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Evaluation of Facility-Based Individual Differentiated Service Delivery Among People Living with HIV in Nairobi, Kenya

By

Rosemary G. Kinuthia

Doctor of Philosophy

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Evaluation of Facility-Based Individual Differentiated Service Delivery Among People Living with HIV in Nairobi, Kenya

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An abstract of

A dissertation submitted to the Faculty of the

James T. Laney School of Graduate Studies of Emory University

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Doctor of Philosophy in Nursing

2022

Abstract

Evaluation of Facility-Based Individual Differentiated Service Delivery Among People Living with HIV in Nairobi, Kenya

By Rosemary G. Kinuthia

Introduction: It is challenging to maintain a high level of engagement for HIV care in regions with a high HIV burden due to health workforce shortages, making it very difficult to realize the goal of universal viral suppression. In response to global workforce shortages impacting access to HIV care, the World Health Organization recommends implementation of differentiated service delivery (DSD). DSD is a patient-centered approach to delivering HIV care and improving access to antiretroviral therapy for persons living with HIV who are established on ART. Out of the four DSD models, facility-based individual DSD is the least complex to implement. Thus, it has been widely implemented in sub-Saharan Africa, which bears the greatest HIV burden globally. This research aimed to study the impact of facility-based individual DSD.

Methods: This study used qualitative and quantitative research methods, including the analysis of retrospectively collected patient data abstracted from electronic medical records and interviews with health workers at a large HIV treatment facility in Nairobi, Kenya. Bivariate analysis was conducted to assess the association between facility-based individual DSD and viral suppression status among DSD-eligible patients who enrolled in DSD vs DSD-eligible patients who enrolled in standard care. In-depth semi-structured interviews with health workers explored their perceptions and experiences with the model. Qualitative descriptive methods were used to analyze interview data.

Results: A total of 814 participants were included in the analysis (41.5% male, 58.5% female). Majority were between 40-49 (37.3%) and 50-59 (38.3%) years of age. A pre-post McNemar's test determined that among those who were eligible and enrolled in DSD, 94.6% maintained an undetectable viral load after 1 year ($p= 0.078$). A McNemar's test looking post-enrollment viral load detection was conducted on 388 eligible matched pairs. The test determined that only 6 (1.6%) of the matched DSD pairs were detectable at the post visit, compared to only 3 (0.8%) of the matched non-DSD members pairs ($p= 0.508$). For Aim 2, a total of 30 HWs were interviewed. Participants primarily expressed their preference for facility-based DSD implementation over standard care, citing that it was beneficial to patients and health workers.

Conclusion: This study demonstrates the effectiveness of facility-based DSD in maintaining viral load suppression in patients and alleviating reduced HIV health workforce challenges in resource-limited settings. Findings will inform best-practices in HIV service delivery and facilitate the development of efficient models of care.

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CHAPTER 1: RESEARCH PROTOCOL

Introduction

Despite advances in scientific discovery and decades of dedicated efforts to better understand, treat, and end the HIV/AIDS epidemic, it has remained a persistent global epidemic. According to the most recent data, there were approximately 38.0 million people living with HIV (PLWH) globally in 2019, however, only two-thirds (26.0 million) PLWH have access to life-saving antiretroviral therapy (ART) (Joint United Nations Programme on HIV/AIDS, 2020a). While this is an improvement from 2016, when only half of all PLWH had access to ART (Joint United Nations Programme on HIV/AIDS, 2016), access to treatment remains a global public health concern, especially in low and middle-income countries (LMICs). The majority of PLWH live in LMICs that are overburdened and under-resourced (Rossouw et al., 2017).

In response to the global HIV epidemic, the Joint United Nations Programme on HIV/AIDS (UNAIDS) initiated the 90-90-90 fast-track targets in 2014 as a strategy to end the AIDS epidemic by 2030. UNAIDS aims for 90% of PLWH knowing their status, 90% of diagnosed persons receiving treatment with ART, and 90% of individuals on ART achieving viral suppression (Joint United Nations Programme on HIV/AIDS, 2014). As highlighted in the 90-90-90 targets, the ultimate goal of treatment in PLWH is viral suppression (AIDSinfo, 2017). Achieving viral suppression eliminates the risk of virus transmission and improves health outcomes of PLWH (Centers for Disease Control and Prevention, 2017). Viral suppression requires adherence to ART and regular attendance of HIV clinic appointments (retention in care), which are strongly associated with and are essential for optimal health outcomes in PLWH (Cheever, 2007; Mountain et al., 2014). Thus, achieving population viral suppression is crucial to ending the AIDS epidemic.

An adequate health workforce is essential for ensuring access to and provision of HIV care to achieve viral suppression. However, a major concern in LMICs is healthcare workforce

shortages. Sub-Saharan Africa is one of the regions that suffers from the greatest shortage of healthcare professionals (World Health Organization, 2016b). The World Health Organization (WHO) recommends a health workforce density of 44.5 doctors, nurses, and midwives per 10,000 population (World Health Organization, 2016b); however, the majority if not all of sub-Saharan Africa is operating below the WHO recommendation of 44.5 health workers. Additionally, the region also carries the greatest health burden and has remained hardest hit by the HIV/AIDS epidemic globally (GBD 2015 Mortality and Causes of Death Collaborators, 2016), which has put additional stress on the health system. It is estimated that about 71% of all PLWH reside in sub-Saharan Africa (Kharsany & Karim, 2016). One of the countries in sub-Saharan Africa that has suffered greatly from the HIV epidemic is Kenya, which had about 1.6 million PLWH, with 46,000 new infections, and 25,000 AIDS-related deaths in 2018 alone (UNAIDS, 2018). Kenya's HIV prevalence rate has slowly been declining and it is currently at 4.7 % (ages 15-49 years); however, it has the 3rd largest HIV epidemic globally (Avert, 2019).

UNAIDS released an update that reported global progress towards the 90-90-90 targets, indicating that although sub–Saharan Africa, particularly, countries in Eastern and Southern Africa, have made significant strides in controlling the epidemic, the region still lags in meeting the UNAIDS targets. In Eastern and Southern Africa, 87% of PLWH know their status, 72% of diagnosed persons are receiving treatment with ART, however only 65% of individuals on ART treatment have achieved viral suppression (UNAIDS, 2020b). These data highlight the importance of targeting sub–Saharan Africa to facilitate continued improvement towards achieving viral suppression and meet the 90-90-90 targets.

Important steps towards achieving viral suppression in PLWH include high adherence to ART and remaining fully engaged in HIV primary medical care (Cheever, 2007; Mountain et al., 2014). For optimal outcomes, it is recommended that HIV-infected individuals visit a healthcare

provider every three to four months for routine HIV care and viral load monitoring (Aberg et al., 2014). As important as this high level of engagement is, it is difficult to maintain a high level of engagement per the recommendations due to the high costs associated with such a model of care coupled with the scarcity of healthcare workers in low-resource areas.

In light of healthcare workforce shortages in low-resource countries with high HIV burden, strategies are being developed to overcome these challenges by utilizing human resources for health (HRH) approaches that implement novel HIV models of care. For example, to maximize the capacity of the healthcare workforce, increase access to HIV treatment services, and provide quality HIV care, the WHO has provided guidelines on the implementation of strategies such as task sharing, nurse-initiated management of ART treatment (NIMART) (World Health Organization, 2007), and differentiated service delivery (DSD) (World Health Organization, 2016a). Task sharing is a collaborative approach whereby tasks and responsibilities are redistributed among healthcare workers to increase access to care and lower costs (World Health Organization, 2007). NIMART is a task sharing approach to delivering HIV treatment and increasing ART coverage whereby as the name indicates, the task of ART initiation, re-prescription, and management is absorbed by nurses who are trained in HIV care; it is an intervention that acknowledges the shortage of physicians (Fairall et al., 2012).

