on a large
sample size and it did not have normality assumptions (Rao & Scott, 1992). The literature
on cluster analysis did not provide a rule of thumb on the minimal sample size needed
and the analysis would render groupings no matter the sample size (Mooi & Sarstedt,
2011). In the ART Study, there were 19 sites in the study and each of the sites had some
element of task-shifting; therefore, the total number of cases of the cluster analysis was
19. The advantage of such an analytic technique was that it employed a more systematic
approach to reviewing large amounts of data compared to a qualitative review of the data,
and it could discover patterns and structure in the data that was not be previously evident.
The cluster analysis involved five major steps:

1. **Selecting measures:** Only 69 variables characterizing task-shifting of ART service delivery were considered for inclusion in the cluster analysis (Appendix A). For example, these variables included: cadre who provided ART prescription, ART monitoring, dispensing ARV drugs, and tracing. Variables describing the health facility and its context, such as facility level, facility type, size of catchment population, and urban/rural locale, were not included to ensure the analysis focused on exploring task-shifting patterns only.

Next, the variables were examined for variability. This was to ensure that only variables that aided the classification of task-shifting patterns were included in the cluster analysis. In consultation with statistician Dr. Larry Moulton, variability was defined as observing differences in at least three of the 19 ART sites per trait of interest. Frequencies were obtained from each of the 69 task-shifting variables. Only 33 variables had sufficient variability to be included in the cluster analysis.

2. **Creating a proximity matrix:** The task-shifting data were binary variables. These measures were not continuous and did not have varying units; therefore, they did not require standardization prior to creating a proximity matrix. The nature of the data informed the selection of algorithms used to generate the proximity matrices. The binary variables were considered asymmetric nominal
data, meaning, the values of the binary outcomes were not equal. For example, not all sites where ART is prescribed by nurses are the same. For this reason, variables were designated as “anominal” in the var statement of the proc distance procedure.

The three most commonly used algorithms for asymmetric, nominal data were the Russell and Rao method, the Jaccard method, and the Dice method (Finch, 2005). Each of these algorithms produced matching coefficients, which measured the response set similarity between any two observations. Observations with more similar patterns of responses on variables of interest were seen as closer to one another than are those with more disparate response patterns.

Given cell $a$ represented the count of the number of $K$ variables for which the two subjects both had the attribute present, cell $b$ represented the count of the number of $K$ variables for which the first subject had the attribute present and the second subject did not have the attribute, cell $c$ represented the count of the number of $K$ variables for which the first subject did not have the attribute present and the second subject had the attribute, and cell $d$ represented the count of the number of the $K$ variables for which neither subject had the attribute present (Table 3), the formulas for calculating the matching coefficients were:
Table 3 2x2 response table for proximity matrix

<table>
<thead>
<tr>
<th></th>
<th>Subject 1</th>
<th>Subject 2</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>1</td>
<td>a</td>
<td>b</td>
</tr>
<tr>
<td>0</td>
<td>c</td>
<td>d</td>
</tr>
</tbody>
</table>

- **Russell/ Rao Index** (Rao, 1948): \( \frac{1}{a+b+c+d} \) - index was the proportion of cases in which both observations had the trait of interest.

- **Jaccard Coefficient** (Sneath, 1957): \( \frac{a}{a+b+c} \) – was similar to the Russel Rao Index but it excluded cases from the denominator where neither subject had the trait of interest (cell d).

- **Dice Coefficient** (Dice, 1945): \( \frac{2a}{2a+b+c} \) – was closely related to the Jaccard coefficient with an additional weight given to cases of mutual agreement (cell a).

These three algorithms were used in proc distance to generate three different proximity matrices. The rationale for using different algorithms in the cluster analysis was to see if the algorithms would produce similar groupings of task-shifting patterns and therefore enhance the sense of validity of the method.

3. **Running the cluster analysis**: The proximity matrix was used as the input for the cluster analysis. Agglomerative hierarchical clustering was performed with the Ward method (proc cluster, method=ward), which produced a hierarchical clustering by starting with each point as a single cluster and then repeatedly...
merging the two closest clusters until a single, all-encompassing cluster remained.

The Ward’s method assumed that a cluster was represented by its centroid (mean of a group of points). It used an analysis of variance approach to evaluate the distances between clusters by calculating the total sum of squared deviations between two cluster centroids. The Ward’s method attempted to minimize the sum of the squared distances of points between two cluster centroids as criterion for fusing the clusters.

4. **Interpreting results and choosing an approximate number of clusters:**

Two statistics, the pseudo F and the pseudo $T^2$, provided measures of cluster fit. The pseudo F-statistic is the ratio of the between-cluster to within-cluster variance, which measured the separation among the clusters at the current level in the hierarchy. If the pseudo F-statistic was large then the mean vectors of all clusters were different. The pseudo $T^2$ statistic was the ratio of the increased within-category variance after joining two clusters to the variance within each of the two clusters. If the pseudo $T^2$ statistic was small then the clusters could be combined. The number of clusters was determined by examining the pattern of change for both statistics. One looked for a local maximum of the pseudo F-statistic, combined with a local minimum of the pseudo $T^2$ statistic and a larger pseudo $T^2$ for the next cluster fusion (Finch, 2005). Also, the pseudo F-statistic was plotted against the number of clusters
to identify the peak or dip, which indicated the natural number of clusters in the dataset.

5. **Comparing the Ward method with other hierarchical methods**: Multiple sensitivity analyses were conducted to compare the Ward method with other hierarchical methods, such as average, min (single), and max (complete). Hierarchical clustering methods were selected because it is appropriate for the binary data. The alternative clustering method was through partitioning or k-means. However, these methods assumed the data were normally distributed and independent, which was not fitting for the binary data. This was to see if similar groupings of sites occurred in order to enhance the validity (or sense that the pattern you observe) was indeed there.

- **Ward** - proximity between 2 clusters was defined as the increase in the squared error that results when 2 clusters are merged
- **Single (Min)** - proximity was defined as the proximity between the closest two points that are in different clusters
- **Complete (Max)** - proximity was defined as the proximity between the furthest two points that are in different clusters
- **Average** - proximity was defined as the average proximity of all pairs of points from different clusters

Results from these additional hierarchical clustering methods, such as the number of clusters and groupings of each ART site, were compared to the Ward method.
The Russel Rao index was selected over the Jaccard coefficient and the Dice coefficient because it was fairly constant in identifying 1,2,12,18 and 5,6,7,8,14. The Ward and Average hierarchical methods were preferred over single (min) and complete (max) because they were not as easily influenced by inliers or outliers.

**DELPHI SURVEY**

Cluster analysis is limited because it cannot interpret the data or assign meaning to the clusters identified. It is possible that the clusters or groupings identified may not prove useful in classifying task-shifted ART profiles. To address this problem, I employed the Delphi Method so that an expert panel reviewed the clusters of variables identified and assessed whether the clusters were meaningful in the context of task-shifting of ART services.

The Delphi method is a “structured group communication process” to make systematic use of expert opinions (Helmer, 1967). It involves an expert panel, two or more rounds of survey with the experts where data are collected and analyzed, and where results from the previous survey are given as feedback so that experts answer the second and any subsequent rounds of surveys under the influence of their colleagues’ opinions. The feedback process allowed for a convergence of opinions, but it also allowed respondents with divergent views to express their opinions (avoiding undue influence and persuasions of groups where the most authoritative member or one with the loudest voice dominates the conclusions drawn).

The main criticism of this technique was low reliability among experts (Landeta, 2006). However, this criticism is drawn primarily from an objectivist epistemology. A
lack of consensus in opinions did not mean the respondent has provided inaccurate information; rather, each respondent is reflecting his/her experiences under varying circumstances. The feedback process in the Delphi Method addressed this criticism by eliciting and documenting each expert’s underlying rationale and process of decision-making. This enabled us to gain a deeper understanding of the complexity underlying perceptions and classification of task-shifting of ART services.

The Delphi Method was implemented in six main steps: 1) identification and creation of an expert panel on task-shifting of ART services; 2) development of an initial questionnaire on models of task-shifting in ART service delivery produced from the cluster analysis and distributed to the expert panel; 3) expert’s individual response to the first questionnaire; 4) summarization of each expert’s response to the first questionnaire to provide a feedback report to the expert panel along with a second set of questions for the panel to respond to; and 5) panel evaluation of the feedback report and provision of individual responses to the report; and 6) analysis and summary of the final group response.

A total of 22 experts were invited to participate in the panel, 18 (82%) of whom completed the Delphi surveys. These experts were identified using one or more of the following criteria: being a lead author on key articles describing and evaluating task-shifting of ART services; advisors working in research and programmatic offices of relevant organizations such as Médecins San Frontiers, FHI 360, CDC, and WHO; and current ART program managers and health system experts from who are responsible for developing the ART clinic staff’s scope of work, such as Ministry of Health representatives for ART or the national council for nursing and midwifery. The majority
of the panel members (16/18, 89%) were experts from or with professional experience in Tanzania, Uganda, and Zambia in order to provide contextually relevant feedback. One-third of the experts (6/18) were also considered international experts to offer insights from other African countries and organizations and potentially expand the generalizability of these results.

The cluster analysis results and the first semi-structured questionnaire were summarized into a 26 page PDF document beginning with a 5 question section collecting information to characterize the expert panels (name, organization, job title, country experience, and years of experience), and then the rest of the document takes participants through the results with 8 embedded questions through the process. These questions were: 1) What are the reasons that ART programs where clinical services are only provided by medical doctors are located in urban areas? 2) What is the reason that ART programs where clinical services are shared by clinical officers and nurses are found only in government sites? Why is this model not found in ART programs supported by non-governmental organizations? 3) What are the reasons why task-sharing by medical doctor, clinical officer, and nurse models are found mainly in sites with large ART population? 4) Do these 3 clusters make sense based on your understanding of how health cadres are distributed in the health system in Tanzania, Uganda, and Zambia? (or in sub-Saharan Africa)? Why or why not? Please state your experiences? 5) Why does this model have the shortest time to ART initiation? 6) Does this model emphasize any clinical services that can only be requested by a medical doctor? 7) Do you think having a government facility explains why this model has the fewest number of sites that provide outreach services? Why or why not? Please state your experiences. 8) This model caters
to the larger ART populations. What strategies are used to improve efficiency, reduce client load, and manage high client flows at ART centers? Finally, the survey ended with a question of “do you have any questions or additional comments?” (Appendix B)

The second questionnaire was 4 pages long and it summarized characteristics of the expert panel, their feedback on the three clusters, and their perspectives on the contextual factors related to the clusters. At this time, individual questions were asked of informants to clarify or expand on their responses. (Appendix C)

All the cluster analysis results and semi-structured questionnaires were shared by email to the expert panel. Sixteen of the participants (16/18, 89%) completed the questionnaires via email. One participant (1/18, 6%) completed the first questionnaire via Skype and the second questionnaire via email. Another participant (1/18, 6%) completed the first questionnaire through an in-person meeting and the second questionnaire via email. For both rounds of data collection, all semi-structured responses were collated into an Excel spreadsheet and analyzed by themes and frequency.

Results from the cluster analysis and Delphi survey were ultimately summarized into a nominal variable used to classify task-shifting models. This variable was later used as the main “exposure” or independent variable of interest to examine the relationship between task-shifted models of ART services and patient adherence to ARV drugs.

**CLUSTER LEVEL ANALYSIS**

The second aim sought to examine the relationship between the task-shifted models of ART services and patient adherence to ARV drugs. The specific study questions were:
1. **Are there differences in patient adherence outcomes by task-shifting model?** Is there any relationship between task-shifting and patient adherence to ART?

2. **Do differences in adherence outcomes by task-shifting model still exist after adjusting for patient characteristics found to influence adherence?** If there is a relationship between task-shifting and patient adherence to ART, is it because of the patient composition, or the model of care?

3. **Do task-shifting models work better for patients who have been on ART for 5 years or longer compared to patients who have been on fewer years of ART?**

   Which model of care would you recommend for long-term maintenance of ART patients?

   We used cluster level analysis to account for the clustered nature of the data⁴ (Haynes & Moulton, 2009). To answer the first study question, we created cluster level summarizes of non-adherence (medication possession ratio <90%) as a crude measure of effect and compared them by task-shifting model of care using paired t-tests to assess whether there was an association between task-shifting model of care and patient adherence. To create the measure of effect, we calculated the proportions of non-adherence (MPR<90%) for each ART clinic and then averaged the results by task-shifting model to obtain the model-specific point estimate. The mean difference of percentages of MPR<90% with 95% confidence interval (CI) calculated by entering the ART clinic summaries weighted by the number of ART clinic patients included in the analysis.

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⁴ We did not use logistic regression because it would not account for intra-cluster correlation. We did not use generalized estimating equations because we did not have enough clusters to conduct robust individual-level analyzes like marginal conditional models. Therefore, cluster level summarizes compared by t-tests were the most appropriate method for clusters with small sample sizes.
analysis into the analysis of variance model. The mean differences of MPR were computed comparing each task-shifting model against another (model 1 minus model 2, model 1 minus model 3, and model 2 minus model 3). Statistical significance was assessed with the paired t-test on the relative risk and the corresponding 95% CI for the mean differences were obtained.

Once an association between task-shifting model of care and patient adherence was established, the second step was to answer the second study question, which was to control for possible individual-level characteristics between groups that might explain why a relationship was observed between task-shifting model of care and patient adherence. A two-stage procedure was used: first, a standard multivariable logistic regression analysis is carried out to obtain a residual for each cluster that is adjusted for the covariates of interest. Logistic regression was used because the dependent variable was binary (MPR<90% or ≥90%). This model incorporated all covariates of theoretical importance (based on literature review and what was available in the dataset) except the intervention effect (the task-shifting model of care). The expected probabilities where MPR<90% were obtained by summing the residuals of each participant in each clinic from the multivariable model. The logarithmic ratio of the expected (E) and observed (O) numbers of non-adherence were calculated for each ART clinic (residual = ln(observed/expected) to give cluster residuals in an Excel Sheet. Second, adjusted relative risks (aRR) were obtained for each pair (e.g., model 1 vs. model 2) using the student t-test. Adjusted significance tests and confidence intervals were calculated as before.
Finally, to answer the third study question, a significance test of interaction between duration on ART and task-shifting model of care was done. A sub-group analysis stratifying participants by duration on ART (≥5.3 years or <5.3 years) and repeating the process described above.

**Phase II: Qualitative Component**

In phase II, qualitative methods were used to understand and further explore quantitative findings from phase I. The scope of the qualitative research was narrowed to Uganda only to ensure feasibility. Uganda was chosen because the country had the most variability in models of ART service delivery of the three countries included in the ART study, which made it a good setting to explore, compare, and develop a comprehensive explanatory model on how task-shifted ART services may influence patient adherence to ARV drugs.

**MULTIPLE CASE STUDY**

*Case Study Methodology:* The case study methodology was adept for a “contemporary” phenomenon and “when boundaries between phenomenon and context are not clearly evident” (p.18) (Yin, 2009). As such, a case study methodology was an especially suitable method of inquiry for this study on how task-shifted models of service delivery relate to patient adherence – a phenomenon bounded within and intertwined with the contexts of the ART clinic and the country’s health system.
A case study is also a very strong method for answering operational research questions because it addresses “how” and “why” types of questions. The following research questions were explored in each case:

- **How is task-shifting implemented at the ART clinic?** This question included specific foci on: 1) the initial rationale for task-shifting (e.g., planned or ad-hoc process), 2) preparation for task-shifting (e.g., criteria and processes of selecting staff, training and on-going support to develop a new skill mix), 3) implementation of task-shifting, and 4) the future of task-shifting (exploring relevant issues to scalability and sustainability of task-shifting).

- **How do task-shifted programmatic services influence (or interact with) individual adherence behaviors?** This question included specific foci on 1) client experiences with ART services, including confidence and satisfaction with staff competence, efficiency, and interaction with staff, and 2) the influence of clinic interventions, such as patient tracing, adherence counselling and support, ART refill schedule, on client adherence behaviors.

- **How do different models of task-shifting potentially influence ART adherence?** This question was addressed by synthesizing the above components.

**Sources of Data:** Case study methodology emphasizes the use of multiple data sources to enhance data credibility (whether description and interpretation of phenomenon rings true or is believable). This approach can help cope with the study circumstances when there are many more variables of interest than data points (Yin, 2009). Data sources in this study included direct observations of events and interactions,
the collection and content analysis of relevant documents and audio-visual materials, and
in-depth interviews with providers and patients. Direct observations enabled us to gain a
contextual understanding of what happened at each study site, in-depth interviews
allowed us to focus questions directly on case study topics, and the collection and content
analysis of documents and audio-visual materials from the study sites and Uganda
Ministry of Health enabled us to gain a comprehensive contextual understanding of ART
service delivery and human resource organization of Uganda’s health system.

**Study Population, Sampling, and Sample Size:** The four ART sites were
purposefully selected using results from the cluster analysis and Delphi survey results to
represent the three task-shifting/task-sharing models of service delivery in unique
contexts. At each case study site, individuals were purposefully sampled and invited to
participate in in-depth interviews because they could inform an understanding of the
research problem and central phenomenon in the study. Two different study populations
were included in the case studies: 1) ART clients, and 2) ART clinic providers, including
lay health workers and ART program managers. All informants were adults 18 years or
older who provided written consent to participate in the research study. ART clinic
provider informants, including lay health workers, were purposefully selected according
to their job description within the ART clinic. Equal numbers of adult female and male
ART patients who had been on ART for at least six months were sampled based on their
experiences with the task-shifted ART services. A total of 8-10 providers and a total of 8-
10 ART patients were interviewed at each study site.

**Data Collection:** Direct observations were the first method of data collection at
each study site. Typically, the Study PI (and observer) spent three to five days conducting
day-long observations at each clinic to see what a typical day at the ART clinic was like. The first day was spent becoming acquainted with the physical space of the health facility and the general clinic flow. Then one or two days were spent to better understand discrete aspects of the ART program from the clinic staff perspective, such as observing expert patients and their pill packing and labelling tasks at the pharmacy, or watching a medical officer review files of patients seen by nurses to ensure quality of care and give feedback to the nurses if necessary. Finally, one or two days were spent following the differentiated care of patients in public spaces, such as the services a stable patient would get beginning from clinic registration to triage, clinical monitoring, to ART refill, or a patient coming for pharmacy refill only visits (or a tuberculosis patient or a pregnant woman). Following direct observations, I conducted in-depth interviews with the ART staff. Clinic staff were recruited during the working days of the clinic. The head of the clinic was asked to introduce the study to all of the clinic staff at a staff meeting and informed them that the research team would invite them to participate in in-depth interviews based on their function at their clinic. Research assistants fluent in the local languages specific to the study sites recruited ART patients to participate in in-depth interviews while they were waiting in the triage area. All interviews took place in a private area out of sight and ear-shot (Appendices E-H). Finally, program and national documents and audio-visual materials were collected throughout data collection at the study sites to build an understanding of the context of these study sites and the history of HIV and ART in Uganda.

Data Management and Analysis: All in-depth interviews were digitally recorded, simultaneously translated and transcribed verbatim from the local languages into English
in Microsoft Word. Each transcript was reviewed for content, interviewing and transcription quality, and annotations were provided as feedback to the interviewer to improve interviewing technique. All transcripts, relevant documents, and observation notes were uploaded and stored into qualitative software MaxQDA 12. A thematic content analysis approach was used to analyze the textual data. The textual data were read and re-read to identify recurrent themes and concepts to develop a coding tree. Codes were applied to the text. Once all the text was coded, memos and display matrices were developed to summarize key codes and codes were examined for sub-themes, nuances, and patterns.

REFERENCES

MANUSCRIPT 1:

Identifying Models of HIV Care and Treatment Service Delivery in Tanzania, Uganda, and Zambia Using Cluster Analysis and Delphi Survey
Abstract

**Background:** Organization of HIV care and treatment services, including clinic staffing and services, may shape clinical and financial outcomes, yet there has been little attempt to describe different models of HIV care in sub-Saharan Africa (SSA). Information about the relative benefits and drawbacks of different models could inform the scale-up of antiretroviral therapy (ART) and associated services in resource-limited settings (RLS), especially in light of expanded client populations with country adoption of WHO’s test and treat recommendation.

**Methods:** We characterized task-shifting/task-sharing practices in 19 diverse ART clinics in Tanzania, Uganda, and Zambia and used cluster analysis to identify unique models of service provision. We ran descriptive statistics to explore how the clusters varied by environmental factors and programmatic characteristics. Finally, we employed the Delphi Method to make systematic use of expert opinions to ensure that the cluster variables were meaningful in the context of actual task-shifting of ART services in SSA.

**Results:** The cluster analysis identified three task-shifting/task-sharing models. The main differences across models were the availability of medical doctors, the scope of clinical responsibility assigned to nurses, and the use of lay health care workers. Patterns of healthcare staffing in HIV service delivery were associated with different environmental factors (e.g., health facility levels, urban vs. rural settings) and program characteristics (e.g., community ART distribution or integrated tuberculosis treatment on-site).
Conclusions: Understanding the relative advantages and disadvantages of different models of care can help national programs adapt to increased client load, select optimal adherence strategies within decentralized models of care, and identify differentiated models of care for clients to meet the growing needs of long-term ART patients who require more complicated treatment management.
BACKGROUND

Critical shortages and inefficient distribution of trained health workers constrains timely and universal access to HIV treatment in SSA (WHO, 2006). Many antiretroviral therapy (ART) programs have coped with staff shortages by extending the scope of practice for existing health workers (Assefa et al., 2012; Bedelu, Ford, Hilderbrand, & Reuter, 2007; Bemelmans et al., 2010; Brentlinger et al., 2010; L. Chang et al., 2009; M. S. Cohen et al., 2013; Dohrn, Nzama, & Murrman, 2009; Fairall et al., 2012; Monyatsi et al., 2012; Sanne et al., 2010; Sherr et al., 2009; Shumbusho et al., 2009; Vasan et al., 2009), and creating new auxiliary cadres, including peer health workers for home-based patient monitoring (L. W. Chang et al., 2010; Selke et al., 2010; Wools-Kaloustian et al., 2009), adherence supporters for clinic-based adherence counselling and home-based patient tracing (Alamo et al., 2012; Assefa et al., 2012; L. W. Chang et al., 2010; Dambisya & Matinhure, 2012; Torpey et al., 2008), and expert patients and community health workers to relieve nurses of administrative tasks, such as patient file retrieval or archival, patient registration, and clinic navigation (de Wet, Wouters, & Engelbrecht, 2011; Mwai et al., 2013; Rasschaert et al., 2011).

Redistributing tasks within the existing health workforce involves task-shifting and task-sharing. Task-shifting is moving tasks from one cadre to another – usually from more to less specialized cadres (e.g., moving ART prescription from doctors to clinical officers (COs) or nurses) (Callaghan, Ford, & Schneider, 2010; Fulton et al., 2011; Zachariah et al., 2009). Task-sharing is a “team-based approach” where “medical care [is] provided to a patient by a set group (team) of different health professionals with different roles that maximize the skills and abilities of each team member” (Olson, 2012).
For example, COs and nurses may initiate ART and monitor stable patients while doctors manage patients with complex opportunistic infections.

Task-shifting and task-sharing in ART services vary tremendously across countries and programs. To date, research has mainly focused on the safety and effectiveness of task-shifting (Assefa et al., 2012; Bemelmans et al., 2010; Brennan et al., 2011; R. Cohen et al., 2009; Fairall et al., 2012; Kiweewa et al., 2013; Sanne et al., 2010; Selke et al., 2010; Shumbusho et al., 2009). Less is known about the relationship between clinic staffing patterns (e.g., who delivers services), the range of HIV care and treatment services offered, and the context in which task-shifting/task-sharing occur (e.g., types of health facilities). Understanding these relationships may identify different models of HIV care, which can be compared on their frequency of use, cost, and association with HIV-related treatment outcomes. Information about benefits and drawbacks of different HIV care models can also inform ART scale-up in RLS, especially following the World Health Organization’s (WHO) recommendation for immediate ART initiation of all HIV-positive individuals (WHO, 2015). Country adoption of this recommendation should lead to increased client volumes and higher proportions of patients who start ART when healthier, underscoring the need to identify successful task-shifting/task-sharing strategies so countries can achieve the ultimate goal of providing lifelong ART and associated care for every HIV-infected person.

In this study, we sought to identify ART task-shifting/task-sharing service delivery models and describe their health facility and environmental characteristics. A cluster analysis of cross-sectional data from 19 diverse ART clinics in Tanzania, Uganda,
and Zambia was conducted. Models of care identified were then verified by 18 experts using the Delphi survey process.

**METHODS**

**Study Design and Setting**

Cross-sectional data for this analysis came from an ART retention and adherence study in Tanzania, Uganda, and Zambia led by FHI 360 (2008-2012). The main study’s purpose was to characterize retention and adherence rates in 19 ART clinics, and to examine programmatic and individual factors related to retention and adherence among adult patients on ART for at least six months. Clinics were purposefully selected with country partners and Ministries of Health (MOH) to include those with ≥300 patients from different socioeconomic and urban-rural locations with varying characteristics, including public/private/faith-based organizations, primary/secondary/tertiary-levels, and different ART adherence and provision strategies. Additional site selection details have been reported elsewhere (Denison et al., 2015; Koole et al., 2014). Information on the 19 ART clinics’ task-shifting/task-sharing characteristics was collected in a cross-sectional survey with ART clinic managers in 2010-2011.

**Measures**

Trained interviewers used a structured survey to systematically document task-shifting/task-sharing practices at each clinic on the following ART-related services on a
typical day: 1) registration, 2) initial patient triage, 3) initial ART prescription based on ART eligibility assessment, 4) ART monitoring and management (including drug side effects, CD4 cell viral load monitoring), 5) clinical services (diagnosis and management of opportunistic infections and management of common non-HIV conditions, i.e. malaria), 6) referral services, 7) ART dispensing, 8) counselling on ART adherence, 9) phlebotomy for laboratory testing, 10) follow-up of patients who missed appointments, and 11) medical records management. Data were stored in EpiData 3.1.

Cluster Analysis

We conducted a cluster analysis to identify models of ART task-shifting/task-sharing service delivery. All statistical analyses used SAS 9.3.

We first ran frequencies on all variables to assess variability, defined as differences observed in at least three of the 19 ART clinics. Only 33 of 69 initial variables had sufficient variability to be included in the analysis.

We then performed agglomerative hierarchical clustering using the Ward Method and the Russel and Rao Index as the measure of similarity – an algorithm selected for the asymmetric nominal nature of the data. The number of clusters were determined based on examination of the generated dendrogram and statistics measuring the cluster fit (pseudo F-statistic and pseudo $T^2$ statistic). Nine sensitivity analyses were performed using other measures of similarity (e.g., Jaccard coefficient and Dice coefficient) and hierarchical methods (average, single, and complete) fitting for the asymmetric binary data, enhancing the reliability of the findings (Choi, Cha, & Tappert, 2010; Finch, 2005; McCarthy,
A cluster analysis based on the Ward method and the Russel and Rao Index was used to create the final solution as: 1) the Ward method compared to average, single, and complete hierarchical methods was not easily influenced by inliers or outliers; and 2) the Russel and Rao Index produced the most constant groupings of ART clinics compared to the Jaccard and Dice coefficients. This process resulted in the generation of a new categorical variable to represent cluster membership of each case in the sample.

Finally, we descriptively explored how the clusters (or models of task-shifting/task-sharing) varied by environmental factors (e.g., country, health facility type) and programmatic characteristics (e.g., time to ART initiation, ART refill schedule). Continuous variables were summarized using means and medians while categorical variables were summarized with frequencies and percentages. No statistical testing was done to compare the clusters given the small numbers of clinics (≤10) within each cluster. Limited power meant the study could only detect extreme differences of one to two standard deviations between clinic means.

**Delphi Survey**

We employed the Delphi Method to make systematic use of expert opinions (Helmer, 1967) to ensure the clusters were meaningful in the context of ART services in SSA. Experts were purposefully identified through peer-reviewed publications on task-shifting/task-sharing and by nomination by colleagues in HIV care and treatment. Experts completed two structured interviews in person or via email. In the first interview, experts reviewed the cluster analysis results and completed an eight-question semi-structured
questionnaire. In the second interview, experts were presented summarized results and asked to clarify and expand on their responses to the first questionnaire. All responses were analyzed and summarized thematically.

RESULTS

Number of Clusters or Models

The hierarchical cluster analysis dendrogram and cluster fit suggested a three-cluster solution, with each cluster representing a model of ART service delivery. The 19 clinics were divided into three groups of 4, 5, and 10 clinics (Table 4). Eight of the nine sensitivity analyses yielded the same groupings of clinics, while one algorithm involving the single method yielded six clusters (data not shown).

The staffing patterns of the three clusters were examined. Two models represented task-sharing of clinical services between doctors and COs, distinguished by whether nurses played a role in clinical care or not. The third model represented complete task-shifting of clinical services from doctors to COs and nurses. Lay health workers (LHWs) task-shared with nurses and counsellors in providing adherence support to patients in all models. In two models, LHWs also provided support essential to efficient clinic flow, such as patient registration and medical file retrieval/archival.
Table 4 Task-shifting and task-sharing of antiretroviral therapy services, by clusters

<table>
<thead>
<tr>
<th>Cadre and Roles*</th>
<th>1 Traditional Model (N=5)</th>
<th>2 Mixed Model (N=10)</th>
<th>3 Task-Shifted Model (N=4)</th>
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<tbody>
<tr>
<td></td>
<td>n</td>
<td>%</td>
<td>n</td>
</tr>
<tr>
<td><strong>Medical doctor</strong></td>
<td></td>
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<td>ART initial prescription</td>
<td>5</td>
<td>100</td>
<td>10</td>
</tr>
<tr>
<td>ART monitoring &amp; management</td>
<td>5</td>
<td>100</td>
<td>10</td>
</tr>
<tr>
<td>Clinical services</td>
<td>5</td>
<td>100</td>
<td>10</td>
</tr>
<tr>
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<td>87</td>
<td>10</td>
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<tr>
<td><strong>Clinical officer</strong></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>ART initial prescription</td>
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<td>40</td>
<td>9</td>
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<tr>
<td>ART monitoring &amp; management</td>
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<td>40</td>
<td>10</td>
</tr>
<tr>
<td>Clinical services</td>
<td>2</td>
<td>40</td>
<td>10</td>
</tr>
<tr>
<td>Referral services</td>
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<td>40</td>
<td>10</td>
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<td></td>
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<tr>
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<td>6</td>
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<td>20</td>
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<tr>
<td>Referral services</td>
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<td>0</td>
<td>7</td>
</tr>
<tr>
<td>ART dispensing at the HIV clinic</td>
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</tr>
<tr>
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<td>8</td>
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<tr>
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<td>5</td>
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<td>0</td>
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<td>Medical records management</td>
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<td><strong>Counsellor</strong></td>
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<td></td>
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<tr>
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<td>0</td>
<td>4</td>
</tr>
<tr>
<td>ART adherence counselling</td>
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<td>40</td>
<td>7</td>
</tr>
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<td>0</td>
<td>3</td>
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<td>2</td>
</tr>
<tr>
<td><strong>Pharmacy technician</strong></td>
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<tr>
<td>ART dispensing at the HIV clinic</td>
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<td>7</td>
</tr>
<tr>
<td>ART adherence counselling</td>
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<td>1</td>
</tr>
<tr>
<td>Patient tracing for missed appointments &amp; defaulters</td>
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<td>20</td>
<td>2</td>
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<td>Medical records management</td>
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<td>2</td>
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<tr>
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<tr>
<td>Registration</td>
<td>1</td>
<td>20</td>
<td>4</td>
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<tr>
<td>Patient tracing for missed appointments &amp; defaulters at the HIV clinic</td>
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<td>0</td>
<td>4</td>
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<tr>
<td><strong>Community health worker</strong></td>
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<tr>
<td>Patient tracing for missed appointments &amp; defaulters at the HIV clinic</td>
<td>3</td>
<td>60</td>
<td>3</td>
</tr>
</tbody>
</table>

*These are actual roles performed by cadres on a typical day in the ART clinic; they may vary from expected roles noted in a country policy guideline.*
Expert Panel Response to the Three Models

Eighteen of the 22 invited experts participated in the survey (82% response rate). Experts had 5 to 21 years of experience implementing ART task-shifting services, policy, or research in 21 African and 9 non-African countries. They represented a range of organizations including MOHs, national and international implementation partners, universities, and funding agencies.

Most experts (14/18, 78%) said the three service delivery models identified were consistent with their knowledge and experience of ART programs in SSA. Four experts (4/18, 22%) said model findings were “artificial” and “context dependent” and only meaningful to the three countries where data were collected.

Model Profiles

Overview

All three task-shifting/task-sharing models included clinics from the three study countries and from every health facility types encompassing national referral, provincial/district, and primary health centers (PHCs) (Table 5). These findings suggested successful application of the cluster analysis, which organized facilities around staffing of ART service delivery. Models are labeled and described in detail below.
### Table 5 Summary of contextual factors, by clusters

<table>
<thead>
<tr>
<th>CLUSTER</th>
<th>ART Site</th>
<th>Facility Level</th>
<th>Facility Type</th>
<th># Current ART Patients</th>
<th>Urban or Rural</th>
<th>Number of providers on a typical clinic day</th>
<th># Medical Officer</th>
<th># Clinical Officer</th>
<th># Nurse/ Midwife</th>
<th># Lay HW</th>
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<td>T2</td>
<td>Provincial</td>
<td>Government</td>
<td>1000-2000</td>
<td>Urban</td>
<td>0 2 9 1</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>U12</td>
<td>District</td>
<td>Government</td>
<td>&lt;1000</td>
<td>Rural</td>
<td>0 1 6 8</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Z18</td>
<td>PHC</td>
<td>Government</td>
<td>2000-4000</td>
<td>Urban</td>
<td>0 2 4 1</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Key:**
- T = Tanzania, U = Uganda, Z = Zambia
- Nat Ref = National Referral, PHC = Primary Health Center
- NPNR = Non-profit, non-religious
- MO = Medical Officer, CO = Clinical Officer, LHW = Lay Health Workers
<table>
<thead>
<tr>
<th>PROGRAMMATIC FACTORS</th>
<th>Model-1 Traditional n=5 clinics</th>
<th>Model-2 Mixed n=10 clinics</th>
<th>Model-3 Task-Shifted n=4 clinics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinic days Per Week (average clinic day is 7 hours)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Avg number of clinic days at the main ART site (min, max)</td>
<td>4.6 (3,6)</td>
<td>4.4 (2,6)</td>
<td>4.8 (4,5)</td>
</tr>
<tr>
<td>Avg number of clinic days at outreach sites (min, max)</td>
<td>3.0 (0,5)</td>
<td>1.3 (0,5)</td>
<td>0.5 (0,2)</td>
</tr>
<tr>
<td>Total avg number of clinic days (min, max)</td>
<td>7.6 (3,11)</td>
<td>5.7 (4,10)</td>
<td>5.3 (5,6)</td>
</tr>
<tr>
<td>Time to ART initiation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt;7 days to determine eligibility</td>
<td>0/5 (0%)</td>
<td>6/10 (60%)</td>
<td>2/4 (50%)</td>
</tr>
<tr>
<td>&gt;7 days to initiate AT if found eligible</td>
<td>1/5 (20%)</td>
<td>4/10 (40%)</td>
<td>2/4 (50%)</td>
</tr>
<tr>
<td>Site requires at least 3 counselling sessions before ART initiation</td>
<td>2/5 (40%)</td>
<td>9/10 (90%)</td>
<td>3/4 (75%)</td>
</tr>
<tr>
<td>One or more stock out of ART in the past 6 months</td>
<td>1/5 (20%)</td>
<td>0/10 (0%)</td>
<td>4/4 (100%)</td>
</tr>
<tr>
<td>Time to Less Frequent ARV Drug Refill (every 2 months instead of monthly)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>In the first month on ART</td>
<td>0/5 (0%)</td>
<td>0/10 (0%)</td>
<td>0/4 (0%)</td>
</tr>
<tr>
<td>Between two and six months on ART</td>
<td>0/5 (0%)</td>
<td>2/10 (20%)</td>
<td>0/4 (0%)</td>
</tr>
<tr>
<td>After six months on ART</td>
<td>1/5 (20%)</td>
<td>8/10 (80%)</td>
<td>1/4 (25%)</td>
</tr>
<tr>
<td>Frequency of laboratory testing after 6 months on ART</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CD4 cell count</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Every 3 months</td>
<td>1/5 (20%)</td>
<td>2/10 (20%)</td>
<td>0/4 (0%)</td>
</tr>
<tr>
<td>Every 6 months</td>
<td>4/5 (80%)</td>
<td>8/10 (80%)</td>
<td>4/4 (100%)</td>
</tr>
<tr>
<td>Viral load testing</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Never</td>
<td>2/5 (40%)</td>
<td>6/10 (60%)</td>
<td>3/4 (75%)</td>
</tr>
<tr>
<td>As needed</td>
<td>3/5 (60%)</td>
<td>4/10 (40%)</td>
<td>1/4 (25%)</td>
</tr>
</tbody>
</table>
Table 7 Summary of HIV care and treatment programmatic factors, by clusters (continued)

<table>
<thead>
<tr>
<th>PROGRAMMATIC FACTORS</th>
<th>Model-1 Traditional</th>
<th>Model-2 Mixed</th>
<th>Model-3 Task-Shifted</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Model-1 Traditional Model: Task-Sharing of Major Clinical Responsibilities between Doctors and Clinical Officers (n=5)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adherence support through the HIV care and treatment clinic</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Require treatment supporter after ART initiation</td>
<td>5/5 (100%)</td>
<td>8/10 (80%)</td>
<td>3/4 (75%)</td>
</tr>
<tr>
<td>Pill count during 1st six months on ART</td>
<td>0/5 (0%)</td>
<td>5/10 (50%)</td>
<td>3/4 (75%)</td>
</tr>
<tr>
<td>Pill count after 1st six months on ART</td>
<td>0/5 (0%)</td>
<td>5/10 (50%)</td>
<td>2/4 (50%)</td>
</tr>
<tr>
<td>Pill count after patient misses ARV drug refill</td>
<td>4/5 (80%)</td>
<td>7/10 (70%)</td>
<td>3/4 (75%)</td>
</tr>
<tr>
<td>People Living with HIV support group</td>
<td>5/5 (100%)</td>
<td>8/10 (80%)</td>
<td>4/4 (100%)</td>
</tr>
<tr>
<td>Adherence support worker</td>
<td>4/5 (80%)</td>
<td>8/10 (80%)</td>
<td>3/4 (75%)</td>
</tr>
<tr>
<td>Home-based care worker</td>
<td>3/5 (60%)</td>
<td>5/10 (50%)</td>
<td>2/4 (50%)</td>
</tr>
<tr>
<td>Community-based services linked to the HIV care and treatment clinic</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ARV drug distribution by providers or lay volunteers</td>
<td>0/5 (0%)</td>
<td>3/10 (30%)</td>
<td>1/4 (25%)</td>
</tr>
<tr>
<td>Adherence support</td>
<td>5/5 (100%)</td>
<td>8/10 (80%)</td>
<td>4/4 (100%)</td>
</tr>
<tr>
<td>Emotional or social support</td>
<td>4/5 (80%)</td>
<td>8/10 (80%)</td>
<td>3/4 (75%)</td>
</tr>
<tr>
<td>Follow-up of missed appointments</td>
<td>4/5 (80%)</td>
<td>7/10 (70%)</td>
<td>3/4 (75%)</td>
</tr>
<tr>
<td>Nutritional supplementation</td>
<td>3/5 (60%)</td>
<td>5/10 (50%)</td>
<td>3/4 (75%)</td>
</tr>
<tr>
<td>Home based care</td>
<td>4/5 (80%)</td>
<td>7/10 (70%)</td>
<td>4/4 (100%)</td>
</tr>
<tr>
<td>Referral for medical care</td>
<td>4/5 (80%)</td>
<td>7/10 (70%)</td>
<td>4/4 (100%)</td>
</tr>
<tr>
<td>Follow-up of missed clinic or pharmacy appointment</td>
<td>4/5 (80%)</td>
<td>9/10 (90%)</td>
<td>4/4 (100%)</td>
</tr>
<tr>
<td>Telephone contact</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>House visit by adherence support worker</td>
<td>3/5 (60%)</td>
<td>8/10 (80%)</td>
<td>3/4 (75%)</td>
</tr>
<tr>
<td>House visit by healthcare worker</td>
<td>1/5 (20%)</td>
<td>5/10 (50%)</td>
<td>1/4 (25%)</td>
</tr>
<tr>
<td>House visit by home-based care worker</td>
<td>3/5 (60%)</td>
<td>7/10 (70%)</td>
<td>3/4 (75%)</td>
</tr>
<tr>
<td>Tracing of patients loss to follow-up</td>
<td>4/5 (80%)</td>
<td>9/10 (90%)</td>
<td>4/4 (100%)</td>
</tr>
<tr>
<td>Telephone contact</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>House visit by adherence support worker</td>
<td>4/5 (80%)</td>
<td>8/10 (80%)</td>
<td>2/4 (50%)</td>
</tr>
<tr>
<td>House visit by healthcare worker</td>
<td>3/5 (60%)</td>
<td>5/10 (50%)</td>
<td>1/4 (25%)</td>
</tr>
<tr>
<td>House visit by home-based care worker</td>
<td>3/5 (60%)</td>
<td>7/10 (70%)</td>
<td>1/4 (25%)</td>
</tr>
</tbody>
</table>
these tasks (40%). Nurses in Model 1-Traditional were not responsible for prescribing ART. Nurses provided clinical services (20%) and ART dispensing (20%) at a few clinics, but generally they were responsible for patient registration (60%) and ART adherence counselling (40%). LHWs also provided clinic- and community-based adherence support, and pharmacists dispensed ART instead of pharmacy technicians.

In this traditional model, 80% of clinics were located in national referral hospitals and 100% in urban centers (Table 5). They were led by mission, government, or non-profit, non-religious organizations. The number of ART patients varied from <1000 to >4000, and there were on average 4 doctors, 1 CO, 5 nurses/midwives, and 2 LHWs on a typical day (Table 5).

We identified several distinguishing features of ART service delivery in Model 1-Traditional clinics: a shorter time to ART initiation, greater access to laboratory testing services, fewer integrated supportive services for TB, and nutritional supplementation, and no community-based ART distribution.

*Shorter time to ART initiation:* All clinics in Model 1-Traditional determined ART eligibility in under 7 days whereas ≥50% of ART clinics in the other models took more than 7 days. Model 1-Traditional clinics also took less time to initiate patients on ART: only 20% took more than 7 days compared to 40-50% in the other models. Further, less than half of Model 1-Traditional clinics required patients to participate in 3 or more counselling sessions before initiating ART compared to 75-90% of clinics in the other two models (Table 6). Some physician experts hypothesized that doctors had greater clinical expertise to make decisions on ART eligibility and could initiate ART more quickly than nurses who may rely on standardized clinical decision-making tools.
However, nurse experts countered this argument, noting that these traditional model clinics were relatively well-resourced tertiary-level facilities. Facilities with more resources were more likely to staff the clinics with pharmacists who could better manage drug stocks and facilitate a shorter time to ART initiation. The idea that more well-resourced clinics can be staffed with pharmacists or pharmacy technicians trained in drug stock management is supported by few reported ART stock-outs in Model 1-Traditional (20%) compared to Model 3-Task-shifted (100%).

**Greater access to laboratory testing services, especially Viral Load Testing (VLT):** All Model 1-Traditional clinics had access to on-site laboratory services for routine patient monitoring, including CD4 cell count, liver function, renal function, white blood cell count and differential, and hemoglobin/hematocrit tests (Table 6). A greater percentage of Model 1-Traditional clinics reported access to VLT for suspected treatment failure compared to the other two models (60% vs. 25-40%; Table 6). Experts suggested that clinics with doctors and COs providing major clinical care were more likely to provide VLT as most were tertiary level facilities with laboratory access and physician capacity to interpret test results.

**Lower proportion of supportive services for TB, nutrition, and community-based ART distribution:** Only 60% of Model 1-Traditional clinics offered TB testing and treatment in the ART clinics, compared to the other two models where 90-100% offered TB testing and 75-90% offered TB treatment (Table 6). Less than half (40%) of Model 1-Traditional clinics provided community-based nutritional supplementation compared to 50-75% in the other two models. While community-based ART distribution was rare
across all three models, none of the Model 1-Traditional clinics used this approach (0% vs. 25-30%).

**Model 2-Mixed Model: Task-Sharing of Major Clinical Responsibilities between Doctors, Clinical Officers, and Nurses (n=10)**

The healthcare staffing pattern in Model 2-Mixed was characterized by doctors and COs sharing nearly equal responsibilities and nurses playing a large clinical role. Doctors and COs had almost the same level of responsibilities for ART prescription (100% doctors vs. 90% COs), ART monitoring and management (100%) and clinical services (100%); they varied in provision of ART adherence counselling (40% doctors vs. 70% COs, Table 4). Nurses had a large clinical role in ART prescription (40%), ART dispensing (40%), provision of clinical services (70%) and referral services (70%). Like Model 1-Traditional, Model 2-Mixed nurses were largely responsible for adherence counselling (80%, Table 4). In contrast to Model 1-Traditional, Model 2-Mixed clinics relied on pharmacy technicians instead of pharmacists to dispense ART. Nearly half of the clinics in the Model 2-Mixed used LHWs to register patients and trace those lost to follow-up (LTFU).

Model 2-Mixed clinics represented the largest programs with >4000 patients on ART per clinic. They were found in provincial/district level facilities or PHCs located in urban areas. Clinics were managed by missions, governments, and non-profit non-religious organizations. There were 2 doctors, 2 COs, 8 nurses/midwives, and 4 LHWs on an average day (Table 5).
The most distinguishing feature of ART service delivery in Model 2-Mixed was strategies for managing high patient volume, including task-shifting patient registration and tracing to LHWs, and extending ART refill times or community-based ART distribution.

Task-Shifting Patient Registration and Tracing to LHWs: In contrast to Models 1-Traditional and 3-Task-shifted where LHWs primarily provided adherence support, Model 2-Mixed had the greatest proportion of sites where LHWs held additional responsibilities in both patient registration and tracing missed appointments (40% vs. 0%-25% for both).

Extending Length of ART Refill or Community-Based ART Distribution to Reduce Client Flow: Model 2-Mixed Clinics were more likely to reduce client flow by providing a longer ART supply (80% provided two-month drug supplies compared to 60% in Model 1-Traditional and 25% in Model 3-Task-Shifted; Table 6). Also, a larger proportion of Model 2-Mixed clinics distributed ART in the community (30% vs. 0-25%).

Model 3-Task-Shifted Model: Task-Shifting of Major Clinical Responsibilities from Doctors to Clinical Officers and Nurses (n=4)

The healthcare staffing pattern of Model 3-Task-Shifted was characterized by task-shifting of clinical responsibilities from doctors to COs and nurses. There were no doctors in these clinics. COs were responsible for all clinical tasks, including ART prescription (100%), ART monitoring and management (100%), clinical services (100%),
and referral services (100%). Substantial task-sharing between COs and nurses occurred: nurses in three-quarters of Model 3-Task-Shifted clinics prescribed ART, provided referral services, and dispensed ART; and nurses in half of the clinics provided clinical services as well. The only clinical tasks not shared among COs and nurses were management of drug resistant infection and monitoring of viral load results (100% CO vs. 0% nurses, Table 4). Similar to Model 1-Traditional and in contrast to Model 2-Mixed, COs did not provide ART adherence counselling; nurses and counsellors provided all adherence counselling services. LHWs also conducted adherence support in clinics (75%) and communities (75%).