Differentiated care is a patient-centered approach to delivering HIV care and improving access to ART. The plan of care. therefore, is customized based on the patient's health needs and preferences (Grimsrud et al., 2016; World Health Organization, 2016a). Studies have shown that task-shifting approaches such as NIMART produce equally good outcomes as physician-led treatment at a lower cost (Kredo et al., 2014; Long et al., 2016) and differentiated care facilitates the scale-up of ART by reducing the workload of patient care within the medical setting and shifting care to community health workers (Grimsrud et al., 2017). However, DSD and some of

the other HIV care delivery models implemented in LMICs lack adequate evidence to support how they impact the viral load and whether they actually alleviate the burden on healthcare workers as intended.

Out of all the various HIV service delivery models recommended by the WHO, DSD is the newest and the agenda is to accelerate DSD implementation to improve treatment coverage in resource limited settings (Ehrenkranz et al., 2019). The DSD framework includes four key components: 1) type of service delivered, 2) location of the service delivery, 3) provider of services, and 4) frequency of services. As seen in Figure 1 below, various aspects of the components in the DSD framework are combined to develop different models of DSD (World Health Organization, 2016a)

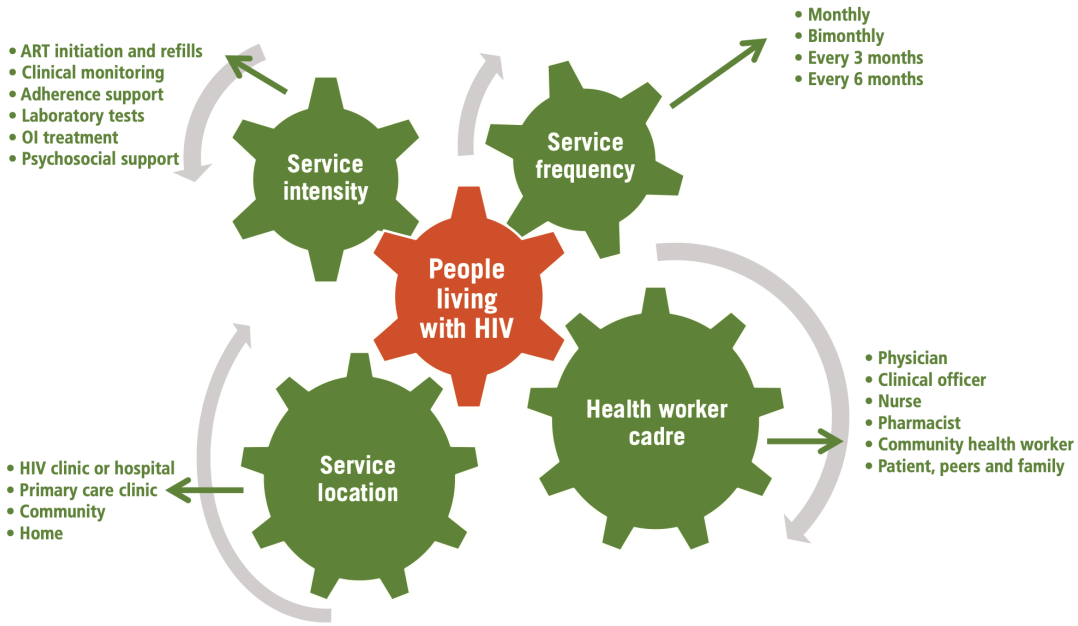

Figure 1| Differentiated Care Framework (World Health Organization, 2016a)

There are four models of DSD: 1) healthcare worker managed group models, 2) client-managed group models, 3) facility-based individual models, and 4) out-of-facility individual models (International AIDS Society, 2017). The facility-based individual model is the least

complex to implement at the health facility level (National AIDS and STI Control Program, 2017), and because it is estimated that majority (95%) of HIV service delivery is facility-based (Joint United Nations Programme on HIV/AIDS, 2014), the facility-based fast track model may be the most widely implemented DSD model with the highest patient uptake (Adjetey et al., 2019). For DSD to be effective in addressing workforce shortages and increasing access to HIV treatment, the goal is to transition all clinically stable patients into a DSD model of care that requires fewer and shorter visits to highly skilled providers. However, at this time, DSD is offered on an opt-in basis, meaning that even if a patient meets the eligibility criteria (described below) to join, they may decline if they prefer the regular standard package of care where they are expected to see their healthcare provider more frequently versus six to twelve months intervals with DSD.

As per the WHO differentiated care recommendations published in the *Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection*, patients are defined as clinically stable, thus eligible to opt-in or enroll in DSD if they meet the following criteria: "received ART for at least one year and have no adverse drug reactions that require regular monitoring, no current illnesses or pregnancy, are not currently breastfeeding and have good understanding of lifelong adherence and evidence of treatment success (i.e. two consecutive viral load measurements below 1000 copies/mL). In the absence of viral load monitoring, rising CD4 cell counts or CD4 counts above 200 cells/mm^3, an objective adherence measure, can be used to indicate treatment success" (World Health Organization, 2016a).

Under the facility-based individual model, DSD-eligible patients have the option to reduce the number of clinical visits and extend the duration of ART refills. With the regular standard package of HIV, patients are typically expected to see their healthcare provider every 1-3 months (depending on country guidelines). However, with facility-based individual DSD,

patients may extend the time between clinical visits to a maximum of 6 months intervals. Through this mechanism of extending the time between clinician visits, it is hypothesized that DSD implementation improves adherence to HIV care for clinically stable patients (Mutasa-Apollo et al., 2017). Therefore, it allows healthcare providers to focus on complicated cases and frees up more time to enroll new patients—thus extending HIV care/treatment to more patients.

Clear evidence supports the development of care delivery models that consider the workforce shortage gaps; however, there is limited research that has investigated the association between care delivery models and treatment outcomes. Specifically, limited studies have examined the effectiveness of facility-based individual DSD as a HIV care delivery model in meeting the last UNAIDS 90 (viral load suppression) globally. There are also limited studies describing factors that influence the implementation of DSD in U.S. President's Emergency Fund for AIDS Relief (PEPFAR)-supported countries and in general. Research is needed to design and test cost-effective care models in LMICs that promote efficient use of scarce resources and yield optimal outcomes. Qualitative research is also needed to shed light on how health workers perceive these care delivery models and what facilitators and challenges they believe are important. It is also important to document how these care delivery models impact the HIV care workforce and patients who participate in different models of care.

Research Question and Study Aims

The overall goal of this research is to understand the impact of facility-based individual DSD in order to potentially maximize the capacity of health care systems in resource-limited settings with high HIV burden. Therefore, two specific aims were formulated:

1. To determine the effectiveness of facility-based individual DSD implementation on viral suppression among PLWH. Viral load, which is a measure for viral suppression is

classified as either undetectable (<=200 copies/ml) or detectable (>200 copies/ml) (Centers for Disease Control and Prevention, 2022).

   a. To describe characteristics of facility-based individual DSD-eligible patients who enroll in the care delivery model vs. those who do not enroll (receive standard package of care). *Hypothesis: patients who enroll in facility-based individual DSD exhibit different characteristics from those who do not enroll.*
   b. To compare viral load detection outcomes of facility-based individual DSD-eligible patients who enroll in the care delivery model vs those who do not enroll (receive standard package of care). *Hypothesis: The proportion of patients who maintain an undetectable viral load status after at least 365 days of enrollment in facility-based individual DSD is similar or better than DSD-eligible patients who receive the standard package for at least 365 days.*

2. Explore perceptions and experiences of health care workers regarding facility-based individual differentiated service delivery. *Exploratory aim: Understanding healthcare workers' perceptions of challenges and opportunities experienced with implementation of facility-based individual DSD will inform how DSD implementation and scale-up might be best achieved.*

Conceptual Framework

The social-ecological model (SEM) (McLeroy et al., 1988) was used as the conceptual framework for understanding how care delivery at the health systems level impacts health outcomes of PLWH. McLeroy et al. (1988) proposed the ecological model of health promotion on the premise that other theories focused on individual behavior and failed to consider the interaction between social environmental factors and health outcomes. This theory-based

framework has undergone several iterations and the version used to guide this research [Figure 2] contains 5 levels: individual, interpersonal, community, organizational, and structural-level factors. There is a complex interplay between all levels of the model; the SEM, therefore, proposes that interventions targeting all 5 levels of the model yield the best outcomes. Each level of the model resides within another, and all levels fall within the context of the problem.

Selection of the SEM as the framework for this study was influenced by findings that suggest that multilevel factors influence HIV transmission risk and health outcomes of PLWH (Baral et al., 2013; Berger et al., 2016) . Most studies have focused on the individual, interpersonal, and community levels, however, the organizational level is often understudied. Due to the paucity of studies investigating the impact of interventions on the organizational level, this study focused on the organizational level, specifically, it focused on HIV care delivery within the health system, while considering factors at the other levels.

Figure 2| The Social Ecological Model (UNICEF, n.d.)

The hypothetical conceptual framework below [Figure 3] illustrates assumed predictors of viral load outcomes at the organizational level. As described earlier, major factors burdening health systems in sub-Saharan Africa include high HIV burden accompanied by workforce shortages. However, because it may not be feasible to increase the number of healthcare professionals, it will be essential to focus research efforts on interventions that facilitate more efficient care delivery within health systems to improve the health outcomes of PLWH.

One feasible intervention is the implementation of facility-based individual DSD. As presented in the conceptual framework, it is hypothesized that in healthcare facilities implementing facility-based individual DSD, viral load suppression outcomes of eligible adult PLWH who enroll, when compared to eligible PLWH who do not enroll in facility-based individual DSD, will be similar or better. The similar or better viral load suppression outcomes may be attributed to the decreased provider visits, which may save time and money, thus improving adherence and retention. It can also be argued that among eligible patients who do not enroll and therefore continue their treatment in the standard package of care, there is an increased risk for poor adherence and retention due to the increased time and costs associated with the regular standard package of care.

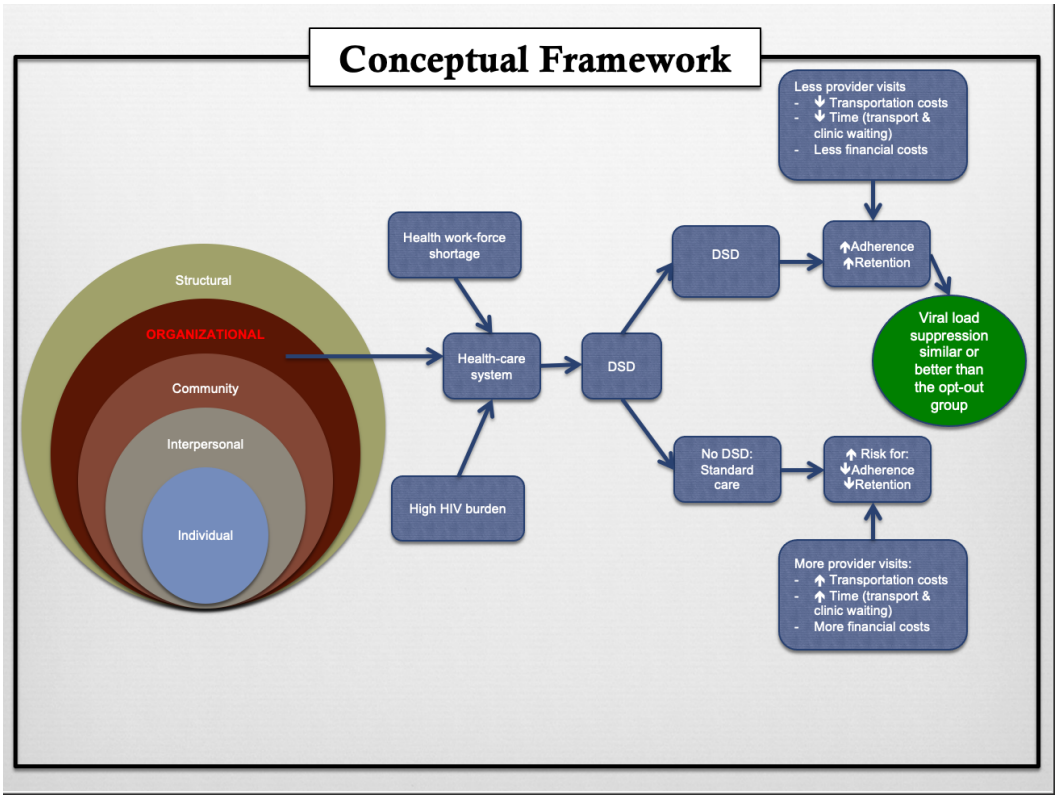

Figure 3| Hypothesized *a priori* SEM model for DSD implementation at the organizational level

However, we cannot neglect to consider that enrollment in facility-based individual DSD may have potential negative effects. We should consider the risk of poor adherence among patients who enroll in the care delivery model because these patients do not get the same frequency of encouragement for adherence when seeing the healthcare provider less often. This risk is probably minimal because DSD-eligible patients are typically stable patients who are accustomed to managing their care without constant supervision. Additionally, it is unlikely that a healthcare provider would recommend enrollment into DSD for patients who may be at risk for poor ART adherence when they are not being monitored closely.

Along with the SEM as the theoretical framework for this proposed study, the RE-AIM model (Glasgow et al., 1999) guided the evaluation of facility-based DSD implementation. Glasgow et al. (1999) identified that lack of a comprehensive evaluation framework led to

delayed progress in public health interventions and subsequently developed the RE-AIM framework to guide planning and evaluation of public health impact of health promotion interventions. The model focuses on 5 dimensions: reach, efficacy, adoption, implementation, and maintenance. The authors of the RE-AIM model explain that failure to comprehensively evaluate all 5 dimensions leads to "waste of resources, discontinuities between stages of research, and failure to improve public health to the limits of our capacity" (Glasgow et al., 1999). Table 1 below provides definitions of the dimensions of the framework and how they were incorporated in the primary aims of this study.