Model 3-Task-Shifted included clinics based at district or provincial levels and in PHC. All were government facilities. Clinic sizes ranged from <1000 to 4000 ART patients. Half were based in rural locations. On a typical day, clinics had on average 2 COs, 6 nurses/midwives, and 5 LHWs.

The distinguishing aspects of ART service delivery in Model 3-Task-Shifted included: fewer clinics with structural support for patient retention and fewer on-site HIV laboratory services. However, these clinics had the greatest proportion of community-based services.

*Reduced structural support for retention:* Seventy-five percent of Model 3-Task-Shifted clinics had an appointment system in contrast to 100% in the other two models (Table 6). None were able to provide a pharmacy report to identify patients who missed ART drug refill compared to 70-80% in the other models. This model also had the smallest proportion of sites that conducted house visits to trace patients LTFU (Table 6). Experts hypothesized that given that the Model 3-Task Shifted clinics were all
government supported they had less access to financial resources and technical support for pharmacy electronic medical records than clinics run by faith-based or other non-profit organizations.

*Greater linkage to community-based services:* Model 3-Task-Shifted clinics had the greatest proportion of sites providing linkages to community-based services, such as ART dispensing (75% vs. 0-60%), nutritional supplementation (75% vs. 40-50%), and home visits to patients who missed clinic appointments (75% vs. 60-70%). Correspondingly, this model had more LHWs. According to experts, these clinics may have relied more heavily on community-based services provided by LHWs because of limited resource, and to reduce clinic congestion.

**DISCUSSION**

This is the first study to identify indigenous models of ART service delivery by examining healthcare staffing patterns across clinics in multiple SSA countries. Three models were identified, distinguished primarily by the availability of doctors, nurses’ scope of clinical responsibility and the use of LHWs. The models reflected historical scale-up of ART services in SSA where ART was initially available only at tertiary-level hospitals in urban centers (Model 1-Traditional) and was later decentralized to peripheral health facilities in peri-urban towns and rural villages, such as district-level hospitals and PHCs (models 2-Mixed and 3-Task-Shifted). In Model 1-Traditional, doctors and COs took the lead on initiating and clinically managing ART patients, and nurses had limited clinical responsibilities. None of the nurses in Model 1-Traditional prescribed ART;
instead, nurses were mainly responsible for patient registration and adherence
counselling. This model most closely resembled the earliest approaches to HIV service
delivery prior to decentralization (Davies, Homfray, & Venables, 2013; Gilks et al., 2006;
Gimbel-Sherr et al., 2007; Monyatsi et al., 2012). Model 1-Traditional clinics received
substantial financial, technical, and infrastructural support from external donors. Many of
these clinics are now considered clinical centers of excellence where patients can access
advanced treatment and laboratory services need to manage third line regimens and
resistance testing.

In Model 2-Mixed, fewer doctors were available and nurses had more clinical
responsibilities, such as prescribing ART for treatment naïve patients and clinical
monitoring of stable patients (WHO, 2015). Model 2-Mixed also had more trained LHWs
performing tasks such as patient registration, medical chart filing, adherence counseling
and tracing of patients LTFU. These clinics match closely to the descriptions of other
international non-government organization-supported ART programs from Ethiopia
(Assefa et al., 2012), Malawi (Bemelmans et al., 2010; Massaquoi et al., 2009),
Mozambique (Gimbel-Sherr et al., 2007), Lesotho (R. Cohen et al., 2009; Ford et al.,
2010), and Uganda (L. Chang et al., 2009), where financial resources may allow the
hiring of doctors. By task-sharing clinical management of stable patients to nurses and
COs, doctors are freed to care for very sick or complex patients who require advanced
medical knowledge and skills (Assefa et al., 2012; Bedelu et al., 2007; Bemelmans et al.,
2010; Brennan et al., 2011; R. Cohen et al., 2009; Ford et al., 2010; Green et al., 2014;
Model 3-Task-Shifted did not typically have doctors present. Both COs and nurses were responsible for initiating and prescribing ART. In addition to their extensive clinical responsibilities, nurses in Model 3-Task-Shifted also performed administrative and patient support work. Nurse-initiated and/or nurse-managed ART programs have been previously described in South Africa (Bedelu et al., 2007; Brennan et al., 2011; Davies et al., 2013; Fairall et al., 2012; Georgeu et al., 2012; Green et al., 2014; Grimsrud, Kaplan, Bekker, & Myer, 2014; Long et al., 2011), Rwanda (Vasan et al., 2009), Lesotho (R. Cohen et al., 2009), and Malawi (Massaquoi et al., 2009; McGuire et al., 2012). We believe our study’s Model 3-Task-Shifted clinics most closely resembled the Lesotho, Malawi, and Rwanda examples (R. Cohen et al., 2009; McGuire et al., 2012; Vasan et al., 2009), and could be distinguished from the early demonstration projects of nurse-managed ART in South Africa where nurses ran “down-referral” or “step-down” ART programs to care for clinically stable patients in the community (Brennan et al., 2011; Davies et al., 2013; Fairall et al., 2012; Georgeu et al., 2012; Grimsrud et al., 2014; Long et al., 2011). In contrast, Model 3-Task-Shifted catered to all patients, including stable patients and those with more complex health needs, such as severe side effects, rare opportunistic infections, and treatment failure. However, there may be fewer distinctions between Model 3-Task-Shifted in our study and the current implementation of nurse-initiated and nurse-managed ART in South Africa because down-referral of clinically stable patients is no longer typical – nurses initiate and manage all kinds of patients as the Government has recognized the critical role of nurses in achieving the 90-90-90 goals (Government of South Africa, 2016).
Our findings also concurred with observations that decentralized ART programs, such as those in Model 2-Mixed and Model 3-Task-Shifted, required fewer clinic visits from patients (Grimsrud et al., 2014). For example, Model 2-Mixed and Model 3-Task-Shifted clinics provided on average two months of ART to stable patients to allow more time between drug refills compared to Model 1-Traditional clinics, which offered one month of ART only to stable patients (Brennan et al., 2011; Grimsrud et al., 2014; Kiweewa et al., 2013). Our study also found that decentralized ART programs, such as Model 2-Mixed and Model 3-Task-Shifted clinics, were more likely than non-decentralized programs to conduct clinic-based pill counts as part of their adherence strategies. This finding contrasts with the discussion from Grimsrud et al., where patients in a decentralized ART program were hypothesized to have fewer opportunities for individual adherence counselling and support because down referral sites had less frequent clinic visits (Grimsrud et al., 2014). Our findings may differ because Grimsrud et al. described a program for clinically stable patients who, in part, qualified for the program by previously demonstrating good adherence.

**Implications.** Our findings identified three models of HIV service delivery for potential application to other high HIV prevalence settings in SSA. Classifying ART models enables further study on their context, frequency of use, costs, and outcomes. For example, future research could assess how a task-shifted model compares to a mixed model in costs and proportion of patients achieving virologic suppression. Resulting data could inform decisions by program planners, policy-makers, and funders on models for scale-up within resource-constrained settings.
Our study also suggested that different patterns of healthcare staffing were associated with different environmental factors and program characteristics. For example, integrated TB treatment varied across the three service delivery models. This issue is important given high rates of TB/HIV coinfection across SSA and highlights how service provision is shaped by health facility levels, rural/urban settings, available health cadres, patient populations, and donor funding. A comprehensive and nuanced understanding of models of HIV care and treatment is especially important following WHO’s test and treat recommendation and donor fatigue after the global economic crisis. Test and treat adoption will likely impact client volumes and client composition, as healthier patients access ART. Understanding the pros and cons of different models of care can help programs determine the best staffing patterns to adapt to increasing client loads immediate ART initiation, and the selection of different adherence strategies most effective for their facility’s patients. Concurrently, national programs will need to identify differentiated models of care for people to meet the needs of long-term ART patients requiring more complicated treatment management, such as third line regimens and treatment for severe comorbidities (e.g., hepatitis, cancer.).

**Strengths and Limitations.** Our sample included 19 ART clinics in three countries – a considerably larger and more diverse sample size than past research, which has generally described task-shifting/task-sharing practices of a few clinics in one country (Alamo et al., 2012; Bedelu et al., 2007; Brennan et al., 2011; L. Chang et al., 2009; Gimbel-Sherr et al., 2007; Kiweewa et al., 2013; Torpey et al., 2008; Wools-Kaloustian et al., 2009). Despite having a considerably larger sample, the study had limited statistical power. While this evaluation offered more information than previously available, sites
were not randomly selected so data may not be generalizable to ART clinics in these countries, or SSA.

Our survey also assessed a wider range of ART service delivery components. While past research mainly described task-shifting/task-sharing in terms of who prescribed ART or provided clinical monitoring, ours accounted for other major tasks within the ART clinic (e.g. patient registration, adherence counselling, patient tracing) and the health cadres providing these tasks. While we examined the presence or absence of a wide range of services at ART clinics, a limitation is that we were unable to consider other important details, such as intensity and coverage of services per patient, or service quality.

Finally, the combination of a cluster analysis with a Delphi survey was stronger than either method alone in identifying meaningful models of ART service delivery. The Delphi survey ensured the three clusters were more than a statistical artefact and held practical meaning and had content validity.

**CONCLUSION**

Findings highlighted the complexity of factors that need to be considered to understand effective ART programs. These models of task-shifting/task-sharing can provide a basis for additional implementation science research, including costing analysis and comparative effectiveness across models of care, to inform the scalability and sustainability of HIV care and treatment in RLS.
REFERENCES


http://www.who.int/hiv/pub/guidelines/earlyrelease-arv/en/


MANUSCRIPT 2:

HIV Care and Treatment Models and Patient Pill Possession Ratio of Antiretroviral Drugs: Cluster Level Analysis of Patients from 18 Routine Programs in Tanzania, Uganda, and Zambia
ABSTRACT

Background: Adherence to antiretroviral therapy (ART) is critical to treatment success, yet few studies have examined how models of HIV care and treatment are associated with patient adherence. Three task-shifted models of ART service delivery were identified from a prior analysis of ART clinics from Tanzania, Uganda, Zambia: model 1-traditional where a majority of clinical responsibilities were divided between doctors and clinical officers, model 2-mixed where clinical responsibilities were shared among doctors, clinical officers, and nurses, and model 3-task-shifted where clinical responsibilities were shifted from doctors to clinical officers and nurses. This study assessed the independent relationship of these three models of care and adherence, using a six-month ART medication possession ratio (MPR), adjusting for individual factors related to adherence.

Methods: The 18 ART clinics were grouped according to models of care: model 1-traditional with 5 clinics, model 2-mixed with 9 clinics, and model 3-task-shifted with 4 clinics. Incomplete adherence, defined as <90% MPR, was assessed among 3,419 adult ART clients. Cluster level analysis was employed to account for intra-cluster correlation in the data. First, percentages of incomplete adherence rates were calculated based on cluster summaries. The mean differences in MPR were computed comparing each model of care with the others (model 1 minus model 2, model 1 minus 3 and model 2 minus model 3); statistical significance was assessed using paired t-tests on the relative risk and the corresponding 95% confidence interval for the mean differences were obtained. Second, an adjusted relative risk was calculated using a two-stage process. A
multivariable logistic regression model was fitted to the individual level data adjusting for demographic, psychosocial, and clinical characteristics. The expected outcomes of incomplete adherence were derived for each ART clinic by summing the residuals for each clinic. Then, adjusted relative risks were obtained for each pair and significance testing and confidence intervals were calculated as before. A sub-group analysis stratifying participants by duration on ART was also conducted to assess for interaction.

**Results:** The adjusted analysis found patients in Model 1-Traditional were 1.60 times more likely than patients in Model 2-Mixed to have MPR<90% (aRR=1.60, 95% CI 1.03, 2.48, \( p = 0.035 \)). Patients in Model 1-Traditional also showed a trend toward being more likely than patients in Model 3-Task-Shifted to have a MPR<90%, but this difference was not statistically significant (aRR=1.58, 95% CI 0.88, 2.85, \( p = 0.1063 \)). There was no evidence of differences in MPR<90% between Model 2-Mixed and Model 3-Task-Shifted (aRR=0.99, 95% CI 0.59, 1.66, \( p = 0.9611 \)).

**Conclusion:** Non-physician-led ART programs can support adherence levels as well or better than physician-led ART programs, and task-shifting and task-sharing of ART services are not associated with poorer patient adherence. Differences in staffing for ART service delivery may result in different implementation approaches. Several factors may have been responsible for differences seen across models of care. First, Model 1-Traditional clinics were less likely to require three adherence counselling sessions before ART initiation compared to Model 2 and 3 clinics so patients in the latter clinics may have been more prepared for lifelong HIV treatment. Second, Model 1-Traditional clinics
were less likely to practice routine pill counts compared to Model 2 and 3 clinics, and prior research suggests routine pill counts have positive “reactive effects” on patient adherence behaviors. Third, Model 2 and 3 clinics provided alternatives to clinic-based pill pick up, such as community-based distribution of ART, which may help overcome common reasons for treatment interruption (e.g., transport costs). Additional research is needed to optimize models of care to support patients on life-long treatment.
INTRODUCTION

Country adoption of the World Health Organization’s (WHO) recommendation to task-shift Antiretroviral Therapy (ART) services has contributed to the rapid scale-up of HIV care and treatment in sub-Saharan Africa. Over the past decade ART access in eastern and southern Africa has increased from 625,000 in 2005 (UNAIDS, 2013) to 10.3 million by 2015 (UNAIDS, 2016). Task-shifting is the redistribution of health tasks from more to less specialized health workers (Callaghan, Ford, & Schneider, 2010) and consists of two predominant practices: 1) extending the scope of practice for existing health workers, for example, allowing nurses and clinical officers to assess ART eligibility, prescribe ART, and manage clinically stable patients (Assefa et al., 2012; Bedelu, Ford, Hilderbrand, & Reuter, 2007; Bemelmans et al., 2010; Brentlinger et al., 2010; L. Chang et al., 2009; Dohrn, Nzama, & Murrman, 2009; Fairall et al., 2012; Monyatsi et al., 2012; Sanne et al., 2010; Sherr et al., 2009; Shumbusho et al., 2009; Vasan et al., 2009); and 2) creating new auxiliary cadres to substitute for health professionals, for example, adherence support workers to provide clinic-based adherence counselling and home-based patient tracing, or expert patients to relieve nurses of administrative tasks, such as patient file retrieval, patient registration, and clinic navigation (Alamo et al., 2012; Assefa et al., 2012; L. W. Chang et al., 2010; Dambisya & Matinhure, 2012; de Wet, Wouters, & Engelbrecht, 2011; Mwai et al., 2013; Rasschaert et al., 2011; Selke et al., 2010; Torpey et al., 2008; Wools-Kaloustian et al., 2009). Another form of redistributing tasks is task-sharing, whereby a team of health cadres provide differentiated care for patients depending on the severity of illness (Olson, 2012). For example, clinical officers and nurses may be tasked with monitoring stable
patients while doctors manage patients with complex opportunistic infections or chronic diseases. Overall, task-shifting and task-sharing practices in ART service delivery vary tremendously by country and program. In light of the WHO’s call for timely access to HIV treatment in order to maximize prevention and treatment benefits for all (WHO, 2015), we need a better understanding of models of ART care in order to identify their frequency of use, cost, and association with HIV-related treatment outcomes. Identifying models of care can then further generate useful information for national policy-makers and funders to make critical decisions on cost-effective ART programs.

To date, five studies using randomized designs have examined the impact of discrete aspects of task-shifting/task-sharing of ART, including prescription and management of ART by nurses in and home-based clinical monitoring by lay health workers on virologic failure (Fairall et al., 2012; Jaffar et al., 2009; Kiweewa et al., 2013; Sanne et al., 2010; Selke et al., 2010) and mortality (Fairall et al., 2012; Jaffar et al., 2009; Sanne et al., 2010). Generally these studies have demonstrated that trained and supervised cadres can provide effective task-shifted HIV care with comparable health outcomes (Fairall et al., 2012; Jaffar et al., 2009; Kiweewa et al., 2013; Sanne et al., 2010; Selke et al., 2010). Two studies have examined the impact of task-shifting/task-sharing on patient adherence: one compared how patients counselled by lay and professional health cadres varied in self-reported adherence in the past 3 days (Torpey et al., 2008), and another compared adherence assessed by pill counts 6-12 months after ART initiation among patients managed in a nurse-peer counsellor model of care versus patients managed in a physician-centered model of care (Kiweewa et al., 2013). Neither study found evidence of significant difference in adherence outcomes.
While existing studies provide a strong evidence base for task-shifting and task-sharing of ART services, they have generally taken a relatively narrow view of task-shifting, focusing only on which cadres of health workers are providing a limited range of services, including ART prescription, management, and adherence counselling. Existing studies have not taken into account staffing of other critical ART-related tasks in HIV care and treatment, such as registration, initial patient triage, diagnosis and management of opportunistic infections and common non-HIV conditions, referral services for complex conditions, ART dispensing, phlebotomy for laboratory testing, follow-up of patients who missed appointments, and medical records management. Further, they have not considered how these different staffing patterns across services come together in models of care. In order to more comprehensively identify models of care, we conducted a cluster analysis and Delphi survey to describe the healthcare staffing of ART services in 18 health facilities in Tanzania, Uganda, and Zambia (Tsui et al., Unpublished). We then examined how the models identified by the cluster analysis varied by environmental and program factors. The analysis identified three models of care: Model 1-Traditional Model, in which major clinical responsibilities were shared between doctors and clinical officers, Model 2-Mixed Model, in which major clinical responsibilities were shared between doctors, clinical officers, and nurses, and Model 3-Task-Shifted Model, in which clinical officers and nurses took on all major clinical duties, while lay health workers played a larger role in ancillary services. These models of care were further characterized by environmental factors (e.g., health facility levels, urban vs. rural settings, and clinic operation by government, mission, or non-profit non-religious organization) and program
characteristics (e.g., ART refill schedule, adherence support strategies, and alternatives to clinic-based distribution of ART).

In this paper, we assess the relationship between these three models of care and the ART medication possession ratio (MPR) measure. The MPR is an adherence measure that indicates the amount of pills a patient has received over a certain amount of time. MPR is based on pharmacy refill data and has been shown to significantly relate to virologic failure among adults (Denison et al., 2015). The objectives of the analysis presented here were two-fold: 1) to determine if there is an association between task-shifting/task-sharing models of care and the MPR, and 2) to determine if the independent association remains after adjusting for patient-level factors.

METHODS

Study Sites

Data for this cross-sectional secondary analysis came from a study on ART retention and adherence in Tanzania, Uganda, and Zambia led by FHI 360 that was conducted from 2008 to 2012. The purpose of the study was to characterize retention and adherence rates in 19 ART clinics, and to examine programmatic and individual factors related to retention and adherence among adult HIV-positive patients who had been on ART for at least six months (Denison et al., 2015; Koole et al., 2014). Clinics were purposefully-selected by the research team with country partners including Ministries of Health. Each country selected diverse ART clinics that had ≥300 patients at the time, including public/private/faith-based organizations and primary/secondary/tertiary levels of care. Facilities were also selected based on having different adherence strategies (e.g.,
routine pill counts, adherence support workers) and experiences with ART provision. Additional details of site selection have been reported elsewhere (Denison et al., 2015; Koole et al., 2014).

Additional information on the 18 ART clinics’ task-shifting and task-sharing characteristics was collected in the study for this analysis. Task-shifting and task-sharing questions were integrated into a cross-sectional survey for ART clinic managers, conducted between 2010 and 2011, which was designed to better understand the ART program and clinic environment.

study participants and data collection

ART Patients

Eligible patients attending the study sites were at least 18 years of age at ART initiation, had initiated ART at least 6 months prior to data collection and spoke one of the study languages were eligible. Participants were systematically sampled, and if a patient was ineligible, unwilling or unavailable, then the study teams selected the next ART patient attending the clinic. All participants underwent a screening and consent process by trained interviewers, and if they consented, were interviewed. After the patient interview, interviewers also abstracted data from the patient’s medical, pharmacy, and laboratory records using structured data abstraction forms. Data collection from patients and medical chart abstractions took place in 2011.

ART Clinic Managers

Trained interviewers used a structured-survey with ART clinic managers to systematically document the task-shifting and task-sharing practices at each ART clinic.
Clinic managers were purposively selected based on their comprehensive knowledge of the overall ART clinic and they would engage other health facility staff to help answer specific questions as needed. Clinic managers reported on the cadre(s) who performed the following ART-related services on a typical clinic day: 1) registration, 2) triage – patient screening at entry to determine why the patient has come to the ART clinic and what services are needed to meet patient needs, e.g., critical symptoms requiring emergency care, routine care, 3) initial ART prescription – starting a patient on ART based on assessment for ART eligibility, 4) ART monitoring and management – the ongoing assessment of patient’s response to ART, including diagnosis and management of any drug side effects, monitoring CD4 cell count and viral load count (where available) to determine if the drug regimen is efficacious, and management of drug resistance, 5) clinical services including diagnosis and management of opportunistic infections, provision of cotrimoxazole prophylaxis, and management of common non-HIV conditions, i.e. malaria, 6) referral services, 7) ART dispensing at the HIV clinic, 8) counselling on ART adherence, 9) phlebotomy for laboratory testing, 10) follow-up of patients who missed appointments or defaulters, and 11) medical records management. Data were stored in EpiData 3.1.

Measures

*Dependent Measure: Medication Possession Ratio*

Participant adherence was assessed by medication possession ratio (MPR) constructed from pharmacy refill data. The MPR summarized the number of pills dispensed to participants in the six months prior to the interview divided by the total number of pills.
the participants should have received during that time (Denison et al., 2015). The MPR was dichotomized into <90% or ≥90%. The MPR cut-off was selected from a previous analysis relating adherence measures to virologic failure on the basis of receiver operating characteristic (ROC) analysis with HIV RNA at least 1000 copies/ml as the reference standard (Denison et al., 2015).

Independent Measure

Task-shifting/Task-sharing Model of Care: The task-shifting/task-sharing model of care variable was constructed by cluster analysis presented elsewhere (Tsui et al., Unpublished). This analysis yielded three task-shifting/task-sharing models of care: Model 1-Traditional, in which task-sharing of major clinical responsibilities were divided between doctors and clinical officers, Model 2-Mixed: in which task-sharing of major clinical responsibilities were shared among doctors, clinical officers, and nurses, and Model 3-Task-Shifted, in which task-shifting of major clinical responsibilities occurred from doctors to clinical officers and nurses.

Other Independent Measures

Individual-level factors relevant to patient adherence to ART in sub-Saharan Africa were identified from previously published literature. These measures have been described in detail in an earlier publication (Denison et al., 2015).

Demographic: Basic demographic variables assessed included age, sex, marital status, and the Demographic and Health Survey (DHS) household wealth index. Age was
dichotomized into <35 years and ≥35 years. Marital status was a 4-category variable of single, separated/divorced/widowed, married/cohabitating, and missing. Finally, the DHS household wealth index was constructed using principal component analysis for each country and grouped into tertiles of low, middle, and high wealth.

**Psychosocial:** Stigma was assessed using the Internalized AIDS Stigma Scale (IA-RSS) with very good fit (RMSEA=0.03, 95% 0.02-0.05 and perfect reliability Tucker and Lewis’ reliability coefficient=1). Internalized stigma, a three question factor retained from the scale, had good internal consistency (Chronbach’s alpha=0.78), and stigma against HIV disclosure, a 2 question factor also retained from the scale had an internal consistency of Chronbach’s alpha=0.72). The stigma variables were dichotomized into high (>country median) and low stigma.

Potential depression was constructed from the depression sub-scale of the Hopkins Symptoms Checklist (HSCL-15) using the standard cut-off of 1.75 with good fit RMSEA=0.055, 95% confidence interval (CI) 0.053-0.058 and reliability (Tucker and Lewis’ reliability coefficient=0.90) and internal consistency (Chronbach’s alpha=0.84).