Table 1 Evaluation of RE-AIM Dimensions. Adapted from Glasgow (Glasgow et al., 1999)

Dimension	Definition	Level	Evaluation/Assessment in Study
Reach	Proportion of the target population that participated in the intervention.	Individual	Direct reach of facility based-individual DSD was evaluated as part of Aim 1. Individual level data from the facility was reviewed and analyzed to determine the proportion of patients eligible for facility-based DSD enrollment. Reach was also assessed qualitatively during interviews in Aim 2.
Efficacy	Success rate if implemented as in guidelines; defined as positive outcomes minus negative outcomes.	Individual	Efficacy of facility-based individual DSD was evaluated as part of Aim 1. Success rate of the care delivery model was be determined by identifying whether the patients who enrolled in facility-based individual DSD maintained viral suppression. This was compared to the viral suppression status of eligible patients who did not enroll in the care model. Efficacy was also assessed qualitatively during interviews for Aim 2.
Adoption	Proportion of settings, practices, and plans that will adopt the intervention	Organization	Adoption of facility-based individual DSD was evaluated qualitatively as part of Aim 2. It is mandatory for all health care workers at the site to participate in the implementation of DSD, however, it can be argued that certain providers are more pro-active in enrolling patients into the DSD model, therefore

			understanding various providers' perspectives regarding any factors influencing adoption or lack of adoption is crucial.
Implementation	Extent to which the intervention is implemented as intended in the real world.	Organization	Implementation of facility-based individual DSD was evaluated qualitatively as part of Aim 2. Implementation was understood at a deeper level by interviewing providers regarding their experiences with facility-based individual DSD as well as perceived factors (barriers and facilitators) that influence its implementation.
Maintenance	Extent to which a program is sustained over time.	Individual or Organization	Maintenance was evaluated qualitatively through interviews with facility leadership as part of Aim 2. Planning for sustainability of facility-based individual DSD implementation, particularly if efficacy is demonstrated, will be crucial to informing the organization and other stakeholders such as the Kenya Ministry of Health on how to continue the implementation of DSD.

Methods

Study Design

This study used a combination of quantitative and qualitative research designs. This approach was selected for the proposed study because it overcomes the limitations of a single design (Johnson et al., 2007). This approach is useful in providing a more complete and comprehensive understanding of facility-based individual DSD implementation than either quantitative or qualitative approaches alone. Additionally, this approach of combining methods and data from multiple sources enhances triangulation, thus increasing data validity. The research activities included literature study, analysis of retrospectively collected patient data abstracted from electronic medical records, and in-depth semi-structured interviews with health workers

Setting

Kenya was chosen as the setting for this proposed research because, like most sub-Saharan African countries, it suffers from a critical shortage of healthcare professionals and carries one of the greatest HIV/AIDS burdens. The study site is a large infectious disease facility located in the capital city, Nairobi, which is one of the leading HIV incidence counties in Kenya (National AIDS Control Council, 2018). The infectious disease center is a HIV care and treatment clinic that is part of a large health system, and it is one of the largest single-site antiretroviral treatment centers in Kenya. The center was established in 2004 after receiving funding from the U.S. Government PEPFAR Initiative to provide comprehensive HIV/AIDS care and treatment services in Kenya. As a collaborative mission-academic medical center, in line with both PEPFAR and the Kenya Ministry of Health goals, the center aims to provide high

quality, family-oriented HIV testing services, HIV care and treatment, and HIV prevention services to people infected with and affected by HIV/AIDS. Facility-based individual DSD has been implemented at the infectious disease center since August 1st, 2017.

Participants

Aim 1:

The population of interest for this aim includes adult facility-based individual DSD-eligible PLWH receiving care at the HIV treatment facility. According to the Kenya differentiated care guidelines, patients are categorized as eligible to enroll in facility-based individual DSD if they meet the following criteria: on ART regimen for > or = 12 months, no active opportunistic infection in the previous 6 months, adherent to scheduled clinical appointments for the previous 6 months, most recent viral load <1,000 copies/ml, completed 6 months of currently prescribed ART regimen, non-pregnant/not breastfeeding, BMI > or = 18.5, >20 years of age and if the healthcare team does not have any concerns regarding prolonged intervals between provider visits (National AIDS and STI Control Program, 2017).

Aim 2:

The population of interest for this aim includes health administrators, staff, and health personnel including physicians, clinical officers, nurses, midwives, counsellors, social workers, and healthcare assistants working at the HIV treatment facility. These cadres were selected due to the level of patient care engagement their professional role requires and these individuals are more likely to have direct involvement in the facility-based individual DSD model.

Sampling Size and Power

Aim 1:

The study used retrospectively collected data abstracted from the electronic medical records of facility-based individual DSD-eligible PLWH receiving HIV care at the treatment facility. The analysis focused on patients seen between December 1st 2017 (5 month post DSD implementation) and July 31st 2020. A few months post-DSD implementation was selected as a starting point to account for the possibility of a "wash out" period and ensure that DSD was fully rolled-out at the treatment facility. This period provides about 2.5 years of data, which is adequate for evaluation purposes. Inclusion also requires a minimum of 12 months follow-up post-DSD enrollment or a minimum of 12 months follow-up in the standard package of care. Additional inclusion and exclusion criteria are described in Table 2.

Table 2 Aim 1 Inclusion and Exclusion Criteria

Population	**Inclusion Criteria**	**Exclusion Criteria**
Patients eligible for DSD (Aim 1)	Eligible for DSD using Kenya guidelines criteria (National AIDS and STI Control Program, 2017). For DSD group- Enrolled in facility-based individual DSD for a minimum of 12 months during the study period. For standard care group- received the standard package of HIV care at the facility for a minimum of 12 months during the study period.	Records missing data on viral load.

	Have at least 1 record of viral load data >12 months post-DSD decision

Viral suppression status of facility-based individual DSD-eligible patients who enroll in the care delivery model and those who do not enroll (receive standard package of care) was used as the primary outcome of this study. Eligibility for enrollment in the care model requires viral suppression (viral load <1,000 copies/ml), thus, all patients in this study are virally suppressed pre-enrollment. Suppression status was dichotomized, with the categories 'detectable' and 'non-detectable'.

Statistical power analysis was conducted using G*Power version 3.1 with an alpha set on 0.05, and a power of 80%. It was estimated that, at minimum, a total sample size of 664 medical records of PLWH will be required i.e., 332 facility-based individual DSD-eligible patients who enrolled in the care delivery model and 332 facility-based individual DSD-eligible patients who do not enroll (receive standard package of care).

Aim 2:

Sampling was based on the role of the health workforce at the study site. To obtain perceptions of the model from as many cadres, maximum variation sampling was suitable for this study. Sandelowski describes that maximum variation is the most frequently employed kind of sampling in nursing research sampling (Sandelowski, 1995). The strengths of purposive sampling methods include that it is one of the most cost-effective and time-effective methods available. Additionally, sometimes it may be the only appropriate method if there are a limited number of primary data sources. A purposive sampling method was selected for this study

because it is targeted and there are pre-established criteria for recruiting healthcare administrators and healthcare personnel [Table 3]. The targeted sample size for the health workers to be interviewed was 30 participants or until thematic saturation was achieved.

Table 3 Aim 2 Inclusion and Exclusion Criteria

Population	**Inclusion Criteria**	**Exclusion Criteria**
Health care workers (Aim 2)	Health administrators, staff, and health personnel including physicians, clinical officers, nurses, midwives, counsellors, social workers, & healthcare assistants working at the study site. Involved in HIV service delivery using facility-based individual DSD. Be able and willing to participate in individual interviews. Worked at the facility for a minimum of 6 months during the study period. Speak and understand English or Swahili.	Inability to schedule a time to participate in individual interviews

Data Collection and Analysis

Aim 1:

All medical record data were abstracted by staff in the data management team into a password-protected and encrypted database stored only on a Health Insurance Portability and Accountability Act of 1996 (HIPAA) -compliant server that is only accessible only to the study

team. All potentially identifiable information were removed from all files that were generated from this database by center staff prior to release to the study team. The de-identified quantitative data was analyzed by descriptive statistics and bivariate analysis was used to assess the association between facility-based individual DSD and HIV viral suppression status among DSD-eligible patients who enrolled in the HIV care delivery model vs DSD-eligible patients who received standard care. All analyses were conducted using SPSS.