Social support was assessed using nine questions from the Duke University, University of North Carolina Functional Social Support Questionnaire and an added question on receiving help to remember to take one’s ART. Exploratory and confirmatory factor analysis identified a two-factor model with adequate fit (RMSEA=0.097, 95% CI 0.093-0.10) and reliability (coefficient=0.83). The first factor, Social Support Care, consisted of seven questions about social support (Chronbach’s alpha=0.76) and the second factor social support help consisted of four questions about instrumental help.
(Chronbach’s alpha=0.78). The social support variables were dichotomized into having a lowest 10th percentile or not.

The four yes/no CAGE questions were used to assess for alcohol abuse. The scores were summed and dichotomized into <2 or ≥2. Scores greater or equal to two suggest presence of alcohol abuse or dependency.

Other psychosocial variables assessed included having ever visited a traditional healer/herbalist because of HIV (yes/no), having ever disclosed one’s HIV status (yes/no), and the average cost and time it took participants to reach the clinic. Average cost was dichotomized into <1 USD or ≥1 USD and average time to reach ART clinic was dichotomized into <30 minutes to ≥30 minutes.

**Clinical:** Patients’ current ART regimen were abstracted from patients’ medical charts and grouped into five major categories: D4T/3TC/NVP, AZT/3TC/EFV, AZT/3TC/NVP, TDF/3TC or FTC/EFV, and other. Time on ART was abstracted from patient medical charts and constructed by calculating the number of years from the date of ART initiation to the date of interview and categorized into three groups: <2.2 years, 2.2-5.3 years, and >5.3 years. Daily pill burden of ART drugs was self-reported by patients and dichotomized into <4 pills or ≥4 pills per day. Twenty questions on self-reported HIV symptoms in the past four weeks were summed into a score and then dichotomized by whether it is greater or equal to the median or not. Both pre-ART WHO stage and pre-ART CD4 cell count were abstracted from patient medical charts. The pre-ART WHO stage was categorized into four categories: Stage I and II, Stage III, Stage IV, and
missing. The pre-ART CD4 cell count was categorized into three categories: \( \leq 250 \) cells/\( \mu l \), >250 cells/\( \mu l \), and missing.

### Statistical Analysis

An intention-to-treat approach was utilized whereby all participants with evaluable data for the outcome measure of MPR<90% were included. One of the 19 ART clinics did not have pharmacy refill data available. Therefore, data from the remaining 18 ART clinics were used for this analysis. First, we assessed the association between task-shifting model of care and patient MPR using a cluster level analysis in order to account for intra-cluster correlation in the data as a result of the study design. A crude measure of effect, mean difference of percentages of MPR<90%, with 95% CI was calculated by entering the ART clinic summaries of their patient’s MPR, weighted by the number of ART clinic patients included in the analysis, into an analysis of variance model. Mean differences of MPR were computed comparing each task-shifting model against another (model 1 minus model 2, model 1 minus model 3, and model 2 minus model 3). Statistical significance was assessed with the paired t-test on the relative risk and corresponding 95% CI for the mean differences were obtained.

Second, to control for possible individual-level characteristics between groups that might bias the association estimate, an adjusted measure of effect (adjusted relative risk) were calculated using a two-stage process. A logistic regression model with MPR<90% as the dependent variable were fitted to individual-level data. Independent variables assessed for inclusion included all variables deemed theoretically meaningful in the literature review and measured in the patient survey, including demographic (age, sex,
marital status, household wealth), psychosocial (internalized stigma, stigma against HIV disclosure, potential depression, ever-disclosed HIV status, social support – care, social support – help, alcohol abuse, ever consulted a traditional healer, cost to clinic, time to clinic), and clinical characteristics (ART regimen at the time of interview, time on ART, pill burden, HIV symptoms index, pre-ART WHO stage, and pre-ART CD4 cell count) collected in the patient cross-sectional survey. All variables that were significantly associated with MPR<90% (p<0.05) in the bivariate analysis were included in the final multivariable logistic regression model. Expected outcomes of an MPR<90% were derived from each ART clinic by summing the residuals of each participant in each clinic. The logarithmic ratio of expected (E) and observed (O) numbers of non-adherence \((\ln(O/E))\) were calculated for each ART clinic. Then, adjusted relative risks (aRR) were obtained for each pair (e.g., model 1 vs. model 2) using the student t-test. Adjusted significance tests and confidence intervals were calculated as before.

In addition, a sub-group analysis stratifying participants by duration on ART (long vs. short) were done. Duration on ART was dichotomized with long defined as ≥5.3 years and short defined as <5.3 years. A significance test of interaction between duration on ART and task-shifting/task-sharing model of care was done. All statistical analyses were performed using SAS version 9.4 and Excel.

**Ethics Statement**

All patients and ART managers provided written informed consent prior to data collection, which was approved by seven Institutional Review Boards (IRB) representing the study teams’ organizations and countries.
RESULTS

Characteristics of the ART clinics and analysis population by task-shifting/task-sharing model and by MPR<90% outcome are summarized in Table 8 and Table 10, respectively.

Characteristics of the ART clinics

Eighteen of the 19 ART facilities were included in the analysis, including seven sites from Tanzania, six sites from Uganda, and five sites from Tanzania; patients from one ART facility without pharmacy refill data were excluded from the analysis. The 18 ART sites were diverse in health facility levels (4 national referral hospitals, 8 provincial or district hospitals, and 5 primary health centers), management (9 government, 5 faith-based missions, and 4 non-profit non-religious organizations), and size (5 sites with <1000 ART patients, 3 sites with 1000-2000 ART patients, 7 sites with 2000-4000 patients, and 3 sites with >4000 ART patients). A majority of the sites were based in urban locales (14 urban, 4 rural) (Table 8). Details on staffing and programmatic factors of each model are summarized in Table 8.
<table>
<thead>
<tr>
<th>Model 1-Traditional</th>
<th>Model 2-Mixed</th>
<th>Model 3-Task-Shifted</th>
</tr>
</thead>
<tbody>
<tr>
<td># ART clinics</td>
<td>5</td>
<td>9</td>
</tr>
<tr>
<td>Contextual</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Characteristics</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>80% (4/5) national referral hospital and 20% (1/5) district hospital</td>
<td>56% (5/9) provincial or district hospital, 44% (4/9) primary health centers</td>
</tr>
<tr>
<td></td>
<td>100% (5/5) urban</td>
<td>78% (7/9) urban</td>
</tr>
<tr>
<td></td>
<td>40% (2/5) run by government</td>
<td>33% (3/9) run by government</td>
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<tr>
<td></td>
<td>60% (3/5) ≥2000 patients on ART</td>
<td>78% (7/9) ≥2000 patients on ART</td>
</tr>
<tr>
<td>Staffing Patterns by Tasks</td>
<td></td>
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<tr>
<td>Register: 60% nurse, 20% lay, 40% data clerk</td>
<td>Register: 20% nurse, 40% lay, 10% data clerk</td>
<td>Register: 50% nurse, 0% lay, 25% data clerk</td>
</tr>
<tr>
<td>Initial prescription: 100% MD, 40% CO, 0% nurse</td>
<td>Initial prescription: 100% MD, 90% CO, 40% nurse</td>
<td>Initial prescription: 0% MD, 100% CO, 75% nurse</td>
</tr>
<tr>
<td>Monitoring: 100% MD, 40% CO, 40% nurse</td>
<td>Monitoring: 100% MD, 100% CO, 60% nurse</td>
<td>Monitoring: 100% CO, 75% nurse</td>
</tr>
<tr>
<td>Counselling: 0% MD, 0% CO, 40% nurse, 40% counsellor, 0% pharm tech</td>
<td>Counselling: 40% MD, 70% CO, 80% nurse, 70% counsellor, 30% pharm tech</td>
<td>Counselling: 0% MD, 0% CO, 50% nurse, 50% counsellor, 0% pharm tech</td>
</tr>
<tr>
<td>Dispensing: 20% nurse, 60% pharmacist, 40% pharm tech</td>
<td>Dispensing: 40% nurse, 20% pharmacist, 70% pharm tech</td>
<td>Dispensing: 75% nurse, 25% pharmacist, 0% pharm tech</td>
</tr>
<tr>
<td>Phlebotomy: 0% nurse, 40% lab tech</td>
<td>Phlebotomy: 50% nurse, 70% lab tech</td>
<td>Phlebotomy: 25% nurse, 75% lab tech</td>
</tr>
<tr>
<td>Tracing: 0% nurse, 0% counsellor, 20% data clerk, 20% lay, 60% CHW</td>
<td>Tracing: 30% nurse, 30% counsellor, 40% lay, 30% CHW</td>
<td>Tracing: 25% nurse, 0% counsellor, 25% lay, 25% CHW</td>
</tr>
<tr>
<td>Programmatic Factors</td>
<td>Model 1-Traditional</td>
<td>Model 2-Mixed</td>
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<tr>
<td></td>
<td>20% require &gt;7 days to initiate ART if found eligible (40% require at least 3 counselling sessions before ART initiation)</td>
<td>40% require &gt;7 days to initiate ART if found eligible (90% require at least 3 counselling sessions before ART initiation)</td>
</tr>
<tr>
<td></td>
<td>20% sites experienced stock out of ART in the past 6 months</td>
<td>0% sites experienced stock out of ART in the past 6 months</td>
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<td></td>
<td>20% sites provide 2-months refill instead of monthly refill for patients who have been on ART ≥6 months</td>
<td>80% sites provide 2-months refill instead of monthly refill for patients who have been on ART ≥6 months</td>
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<tr>
<td></td>
<td>60% sites provided viral load testing as needed</td>
<td>40% sites provided viral load testing as needed</td>
</tr>
<tr>
<td></td>
<td>0% sites had routine pill count for patients &lt;6 months and ≥6 months on ART</td>
<td>50% sites had routine pill count for patients &lt;6 months and ≥6 months on ART</td>
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<tr>
<td></td>
<td>0% community-based distribution of ART</td>
<td>30% community-based distribution of ART</td>
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</table>

**Characteristics of the analysis population**

A total 3,419 participants were eligible for analysis using <90% medication possession ratio as the main outcome measure related to non-adherence. Overall, 73% (2496/3419) were 35 years or older at the time of interview, 67% (2282/3419) were female. Just 25% (859/3419) on ART has been for less than 2.2 years (Table 2). Overall, 25% of patients (842/3411) attended model 1-traditional clinics, 54% (1843/3411) attended model 2-mixed clinics, and 21% (726/3411) attended model 3-task-shifted clinics. Patients with <90% MPR were significantly younger, wealthier, and needed less time to travel to the clinic than patients who achieved better MPR (Table 10). Patients with <90% MPR also reported significantly greater levels of internalized stigma against
HIV, positive screening for depression, higher pill burden, and were more likely to have missing pre-ART CD4 cell count than patients with higher MPR (Table 10). Finally, significantly fewer patients with <90% MPR were on AZT/3TC/EFV regimen and had more than 5.3 years of experience on ART than patients with higher MPR (Table 10).

Table 9 Percentages, mean difference, and adjusted relative risks of incomplete adherence between the three task-shifting/task-sharing models of care in antiretroviral therapy

<table>
<thead>
<tr>
<th></th>
<th>Model 1: Traditional</th>
<th>Model 2: Mixed</th>
<th>Model 3: Task-Shifted</th>
<th>Effect Estimates</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of ART clinics</td>
<td>5</td>
<td>9</td>
<td>4</td>
<td></td>
<td></td>
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<tr>
<td>Percentages of non-adherence based on cluster summaries (SD)</td>
<td>57.30 (17.59)</td>
<td>34.77 (12.92)</td>
<td>33.88 (17.37)</td>
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<tr>
<td>Mean Difference and 95% CI</td>
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<tr>
<td>Model 1-Traditional minus 2-Mixed</td>
<td>-22.54 (-42.07, -3.01)</td>
<td></td>
<td></td>
<td>0.0272</td>
<td></td>
</tr>
<tr>
<td>Model 1-Traditional minus 3-Task-Shifted</td>
<td>-23.42 (-55.17, 8.33)</td>
<td></td>
<td></td>
<td>0.1246</td>
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<tr>
<td>Model 2-Mixed minus 3-Task-Shifted</td>
<td>-0.88 (-21.64, 19.87)</td>
<td></td>
<td></td>
<td>0.9270</td>
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<tr>
<td>Analyses based on ratio-residuals</td>
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<tr>
<td>Adjusted* Relative Risk and 95% CI</td>
<td></td>
<td></td>
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<tr>
<td>Model 1-Traditional vs. 2-Mixed</td>
<td>1.60 (1.04, 2.46)</td>
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<td></td>
<td>0.0354</td>
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<tr>
<td>Model 1-Traditional vs. 3-Task-Shifted</td>
<td>1.59 (0.88, 2.85)</td>
<td></td>
<td></td>
<td>0.1054</td>
<td></td>
</tr>
<tr>
<td>Model 2-Mixed vs. 3-Task-Shifted</td>
<td>0.99 (0.59, 1.65)</td>
<td></td>
<td></td>
<td>0.9720</td>
<td></td>
</tr>
</tbody>
</table>

*Adjusted for age, household wealth, internalized stigma against HIV, potential depression, time to clinic, ART regimen, time on ART, pill burden, and pre-ART CD4 cell count.
Unadjusted proportions and relative risks of an MPR<90% by task-shifting/task-sharing models of care

Cluster level analysis found that 57% of patients had MPR<90% (SD 17.59) in Model 1-Traditional, 35% (SD 12.92) for Model 2-Mixed, and 34% (SD 17.37) for Model 3-Task-Shifted (Table 9). Patients in Model 1-Traditional were significantly more likely than patients in Model 2-Mixed to have an MPR<90% (Difference in mean = -22.54 95% CI -42.07, -3.01, p=0.03) and a similar trend was observed comparing patients in Model 1-Traditional to patients in Model 3-Task-Shifted (Difference in mean = -23.42 95% CI -55.17, 8.33, p=0.12). There is no evidence of statistical difference in MPR<90% between patients in Model 2-Mixed and Model 3-Task-Shifted (Difference in mean = -0.88, 95% -21.64, 19.87, p=0.93) (Table 9).

Adjusted relative risks of non-adherence by task-shifting/task-sharing models of care

After adjusting for patient age, household wealth, internalized stigma, potential depression, time to clinic, ART regimen, time on ART, pill burden, and pre-ART CD4 cell count, results from the cluster level analysis on non-adherence found that patients in Model 1-Traditional were 1.60 times more likely than patients in Model 2-Mixed to have MPR<90% (aRR=1.60, 95% CI 1.03, 2.48, p=0.035). Patients in Model 1-Traditional also showed a trend toward being more likely than patients in Model 3-Task-Shifted to have an MPR<90%, but this difference was not statistically significant (aRR=1.58, 95% CI 0.88, 2.85, p=0.1063) (Table 9). There was no evidence of a difference in proportions of patients with an MPR<90% between Model 2-Mixed and Model 3-Task-Shifted (aRR=0.99, 95% CI 0.59, 1.66, p=0.9611) (Table 9).
DISCUSSION

Patients in Model 1-Traditional were 60% significantly more likely to have an MPR<90% than patients in Model 2-Mixed. Similarly, there was some indication that patients in Model 1-Traditional were more likely to have an MPR<90% than patients in Model 3-Task-Shifted, but this difference was not statistically significant. These results suggest that differences in ART service delivery are related to varying patient ART MPR by model of care.

Differences in ART service delivery may result from the different cadres providing the health services, or from differences in how ART and related tasks are implemented. Our findings indicate that non-physician-led ART programs can support adherence levels better than physician-led ART programs, and task-shifting and task-sharing of ART services are not associated with worse patient adherence. The observation of adherence is congruous with other research that have demonstrated comparable standards of care in HIV care and treatment by trained clinical officers and nurses compared to doctors (Brentlinger et al., 2010; Monyatsi et al., 2012; Vasan et al., 2009; Weigel et al., 2012), and similar mortality, mean CD4 cell count, and virologic failure in effectiveness studies (Fairall et al., 2012; Jaffar et al., 2009; Sanne et al., 2010; Selke et al., 2010).

Differences in staffing to ART service delivery may result in different implementation approaches. Recognizing this is a complex subject and the observed differences in models of care cannot explain completely the differences observed in the MPR outcome, we noted three main aspects that differentiate the three models of care and
hypothesize that implementation approaches in Models 2-Mixed and 3-Task-Shifted may help optimize patients picking up their pills.

First, Model 1-Traditional clinics were less likely to require three adherence counselling sessions before ART initiation compared to Models 2 and 3 clinics (40% clinics in Model 1-Traditional Traditional required ≥3 pre-ART counselling sessions compared to 90% of clinics in Model 2-Mixed and 75% clinics in Model 3-Task-Shifted). It is possible that adherence was greater among patients in Models 2 and 3 because these patients had more pre-ART counselling sessions and they were more prepared for lifelong HIV treatment. However, research on the value of more pre-ART counselling sessions and improved adherence is inconclusive (Myer, Zulliger, & Pienaar, 2012; Siedner et al., 2012). The benefits of pre-ART counselling must be balanced by considerations for risks of early mortality and greater morbidity associated with delayed ART initiation (M. S. Cohen et al., 2013). As test and treat rolls out, strategies to strengthen post-initiation adherence include providing support for life-long HIV treatment while encouraging early ART initiation (Wilkinson et al., 2015) and task-sharing of adherence counselling to lay or peer health workers (Torpey et al., 2008).

Second, Model 1-Traditional clinics were less likely to practice routine pill counts for patients during ART refill visits in contrast to Model 2-Mixed and Model 3-Task-Shifted clinics (no clinics in Model 1-Traditional conducted routine pill count for patients on ART for less than six months compared to 50% clinics in Model 2-Mixed and 75% of clinics in Model 3-Task-Shifted; no clinics in Model 1-Traditional conducted routine pill counts for patients on ART for 6 months or more compared to 50% clinics in Model 2-Mixed and Model 3-Task-Shifted). While most literature discusses pill count as a
measure of adherence, some have hypothesized that routine pill counts serves as an intervention to influence patient adherence behavior. This hypothesis is supported by a recent study in Kenya which found a dose-response relationship between clinician pill count and adherence – the greater the numbers of pill counts conducted, the more adherent patients were (Achieng et al., 2013).

Finally, Models 2 and 3 clinics provided patients with alternatives to clinic-based pill pick up, which may have helped patients overcome common barriers to non-adherence by making ART more accessible and affordable (Bemelmans et al., 2014; Decroo et al., 2013; Mukherjee, Barry, Weatherford, Desai, & Farmer, 2016). Thirty percent of clinics in Model 2-Mixed and 25% of clinics in Model 3-Task-Shifted offered community-based distribution of ART compared to 0% of clinics in Model 1-Traditional. Models of community-based distribution of ART varied from mobile, satellite ART clinics available in the community so patients could pick up their drugs closer to home, and to home-based distribution of ART by trained lay workers. Not only can community-based ART refill allow patients to travel shorter distances and spend less on transport-related costs, it can significantly reduce time spent for medication pick-up (Decroo et al., 2013).

These differences in implementation approaches warrant additional research to see how HIV care and treatment services can be optimized to support patient adherence to life-long treatment.
Strengths and Limitations

Our study had multiple strengths and limitations. A major strength of our sample included 18 routinely implemented ART programs in three countries – a considerably larger and more diverse sample size than past research (Alamo et al., 2012; Bedelu et al., 2007; Brennan et al., 2011; L. Chang et al., 2009; Gimbel-Sherr et al., 2007; Kiweewa et al., 2013; Torpey et al., 2008; Wools-Kaloustian et al., 2009), which has generally described task-shifting/task-sharing practices of a few clinics in one country. While this evaluation offered more information than previously available, 18 clinics were still inadequately powered to examine all the associations between models of care and ART adherence. Also, the sites were not randomly selected so data may not be generalizable to ART clinics in these countries or sub-Saharan Africa. Nevertheless, these sites were selected in consultation with country stakeholders and aimed to assess a variety of programmatic characteristics that might influence adherence.

Our comprehensive measure on task-shifting/task-sharing practices of HIV service delivery to characterize model of care is another strength. Prior research typically describes task-shifting/task-sharing models of care are broadly described as “doctor-centered”, “nurse-centered”, “non-physician care” “peer-led” or “community-supported” care (Brennan et al., 2011; Brentlinger et al., 2010; L. Chang et al., 2009; R. Cohen et al., 2009; Davies, Homfray, & Venables, 2013; Fairall et al., 2012; Ford et al., 2010; Grimsrud, Kaplan, Bekker, & Myer, 2014; Kiweewa et al., 2013; Sanne et al., 2010; Selke et al., 2010; Shumbusho et al., 2009; van Griensven et al., 2008) and the model of care is based on a few discrete ART-related tasks, such as non-physician ART initiation or clinical monitoring of patients (Bemelmans et al., 2010; Brennan et al., 2011; Gimbel-
Sherr et al., 2007; Kiweewa et al., 2013; Long et al., 2011; Sanne et al., 2010; Shumbusho et al., 2009) or lay health worker adherence counselling and support (L. W. Chang et al., 2010; Torpey et al., 2008). In contrast, our measure includes healthcare staffing patterns from patient registration, triage, ART prescription, adherence counselling, dispensing, clinical monitoring, phlebotomy for laboratory testing, to tracing of patients lost to follow-up and medical records management, and adds clarity to what the model of care entails. This comprehensive measure better takes into account the many facets that contributes to patient outcome. A limitation to this measure on model of care is that we are unable to consider other important details, such as intensity and coverage of services per patient, or service quality.

Another strength is our analysis assessed a comprehensive range of individual level factors affecting adherence, including socio-demographic, psychosocial, clinical, and structural characteristics. However, the cross-sectional design of the study restricts interpretations to associations rather than temporal relationships and causation. Nevertheless, the analysis yielded insightful and hypothesis-generating data that has furthered our understanding on how ART-related services can be optimized to enhance patient adherence underlying the efficacy of HIV treatment.

MPR as an adherence measure is limited because we are unable to definitely know if the patient has ingested the drug. However, MPR is not as vulnerable as patient self-reported measures to social bias. Another advantage of MPR is there are few adherence measures that can capture both individuals’ ability to access drugs and the system’s ability to dispense drugs to facilitate maximum possible adherence. Our findings suggest a relationship between model of care and MPR. However, it is not possible to
isolate whether it is the health cadres or the ART program that is making a difference to MPR, and further research is needed to elucidate these complex relationships.

CONCLUSION

Patient data drawn from 18 routinely implemented ART programs in Tanzania, Uganda, and Zambia provide further evidence that non-physician clinicians can support high levels of ART adherence and result in non-inferior adherence outcomes. Data on task-shifting/task-sharing models of care suggest that there is room to optimize the implementation of ART services in order to improve patient adherence, and additional research on enhancing post-ART initiation adherence support, routine pill counts, and alternatives to clinic-based pill pick-up is needed.