Aim 2:

A qualitative descriptive research design (Sandelowski, 2000) was used. Qualitative research data from in-depth semi-structured interviews was audiotaped and transcribed professionally. Transcripts were organized in NVivo qualitative software, and a coding scheme was developed to analyze the qualitative data with the goal of identifying and categorizing all factors associated with facility-based individual DSD.

Study Relevance

It is imperative to explore workforce strategies implemented in high HIV burden LMICs and investigate how HRH shortages impact access to HIV care and population-level HIV health outcomes. Examining this relationship will promote the understanding of efficient HIV care delivery models and provide a better understanding of features that will facilitate closing the gap across the HIV care continuum. This study will evaluate the impact of facility-based individual DSD implementation at a large HIV treatment facility in Nairobi, Kenya, to potentially maximize the capacity of health care systems in resource-limited settings with high HIV burden. It will provide insights into opportunities to improve the health outcomes of present and future

PLWH receiving care at the study site and other similar settings. HIV healthcare workers and researchers may benefit from the findings of this study by providing a greater understanding of health worker perspectives of the care delivery model and how implementation of facility-based individual DSD influences viral suppression. This research will also minimize gaps related to DSD implementation and inform best-practices in HIV service delivery, and facilitate the development of efficient models to implement in regions with a high HIV burden and health workforce shortages.

Ethics and Dissemination

Ethical Considerations

This research involves human subjects, thus, in implementing the study protocol, the study team adhered to the ethical principles established for human subjects research and complied with federal regulations that pertain to human subjects protection at 45 CFR, Part 46 and 21 CFR, Part 56 and any other pertinent regulations and guidance.

Informed Consent and Institutional Review Boards

The study received approval from the Institutional Review Boards (IRB) of Emory University, Atlanta, GA, USA and Aga Khan University, Nairobi, Kenya. In addition, approval was obtained from the study site and a research permit was obtained from the National Commission for Science Technology and Innovation (NACOSTI).

De-identified retrospectively collected data from patient electronic medical records were be used for Aim 1. There was no direct contact with patients for recruitment, enrollment, or consent. For Aim 2, recruitment of participants took place in collaboration with leadership and

head of departments at the healthcare facility. The researchers informed study participants verbally and in written format about the purpose of the study and research activities. During recruitment and prior to individual interviews, a guarantee of confidentiality and anonymity was given. Participants were given the opportunity to ask questions. Participants were informed that they could withdraw from the study at any time. All participants were asked to provide verbal consent. Verbal consent was elected by the researchers and approved by the IRB because the interviews with healthcare workers and administrators represent minimal risk, and no sensitive topics will be discussed with participants. All participants were assured that study participation (or lack of participation) would not in any way adversely affect their employment. To maintain anonymity and address fears that participating in interviews could adversely affect the participants' employment, no personal identifying information were collected, and consent was verbal in order to ensure that no record of participation exists.

Confidentiality

To ensure confidentiality, the study team ensured that there were no personal identifier information included in the EMR data extracted for the study. The study team ensured that all extracted data for the final dataset were encrypted and stored in password protected files on institutionally maintained servers with limited access to the research team only. No identifying information was collected during the semi-structured interviews. Data was not linked to individual participants. Identifying information was only used to schedule participants for the interviews, however this information was destroyed immediately after participation in interview. The audio-recordings, transcripts and analyzed data were stored on a designated password-protected research drive on a secure server. Written field notes and digital voice recordings were

stored in a locked cabinet at the study site. All digital copies were stored in a password-protected data management/sharing system. The study team ensured that the transcription service selected to transcribe the interviews met all requirements regarding confidentiality. The transcribed data did not include subjects' names or private information. The subjects' names were replaced with pseudonyms where necessary. The research drive was only accessible to the research team. Audio recordings and other hard copies of documents were destroyed once transcripts ere compared with the recordings and the study was completed. All publications and written reports generated from this study will not contain any identifiable private information of subjects.

Outline of the Dissertation

The research team anticipates publishing at least three papers that report the research priorities of this study. The proposed publications include the following remaining chapters: **Chapter 2:** A literature review/synthesis on the implementation of facility-based DSD implementation in sub-Saharan Africa; **Chapter 3)** A quantitative report describing the effectiveness of facility-based individual DSD in maintaining viral suppression (Specific Aim 1); **Chapter 4)** a qualitative report describing health workers' perceptions and experiences with facility-based individual DSD (Specific Aim 2). **Chapter 5:** An integrative summary and synthesis of this study, implications for future research, practice, and policy.

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CHAPTER 2: AN INTEGRATIVE REVIEW OF FACILITY-BASED INDIVIDUAL DIFFERENTIATED SERVICE DELIVERY MODELS FOR HIV TREATMENT IN SUB-SAHARAN AFRICA

Abstract

Differentiated service delivery (DSD) is a client-centered HIV care model whereby services are adapted to suit clients' needs while alleviating the burden on healthcare systems. DSD is recommended for regions with high HIV prevalence, healthcare workforce shortages, and limited resources. Models can be within or out-of-facility, for either groups or individuals, and are managed by clients or healthcare workers. Persons living with HIV who are established on antiretroviral therapy can select the model that suits their needs and circumstances. Facility-based individual DSD model is the least complex to implement and most popular among PLWH. The purpose of this review was to explore the current state of the science on facility-based individual DSD implementation in sub-Saharan Africa. A search was conducted using PubMed, Embase, Web of Science, CINAHL, and Google. Twenty-six studies meeting the inclusion criteria were reviewed. Results indicate that by extending the time between provider visits, the care model may be helpful in saving costs, improving adherence and retention in care, reducing patient and workforce burden, and increasing access to HIV treatment. A potential downside of facility-based individual DSD is that patients do not perceive it as beneficial in increasing peer support or enhancing community participation. We found a limited number of studies (6 studies) of healthcare workers' perceptions and experiences with DSD models. Additionally, we found few studies investigated how the implementation of facility-based individual DSD impacts HIV health outcomes. Further research should address these gaps.

Keywords: HIV, ART, antiretroviral therapy, differentiated care, models of care, literature review

Teaser Key Message: Facility-based individual differentiated-service delivery appears to be efficient in achieving and maintaining optimal HIV outcomes and lowering costs of HIV care. It is also a preferred model of care among HIV healthcare workers and patients.

Detailed Key Messages

- Conducting research to understand the unique factors that influence HIV service delivery can help to address unmet needs in regions with high HIV burden and limited resources.
- Policy makers and governments can help to accelerate meeting the UNAIDS 90-90-90 targets by encouraging and mandating implementation of facility-based individual differentiated service delivery.
- Healthcare workers are in a position to assess context specific factors that influence implementation of facility-based individual differentiated service delivery and can improve health outcomes by customizing the intervention based on patient needs and available resources.