REFERENCES


Fairall, L., Bachmann, M. O., Lombard, C., Timmerman, V., Uebel, K., Zwarenstein, M., . . . Bateman, E. (2012). Task shifting of antiretroviral treatment from doctors to primary-


Siedner, M. J., Lankowski, A., Haberer, J. E., Kembabazi, A., Emenyonu, N., Tsai, A. C., . . . Bangsberg, D. R. (2012). Rethinking the "pre" in pre-therapy counseling: no benefit of additional visits prior to therapy on adherence or viremia in Ugandans initiating ARVs. *PLoS One, 7*(6), e39894. doi:10.1371/journal.pone.0039894


Table 10 Summary of analysis population by task-shifting/task-sharing model and adherence outcome measured by <90% pill possession ratio of antiretroviral therapy in the last three months among adults ART patients in Tanzania, Uganda, and Zambia, 2011

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<th>Model 3 Task-Shifted % (n=726)</th>
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<td>570</td>
<td>12.95</td>
<td>15.57</td>
<td>23.97</td>
<td>&lt;.0001</td>
<td>16.71</td>
<td>15.63</td>
<td>17.48</td>
<td>0.814 (0.639, 1.038)</td>
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<tr>
<td>2=AZT,3TC,EFV</td>
<td>659</td>
<td>26.72</td>
<td>15.52</td>
<td>20.39</td>
<td>19.32</td>
<td>14.92</td>
<td>22.43</td>
<td>0.606 (0.477, 0.769)</td>
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<tr>
<td>3=AZT,3TC,NVP</td>
<td>1227</td>
<td>26.84</td>
<td>49.75</td>
<td>34.44</td>
<td>35.97</td>
<td>39.46</td>
<td>33.50</td>
<td>1.072 (0.871, 1.320)</td>
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<tr>
<td>4=Other regimen</td>
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<td>12.75</td>
<td>13.77</td>
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<td>15.01</td>
<td>15.84</td>
<td>14.42</td>
<td>1</td>
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<td></td>
<td>N=3411</td>
<td>Model 1 Traditional % (n=842)</td>
<td>Model 2 Mixed % (n=1843)</td>
<td>Model 3 Task-Shifted % (n=726)</td>
<td>P</td>
<td>Total %</td>
<td>MPR &lt;90% (n=1997)</td>
<td>MPR ≥90% (n=1414)</td>
<td>On MPR&lt;90% Odds Ratio (95% CI)</td>
</tr>
<tr>
<td>--------------------------</td>
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<tr>
<td><strong>Time on ART</strong></td>
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<td></td>
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<tr>
<td>&lt;2.2</td>
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<td>19.60</td>
<td>29.19</td>
<td>21.49</td>
<td>&lt;.0001</td>
<td>25.18</td>
<td>23.55</td>
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<tr>
<td>2.2-5.3</td>
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<td>47.39</td>
<td>49.81</td>
<td>54.68</td>
<td>.0008</td>
<td>50.25</td>
<td>55.37</td>
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<td>&gt;5.3</td>
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<td>33.02</td>
<td>21.00</td>
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<td>24.57</td>
<td>21.07</td>
<td>27.04</td>
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<td>&lt;4</td>
<td>2766</td>
<td>86.22</td>
<td>81.55</td>
<td>73.97</td>
<td>&lt;.0001</td>
<td>81.09</td>
<td>78.15</td>
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<td>≥4</td>
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<td><strong>HIV symptoms index (≥ median)</strong></td>
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<td>50.00</td>
<td>56.81</td>
<td>46.83</td>
<td>&lt;.0001</td>
<td></td>
<td>53.00</td>
<td>54.17</td>
<td>52.18</td>
<td>0.923 (0.805, 1.058)</td>
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<td>5.81</td>
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<td>39.60</td>
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<td><strong>Pre-ART CD4+ cell count (cells/µl)</strong></td>
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<td></td>
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<tr>
<td>Missing</td>
<td>671</td>
<td>17.22</td>
<td>18.77</td>
<td>24.79</td>
<td>&lt;.0001</td>
<td>19.67</td>
<td>21.78</td>
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MANUSCRIPT 3:

How Healthcare Delivery Programs Can Facilitate Adult Patient Adherence to Antiretroviral Therapy: a Multiple Qualitative Case Study of Four HIV Care and Treatment Clinics in Uganda
ABSTRACT

Background: Significant research has focused on understanding how individual, interpersonal, community, and structural factors influence adherence. Less attention has focused on how routine antiretroviral therapy (ART) programs can facilitate or support patient adherence behaviors. This study explores how ART programmatic factors facilitate or hinder adult patient adherence in Uganda, building upon prior analyses which found models of care were associated with adherence above and beyond individual measures.

Methods: We conducted a multiple case study analysis with four ART clinics from Central and Western regions of Uganda from February to November, 2016. The ART clinics were purposefully selected to represent different models of service delivery. Case study data collection included direct observations of clinic activities, collection of documents and audio-visual materials from each ART program and the Uganda Ministry of Health, and 79 in-depth interviews with 39 ART providers and 40 clients. Data analysis followed an iterative process of developing a contextual understanding of the epidemiology and history of HIV and ART in Uganda, analyzing the data by chronological events and by clinic flow, developing case descriptions for each study site, and conducting cross-case synthesis of ART programmatic factors affecting patient adherence.

Results: Three key programmatic factors emerged from the cross-case analysis. First, longer ARV refills reduced the indirect costs of transport and time and facilitated patient
adherence by minimizing common structural barriers to treatment interruption. Second, expert patients played a critical role in linkage and retention in care and promotion of optimal ART adherence among patients. In exchanging phone numbers to follow-up patients, they created new social support for people living with HIV. Further, expert patients made ART services more patient-centered by facilitating medication pick-up out of regular clinic hours. Finally, routine pill counts were found to trigger additional adherence interventions, such as education, counselling, and home visits, which supported patient adherence.

Conclusions: As ART expansion and decentralization continues across sub-Saharan Africa and elsewhere, patient adherence to ARV drugs features prominently in program success. Clinics should consider how task-shifting may facilitate aspects of service delivery, such as longer ARV drug refills, expert patients, and routine pill counts, that come together as a package to support patient adherence.
INTRODUCTION

Treatment and prevention benefits of antiretroviral therapy (ART) can only be realized when people living with HIV adhere to ART well enough to suppress the virus. Adherence to ART was a major concern in the late 1990s to early 2000s during the emergency scale-up of ART in developing countries. Donors feared patients could not adhere to treatment and would waste costly drugs and investments used to make HIV care and treatment available in resource-limited settings with weak health systems. However, these fears were assuaged as data showed patients on ART in sub-Saharan Africa had higher levels of adherence than patients in North America (Mills et al., 2006). There have been many changes to facilitate patient adherence since the early days of scaling-up ART in resource-limited countries. The introduction of fixed dose combinations of ART has significantly simplified regimens and decreased pill burdens for patients (Langebeek et al., 2014). Decentralization of ART service delivery (e.g., from tertiary level hospitals to primary health centers) (Bedelu, Ford, Hilderbrand, & Reuter, 2007; Bemelmans et al., 2010; Brennan et al., 2011; Kredo, Ford, Adeniyi, & Garner, 2013; Loubiere et al., 2009; McGuire et al., 2012; Mutevedzi et al., 2010; Shumbusho et al., 2009; van Griensven et al., 2008), including increased options for ART care in the community (e.g., home visits, someone picking up your drugs for you) (Alamo et al., 2012; Bedelu et al., 2007; L. Chang et al., 2009; L. W. Chang et al., 2010; Cohen et al., 2009; Decroo et al., 2013; Denison et al., 2015; Kabore et al., 2010; Koole et al., 2014; Mukherjee, Barry, Weatherford, Desai, & Farmer, 2016; Mwai et al., 2013; Selke et al., 2010) and the task-shifting of responsibilities from highly trained to less trained cadre of workers, have made treatment access easier for patients.
Despite these improvements, adherence to ART continues to be a prominent concern for several reasons. First, there is a growing population of patients who have been on ART for many years, and less is known about how to support these individuals to maintain high adherence over a lifetime. Longitudinal data suggest that adherence decreases over time and treatment fatigue is real (Amberbir, Woldemichael, Getachew, Girma, & Deribe, 2008; Etard et al., 2007; Laurent et al., 2002). Second, adherence has received renewed attention in light of the World Health Organization (WHO)’s 2016 recommendation of immediate initiation of ART for all people living with HIV, regardless of CD4 count – so called “Test and Treat” (WHO, 2016). Frontline providers in Uganda often attribute high adherence to patient experience of HIV-related sickness before starting ART, and they worry that initiating newly diagnosed HIV positive patients quickly onto ART will result in lower adherence because these patients would not appreciate the impact of ART on their lives as they have never been sick without the medication. This issue of health status before ART initiation has garnered attention in relation to the Test and Treat recommendation (Bock et al., 2016; Heestermans, Browne, Aitken, Vervoort, & Klipstein-Grobusch, 2016; Shubber et al., 2016), with one systematic review finding that “not feeling sick” was a barrier to adherence (Heestermans et al., 2016), while data from other systematic reviews found no difference in adherence by CD4 cell count at initiation and that feeling sick was a greater barrier to adherence than feeling well (Bock et al., 2016; Shubber et al., 2016). These mixed findings support the need for further research on this topic.

Significant research attention has focused on understanding how individual, interpersonal, community, and structural factors influence adherence (Heestermans et al.,
Recent systematic reviews have mainly examined the effectiveness of individual-level interventions to promote adherence, such as cognitive-behavioral interventions, education, and active adherence reminder devices (e.g., mobile phone text messages). These reviews have also examined discrete service delivery components of an ART program, such as the use of treatment supporters, directly observed therapy, and the provision of food rations (Barnighausen et al., 2011; Chaiyachati et al., 2014). Less attention has focused on how multiple components of different models of ART service delivery come together to facilitate patient adherence behaviors.

This study explores how ART programmatic factors facilitate or hinder adult patient adherence in Uganda. It builds upon prior analyses which found models of ART care associated with adherence, measured by a six month pill possession ratio, above and beyond some individual measures (Tsui, Kennedy, et al., Unpublished). To better understand why some models of service delivery appear to better support patient adherence to ART, case studies were conducted with four ART clinics in Uganda with each clinic representing a unique model of care and context identified from prior analyses. This paper describes programmatic trends that facilitate patient adherence while comparing and contrasting the different ART service delivery models.

**METHODS**

*Design:* We utilized a multiple case study design to explore how ART programmatic factors relate to patient adherence. A case study approach describes how a bounded system (case) or multiple bounded systems (cases) relate to its context over time.
using multiple sources of information, such as observations, interviews, audio-visual materials, documents and reports (Creswell, 2007). This study design is especially useful for understanding a “contemporary” phenomenon and when “boundaries [of the case] and context are not clearly evident” (Yin, 2009) – such as how different models of ART service delivery relate to patient adherence – a phenomenon bounded within and intertwined with the contexts of the ART clinic and the country’s health system. Further, a case study is an ideal approach to answer implementation science questions because it addresses “how” and “why” types of questions.

Sampling Strategy and Study Setting: Four ART clinics were purposefully selected to represent three unique models of care and context identified from a prior analysis on diverse models of ART service delivery in Tanzania, Uganda, and Zambia (Tsui, Denison, et al., Unpublished). The three models of care included: 1) a traditional doctor led model of service delivery; 2) a mixed model that had doctors but relied more on clinical officers and nurses for day-to-day operations; and 3) a task-shifted model where there were no doctors and clinical officers and nurses took on all the clinical and administrative responsibilities. Additional details of each clinic setting can be found in the case description under Results.

Data Sources, Data Collection, and Data Management: Multiple sources of data were collected from each clinic to corroborate and complement information on the model of care and how it may affect patient adherence to ART. These data sources included direct observations at the clinic, collection of documents, and audio-visual materials from each ART program and the Uganda Ministry of Health, and in-depth interviews with ART providers and clients. Specifically, about three to five day-long direct observations
were conducted at each clinic to observe a typical day of ART service delivery and gain a contextual understanding of what happens at the clinic. During observations, we focused on questions such as how is the ART clinic and its building situated within the larger health facility, how are ART program activities organized according to clinical team, how are ART program activities organized according to the non-clinical team, how do patient visits flow at the clinic, and how were community services conducted? Direct observations and review of documents and audio-visual materials were summarized into field notes. In-depth interviews were conducted in English with different cadres of clinic providers. Exact cadres differed across clinics based on the different models of care; for example, some clinics did not employ clinical officers or pharmacists. In-depth interviews were also conducted with expert patients and ART patients in the local language of their choice (Luganda or Runyankore) to understand their experiences with the ART program. The lead author conducted all the key informant and provider interviews and two research assistants who spoke Luganda or Runyankole conducted the patient interviews. All interviews were digitally recorded and transcribed and translated into English verbatim. Finally, documents and audio-visual material that were provided by the clinics or available on the internet were reviewed to glean additional background information on the model of care and on the Ugandan health system. Clinics made available quarterly and annual reports, short videos and websites of their organizations and their mission, as well as ministry of health documents on the health system and policies on HIV care and treatment in Uganda. Data collection took place from February

5 Expert patients are HIV patients identified, trained and supported by the ART clinic to provide select tasks. Tasks may vary depending on the education and skill level of the person. Expert patients are supported by the external project supporting the ART clinic – they are not on staff payroll with a contract but are given a small stipend to compensate for transport.
2016 to November 2016 with a total of 39 provider and 40 patient in-depth interviews. All data, including audio-digital files, Microsoft Word transcripts, and Microsoft Excel sheets, were stored on a password protected computer server and backed up daily on a secure server, and all textual data were stored in Max QDA 12.0. Only the study team members trained in research ethics, including how to maintain study confidentiality had access to the study files.

**Data Analysis:** Data analysis was iterative and proceeded through several phases. First, we developed a contextual understanding of the epidemiology and history of HIV and the ART program in Uganda. This process involved an iterative review of in-depth interviews with informants from the Ministry of Health (MOH), clinic staff, and patients, followed by document reviews, informal conversations, and clarifying emails. The focus of this process was on the roll out of PEPFAR in Uganda and the development of various local and international non-governmental organizations (NGOs) to provide comprehensive ART, to relate the evolution of the ART program with key global and national ART recommendations and policies (e.g., use of point of care CD4 cell count machines, routine viral load testing, test and treat, option B+ prevention of mother-to-child transmission (PMTCT), longer ART refills, eliminating the need for treatment buddies to initiate ART). Data from this first phase were first summarized into memos by chronological events (e.g. 1980s, 1990s, 2000s, PEPFAR 1, PEPFAR 2, PEPFAR 3) and by clinic flow (e.g., registration, triage, adherence counselling, clinical monitoring, laboratory monitoring, pharmacy refill, etc.), and then reduced into matrices by models of care (traditional, mixed, and task-shifted). Second, we developed case descriptions for each ART clinic using the data matrices from the first phase. The case description
narrative covered the physical, historical, and model of service delivery of the ART clinic. Third, we conducted cross-case synthesis of ART programmatic factors affecting patient adherence. In-depth interviews were analyzed using a thematic content approach. Each transcript was read and re-read to answer questions on the a priori topics set by the study objective, to identify emergent themes, and to develop a codebook. Themes were coded and stored in MaxQDA 12.0. Coding reports were generated to analyze each theme and findings were summarized in memos.

RESULTS

Case Descriptions

Case 1: Tradition Model 1

*Physical Description:* Case 1 is a non-profit, non-governmental clinic located within a national referral hospital in Central Region, approximately 4 km by road from the city’s central business district. The hospital is a tertiary level health facility - the largest regional referral hospital in Uganda with an admitting capacity of 600 beds. It serves the Kampala Metropolitan Area. Case 1 is one of four independent outpatient HIV clinics within the hospital complex. Although the clinic is situated within the grounds of the referral hospital, it operates independently of the referral hospital and is visibly more financially well-resourced than the public hospital. It has its own two-storied building, including consultation rooms, urgent care sick bay, pharmacy, state-of-the-art laboratories, research offices, library, and training rooms. Case 1 also hires its own staff with different salary rates and benefits from what providers at the national referral
hospitals who are employed by the Ministry of Health receive. Nearly every function at Case 1 is independent of the hospital – for example, the ART clinic pharmacy makes its own requisitions apart from the hospital pharmacy.

_Historical Description:_ Case 1 was one of earliest sites to provide ART before comprehensive HIV care and treatment was available in Uganda. The clinic started as an academic and public private partnership where patients enrolled into research studies could access life-saving ART. Patients ineligible for ART were counselled, given cotrimoxazole, and entered onto waiting lists to participate in clinical trials and access ART. Case 1 started providing comprehensive HIV care and treatment services in the emergency scale-up of ART in 2004 (PEPFAR 1.0 2003-2007). The clinic prioritized clients with CD4 <50 cells/mm$^3$ even when the formal ART initiation criterion was CD4 <200 cells/mm$^3$. In PEPFAR 2.0 2008-2012, the ART initiation criterion was raised to CD4 <250-300 cells/mm$^3$. First line ART regimens were standardized to one pill per day – even for pregnant women and women of childbearing age – which greatly simplified treatment plans for providers and adherence for clients. It was during this time (2009) that Case 1 began in-house training of nurses to prescribe and re-prescribe ART regimen for “stable” patients (stable: patients who do not present with any complaints or opportunistic infections). This enabled stable patients to be monitored by nurses instead of only by the medical doctors, facilitating a more efficient client flow. In PEPFAR 3.0 (2013-present), the ART initiation criterion was raised to CD4 <500 cells/mm$^3$ in all adults and to start at any CD4 cell count in people with active TB, hepatitis B co-infection, sero-discordant couples, and all pregnant and breastfeeding women. Two major changes occurred in PEPFAR 3.0 (2013-present). First, there were major reductions in staff and an increase
usage of expert clients, known as Friends, in the running of the clinic. Expert clients work extended from supporting patient registration, file retrieval, and escorting patients to different parts of the clinics, to pill packing and labelling at the pharmacy, recording patient weight at triage, mobilizing patients to participate in research studies, peer counselling for those who have missed appointments, and keeping up the urgent care bay (e.g., washing sheets, organizing the room, etc.). Expert clients do not have an employment contract with the clinic but they receive regular small stipends to compensate for their transport and time at the clinic. Second, Case 1 re-positioned itself as a “specialized HIV/AIDS service provider” – a place for advanced HIV/AIDS care for patients with complex needs. As part of this repositioning, Case 1 also strengthened its referral model and actively transferred out 4,000 to 5,000 stable and willing patients who were not enrolled in its research studies to ART services provided by city clinics.

*Description of ART Service Delivery:* Patient experts (Friends) registered patients, retrieved their medical files, and provided patients with paper slips with numbers indicating their position in the queue. Nurses triaged the patients and recorded their temperature, blood pressure and checked their files to make sure they were not missing a laboratory test. An expert client helped the triage nurse by weighing patients and recording their weight. Patients who did not require clinical monitoring collected their ARV drugs from the pharmacy. They could collect 3 or 6 months of ARV drug refills at a time. In order to reduce client burden at the clinic, patients who presented two consecutive undetectable viral loads were eligible to receive up to six months of drugs at a time. ARV drugs were dispensed by pharmacy technicians who were supported by expert clients who helped pack and label the drugs into monthly or 3-month supplies.
Patients who required clinical monitoring or have physical complaints were divided between nurse and medical officer clinicians. Both nurse and medical officer clinicians assessed patient adherence (usually through patient self-report) diagnosed, requested and interpreted laboratory results, and prescribed medications and family planning commodities. Nurses could consult medical officers regarding more complex cases. Nurses in the Sexual and Reproductive Health Unit were trained to provide pap smears and to insert implants and intrauterine devices. Patients struggling with adhering to appointments, treatment, or other psychosocial issues were referred to counsellors for additional counselling. Case 1’s counselling department had nine counsellors with specialized roles for patients with tuberculosis, sexual and reproductive health needs, young adults, serodiscordant couples, key populations (sex workers, men who have sex with men, long distance truck drivers, and fisher folks), patients lost to follow-up, and elderly patients. Counsellors saw patients with problems and provided routine care for patients at visits every 6 months. Finally, patients who required laboratory investigations were sent to the laboratory to have blood drawn by one of three laboratory technicians who collected the samples and sent them for analysis in the same building.

Case 2: Mixed Model 2 Rural

Physical Description: Case 2 was a non-profit, non-governmental clinic located within the Health Center IV complex of a municipal clinic in Western Region, approximately 290 km southwest of Kampala. Case 2 was the second accredited ART clinic to be opened in 2008 after the first ART clinic located inside the regional referral hospital became too congested and two additional HIV care and treatment clinic were
opened to expand access to care. Case 2 opened to expand care to clients based in or near town center. Although the clinic was situated within the grounds of the health center IV (a health center IV serves a county, in addition to an out-patient clinic, maternity ward, and laboratory, it should be able admit patients with wards for men, women, and children, and have a theatre for emergency operations), it operated independently and was relatively better resourced than the rest of the health center. It had its own series of buildings for patient consultation, ART dispensing, file archival and data records entry into computers, as well as a laboratory that also served the rest of the health center. The ART clinic staff, except for the laboratory staff, were employed by a non-profit, non-governmental organization was tasked to provide comprehensive HIV care and treatment services. The non-profit NGO staffed half of the team of phlebotomists and laboratory technicians that ran the laboratories and the Ministry of Health also contributed the other half of the team. The non-profit NGO also provided for the laboratory materials.

**Historical Description:** The non-profit NGO started in 2004 during the emergency phase of PEPFAR (2003-2007). Funded by PEPFAR-CDC, it was the first provider of comprehensive HIV/AIDS services to western Uganda. In the second phase of PEPFAR (2008-2012), the organization won additional rounds of funding to provide comprehensive ART services. Case 2 was opened as part of decentralization of ART services beyond tertiary hospitals to health centers because of patient congestion at the hospitals and to deliver care to patients closer to their homes. At this time, the non-profit NGO still provided direct service delivery so it hired all the clinic staff and ran its HIV care and treatment programs. In the third phase of PEPFAR (2013-2019), the non-profit NGO changed its model to an indirect service delivery approach recognizing that direct
service delivery attracted huge volumes of patients and it was difficult to disengage their support of care and that it would be better to build capacity through training, supervision, and support through health systems strengthening. Therefore, the non-profit NGO started providing technical assistance to 19 local government facilities (mainly health center IIIs – facility found in every sub-county that runs a general outpatient clinic and maternity ward by a senior clinical officer and nurses - and a few health center IIs – facilities found in every parish by enrolled nurses and midwives to treat common diseases and offer antenatal care – to provide ART) and to help them achieve and maintain ART accreditation. Going forward since September 2016, the non-profit NGO handed over all of its clinics to another non-profit NGO because the main donor PEPFAR/CDC consolidated its partners by region. At the time of interview, the other non-profit NGO said it intended to change its model of service delivery and support to one of providing technical assistance and supportive supervision to facilities using the Ministry of Health staffing structure but continue funding support for the expert patients known as peer educators. This would likely reduce the number of staff, such as the medical officer and counsellor cadres based at the Case 2 study site.

*ART Service Delivery:* Patients were registered by expert clients known as peer educators. While patients waited to be triaged, the peer educators provided health education talks and also directed patients on where to go. Nurses triaged the patients by identifying the very sick to be seen first, checking the records to see if patients need a lab test (e.g., CD4 cell count or viral load testing), and assessing for adherence (e.g., usually self-report). Patients deemed to have adherence problems were sent to take to the counsellors. Others saw the clinicians, who could be nurses, clinical officers, or medical
officers. Clinicians conducted a pill count, ordered tests if necessary, prescribed or re-prescribe ART, and dealt with any clinical symptoms. Patients were then seen at the pharmacy by the pharmacy technician who confirmed pill counts in the electronic database and the ART regimen. Pharmacy technicians were assisted by one or two expert clients who packed or labeled pills. Stable patients could get up to 2 months-worth of drugs and they could even send an attendant to pick up their drugs for them as long as their lab work was up to date. Stable patients were also given a 4-month clinical visit appointment.

Case 3: Mixed Model 2 Urban

*Physical Description:* Case 3 was a Catholic faith-based non-profit non-governmental organization that managed four static ART clinics and nearly ten satellite ART clinics in low-income neighborhoods (e.g., slums, resettlement areas for internally displaced people) and vulnerable areas (e.g., fishing villages with high HIV prevalence) in Central Region. All the static and satellite clinics were accredited by the Ministry of Health to provide ART. Case 3 used a model of three clinical teams – two teams that were each assigned to serve two static clinics and one mobile team that was assigned to rotate through the satellite clinics. The static clinics were considered health center IVs (the highest level primary health center before a facility was designated a hospital with admitting capacity; it was usually staffed with a medical officer in addition to a clinical officer and multiple nurses) and the satellite clinics in which the mobile team supports were typically health center IIs (the lowest level primary health center was staffed only by nurses). The case study was conducted with the clinical team associated with the
Mixed Model 2 Urban ART clinic – the oldest static clinic. It was a health center IV and was strictly for outpatient care only.

Case 3 was located 10 km by road to the city’s central business district in a town in Central Region. Like all four of Case 3’s static clinics, this clinic was built on land donated by the Catholic Parish and the ART buildings were located in the same compound as the church buildings. Clinic related activities took place in two buildings. The clinical department occupied the ground floor of one building where all clinical activities took place, from triage, clinical consultations, and medication dispensing to laboratory work. The upstairs was occupied by the Case 3 headquarters office (e.g. the finance, monitoring and evaluation, human resources, and management offices) and had a training space. The other building was a small one floor building sub-divided into many small rooms (enough space for a small desk and two chairs) and was used for counselling as well as for the mobile team to plan for their outreach services in the satellite clinics. Also within the church and clinic compound was a community nursery school and a small tailoring shop where women belonging to Case 3’s small savings and livelihood groups could sell their products.