Introduction

Advances in HIV research have contributed to a 40% decline in new infections since 1998 when HIV was at its peak. Advances such as effective HIV treatment with antiretroviral therapy (ART), prevention of mother-to -child transmission (PMTCT) of HIV, pre-exposure prophylaxis (PrEP) for HIV prevention, HIV point-of-care testing, and progress in vaccine development, have led to reductions in AIDS-related deaths (UNAIDS, 2020c). This has contributed to increased life expectancy of people living with HIV (PLWH), resulting in classification of HIV as a chronic illness. When existing health systems are not prepared to accommodate the individuals seeking long-term HIV treatment services, these systems are limited in their ability to treat patients as needed. Thus, HIV remains a persistent global health concern and a leading cause of morbidity and mortality in low- and middle-income countries in Africa and Asia (UNAIDS, 2021)

To end the HIV epidemic, the Joint United Nations Programme on HIV/AIDS (UNAIDS) initiated the 90-90-90 targets, which aims for 90% of PLWH knowing their status, 90% of diagnosed persons receiving treatment with ART, and 90% of individuals on ART achieving viral suppression by 2020 (Joint United Nations Programme on HIV/AIDS, 2014). The targets were not met globally as planned, however, significant strides have been made, and new targets have been set to achieve a goal of 95-95-95 by 2030 (Joint United Nations Programme on HIV/AIDS, 2015). Ensuring access to treatment with ART for at least 90% of PLWH is particularly challenging in resource-limited settings with high HIV burden (UNAIDS, 2020a). Therefore, to achieve the next set of targets, it will be crucial to explore strategies to ensure that more PLWH have access to and receive life-saving ART.

As crucial as ART access and treatment is in achieving the UNAIDS targets, chronic healthcare workforce shortages coupled with the global HIV burden(World Health Organization, 2016b), make access to HIV treatment challenging. This is evident in sub-Saharan Africa where the HIV epidemic is disproportionally concentrated. It is estimated that the region accounts for more than 70% of the global HIV burden and 74% of all AIDS-related deaths (Kharsany & Karim, 2016). Sub-Saharan Africa is also burdened with a low healthcare workforce density that is significantly below the recommended World Health Organization (WHO) threshold of 44.5 doctors, nurses, and midwives per 10,000 population (World Health Organization, 2016b). These challenges contribute to the delay in accessing HIV treatment for infected individuals.

Implementation of differentiated service delivery (DSD) for HIV treatment, which is a client-centered approach to delivering HIV treatment (Grimsrud et al., 2016), may be a potential solution to achieving the UNAIDS targets in a world without universal healthcare. The WHO recommends the implementation of DSD as a model of care in settings with high HIV burden, limited resources, and high health workforce shortages. The DSD framework includes four key components: type of service, location of the service delivery, provider of service, and frequency of services (World Health Organization, 2016a). The components in the DSD framework are integrated to develop four models of DSD, which include: i) healthcare worker-managed group models, ii) client-managed group models, iii) facility-based individual models, and iv) out-of-facility individual models (International AIDS Society, 2017).

An estimated 95% of HIV service delivery is facility-based (Joint United Nations Programme on HIV/AIDS, 2014). Under the facility-based individual model, individuals on ART receive their HIV treatment services and pick up prescription at a HIV clinic or hospital; however, a less intensive treatment package including a reduction in the number of provider

visits is offered (World Health Organization, 2016a). Facility-based individual DSD is the least complex to implement at the clinic level (National AIDS and STI Control Program, 2017), which explains why it is the most widely implemented DSD model. It is also patient-preferred (Rabkin et al., 2020; Strauss et al., 2020; Zakumumpa et al., 2020) with the highest patient uptake (Adjetey et al., 2019). The WHO guidelines state that under the facility-based individual DSD model, patients who meet the WHO eligibility criteria and country-specific HIV treatment and DSD guidelines have the option to extend time between clinical visits. Generally, standard care for HIV recommends following-up with a health provider every 1 to 3 months; however, with DSD, eligible patients who are established on ART, per WHO criteria (World Health Organization, 2016a) may prolong the interval between appointments up to 6 months—cutting the number of provider visits by at least half, freeing up providers to attend to more new patients and those who have not achieved optimal health outcomes. Oftentimes, patients receive a 3-month ART supply and return after 3 months for an expedited non-clinical visit for the remaining 3 months of ART. However, guidelines are being updated by WHO to accommodate dispensing 6 months of ART to eligible clients. This mechanism of prolonging intervals between clinical visits allows providers to focus on complex patients and improves access to care (World Health Organization, 2016a).

The popularity of facility-based individual DSD among patients and its ease in implementation have prompted advocacy for its scale-up in sub-Saharan Africa; however, it lacks adequate formal documentation in the literature. To gain a better understanding of this fast-growing HIV service delivery model, this integrative review focused on facility-based individual DSD, with the primary purpose of exploring and summarizing the current state of the science regarding the implementation of the care delivery model in sub-Saharan Africa. This review

focused on outcomes, patient perspectives, and health worker perspectives of the care delivery model. A secondary goal is to identify gaps in the knowledge base that need to be addressed as we work towards achieving the UNAIDS global targets for universal treatment. This is crucial for improving HIV service delivery in regions that are disproportionally burdened by a high HIV burden and limited resources.

Methods

A comprehensive literature search on facility-based individual DSD implementation focusing mostly on sub-Saharan Africa was conducted in PubMed, Embase Web of Science, and CINAHL. Grey literature and abstracts from conference proceedings were searched using conference web pages and Google Scholar. The search terms included “facility-based delivery”, “differentiated care”, “multi-month scripting”, “pharmacy fast-track refill”, and “sub-Saharan Africa” (see Table 1 for a full list of search terms). No specific date ranges were used for the literature search. The search was conducted between September 2020 and November 2021. Broad keywords were used and yielded 403 studies. After deleting duplicates, a total of 205 studies published between 1996 and 2021were identified. Article titles and abstracts were reviewed for relevance. Research designs included randomized control trials (RCT), systematic reviews and meta-analyses, pre-post interventional studies, retrospective cohort analyses, program evaluations, cross-sectional mixed methods, and qualitative research studies. We also included conference abstracts. Articles met the following inclusion criteria: 1) adult populations; 2) studied facility-based individual DSD or elements that are characteristic of the care delivery model; and 3) took place in sub–Saharan Africa. Some studies, though relevant to facility-based individual DSD, were eliminated because they focused on pediatric and adolescent populations or were solely conducted in regions other than sub-Saharan region. Due to sparse evidence, one

study, a systematic review and meta-analysis that included 2 US studies and 1 Spain study (out of a total 11 studies) was included in the review. When the literature search was restricted to facility-based individual DSD only, there were very few studies, therefore the search criteria was expanded to include studies that looked at facility-based individual DSD as well as other DSD approaches. However, where possible, only the aspects relating to facility-based individual DSD were reported in this review.

Results

Twenty-six studies (17 articles published in peer-reviewed journals and 9 abstracts from international conferences) met inclusion criteria and were reviewed for this paper. Findings were categorized into three areas: health outcomes (*n*= 11 studies), cost-effectiveness (*n*= 4; financial cost) and (*n*= 2; time cost studies), and health worker perspectives (*n*= 6 studies) and/or patient perspectives (*n*= 8 studies). Five of the studies covered more than one of the categories.

Outcomes

We found one RCT (Hickey et al., 2020), one systematic review (Mutasa-Apollo et al., 2017), and nine individual studies that examined health outcomes (Bekolo et al., 2017; Bosomprah et al., 2020; Cassidy et al., 2018; Kaimal et al., 2017; Mody et al., 2018; Obua et al., 2014; Sanwo et al., 2021; Shigayeva et al., 2020; Wringe et al., 2018).