*Historical Description:* Case 3 was also one of earliest sites to provide ART before comprehensive HIV care and treatment became available for free in Uganda. Case 3 began in 2001 as a small community initiative to support its fourteen church parishioners living with HIV/AIDS. Its four volunteers provided prayer and support to its parishioners in the church hall. Notably, the wife of one of the church’s social programs was a medical doctor and she started a fundraising group to buy cotrimoxazole and paracetamol for its HIV-positive patients. In 2002, Case 3 started to provide counselling
and treatment of opportunistic infections and HIV testing in collaboration with a health center IV. Also, patients were enrolled in clinical trials so they could access CD4 monitoring and ART. In 2003, Case 3 was accredited by the Government of Uganda to dispense ART and began providing ART in the emergency scale up of ART in 2004 (PEPFAR 1.0 2003-2007). In 2005 Case 3 established laboratory services to routinely monitor patients. From the start, Case 3 used a “low cost model” by using the least number of doctors and maximum number of nurses in order to make the program more financially sustainable. This approach resulted in task shifting of tasks from doctors to nurses. At Case 3, nurses, clinical officers, and medical doctors could all prescribe and monitor an HIV patient. They could consult each other if there were any questions or if a patient was experiencing complications. Nurses also took on the roles of focal persons, e.g., for PMTCT or TB. Notably, Case 3 had funding from the CDC until 2010 to provide a 6-month comprehensive training for nurses on HIV care and treatment. Nurses who were trained then have now become the district HIV focal persons providing training at the health center level. Currently the government has replaced the 6 months program with a 5-day training course on how to manage HIV so nurses can prescribe ART. Nurses also could ask for help through a PEPFAR-supported toll-free number. In 2012, Case 3 replaced its existing guidelines with the Ministry of Health guidelines and data capturing tools in order to align themselves with the MOH roadmap – a strategy towards sustainability in long-term ART provision. Up until 2014, Case 3 provided HIV care and treatment only to clients who resided within its catchment areas because of its community model of care whereby consenting patients were assigned a community health worker who could be followed up at home if they missed clinic appointments or were too sick to
come to the clinic. However, in 2014, Case 3 opened its program to any HIV-positive client in Uganda in order to meet its targets of enrolling new clients.

*ART Service Delivery:* Expert patients registered and retrieved files of patients who arrived at the clinic. Clinical officers triaged patients and then conducted pill counts to assess their adherence, measured patient weight, and assessed patients for the purpose of the clinic visit. Patient with a specific clinical complaint were delegated to a provider depending on the patient’s severity of complaint (simple to nurse, more complex to clinical officer, and very complex to medical officer if s/he is available). Patients coming for a regular pill pick up or clinical monitoring visit were divided among the available providers. Nurses were responsible for most of the clinical monitoring visits. Clinical officers and medical doctors were generally responsible for fewer clinical visits because they had other administrative responsibilities, such as report-writing, reviewing a sample of patient files seen by nurses to make sure there were no mistakes in clinical diagnosis or prescription. Clinical visits ranged from provision of initial ART prescription, dealing with clinical complaints (e.g., a patient having specific symptoms, not feeling well), providing consultations to their colleagues, and medical doctors providing countersignatures to nurses and clinical officers on their prescriptions. At Case 3, patients were grouped by certain characteristics and the frequency of their clinical visits depended on those characteristics. Pregnant women, children, HIV-exposed infants, patients considered to have poor adherence to ART, adolescents, patients with non-communicable diseases requiring regular monitoring, such as hypertension or diabetes, were required to make monthly visits for clinical monitoring and pill pick-up. Others considered stable with good adherence were given clinical appointments for up to every 3 or 6 months.
Besides clinical monitoring, Case 3 provided on-site counselling, on-site PMTCT (including antenatal care, post-natal care, and immunization services for babies), as well as extensive community services. Example community services included a home visit program for patients with incomplete adherence and patients with TB, adolescent expert patients known as “adolescent peers” who conducted home visits and ran support groups for HIV-positive teenagers between 15-25 years, a Saturday Children’s program for home-based HIV counselling and testing of children of adults living with HIV, sharing sexual and reproductive health information with youth by Case 3 counsellors, and community health worker support programs for anyone enrolled in the HIV care and treatment program.

Case 4: Task-Shifted Model 3

*Physical Description:* Case 4 was a government clinic located within a district hospital of Central Region, located approximately 77 km west of Kampala – Uganda’s capital. The district hospital was a tertiary level health facility with an admitting capacity of 100 beds. The district hospital served the residents of a town and its surrounding villages. Case 4 was located on the second floor of the district hospital, across from the antenatal care and maternal health wing and next to the diabetes clinic and the orthopedic clinic. Case 4 consisted of a large waiting area with benches in a central location surrounded by six small rooms – these small rooms included one room for ART dispensing, two rooms for ART adherence counselling, two rooms for consultations, and one room for phlebotomy. There was also another a small corridor where there were 3 rooms – one room where patients made appointments, ART files were kept, and the
medical records assistants entered data into the health management system computer, a staff room where staff kept their belongings and had tea, and a stockroom. Sometimes this corridor was also used for consultations when client flow was particularly high. The majority of the staff were employed by the Ministry of Health. This meant that the Case 4 staff were subject to regular rotation as any other staff in the hospital were. Usually, staff could be placed at the ART department for up to 5 years and then rotated to another department. There was no clear linear career progression within the ART department. A Ugandan non-profit non-governmental organization known for providing comprehensive HIV and AIDS prevention, care and treatment and training services supported Case 4 by providing direct salary support to place an adolescent counsellor at the clinic and by providing indirect salary support (paying the district level Ministry of Health) for a clinical officer and a medical officer. The non-profit NGO also provided a lot of technical support to the staff at the clinic – for example, the nurse that dispensed ART was trained by the non-profit NGO on how to manage stocks and dispense ART, nurses and clinical officers learned how to prescribe ART through this non-profit NGO, and the data clerk received a small stipend from the non-profit NGO to dispense condoms at the clinic.

Notably, there were two volunteer counsellors at the clinic. They were not paid by the Ministry of Health nor by the non-profit NGO. These volunteers worked daily at Case 4 for nearly two years in hopes that they will get a paid position when an opening becomes available. According to one of the medical records assistant, this also occurred with other positions in the hospital (e.g. nursing, records clerk) as a way to obtain paid employment. In the meantime, the volunteers obtained infrequent lunch or transport stipends to attend a
training or an outreach event from the non-profit NGO as compensation for their work at the clinic.

*Historical Description:* Case 4 was the first in the area to make free HIV treatment available in 2004. There were long queues of patients at that time – not only because it was the only ART clinic providing free treatment, but because it was a very small facility run out of two small rooms – one room where the drugs and files were kept and another room were the nurse saw patients. ART patients used to lie on the grass under the sun with no shelter. The ART clinic did not have a laboratory and depended on the non-profit NGO’s weekly mobile laboratory services which started in 2011 – nurses would collect blood samples every Wednesday for CD4 monitoring and the non-profit NGO would send a van to collect the samples for analysis at its central laboratory. In 2014-2015, the district fell under CDC’s major health systems strengthening investment. The old district hospital compound (a series of small, dilapidated brick one storied buildings with no running water or electricity) was left and a new hospital complex was built adjacent to the old site. The new hospital complex was made of concrete, had two stories with lots of ventilation, and wired with electricity and plumbing. Now, ART patients had a sitting room with benches. Furthermore, there were now small rooms where patients could get their blood drawn and ART dispensing services within the ART clinic. These services remained staffed by the larger departments of the hospital – the central laboratory and pharmacy departments. Another major change for Case 4 was the non-profit NGO’s role over time. In the early phase of PEPFAR 2.0 (2008-2010), the non-profit NGO provided direct support to the clinic by directly paying for some of the staff salaries (e.g., the medical record assistant), analyzing the blood samples of ART
patients for CD4 monitoring and viral load testing as needed, and training staff to fulfill roles within the clinic (e.g., to teach nurses how to manage stocks and dispense ART and related medications, train medical records assistants to manage the monitoring and evaluation systems, and provide continuing medical education for ART prescription for nurses and clinical officers). Since 2010, the non-profit NGO shifted to indirectly supporting salaries by paying the local government to pay the staff salaries. The non-profit NGO and the Ministry of Health often co-facilitated the continuing medical education and trainings on comprehensive HIV care. Finally, another major change in the ART clinic was the rise in ART accreditation of private and public facilities in this district. This has resulted in declining number of new clients for the district hospital ART clinic and the clinic was not able to meet its target of enrolling new HIV-positive clients in 2016.

*ART Service Delivery:* Expert clients registered patients, measured their weight and nutritional status, and retrieved their files. Expert clients also conducted health education talks in the waiting rooms on ART adherence and the importance of suppressing the HIV. Patients were given a queue number to see the clinician, who could be a nurse, clinical officer, or medical officer. The clinician was responsible for assessing the patient’s adherence, managing their side effects and any opportunistic infections, prescribing or re-prescribing ART, and providing basic adherence counselling if necessary. Those with poor adherence were referred by the clinician to see a counsellor; otherwise, patients saw the nurse dispenser to get their drugs. At the time of the study, an intern pharmacist was rotating through the ART clinic for 3 months so there was also a pharmacist available but this cadre is usually unavailable to the clinic. The ART clinic
did not see PMTCT patients. These women were seen at the ANC/MCH clinic, which was in an adjacent wing of the hospital. When the women had their babies and follow-up care, they were then referred back to the ART clinic. Patients at the ART clinic could get basic family planning and care for sexually transmitted infections but they could not get basic primary health care.

**Thematic Analysis**

**ART provision**

*Longer ART Refills:* As ART programs have matured over time, the length of ART refills for stable patients have also lengthened from two weeks after ART initiation to one month and then to two month, three month or four month prescriptions, and even up to six month prescriptions for patients with two consecutive undetectable viral load results. All four clinics have created “pharmacy visit only” programs, where patients with ART prescriptions do not have to see a clinician and can go straight to the pharmacy to pick up their ART supply. The purpose of these longer ART refills is two-fold. First, it serves to reduce client volume for clinical monitoring so that the clinic can prioritize seeing patients who need care. A pharmacy technician explained,

“Some years back, like around 2008, they realized that patients were becoming many, and patients were going to see the clinicians even when they did not need to. Some were just coming for a refill and were not feeling sick. So pharmacy only visits were considered where by a patient comes you prescribe drugs for let’s say four months. So at the pharmacy we give the drugs for two months at most and ask the patient to come back after two months, but when they come back, the visit will be a pharmacy only visit. They will not come back to the clinician or the triage, they will just come to the pharmacy, pick their refills, and go.” (Case2, Pharmacy Technician)
Second, longer ART refills and refill only-visits enabled patients to make fewer and shorter clinic visits. Many patients emphasized how transport fees were a cause of treatment interruption. One patient said, “When I began taking the drugs I did not feel bad but I did get some problems which was the transport issue. The distance was long and I did not have any money, so time went by without me taking the drugs. I have just resumed recently.” (Case 4, Patient) Having longer ART refills benefited patients not only by saving them indirect costs such as transport fees from fewer clinic visits but also by lowering the likelihood of treatment interruptions. Refill-only pharmacy visits also make clinic visits much shorter because patients did not have to wait for triage and clinical monitoring, and enabled the patient to go about their regular day after they picked up their drug refill.

*More alternatives for ART pick up:* ART programs have also increased the number of ways patients can pick up their medications. Early ART programs only allowed patients and their designated treatment supporters written on their ART card (usually a spouse or another family member) to pick up medications from the ART clinic. As of 2016, all four clinics had become more flexible, allowing patients to give their ART cards to their spouses, neighbors or friends to pick up the medications from the ART clinic for them. This allowed the patients to continue with treatment even if they did not have the means to come to the clinic themselves. For example, in the vignette below, a female patient reported being in Eastern Uganda and not having money to return to her ART clinic in Central Uganda. However she was able to send her husband to pick up the medications for her:

“There was a time when I was in Mbale and had no money to bring me here, so I started getting palpitations. So I told the nurse I was worried about the transport.
So he told me not to worry and then asked how long I was going to take there, and I told him I was not sure. So he asked if he could write for me medicine to last me two months and I said he. And he wrote it for me without hesitation. So I figured by the time I finished the meds I would have gotten the money [for transport]. I thought to myself that if I had not talked about it I would have brought problems to myself. As the end of the first month came close I called my husband and asked him to go pick my meds and he was given meds for two more months – this I never expected but I thank God for it.” (Case 4, patient)

While most clinics allowed a patient representative to pick up medications up to two or three consecutive times, providers would request patients to come for clinical monitoring and update their files if they had not visited the clinics for a few pick-ups.

Another alternative allowed patients to pick up their medications from expert patients outside of clinic hours. This occurred at one of the case study sites that had a particularly strong community support component. Expert patients were directly responsible for the following-up patients residing in their geographic areas. These patients had individual relationships with the expert patient and could phone in to pick up their medications after clinic hours if they were not able to come in during their appointment times. As one expert patient explained,

“So if a day comes like today we have an expected number of 75 [patients], at least at this site. I have mine outside the catchment area – 18 – and I’ve already seen like 11 so there are like 7 or 8 who have not yet reported. So when it clocks midday I start reminding them. If there is any problem, or if they will reach very late in the evening, I can take the drugs, wait for them in the evening, because we always close at 4.30 and I can wait – I can wait up to 5.30 yeah for those who are sure they will be coming… They always call. Either I call or they call and say ‘No I’ll not make it before three to Kampala to get my drugs. I’ll get them from you.” (Case 3, Expert Patient)

**Staff/ people support**

*Expert patients:* Expert patients have become a critical cadre to HIV care and treatment service delivery in all four clinics. Clinic staff value expert patients because
they help run the clinic, and compensate for staff shortages by taking on critical task-shifted roles. Expert patients present daily, register patients, escort patients to different parts of the health facility, retrieve and archive files, and pack and label drugs at the pharmacy. Often, expert patients are asked by the senior nurse or counselor to give health education talks on nutrition or adherence to other patients who are waiting for clinical monitoring. Two of the clinics also ask their expert patients to help with some clinical activities, such as taking vital signs (e.g., weight, temperature, nutritional status) and counselling for patients found to have problems with drug adherence. Patients also recognize how expert patients facilitate greater efficiency at the clinic because of staff shortages. In addition, some patients mentioned how knowing an expert client helps them access services more easily. “As soon as I arrive, the peer educator recognizes me and they know that I have go back to work so they help me get services really fast. I never spend more than 30 minutes.” Case 3, patient)

Besides clinic flow and efficiency, patients value expert patients for their experience and knowledge. Patients look at expert patients as role models and appreciate them for giving advice based on experience. One patient said, “There are things they [expert patients] have taught us that they themselves have been through like the way we should swallow the meds… so they keep building on your knowledge which is a good thing” (Case 4, patient). Another patient said, “I just see them working there – they tell us to persist with the medicine because they are doing the same. Because some people wonder why they look good. You also keep taking the drugs and you’ll get better. And we are also encouraged” (Case 4, patient). When patient interviewees were asked to name their preferred counsellor – nurses or expert patients – patients across all four sites
overwhelmingly preferred being counselled by expert patients because they felt that an expert patient could understand what they were going through. “I prefer a person who is HIV positive like me to counsel me because he or she is in the same state as I am so is likely to understand the pain I am going through.” (Case 4, patient)

Reminders and checks

_Routine pill counts:_ Three of the four ART clinics conducted routine pill counts to check patient adherence. The other ART clinic relied on patient self-report to assess adherence. Among the three clinics that did routine pill counts, one clinic built in routine pill counts for every ART patient by routinely checking the balance of pills at triage. The other two clinics only conducted pill counts when the patient was due for a clinical monitoring visit. This meant that a patient eligible for a pharmacy refill – one who could skip triage and go straight to the pharmacy – would not get this accountability check.

Pill counts were done by clinicians (medical doctors, clinical officers, or nurses) together with patients. A medical doctor described the process like this: “We do pill counts – the clinicians when you are seeing the patient. You ask them [patients] what is their balance so they will get it out, count it, you count it together, and you write it on the paper.” (Case 2, Doctor) Clinicians viewed routine pill counts as helpful to assessing patient adherence and whether they are taking the correct regimen. One nurse explained, “We do a pill count. We check the balance they have. We tell them to come with their drugs because if you don’t, they will make mistakes. So when they come with the drugs we ask them, ‘tell me, how you have been taking these drugs?’ Especially the children,
they can mix the combinations, so if you do not tell them to come back with the drugs, they can just mix wrong drugs.” (Case 4, Nurse)

Patients who have pills exceeding the number of days they have been away from the clinic (meaning they have missed doses) are referred to an ART adherence counsellor. “When they [patients] first come, they go to the clinic on the pill count table. So those who need counselling services from the pill count table they refer them here.” (Case 3, Counsellor) At one ART clinic with a strong community component in its service delivery model, the community health worker was then assigned to do a follow-up visit at home to help problem-solve and support the patient for better adherence. A nurse explained how community health workers work in hand with the clinical team:

“Like I told you, they [community health workers] find out their problems at home because they might be seeing this patient miss an appointment every now and then, [and] if they do [a] pill count she is not taking her pills well, they come [to her home] they are more close to the patients because we send them out to the communities to find out more of what is happening, what is the problem, hmm, it’s them who sometimes even tell us that lady has never disclosed to the husband that’s why this, you know they dig more, hmm, they are more closer to the community.” (Case 3, Nurse)

Patients did not bring up routine pill counts as one of the ways in which the ART program helps them maintain adherence.

*Patient follow-up:* Only one of the four ART clinics (the one with the strong community component) had instituted a phone call mechanism for expert patients to call and remind patients the day before to come for their clinical monitoring or pharmacy refill appointment. All four clinics had formal mechanisms to trace patients after they missed a clinical monitoring or pharmacy refill visit. Clinics typically assigned data clerks or expert patients to conduct phone tracing, and all four clinics had phones and airtime dedicated for tracing. Notably, three of the four ART clinics reported not having
enough airtime to do these follow-up calls. A data clerk described on how she conducts phone tracing: “We get an appointment day. We see those that have not returned back. We make a list with their phone numbers. We call them. We get airtime from [an NGO providing technical assistance to district level hospitals providing comprehensive HIV care and treatment] but it is not enough”. (Case 4, Records)

All four clinics technically included home-visits as a program strategy although only two had funds to consistently implement this program component. One nurse described how the follow-up system was for the Mother-Baby Care Point for PMTCT: “So if a mother misses an appointment, we collaborate with her through phone calls. When she explains that I’m coming back in a week, we try waiting for her during that one week. If she fails [to come], we try organizing a home visit” (Case 3, Nurse).

Generally patients spoke positively of phone calls and home visits because they were perceived as supportive – that someone cared about them. However, it should be noted that none of the patients interviewed directly experienced these follow-ups in person. One patient described his wife’s home visit from an expert patient:

“Well, those [expert patients] are good people because here patients talk about them. They help, they educate patients, they teach them how to make handicrafts, they counsel them, make phone calls to them, visit them at home, so each home visit renews a patient’s hope, it’s akin to receiving a visit from a friend, so they give hope to the patients they visit. For me they have never visited me but they visited my friends and even my wife and many times they will not find me at home but it renews hope and you are then reassured that there are people who care about you. It’s like if your boss at work comes to visit you, it encourages you and renews hope.” (Case 1, patient)

Another patient also talked about follow-ups by expert patients: “They [expert patients] do a good job, especially when it comes to those who miss their days [clinic days]. These peer educators do follow-up, they look for you, they call you or even come to your home.
They counsel you and also encourage you. They are the ones who follow-up to know whether someone died or if they [are] sick at home.” (Case 2, patient)

**DISCUSSION**

Through a case study analysis of four ART clinics in Uganda, we examined how the structure of ART service provision may affect patient adherence to HIV medications. In the cross-case analysis, we found three main programmatic factors which supported long-term patient adherence to ART: longer ARV drug refills, expert patients, and routine pill counts. These programmatic factors were enabled by the task-shifting of many services to lower-level cadres of providers, including expert patients. Without these staffing changes, clinics would not have been able to provide ART services with such high client volume or additional counselling, follow-up, and social support offered by expert patients, which appeared instrumental in supporting patient adherence.

Longer ARV drug refills emerged from our findings as a key structural factor shaping patient adherence. Many patients on HIV treatment live in poverty and are faced with competing basic needs. While ART is provided free-of-charge in Uganda, patients are responsible for indirect costs associated with transport or loss of wages from time spent at the clinic. Transport costs have been cited as a major reason why patients are not able to get to the clinic to refill medications (Coetzee, Kagee, & Vermeulen, 2011; Fried, Harris, & Eyles, 2012; Hardon et al., 2007; Idindil, Jullu, Mugusi, & Tanner, 2012; Lubega et al., 2013; Tabatabai et al., 2014; Ware et al., 2009). Provision of longer ARV drug refills reduces the frequency of clinic visits and reduces transport-related ART costs (Harries, Zachariah, Lawn, & Rosen, 2010). Provision of longer ARV drug refills thus enables patients to “choose” adherence in their competing costs and systems’ resource
constraints (Gusdal et al., 2009). Longer ART prescriptions are associated with the adoption of routine viral load testing and differentiated care. In Uganda, country adoption of routine viral load testing in 2016 enabled all four case study sites to implement differentiated care based on viral load. Patients with undetectable viral loads are considered “stable” and are given longer ART prescriptions (e.g., from 3 to 6 months) and only need to visit the pharmacy for refills. Such differentiated care allows stable patients to benefit from fewer clinic visits and therefore fewer indirect costs in relation to transport and time. Differentiated care also benefits the clinic by freeing up provider time to focus on initiating more patients onto ART or caring for patients who are not virologically suppressed (Geldsetzer et al., 2017; Phillips et al., 2015).

Second, we found that expert patients are an important clinic-level factor that can impact patient adherence and improve daily clinic functions. Task-shifting of non-clinical responsibilities to expert patients has been documented in ART programs elsewhere in sub-Saharan Africa (Bedelu et al., 2007; Bemelmans et al., 2010; Decroo et al., 2013; Landes et al., 2017; Tabatabai et al., 2014). While providers acknowledge that expert patients help lighten their workload and enhance efficiency of clinic flow, and patients appreciate expert patients as role models with lived experience of HIV, much less attention has been paid to the critical role that expert patients play in monitoring, follow-up, and support of patients to ensure retention in care and adherence to ART (Moyer, 2014). Expert patients play a critical role in the whole HIV continuum of care, including escorting patients from testing and treatment or other ART-related services (e.g., off-site PMTCT or TB services) to the HIV clinic to prevent drop-out from care, exchanging phone numbers with patients and their family members to enhance follow-up and thereby
creating new social support networks, and conducting home visits to help problem-solve issues related to missed clinic appointments or incomplete adherence (Moyer, 2014; Saleem, Kyeyagaire, & Lunsford, 2014). Despite their critical role in promoting patient retention and adherence, expert patients are too often framed only as people who fill in gaps in an overburdened health system by taking over roles that were originally filled by nurses, counsellors, or professional administrators. Expert patients are seen as an inexpensive and temporary solution to a strained national health program rather than integral to programmatic success. Expert patients in Uganda are funded by external projects and are not integrated into the Ministry of Health scope of work. Growing donor fatigue towards supporting comprehensive HIV care and treatment services in resource-limited settings is propelling changes in models of HIV care to rely on greater country ownership of these programs. This evolution is evidenced by the scale-up strategies of ART programs supported by PEPFAR. Programs have changed from expanding numbers of decentralized ART clinics to expanding mobile teams to provide technical assistance to support public health facilities and their existing staffing capacities to provide comprehensive HIV care and treatment services. Three of the four case study sites had realized the heavy costs associated with building and expanding external clinics, and had decided to support MOH staff capacities and infrastructure to further patient HIV services. The fact that expert patients play such a major role in ART service delivery yet are not officially recognized within the national health system poses a critical challenge towards providing sustainable ART care.

Finally, although patients in our study did not identify routine pill counts as one of the ways in which they felt the ART program helped them maintain adherence, we
concluded that overall, routine pill counts did appear to be important as a way in which the structure of ART clinic services support patient adherence. Our research suggests that identification of incomplete adherence through routine pill counts triggers additional adherence interventions, such as patient education, counselling, or home visits. These additional services further support adherence. This finding corresponds with previous studies from Kenya (Achieng et al., 2013) and Uganda (Tsui, Kennedy, et al., Unpublished) that found that routine pill counts were associated with higher adherence. Prior research suggests that the repeated process of expecting to have your pills counted, organizing your medication for pill counts, and receiving increased attention from the person conducting the pill count can have a “reactive effect” for patients resulting in improved ART adherence (Kalichman et al., 2010). This potential “reactive effects” by patients, combined with the service program response in terms of triggering additional adherence services, support patient adherence. The four case study sites also demonstrated the feasibility of both conducting routine pill counts in high volume ART clinics and of incorporating pill counts at different points of the clinic flow (e.g., during triage or clinical visit). A case study clinic also confirmed the feasibility of task-shifting routine pill counts to expert patients. Routine pill counts are an easy to perform and relatively low-cost intervention that can provide tangible evidence of adherence to both providers and patients; therefore, settings that are not already implementing this can consider doing so.
**Strengths and Limitations**

Findings from this study must be seen in light of its limitations. The four cases selected were not intended to be generalizable to all ART clinics in Uganda or sub-Saharan Africa. Further, we were unable to document temporal or causal relationships between the programmatic factors described and actual client adherence behaviors. Nevertheless, our case study approach was comprehensive in documenting a range of perspectives, including both client and provider perspectives, as well as structural and historical aspects of clinic organization that may have affected ART adherence. With the continued prominent position of ART adherence in concerns surrounding scale-up and decentralization of ART services across sub-Saharan Africa, this study points to the importance of considering programmatic shaping patient adherence.

**CONCLUSION**

In sum, we described a comprehensive case study of four ART clinics in diverse settings across Uganda and noted how aspects of service delivery across cases, including longer ARV drug refills, expert patients, and routine pill counts, may impact patient adherence. As ART expansion continues across sub-Saharan Africa and elsewhere, we encourage continued consideration of how aspects of ART programs may influence the key goals of such programs, including patient adherence to ARV drugs.
REFERENCES


CONCLUSIONS

Overall Findings

This dissertation identified task-shifting/task-sharing models of antiretroviral therapy (ART) service delivery in Tanzania, Uganda, and Zambia, examined the relationship between these models of ART service delivery and ART adherence among adults on treatment, and then conducted case studies of four ART programs in Uganda to see how program-level factors may influence or interact with patient adherence.

Manuscript one presented cluster analysis and Delphi survey results identifying three task-shifting/task-sharing models using data from 18 routine HIV care and treatment programs in Tanzania, Uganda, and Zambia. The main differences across the models were the availability of medical doctors, the scope of clinical responsibility assigned to nurses, and the use of lay health care workers. Patterns of healthcare staffing in HIV service delivery were associated with different environmental factors (e.g., health facility level, urban vs. rural setting) and program characteristics (e.g., community ART distribution or integrated TB treatment on-site). Having a data-driven classification of models of care is the first step towards understanding the relative advantages and disadvantages of these different models of care. In turn, this information can help national programs adapt to increased client loads, select optimal adherence strategies within decentralized models of care, and identify differentiated models of care for clients to meet the growing needs of long-term ART patients who may require more complicated treatment management.
Manuscript two presented cluster-level analysis results of the relationship between task-shifting/task-sharing models of care (identified from manuscript one) and adherence. This analysis defined adherence with a medication possession ratio, and adjusted for individual-level factors that influence patient adherence. The adjusted analysis found patients in the traditional, doctor-led model were 1.6 times more likely than patients in the mixed model, where doctors, clinical officers, and nurses shared clinical responsibilities to have MPR<90% (aRR=1.60, 95% 1.03, 2.48). Although not statistically significant, the findings also show a trend with patients in doctor-led clinics of being more likely than patients in the task-shifted model, where doctors shifted clinical responsibilities to clinical officers and nurses, to have MPR<90% (aRR=1.58, 95% 0.88, 2.58). There was no evidence of difference in incomplete adherence between the mixed and task-shifted models (aRR=0.99, 95% 0.59, 1.66). We conclude that non-physician-led ART programs can support adherence levels as well than physician-led ART programs, and task-shifting and task-sharing of ART services were not associated with worse patient adherence. Further, differences in staffing may result in different implementation approaches. Factors that differentiated the mixed and task-shifted models from the traditional model of care included longer ART initiation counselling, routine pill counts, and the clinic having more alternatives to clinic-based pill pick-up. These programmatic aspects may have made it easier for patients to pick up their medications and therefore supported adherence.

Manuscript three presented the results of a multiple case study of four diverse ART clinics in Uganda that explored the healthcare delivery factors facilitating patient adherence to ART. Three key programmatic factors emerged from the cross-case
analysis. Longer ARV refills have reduced the indirect costs of transport and time and facilitated patient adherence by minimizing the common structural barriers to treatment interruption. Expert patients played a critical role in linkage and retention in care and promotion of optimal ART adherence among patients. In exchanging phone numbers to follow-up patients, they created new social support for people living with HIV. Further, expert patients made ART services more patient-centered by facilitating medication pick-up out of regular clinic hours. Finally, routine pill counts were found to trigger additional adherence interventions, such as education, counselling, and home visits, which helped support adherence.

**Recommendations for researchers, program planners, and policy makers**

Findings from the three manuscripts suggest a number of recommendations and next steps for researchers, program planners, and policy makers.

How ART services are delivered influences patient adherence. Few studies, however, have examined how models of care and how combinations of services combined with task-shifting may support patient adherence. Manuscripts one and two illustrated the value of examining models of care and how the historical push to scale-up ART services resulted in more task-shifted and decentralized approaches to facilitate entry into HIV treatment and care. These manuscripts also showed how such models, known for expanding access, have also supported adherence among treatment experienced adults. This contributes to the evidence base that task-shifting, not only from doctors to clinical officers and nurses, but nurses to expert patients, and from central
hospitals to primary health centers, present a viable way of sustaining lifelong HIV care services.

For researchers, there is a relative lack of empirical data on models of ART service delivery, particularly how staffing is related to implementation approaches and key program outcomes such as adherence. Further, models of care are constantly adapting and changing in response to funding and management trends. Additional research with a larger and more diverse sample of ART clinics could validate the models of service provision identified in this dissertation, identify new models that may have developed in recent years, and generate information about the relative benefits and drawbacks of these different models to inform the scale-up of ART and associated services in resource-limited settings.

ART adherence is vital for virologic suppression, especially so to achieve the third aim of the 90-90-90 targets of viral suppression of 90% of all people receiving antiretroviral therapy by 2020. While significant research has focused on understanding individual, interpersonal, community, and structural factors influencing adherence, less attention has focused on how routine ART programs can facilitate or support patient adherence behaviors. Our findings from manuscripts two and three add to the nascent and limited body of literature that suggests that routine pill counts can have positive “reactive effects” on patient adherence behaviors (Kalichman et al., 2010) and provides evidence that there is a dose-response relationship between the numbers of clinician pill counts performed, increased patient adherence, and decreased treatment failure (Achieng et al., 2013). Our findings suggest that researchers should examine the effect of routine pill counts on patient adherence over time and assess the cost-effectiveness of this relatively
simple and low-cost intervention to promote adherence because additional research on this area can likely further the 90-90-90 goals.

For program planners, findings from manuscript two that task-shifting and task-sharing of ART services are not associated with worse patient adherence are promising and are consistent with other findings of non-inferiority outcomes of task-shifted ART services and virologic suppression (Brennan et al., 2011; Fairall et al., 2012; Kiweewa et al., 2013; Kredo, Adeniyi, Bateganya, & Pienaar, 2014; Sanne et al., 2010). Task-shifting and task-sharing models of HIV service delivery will almost certainly be scaled-up regionally, given the need to achieve the second of the 90-90-90 goals - having 90% of all people with diagnosed HIV infection receiving sustained antiretroviral therapy – and implement the World Health Organization’s Test and Treat recommendation.

Our findings also highlight the need for Ministries of Health in sub-Saharan Africa, who have been assuming greater financial responsibility for sustainability ART services, to determine how expert patients may be formally integrated into HIV care services. For program planners and policy makers, findings from the case studies presented in manuscript three suggest that expert patients play a critical role in linkage and retention in care and promotion of optimal ART adherence among patients. On the surface expert patients may appear to perform logistical tasks of tracking patients (e.g., updating phone numbers, documenting attendance, tracking patient files). However, the seemingly informal interactions between expert patients and patients (e.g., exchanging phone numbers for reminders and follow-up, escorting patients to various services within the health facility compound, facilitating conversations with clinicians, facilitating medication pick-up outside of regular clinic hours) are also foundational in providing
Social support, including emotional, informational, and instrumental support to patients, and in making ART services more patient-centered. Program planners should consider the critical role of expert clients by ensuring they have appropriate compensation and support for their work. This can mean having enough airtime to do their reminder and follow-up calls. For policy makers, expert patients are not part of the Ugandan national health system’s cadre for HIV service delivery. Expert patients work in Uganda are funded entirely by donors through external projects and this poses a critical challenge to the provision of sustainable ART care, especially as HIV programs move towards country ownership. National policy makers need to consider the long-term role of expert patients within the context of the national health system and how ART will be provided sustainably.

Differentiated care – triaging patients by clinical status and providing different levels of services accordingly – has received attention in the global HIV community. Findings from this dissertation support the development of such models, and the use of task-shifting to provide differentiated services in these models. Manuscript three’s finding on how longer ARV refills for stable patients support patient adherence and free up provider and clinic resources to initiate new patients onto ART and provide care for those who are not virologically suppressed.

All in all, all three manuscripts contribute to the implementation science of ART service delivery in sub-Saharan Africa, and ultimately, to improve the well-being of people living with HIV and AIDS.
Strengths and Limitations

Limitations. There are several limitations to the research presented in this dissertation. First, the cross-sectional design and a lack of temporality limit the causal inferences we can draw in manuscripts 2 and 3. However, the directionality between the relationship of task-shifted ART models and adherence outcomes is such that it is unlikely patient adherence affects the programmatic services and task-shifting practices of clinics. Second, there was a significant temporal lag between the first and second phase of research: the task-shifting and adherence data used in manuscripts 1 and 2 were collected in 2010-2012, while the case study data were collected in 2016. ART services changed significantly over this period of time, as evidenced by the models of care presented in manuscript 1 compared with the models of care presented in manuscript 3. Preparedness for ART initiation have changed: the three pre-ART counselling sessions and having a treatment buddy attend these sessions are no longer requirements for ART initiation. Laboratory monitoring practices have changed: annual viral load monitoring is now available at all sites; CD4 testing has scaled down to only pre-ART patients; and point-of-care testing for CD4 is now available at all the sites whereas previously the primary health care sites had to collect blood samples and package them for analysis at the district or central level. These changes limit the extent to which qualitative data in manuscript 3 can explain the quantitative findings from manuscripts 1 and 2 and the kinds of conclusions we can draw across these items. However, it is encouraging that many of the programmatic factors identified in manuscript 2 as potentially supportive of patient adherence, above and beyond individual factors, were nearly all implemented in all of the clinics studied in manuscript 3.
Strengths. There are also strengths to the research presented in this dissertation.

First, this study focused on an important aspect of quality HIV treatment that has not yet been comprehensively examined. Second, health system factors are rarely considered in adherence research so this study makes a unique contribution by examining the influence and interaction of health service delivery factors and adherence behaviors. Third, this study followed a true mixed methods approach, drawing from strengths and limitations of each methodology to maximize our understanding on the relationship between task-shifted ART services and ARV drug adherence. The three task-shifting/task-sharing models of care was based on the cluster analysis of 33 out of 69 task-shifting/task-sharing characteristics – a much more comprehensive measure than used in previous studies. Finally, through the use of Delphi Method, this study drew on the knowledge of global and local experts to enhance the interpretation and translation of this research for programs and policies.

REFERENCES


APPENDICES:
STUDY INSTRUMENTS
Appendix A: Measures collected to describe task-shifting/task-sharing models of care in 18 antiretroviral therapy clinics

- Level of health facility (national referral, provincial, district, primary health care)
- Type of health facility (government, mission supported by government, mission not supported by government, non-religious non-government not for profit organization, private for profit)
- On-site HIV care and treatment services (HIV counselling & testing, Diagnostic HIV testing, Paediatric ART, Paediatric HIV care (not ART), OI prophylaxis, Management of OI, CTX prophylaxis, TB testing, TB prophylaxis (INH), TB treatment, Lab services, STI treatment, PMTCT services, Palliative care, Nutritional supplementation, Nutrition education & advice, FP services, Counselling of HIV infected patients in prevention, Post exposure prophylaxis (PEP)) - by cadres of health providers, if there were changes to type of health cadre provider, and if there were changes then were there any pre-service, in-service, and continuing education training
- Any cost to patients (Registration, HIV test, ARV drugs per month, cost of specific lab tests)
- Clinic days at the main clinic
- Clinic days at outreach locations
- Type and number of staff providing HIV care and treatment on a typical day
- Supervision visits from MoH
- Supervision visits from non-MoH
- Number of patients ever registered at HIV clinic
- Number of patients currently registered at HIV clinic
- Number of patients currently receiving HAART at HIV clinic
- Number of patient visits at the HIV clinic in the past 30 days
- Number of patients a clinic sees on a typical clinic day
- Parent and child seen together at same HIV clinic on same day
- When clinic started providing HAART
- Sources of funding (religious mission, non-profit organization, university/research organization, government, other)
- Types of first line ART regimen available (AZT, d4T, NVP, EFV, tenofovir, other)
- Types of second line ART regimen available
- Refill schedule in first month of treatment
- Refill schedule between second and six months of treatment
- Refill schedule after completing first six months of treatment
- Ways ARV drugs are dispensed (facility pharmacy in hospital, facility pharmacy with separate ART window in hospital, HIV clinic, in community)
- Number of staff dispensing ARV drugs on a typical day
- CTX dispensing at HIV clinic
- ART-related lab tests performed at health facility
- Type of ART-related labs at health facility (CD4 cell count, TLC, VLT, liver function, renal function, WBC, haemoglobin)
- Frequency of lab tests before ART initiation
- Use of ARV drug adherence guidelines
- Use of ARV drugs job aides
- Providers who provide adherence counselling to patients (medical doctor/office, clinical officer, nurse/midwife, treatment nurse, nurse attendant, lab staff, pharmacy staff, nutritionist, social worker, lay ART support worker)
- ARV adherence counselling before a patient starts ART
- Number of ARV adherence counselling sessions while starting ART
- Follow-up ARV adherence counselling after patient has started ART
- Methods of adherence counselling (Individual, treatment supporter or buddy, part of a group, pill count)
- Adherence counselling frequency (at preparedness visits, during 1st six months of ART initiation, after first six months of ART initiation, when patient misses clinic apt, when patient misses pharmacy refill visit, when patient has OI, at every refill visit)
- How is adherence assessed by pharmacist or ART dispenser (patient self-report, pill count, pharmacist assessment, electronic pill cap count, verifying refill dates)
- Adherence support services (PLWHIV support group, adherence support workers, home-based care workers, treatment buddies or supporters)
- Requirement to have treatment buddy when starting ARV drugs
- Linkage to community based health workers or volunteers
- Community based services (distribute ARV drugs, referral for medical care, home-based care, ARV adherence support, emotional or social support, follow-up missed appointments, nutritional support)
- Community based health workers or volunteers trained in ART adherence support
• Referral system from ART clinic to community based health worker
• System to make patient appointments at HIV clinic
• System to identify missed appointments
• Clinic methods to contact patients who have missed appointments (telephone call, house visit by adherence support worker, house visit by healthcare worker, house visit by home-based care worker)
• System to trace patients lost to follow-up
• Methods to trace patients lost to follow-up (telephone call, house visit by adherence support worker, house visit by healthcare worker, house visit by home-based care worker)
• System to trace transfer of patients to another ART facility
Appendix B: Delphi Survey Round 1

Round 1

Slide 1. Understanding Models of Task-Sharing of Antiretroviral Therapy in Tanzania, Uganda, and Zambia

Slide 2. Introduction

- My ultimate goal is to understand how different task-sharing strategies of ART service delivery relate to patient outcomes so that we can promote ART models that best support health

- For the purposes of this exercise, task-sharing includes redistribution of tasks among health professionals (e.g., task of ART prescription from doctor to nurse) and from health professionals to lay cadres (e.g., task of patient registration from nurse to expert patient)

- I explored key ART service delivery tasks, including registration, triage, initial ART prescription, ART monitoring and management, clinical services, referral services, ART dispensing, drug adherence counselling, phlebotomy, follow-up on missed appointments and defaulters, and medical records management

Slide 3. Introduction (continued)

- What I did – I performed a cluster analysis to identify major task-sharing strategies used in ART service delivery and their contextual factors in 19 diverse ATR programs in Tanzania, Uganda, and Zambia

- What I need your help on – As an expert panel member, your knowledge and experience of ART programs in sub-Saharan Africa will help me interpret the cluster analysis results to identify meaningful task-sharing models of ART services

Slide 4. Data

- I collected task-sharing data through the 2008-2012 Adult ART Retention and Adherence Study, which sought to characterize retention and adherence among ART clinic patients across 19 diverse settings in Tanzania, Uganda, and Zambia; and identify important individual risk factors and programmatic characteristics associated with ART retention and adherence

Slide 5. Methods

- Step 1. Cluster Analysis – I performed a cluster analysis to explore how variables on task-sharing of ART services grouped together and identify models of task-sharing of ART service delivery

- Step 2. Delphi Method – Now I am implementing the Delphi Method to systematically collect and analyze expert opinions on the cluster analysis results.
This process serves to ensure that the task-sharing variables are not just grouped together statistically, but they hold practical meaning.

Slide 6. Instructions for Expert Panel
- Please fill in your responses in the attached Word document, following the order of the questions as listed in this presentation
- Please write your response in full sentences and with as much detail as you can provide. Provide specific examples where possible. There is no page limit!
- Please email your responses to Sharon Tsui at stsui@jhu.edu
- Thank you for your participation!

Slide 7. Expert Panel Participant Survey
- What is your name?
- What organization do you work for?
- What is your job title?
- Please list all the countries where you have worked on ART programs (research, policy, or service delivery)
- How many cumulative years of research, policy, or service delivery experience do you have as it relates to task-shifting or task-sharing of ART services?

Slide 8. Result 1 Emergence of 3 clusters
- Al cluster analysis results, including 9 sensitivity analyses grouped the 19 ART programs into 3 clusters
- The clusters or models of task-sharing of ART service delivery can be broadly described as 1) clinical services by medical doctors only, 2) clinical services provided by clinical officers and nurses, there are no medical doctors, and 3) clinical services shared by medical doctors, clinical officers, and nurses
- See table 1 for summary of task-sharing characteristics of the 3 clusters

Slide 9. Table 1 Task-sharing of antiretroviral therapy services, by clusters

Slide 10. Definitions of terms used in table 1 (triage, ART initiation prescription, ART monitoring and management, clinical services)

Slide 11. Result 2 Contextual factors of the 3 clusters
- As a next step, I looked at some of the contextual factors of these three task-sharing models (see table 2)
- In general, I noticed a) all three countries are represented in each task-sharing model, and b) different health facility levels (e.g., national referral, provincial, district, and primary health centres) are represented in each task-sharing model
Slide 12. Table 2 Summary of contextual factors, by clusters

Slide 13. Result 2 continued

- The model where clinical services are only provided by medical doctors is found in urban sites only
- Question 1. What are the reasons that ART programs where clinical services are only provided by medical doctors are located in urban areas?

Slide 14. Result 2 continued

- In this study, the model where clinical services are shared by clinical officers and nurses and there is no medical doctor is found in government-supported sites only.
- Question 2. What is the reason that ART programs where clinical services are shared by clinical officers and nurses are found in government sites? Why is this model not found in ART programs supported by non-governmental organizations?

Slide 15. Result 2 continued

- The model where clinical services are shared by medical doctors, clinical officers, and nurses is found mainly in sites with large populations of patients on ART.
- Question 3. What are the reasons why task-sharing by medical doctor, clinical officer, and nurse model are found mainly in sites with large ART populations?

Slide 16. Result 2 continued

- Question 4. Does these 3 clusters make sense based on your understanding of how health cadres are distributed in the health systems in Tanzania, Uganda, and Zambia? (Or in sub-Saharan Africa)? Why or why not? Please state your experiences.

Slide 17. Result 3 Programmatic Factors of the 3 Clusters

- Finally, I looked at how programmatic factors varied across these three task-sharing models (see table 3)
- I noticed that a) ART programmatic components (e.g., registration, triage, ART prescription, ART monitoring and management, ARV drug adherence counselling, ARV drug dispensing, medical records management, etc.) appear to be similar across the three task-sharing models; and b) this is not surprising as differences are mainly expected in terms of different cadres performing the tasks in ART service delivery

Slide 18. Table 3 Summary of HIV care and treatment programmatic factors, by clusters

Slide 19. Result 3 continued
• The model where clinical services are only provided by medical doctors has: the greatest number of clinic days at outreach sites, the shortest time to ART initiation, fewer sites requiring at least 3 counselling sessions to initiate ART, greatest percentage of sites who provide viral load testing as needed, no pill counts to support adherence in the first 6 months of treatment, no community-based distribution of ARV drugs

Slide 20. Result 3 continued

• Question 5. Why does this model have the shortest time to ART initiation?
• Question 6. Does this model emphasize any clinical services that can only be requested by a medical doctor?

Slide 21. Result 3 continued

• The model where clinical services are shared by clinical officers and nurses and there is no medical doctor has: the fewest number of clinic days at outreach sites, does not provide CD4 cell count less than 6 months, the greatest proportion of sites that provide community-based services on adherence support, home-based care, and referral for medical care

Slide 22. Result 3 continued

• Question 7. Do you think having a government facility explains why this model has the fewest number of sites that provide outreach services? Why or why not? Please state you experiences.

Slide 23. Result 3 continued

• The model where clinical services are shared by medical doctors, clinical officers, and nurses has: the greatest proportion of sites requiring more than 7 days to determine ART eligibility, the greatest proportion of sites requiring at least 3 counselling sessions before ART initiation, the greatest proportion of sites providing 2 months of ARV drug supplies after patient has initiated the first month of ART, the greatest proportion of sites to provide community-based ARV drug distribution, the greatest proportion of sites providing house visits by health care worker for follow-up of missed clinic of pharmacy appointment and tracing of patients lost to follow-up

Slide 24. Result 3 continued

• Question 8. This model caters to the larger ART populations. What strategies are used to improve efficiency, reduce client load, and manage high client flows at the ART center?

Slide 25. Thank you

• For participating in my dissertation research as an expert panel member on task-sharing of ART services in sub-Saharan Africa!

Slide 26. Do you have any questions or additional comments?
Appendix C: Delphi Survey Round 2

Dear Expert Panel Member:

Thank you for your participation in the Delphi method survey to explore cluster analysis results on task-shifting/ task-sharing strategies in 19 ART sites in Tanzania, Uganda, and Zambia. I am writing to share a summary of participant responses.

1. Respondent characteristics

Eighteen of the 22 key informants participated in the survey with an 82% response rate. (THANK YOU for making that possible!) Key informants were purposefully identified through publications on task-shifting/ task-sharing, or nomination by colleagues in the field of HIV care and treatment. Informants had between 5 and 21 years of experience in task-shifting of HIV care and treatment implementation, policy, or research. Informants represented a wide range of organizations from ministries of health, to national and international implementing partners, to universities, to funding agencies for global health programs, policy, and research. Informants shared their experiences from 21 African countries and 9 non-African countries.