Health

Hickey and colleagues (Hickey et al., 2020) conducted an RCT (SEARCH study) in Kenya and Uganda that assessed the effect of streamlined DSD on viral suppression at baseline and after 3 years among ART eligible (per country treatment guidelines) PLWH (Study #1; Table 2). The treatment group included PLWH enrolled in the SEARCH streamlined care model

and the control group included PLWH not enrolled in the SEARCH streamlined care model (receiving standard care). Though the study is not focused on facility-based individual DSD only, streamlined DSD included key aspects that are characteristic of facility-based individual DSD such as incorporating a patient-centered approach and increased spacing between clinic appointments. Analysis of the data collected between 2013 and 2017 showed that in patients with a previous history of ART, streamlined care was associated with higher viral suppression (67% vs 47%, RR 1.41, 95% CI: 1.05 to 1.91). However, in ART-naïve persons (patients with no history of ART), viral suppression was not significantly higher with streamlined care (83% vs 79%, RR 1.05, 95% CI:0.95 to 1.16). Since individuals established on ART is the target population for facility-based individual DSD, the results of this RCT indicate that the care delivery model is beneficial in maintaining viral suppression in these patients.

A systematic literature review and meta-analysis conducted by Mutasa-Apollo, et al looked at the effect of clinic visit frequency on ART treatment outcomes and concluded that extending the time between clinician visits and reduction in clinical visits leads to increased retention in care (Study #2; Table 2)(Mutasa-Apollo et al., 2017). Twenty-one articles pertaining to sixteen individual studies met the inclusion criteria for this systematic review. Eleven of the sixteen studies were included in the quantitative synthesis and the five were included in the qualitative synthesis. For the quantitative synthesis, five studies examined the effect of reduced clinic visit frequency and the remaining studies looked at the frequency of clinic attendance combined with task shifting of health workers. In this review, researchers found that reduced clinic visits (up to once every 6 months) led to increased odds of retention in care [OR: 1.90; 95% CI: 1.21-2.99] and reduced ART prescription visits supported retention in care [OR: 1.93; 95% CI: 0.62-6.04] when compared to required visits offered in the standard package of HIV

care, usually every 1-3 months. The authors concluded that by improving retention in care, a reduction in clinic visits may improve adherence to HIV care for clinically stable patients(Mutasa-Apollo et al., 2017). Requiring fewer provider visits allows healthcare providers to focus on complicated cases. Majority of the studies included in this review and analysis were from sub-Saharan Africa, however, it also included a few studies from other regions. It also included a few studies that incorporated community DSD approaches.

To assess the impact of interventions to address poor clinic flow, congestion, delays in ART dispensing, and long wait times at the clinic, an interventional cohort study in Uganda (Study #3; Table 2) (Obua et al., 2014) employed various aspects associated with the facility-based individual DSD model (an appointment system, fast-tracking, and longer time between ART prescription visits for patients meeting the criteria) for 12 months. The researchers used mixed-effects models to assess the effects of the intervention on retention in care and adherence to ART in two groups: an experienced cohort (patients in treatment at least 12 months prior to the interventions) and a newly treated cohort (patients who initiated treatment during the 6 months prior to the intervention). A total sample of 1481 patients files from 6 facilities were analyzed using the following adherence outcome measures: number of missed appointments, medication gaps, and a surplus of dispensed medication. In the experienced cohort, there was a small, but statistically significant reduction of missed appointments (from 24.4% to 20.3%), a statistically significant decrease in the medication gap of 3 or more days (from 20.2 to 18.4%), and a statistically significant increase in the proportion of patients with more than 30 days of dispensed medication days (from 4.3% to 9.3%). Among the newly treated cohort, there was a 44% reduction in the hazards of experiencing a medication gap. The authors concluded that there was improved adherence to ART in both patient groups because of their intervention. The

findings demonstrate that implementing a facility-based individual DSD approach is beneficial to PLWH regardless of how long they have been enrolled in HIV treatment.

A retrospective cohort analysis (Study #4; Table 2) (Wringe et al., 2018) evaluated the implementation of longer intervals between clinic visits with a healthcare provider and fast-track drug refills to assess whether these interventions improve retention in care for clinically stable PLWH. Patients who attended six-monthly clinical consultations (SMCC) and had three-monthly ART refills from community health workers were compared with those attending visits every 1-2 months. Attrition was defined as either death or loss to follow-up. Data extracted from an electronic database collected between 2008 and 2015 from 11 facilities were analyzed. As a result of SMCC with three-monthly ART refills, the group with longer clinical intervals had a greater probability of retention in care at 5 years when compared with those attending every 1-2 months- 97% vs 86%, respectively.

Studies #5 to #11 (Table 2) looked at health outcomes of patients who received HIV care in facilities that implemented differentiated care approaches by incorporating reduced clinic visits and fast-track ART refills. The results of these studies are consistent with the four previously described studies looking at health outcomes. They demonstrate that facility-based differentiated models of care are effective in improving adherence, retention in care, and viral suppression (Bekolo et al., 2017; Bosomprah et al., 2020; Cassidy et al., 2018; Kaimal et al., 2017; Mody et al., 2018; Sanwo et al., 2021; Shigayeva et al., 2020).

Cost-Effectiveness Outcomes

Several research studies looked at the cost of implementing facility-based individual DSD in Africa. We found six studies looking at cost-effectiveness (Alamo et al., 2013;

Babigumira et al., 2011; Jakubowski et al., 2016; Prust et al., 2017; Roberts et al., 2019; Shade et al., 2017)

Financial Cost

A systematic review was conducted to assess the cost of differentiated antiretroviral therapy (DART) in sub-Saharan Africa (Study #12; Table 2) (Roberts et al., 2019). DART models include the 4 types of differentiated service delivery described earlier. In this review, DART, therefore, was not limited to facility-based individual DSD only; it also included other DSD approaches such as community distribution points, community ART groups, and adherence clubs. However, the majority (11 of the 16) models included in the systematic review were facility-based individual models. There were varied cost outcomes with some studies documenting increased costs and others demonstrating reduced costs of HIV treatment. DART was found to save costs in seven out of the eleven models, with an average annual cost saving of $67 per patient in cost-saving models only.

Babigumira, et al conducted a retrospective cost-effectiveness analysis of a Pharmacy Refill Program (PRP) which included task shifting (World Health Organization, 2007) (Study #13 in Table 2) (Babigumira et al., 2011) . To alleviate human resources for health challenges, PRP was implemented to enable access to care. Using pre-established eligibility criteria demonstrating patient stability, eligible clients picked up their ART prescription from the pharmacy monthly, without seeing a physician, and arranged to see a physician every 6 months. The authors of this study found that PRP implementation, compared to standard care, yielded comparable health outcomes (using CD4 as a measure) and was more cost-effective (US$520 vs. $655 annually) when compared to standard care.

A mixed-methods process evaluation was conducted by Prust and colleagues to facilitate ART scale-up and optimize HIV service delivery in Malawi (Study #14; Table 2) (Prust et al., 2017). They implemented changes to the standard care delivery model to include multi-month scripting (MMS) of ART and fast-track ART refills (FTR) in 30 healthcare facilities. With MMS, stable patients receive three months of ART refills instead of one month. In FTR, eligible patients visit the healthcare facility four times annually, but only two visits are standard care visits with a physician. Eligible patients were enrolled in a six-month clinical appointment program. After a 3-month data collection period, the researchers determined that patient travel time to the health care facility and the costs associated with care were reduced by 67% for stable patients enrolled in the new service delivery model when compared to stable patients that receive the standard care requiring monthly visits. The results of this study are consistent with a similar study conducted by Shade and colleagues (Study #15; Table 2)(Shade et al., 2017), which looked at differentiated care costs. Results of this study indicated that implementation of streamlined HIV care averaged at $275 per -person-per-year and was less costly or similar to standard care, which was estimated to cost $224 to $1089 per-person/per-year.