2. Do the three clusters make sense?

Most key informants (14/18, 78%) said the three clusters of HIV care and treatment models, broadly labelled as “cluster 1: doctor-led ART”, “cluster 2: clinical officer and nurse-led ART” and “cluster 3: task-sharing among doctors, clinical officers, and nurses”, made sense in the context of the countries in which they have worked. Other key informants (4/18, 22%) said the cluster findings were “artificial” and “context dependent” and only meaningful to the three countries where the data were collected.

Based on the feedback by key informants, I revised the cluster labels to be more nuanced. The new labels describing each cluster are as follows:

<table>
<thead>
<tr>
<th>Cluster</th>
<th>Old Label</th>
<th>New Label</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Doctor-led ART</td>
<td>Task-sharing of clinical tasks among medical doctors and clinical officers</td>
<td>There is no model of care where services are solely given by medical doctors. The new label indicating task-sharing of clinical tasks among medical doctors and clinical officers more accurately describes cluster 1. In this cluster, nurses did not play a role in clinical tasks.</td>
</tr>
</tbody>
</table>
### 3. Contextual factors related to clusters

Below is a summary of feedback from key informants on the contextual factors related to each cluster. I have relabeled “contextual factors” as “health facility and environmental factors” to further specify what these contextual factors are.

<table>
<thead>
<tr>
<th>Cluster and Label</th>
<th>Health Facility and Environmental Factors</th>
</tr>
</thead>
</table>
| 1: Task-sharing of clinical tasks among medical doctors and clinical officers | - Cluster 1 clinics where clinical tasks were performed predominantly by medical doctors (100%) and some clinical officers (40%) are found in urban areas only.  

Medical doctors are more likely to work in urban areas because they can have a better quality of life, such as nicer living amenities, good schools for children, improved earning potentials (most doctors also practice in a private clinic in addition to their position at the ART clinic), and better opportunities for career progression (e.g., access to trainings/workshops).  

- Cluster 1 clinics tended to be based in national or regional level referral hospitals.  

Medical doctors are hired at tertiary level health facilities. Medical doctors are attracted to work at higher level health facilities so they can practice their specialized training and have greater access to resources that can support this specialty care. Nurses in the context of a tertiary level facility are not given permission to practice primary clinical tasks (e.g., ART prescription) but play a non-clinical role (e.g., registration, ART adherence counselling). |
2: Task-shifting of clinical tasks from medical doctor to clinical officers and nurses

- Cluster 2 clinics include a range of levels in health facilities from a primary health center to provincial or district level hospitals. All of these clinics are government-supported sites only. There are no mission or non-profit non-religious organizations supporting these sites.

While medical doctors are hired at government-supported secondary level health facilities, these positions often remain unfilled if they are not in a desirable location (rural or remote area) or do not offer adequate career progression. For example, the decentralization of hiring health personnel in Uganda has made it more difficult for district level hospitals outside of Kampala to attract medical doctors because doctors hired into this system would not have an opportunity to be promoted to work in tertiary level hospitals found in Kampala.

3: Task-sharing of clinical tasks among medical doctors, clinical officers, and nurses

- Cluster 3 clinics tended to have large ART patient populations (7/10 clinics had at least 2000+ patients).

Task-sharing in clinics with high client load is “to be expected” because “necessity is the mother of innovation” – clinics have to develop new systems of care to manage all the patients they have. Small clinics with low client load will task-share simply because doctors or clinical officers are not available full time for the ART clinic.

4. Next steps

I will be writing up these results in a peer-reviewed journal format my dissertation. I will be happy to share this with you once it is ready! Further, I will translate these 3 clusters into a summary variable for “ART staffing model of care”. I will then explore the relationship between task-shifting/ task-sharing models of care and individual patient outcomes, specifically retention to the ART program and adherence to ARV drugs. I hope this analysis will provide insight into which models of care can best support positive health outcomes for patients.

Thank you again for sharing your insights on task-shifting of ART services!

Sincerely,

Sharon Tsui
Appendix D - Description of Stigma, Depression, Social Support, and Self-Efficacy

Measures from the ART Study

NOTE: The descriptions of these measures are taken directly from the statistical analysis plan of ART Study written by Dr. Joris Menten, Dr. Julie Denison, Sharon Tsui, and Dr. Olivier Koole.

Stigma

Self-perceived stigma associated with HIV is assessed using five questions from the Internalized AIDS Stigma Scale (IA-RSS) (Simbayi, 2007; Kalichman, 2009).

- It is difficult to tell other people about my HIV positive status
- I feel guilty that I am HIV positive
- I am ashamed that I am HIV positive
- I sometimes feel worthless because I am HIV positive
- I don’t let others know my HIV status

As described in Kalichman et al (2009) the items in this scale “reflect dimensions of stigma and focus on self-blame and concealment of HIV status”. The sixth question usually included in this scale “Being HIV positive makes me feel dirty” was dropped from the CDC ART Study based on the pre-test results. Essentially this question should capture negative self image, but during the pre-test it was clear that respondents related it to sexual immorality, promiscuousness or engaging in prostitution.

Dichotomous responses (1 = agree, 0 = disagree) are provided for each question. The final score will be calculated as the sum of all of the “agree” responses, thus providing scores ranging from 0-5, with higher scores representing greater internalized stigma.

Depression

The Hopkins Symptoms Checklist depression subscale (HSCL-15) will be used to assess symptoms of depression among study participants. The sub-scale consists of 15 questions. One additional question “Feeling like I don’t care about what happens to my health”, was also included as recommended and carried out in previous research to specifically address ARV patients (Martinez et. Al 2007; Bolton & Ndogoni, 2001). The depression score will be calculated by determining the average score based on a four-point scale (1 = “not at all”, 2 = “a little”, 3 = “quite a bit”, 4 = extremely”). The standard
cut-off for the HSCL, 1.75, will be used to identify possible symptoms of depression (Kaaya, 2002).

**Social Support**

Social support will be assessed using a series of 10 questions, 9 of which were utilized in a previous study of HIV patients in Tanzania (Antelman, 2007) and derived from the Duke University – University of North Carolina Functional Social Support Questionnaire (Broadhead, 1998). The tenth question “My friends or family members help me remember to take my ARV drugs” was added specifically for this study. Scoring for this scale is based on determining the sum of responses to questions based on a four-point scale (1 = “as much as I would like”, 2 = “less than I would like”, 3 = “much less than I would like”, 4 = “never”). Prior to analyses, the scores of the scale will be reversed so that higher scores equate to greater social support. The sum of the questions will then be divided by 10 to determine the mean score. Respondents whose mean score falls within the lowest 10th percentile of the social support scale scores will be categorized as having low levels of social support.

**Self Efficacy**

Ten self-efficacy questions have been adapted from a twelve question HIV adherence self-efficacy scale (HIV-ASES) (Johnson et al. 2007). The final questions include 9 adherence integration questions and one adherence perseverance question. Two of the original scale’s adherence perseverance questions were dropped due to pre-testing results. The self-efficacy score will be calculated by determining the average score based on a four-point scale (1 = “not at all confident”, 2 = “a little confident”, 3 = “mostly confident”, 4 = completely confident”) with a higher score indicating higher adherence self-efficacy. CFA will be conducted to confirm the theoretical factor structure of the scale within the study population. Goodness of fit statistics to be reported for the CFA will include RMSEA, along with 90% confidence interval, the CFI, and TLI.
Appendix E: In-Depth Interview Guide with ART Manager (At HQ, At Site)

Introduction
[Interviewer Read Aloud]: Thank you for participating in this in-depth interview to help me understand more about task-shifting of Antiretroviral Therapy services at [insert ART site name]. For the purposes of this study, I will use the term “task-shifting” interchangeably with “task-sharing” and “substitution”.

General Questions about Participant
• What is your professional training?
• How long have you worked with this particular organization?
• How long have you worked at this particular site?

General Questions on Task-Shifting
• How do you define “task-shifting” or “task-sharing”?
• What is the rationale for “task-shifting” antiretroviral therapy services?

Current Formal and Informal Task-Shifting Practices
• Please give me a historical account of task-shifting of ART services at [insert organization name]. This can include both formal and informal task-shifting practices. Formal practices refers to tasks guided by clinic policy or procedures. Informal practices refers to task-shifting of tasks that happened more organically.
• When did task-shifting begin?
• What health service delivery tasks does it involve?
• What cadres are involved?
• Why is this (insert new cadre) selected to take of the task of the (insert new cadre)?
• What preparation for task-shifting was undertaken?
  o Probe: What kind of training was provided to develop this new skill among XXX?
  o Probe: What kind of ongoing support was provided to maintain this new skill among XXX?
• What kinds of incentives, if any, are used to support task-shifting of XXX?
  o Probe: What works well? Why or why not?
  o Probe: What doesn’t work well? Why or why not?
• What has been the impact of task-shifting of XXX?
  o Probe: How has task-shifting of XXX affected the roles/tasks of other clinic staff?
  o Probe: How has task-shifting of XXX affected patient enrolment to HIV care and treatment?
  o Probe: How has task-shifting of XXX affected patient initiation to ART?
  o Probe: How has task-shifting of XXX affected clinic flow (efficiency, clinic wait times, meeting performance targets)?
o Probe: How has task-shifting affected the range of services (e.g., adherence counselling, patient tracing, etc.) provided by the ART program?

o Probe: How has task-shifting of XXX affected staff dynamics at the clinic? Please give me an example.

o Probe: How has task-shifting of XXX affected staff morale at the clinic?

o Probe: How has task-shifting of XXX affected patient satisfaction of ART services? Please give me an example.

- What are some of the anticipated challenges as a result of task-shifting of XXX?
- What are some of the unexpected challenges as a result of task-shifting of XXX?

**Scalability and Sustainability of Task-Shifting**

- What do you think of the future task-shifting of XXX at [insert organization]?
  - Probe: What would you continue doing?
  - Probe: What would you do differently?

- Do you think task-shifting of XXX should be formalized in the national policy? Why or why not?

- What would it take to formalize task-shifting of XXX? (Probe on: policy changes, resources, capacity building)

**Summary Conclusion**

[Interviewer Read Aloud]: We have covered all the questions I have at the moment. Thank you so much for participating in this interview and sharing your knowledge and experiences. Would it be alright to contact you again if I have some follow-up questions?
Appendix F: In-Depth Interview Guide with Medical Doctors, Clinical Officers, Nurses, Counsellors, Pharmacists, Pharmacy Technicians, Laboratory Technician

Introduction
[Interviewer Read Aloud]: Thank you for participating in this in-depth interview to help me understand more about task-shifting of Antiretroviral Therapy services at [insert ART site name]. For the purposes of this study, I will use the term “task-shifting” interchangeably with “task-sharing” and “substitution”.

General Questions on Task-Shifting
- How do you define “task-shifting” or “task-sharing”?  
- What is the rationale for “task-shifting” antiretroviral therapy services?

Implementation of Task-Shifting
- Please tell me about your work at [insert organization name].  
  - What health service delivery task do you provide?  
  - Which health cadres do you work with?  
  - How long have you been working at this clinic?  
- What kind of preparation did you undergo to implement XXX?  
  - Probe: What kind of training did you have to develop this new skill (or this new supervisory role) among XXX?  
  - Probe: How did the training help or not help you to prepare for the task?  
  - Probe: What kind of ongoing support do you get to maintain this new skill?  
  - Probe: What kind of support would you like to have now to help you do this task?  
- What kinds of incentives, if any, are used to support task-shifting of XXX?  
  - Probe: What works well? Why or why not?  
  - Probe: What doesn’t work well? Why or why not?

Impact of Task-Shifting on Clinic
- How has task-shifting impacted your workload at the clinic?  
- How has task-shifting affected the roles of other (insert specific) staff?  
- How has task-shifting impacted the efficiency of patient service delivery?  
- How has task-shifting impacted staff dynamics in general?  
- How has task-shifting impacted your relationship with XXX (another cadre) at the clinic?  
  - Probe: Tell me more about this.  
- What are some of the anticipated challenges as a result of task-shifting of XXX?  
- What are some of the unexpected challenges as a result of task-shifting of XXX?

Impact of Task-Shifting on Health Cadre Personally
- How has task-shifting affected your motivation to work at the HIV care and treatment clinic?
Impact of Task-Shifting on Patient Relationships, Retention, and Adherence?
• How has task-shifting impacted your relationship with ART clients at the clinic?
• How has task-shifting impacted the quality of patient care?
• What role do you play in the clinic, or in outreach sites, to impact patient retention in the ART program? Probe: why or why not?
• What role do you play in the clinic, or in outreach sites, patient adherence to ARV drugs? Probe: why or why not?

Scalability and Sustainability of Task-Shifting
• What do you think of the future task-shifting of XXX at [insert organization]?
  o Probe: What would you continue doing?
  o Probe: What would you do differently?

Summary Conclusion
[Interviewer Read Aloud]: We have covered all the questions I have at the moment. Thank you so much for participating in this interview and sharing your knowledge and experiences. Would it be alright to contact you again if I have some follow-up questions?
Appendix G: In-Depth Interview Guide: Expert Patients or Lay Health Workers

Introduction
[Interviewer Read Aloud]: Thank you for participating in this in-depth interview to help me understand more about task-shifting of Antiretroviral Therapy services at [insert ART site name]. For the purposes of this study, I will use the term “task-shifting” interchangeably with “task-sharing” and “substitution”.

General Questions on Task-Shifting
- How do you define “task-shifting” or “task-sharing”?
- What is the rationale for “task-shifting” antiretroviral therapy services?

Implementation of Task-Shifting
- Please tell me about your work at [insert organization name].
  - What health service delivery task do you provide?
  - Which health cadres do you work with?
  - How are you facilitated to do your work? (Probe on method of compensation: volunteering, in-kind, stipend, salary)
- What kind of preparation did you undergo to implement XXX?
  - Probe: What kind of training did you have to develop this new skill (or this new supervisory role) among XXX?
  - Probe: What kind of ongoing support do you get to maintain this new skill?
  - Probe: What kind of support would you like to have now to help you do this task?
- What kinds of incentives, if any, are used to support task-shifting of XXX?
  - Probe: What works well? Why or why not?
  - Probe: What doesn’t work well? Why or why not?

Impact of Task-Shifting on Clinic
- How has task-shifting impacted your workload at the clinic?
- How has task-shifting affected the roles of other (insert specific) staff?
- How has task-shifting impacted the efficiency of patient service delivery?
- How has task-shifting impacted staff dynamics in general?
- How has task-shifting impacted your relationship with XXX (another cadre) at the clinic?
  - Probe: Tell me more about this.
- What are some of the anticipated challenges as a result of task-shifting of XXX?
- What are some of the unexpected challenges as a result of task-shifting of XXX?

Impact of Task-Shifting on Health Cadre Personally
- How has task-shifting affected your motivation to work at the HIV care and treatment clinic?
  - Probe: What do you hope to continue doing? Why or why not?
Impact of Task-Shifting on Patient Relationships, Retention, and Adherence?
- How has task-shifting affected your professional goals?
- How has task-shifting impacted your relationship with ART clients at the clinic?
- How has task-shifting impacted the quality of patient care?
- What role do you play in the clinic, or in outreach sites, to impact patient retention in the ART program? Probe: why or why not?
- What role do you play in the clinic, or in outreach sites, patient adherence to ARV drugs? Probe: why or why not?

Scalability and Sustainability of Task-Shifting
- What do you think of the future task-shifting of XXX at [insert organization]?
  - Probe: What would you continue doing?
  - Probe: What would you do differently?

Summary Conclusion
[Interviewer Read Aloud]: We have covered all the questions I have at the moment. Thank you so much for participating in this interview and sharing your knowledge and experiences. Would it be alright to contact you again if I have some follow-up questions?
Appendix H: In-Depth Interview Guide: ART Patient

General Questions about ART Patient

- Tell me the story of how you came to be an ART patient at this clinic. (Allow participant to speak. Probe further on the following questions):
  - When did you learn that you were HIV positive?
  - How long have you been registered at this HIV care and treatment clinic?
  - How long have you been on ART?
  - Have you received care at a different HIV clinic?

Perceptions of Staff Competency and Quality of Care

(This section of questions apply to all clinical cadres, including lay health workers or peer/expert patients if applicable)

- Tell me about what a typical visit to the HIV care and treatment clinic is like for you. Please take some time to describe what happens and who you meet from the moment you enter the clinic until you leave the clinic.
- What do you think about XXX cadre providing XXX care for you? (E.g., how do you feel about lay providers checking you in, taking your vital signs, or talking with you about adherence?)
  - Probe: What do you like? What do you dislike? Why or why not?
  - Probe: How confident are you that XXX cadre can provide high quality care for you? Why or why not?
  - Probe: How comfortable are you talking to XXX cadre? Why or why not?
  - How well trained do you think XXX cadre is in performing XXX task?
- For sites that do not have certain kinds of task-shifting, ask, Would you feel comfortable with XXX cadre providing XXX task for you? (E.g., Would you be comfortable with a lay counsellor talking about adherence with you? Or would you be comfortable with a nurse giving you your ART prescription?)
- What is most important to you in terms of quality of care? Why or why not?
  - Probe on: range of services, efficiency, cost, wait times, availability of drugs or other commodities, staff skills
- What services can be improved at this clinic?
  - Probe: Why or why not?
  - Probe: What do you think can be done to improve this?
- How does XXX cadre affect the care of other ART patients?
- How does XXX cadre affect the work of clinic staff?

Staff Impact on Retention and Adherence

- How does XXX cadre affect your motivation/ intention/ ability to keep attending this ART program?
- How does XXX cadre affect your motivation/ intention/ ability to keep taking the ARV drugs as prescribed?
CURRICULUM VITAE
Sharon See-Lun Tsui

PERSONAL DATA

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EDUCATION AND TRAINING

Ph.D., expected 2017. Department of International Health, Social and Behavioral Interventions Johns Hopkins School of Public Health, Baltimore, Maryland.


PROFESSIONAL EXPERIENCE

Conducted data cleaning and analysis to evaluate the Emorikinos Daadang Etogogogitoth Alatanakithi Ngidwe (EDEAN) project using a difference-difference estimation approach to estimate causal effects of pre and post data and exploratory factor analysis to develop psychosocial measures.

Researcher. Makerere University Regional Center for Quality of Health Care, Kampala, Uganda, 2014-2016.
Wrote research and capacity building grants in response to call for proposals from the National Institute of Health (R01, R21, U01), Elma Foundation, CDC, and USAID; taught qualitative research methods and analysis to graduate students at the Makerere School of Public Health; mentored clinical researchers on quantitative data analysis and manuscript writing; represented the Center at national stakeholder, technical group, and donor meetings as necessary.

Research Assistant, Johns Hopkins Bloomberg School of Public Health, Baltimore, Maryland, 2011-2015.
Conducted in-depth interviews, secondary data analyses, and literature reviews; supported senior scientists in the development of grant proposals by meeting with in-country partners and stakeholders as needed, proposal writing, and budget development. Specific projects included: alcohol use and adherence to Antiretroviral Therapy in Uganda, school-based HIV testing in Uganda, depression among HIV-infected men in the Multicenter AIDS Cohort Study, feasibility and acceptability of mHealth-enhanced peer navigation to improve retention of ART-eligible out of care injecting drug users in Baltimore, Maryland, large scale implementation of community health worker programs, and sexual risk behaviors of HIV-infected injecting drug users in Thailand.

**Teaching Assistant, Johns Hopkins Bloomberg School of Public Health, Baltimore, Maryland, 2012-2014.**
Assisted professors in instruction, grading, and development of course materials in the following classes: Qualitative Research Theory and Methods, Qualitative Data Analysis, Summer Institute of Qualitative Research Methods and Data Analysis, Training Methods and Continuing Education of Health Workers, Social and Behavioral Foundations of Primary Health Care, and Urban Health in Low and Middle Income Countries.

**Consultant, Catholic Relief Services, Baltimore, Maryland, 06/2014-08/2014.**
Developed qualitative research methods training materials, including didactic lectures, participatory exercises, and audio files, for CRS’ Implementation Science Workshop. Specific topics included: Introduction to Qualitative Research Methods, Framing Qualitative Research Questions, Sampling in Qualitative Research, How to Conduct In-Depth Interviews, How to Moderate Focus Group Discussions, and Qualitative Data Documentation and Analysis.

**Consultant, Jhpiego, Maseru, Lesotho, 06/2013-02/2014.**
Ensured quality data collection and management of survey and focus group discussions (conducted fieldwork from Jun-Sep 2013); cleaned and analyzed quantitative data using EpiInfo 7.0 and SAS 9.3; analyzed qualitative text by preparing a coding tree, coding text, and thematic reports; reviewed literature on the acceptability and implementation of medical male circumcision in sub-Saharan Africa; authored a final report and manuscript; designed a follow-up study to examine community-wide perspectives on VMMC in Lesotho.

**Researcher, FHI 360 (formerly known as Family Health International), Durham, North Carolina, 2006-2012.**
- Associate Scientist II, 01/2011-03/2012
- Associate Scientist I, 10/2009-01/2011
- Research Associate I, 10/2007-10/2009
Conducted reproductive health and HIV/AIDS related research in South Asia and Africa; key studies included microbicide acceptability, retention and adherence to antiretroviral therapy, integration of family planning and HIV services, evaluation of a school-based peer education model for HIV and pregnancy prevention, and fertility desires and contraceptive practices of young people, sex workers, and HIV-infected women.
Developed study protocols, data monitoring and analysis plans, data collection instruments, and training manuals; prepared and managed budgets, scope of works, ethics documentation; trained field teams on research ethics, data collection and management procedures; monitored, managed, and analyzed quantitative and qualitative data; prepared final reports, research briefs, and manuscripts; conducted dissemination meetings. Provided technical assistance to colleagues and partners on SAS programming, use of PDAs for data collection, and qualitative and quantitative analysis. Represented FHI 360 at project sites, donor meetings, and professional meetings.


Assisted development of a serial cross-sectional study to assess the impact of structural interventions for HIV prevention among female sex workers in Andhra Pradesh, India; ensured quality interviewing and data transcription; generated coding tree, coded text with N6; prepared literature reviews and project documentation as needed.

*Research Fellow, BRAC (formerly known as Bangladesh Rural Advancement Committee), Dhaka, Bangladesh, 05/2005-09/2005.*

Assessed the Health Benefit Card program’s strengths and limitations to reaching the very poor with free Essential Services Package; developed study protocol and data collection instruments; conducted surveys, clinical observations, in-depth interviews, and focus group discussions; analyzed Management Information System data; prepared literature review and policy analysis on the health-seeking behaviors of the chronically poor; presented results at the Yale Committee on International Health Symposium.

*Intern, Jian Hua Foundation, Qinghai, China, 05/2003-05/2004.*

Conducted formative research on Amdo Tibetan’s etiology of tuberculosis and assessed factors influencing patient adherence to Directly Observed Therapy, Short Course to TB (fieldwork from May-Dec 2003); prepared research protocol, survey, and interview guides; carried out direct observations, in-depth interviews, focus group discussions, and survey; analyzed quantitative data using Excel and qualitative data using theme-content analysis; presented results at the Wheaton College Human Needs and Global Resources Symposium. In addition, carried out needs assessment of 13 villages in Qukuhu Township and coordinated medical upgrade training of township level doctors in Qinghai, Province.

**HONORS AND AWARDS**


Yale School of Medicine Student Research Fellowship. Yale University, 2015.

Wilbur Downs International Health Student Travel Fellowship. Yale University, 2015.


PUBLICATIONS

Peer-reviewed journal articles


Final reports


Worker Programs at Scale: A Reference Guide for Program Managers and Policy Makers.


**PRESENTATIONS AND POSTERS**

**Oral presentations at scientific meetings**


**Poster presentations at scientific meetings**


Tsui S (2005) “Sustainable health financing: finding consensus on health equity and cost-recovery.” Poster presentation at the Committee of International Health Symposium, Yale University, New Haven, CT, October 20, 2005.