Time

To optimize the clinic efficiency of an ART treatment program, a pre-post study was conducted in Uganda to assess the impact of implementing modifications to the provider visit interval schedules for stable PLWH (Study #16; Table 2) (Alamo et al., 2013). Before facility implementation changes in service delivery, patients returned to the clinic monthly for clinical assessment and refill of ART. After implementing the recommended modifications at the community clinic, stable patients received a 2-month provider visit appointment with a fast-track ART refill. Using a time and motion study conducted in 2008 as the baseline, an evaluation of

the program approximately 6 months post-implementation of the modifications demonstrated that the service delivery changes that were implemented led to a significant reduction in overall median time patients spent at the clinic, from 206 minutes to 83 minutes per visit. In another study looking at the effect of DSD on time costs (Study #17; Table 2) (Jakubowski et al., 2016), Jakubowski and colleagues administered surveys to PLWH in 32 communities and found that when compared to a standard HIV model of care, patients who received care in streamlined DSD models had a significant reduction in time spent at the healthcare facility (4.4 hours per month at baseline vs. 1.78 hours per month at follow-up, $p<0.001$).

Perspectives

Several studies have looked at patient and healthcare worker (HCW) perspectives and experiences with facility-based individual DSD implementation in Africa. We found 8 studies looking at patient perspectives (Assefa et al., 2018; Bemelmans et al., 2014; Hubbard et al., 2020; Jere et al., 2018; Mantell et al., 2020; Prust et al., 2018; Rabkin et al., 2020; Roy et al., 2019b) and 6 looking at healthcare worker perspectives (Hubbard et al., 2020; Jere et al., 2018; Phiri et al., 2021; Prust et al., 2018; Rabkin et al., 2020; Roy et al., 2019b)

Patient Perspectives

HIV service delivery optimization was assessed in a Médecins Sans Frontières programmatic evaluation study investigating HIV service delivery in four sub-Saharan African countries. Routine patient and health system data were assessed (Study #18; Table 2) (Bemelmans et al., 2014). Each country implemented one of the four models of DSD. In Malawi, service delivery was modified to include aspects of facility-based individual DSD, thus, appointment spacing and fast-track drug refill approaches were assessed. The other three

countries did not implement or assess facility-based individual DSD and thus, were not included in our integrative review. Results in Malawi indicated that patients perceived that this new approach to care delivery led to reduced travel time and costs for patients, and reduced burden on the health system due to reduced clinic attendance.

A literature review by Roy and colleagues (2019) provides a comprehensive overview and summary on the implementation of DSD (Study #19; Table 2) (Roy et al., 2019b). The review included both qualitative and quantitative studies. The authors identified that longer appointment spacing and fast-track drug refill programs were perceived by patients to lower treatment-related costs by reducing the number of clinical visits and less time spent at the clinic for ART refills. However, patients don't perceive facility-based DSD as a way to increase peer support or enhance community participation (Roy et al., 2019b). This is a potential downside to facility-based DSD implementation because previous studies have shown that peer support increases ART adherence among HIV-positive patients (Kanters et al., 2016). The studies included the literature review did not examine adherence as an outcome.

Studies #20 to #25 (Table 2) looked at patients' perspectives of DSD using qualitative methods (focus groups and individual interviews). Researchers found that facility-based individual models of care were perceived by patients to be beneficial in decongesting the clinic, reducing transportation costs, lost wages, time spent traveling to the health facility, and waiting time at the clinic (Hubbard et al., 2020; Jere et al., 2018; Pascoe et al., 2019; Rabkin et al., 2020). However, DSD was not always perceived as beneficial; some clients expressed that a challenge associated with DSD included drug stock-outs, which meant that patients' visits to the facility are not reduced (Prust et al., 2018). Despite DSD being perceived as mostly beneficial, some patients declined enrollment due to concerns regarding inadvertent disclosure to having large volumes of

ART (Assefa et al., 2018), medication storage, reduced clinic frequency visits, and misunderstandings about the care delivery model (Mantell et al., 2020).

Healthcare Worker Perspectives

In the above-mentioned qualitative study by Roy and colleagues a reduction in workload by nurses and pharmacists was reported (Study #26; Table 2) (Roy et al., 2019b). Additionally, health workers perceive facility-based individual DSD as beneficial in reducing workload and improving retention in care for patients. However, the researchers did not examine HCWs' perceptions of new models in patient adherence or retention in care.

Studies #27 to #31 (Table 2) described additional qualitative studies presenting results consistent with Roy et al,(Roy et al., 2019b) describing several perceived benefits from the health worker standpoint. In addition to reducing workload, health workers perceived that facility-based individual differentiated care alleviates clinic congestion and reduces the time waiting to see a provider (Hubbard et al., 2020; Jere et al., 2018; Pascoe et al., 2020; Phiri et al.; Prust et al., 2018; Rabkin et al., 2020). Similar to patients' perceptions regarding low stock of drugs, health workers reported that drug stockouts are a challenge, thus prohibiting full implementation of DSD as intended, because patients still have to return to the clinic frequently to pick up drugs due to the facilities' inability to dispense the full amounts of ART as prescribed (Prust et al., 2018).

Discussion

This integrative review provides evidence of the benefits of facility-based individual DSD models and sheds light on the challenges that impede progress towards meeting the UNAIDS targets. If the UNAIDS goal of near-universal viral suppression is to be achieved, HIV-infected individuals must be able to adhere to life-saving HIV ART and remain fully engaged in

HIV treatment. Healthcare systems also need to quickly identify infected persons and provide access to affordable, available and effective care as soon as possible. The latter requires an expansion of care that may not be feasible for LMICs with low budgets and shortages of HCWs. Thus, ensuring access to HIV care should be non-negotiable and should be prioritized. Prolonging the intervals between healthcare provider visits for stable PLWH, as is the case with facility-based individual DSD, is fairly straight-forward and requires little to no financial investment from the healthcare system. This review found that facility-based individual DSD is likely to save costs to the health care system, allowing providers time for enrolling more patients needing treatment, and provides more time with patients to ensure improved quality of care. Findings from the studies we reviewed suggest that facility-based individual DSD is an efficient care delivery model. It saves time and cost to the patients, allowing them to pursue other activities. Its implementation has improved quality of care, which translates to better health outcomes for PLWH. It is, therefore, a strategy worth implementing and exploring further.

One of the goals of DSD is to improve access to care and enroll more patients who otherwise may have difficulty enrolling in care and/or encounter delays in accessing treatment. None of the studies available for this review explored whether healthcare institutions can enroll more patients as a result of DSD implementation. Therefore, there is a need for this type of research to better understand the total expansion of care which would allow more patients to receive HIV treatment in resource-limited settings. One study reported the potential downsides of drug stock-outs and [patient-perceived] reduced peer support as a result of facility-based individual to DSD implementation. Adding these aspects to studies would also further identify and quantify these downsides so that improvements can be made to alleviate them.

Limitations

A limitation of this review is the small number of studies on facility-based individual DSD. The lack of evidence on this topic may be attributed to the fact that differentiated service delivery, as it is formally defined in the literature and clarified by guidelines by WHO, is still a novel idea and has not been adequately implemented, and thus studied, for a longer period. While the terminology is new, the concept of patient-centered HIV care is not. Thus, this review adapted to this challenge by broadening the search criteria to incorporate other search terms that are included in the concept of facility-based DSD e.g., multi-month prescriptions and fast-track ART refills. Only one recent RCT was identified during the literature search. RCTs are regarded as the gold standard for evaluating interventions but there is a significant gap in available studies implementing this methodology. Additionally, the studies available for this review were not restricted to facility-based individual DSD models only and included a few studies which incorporated other DSD models along with a facility-based DSD approach.

There is also no standardized approach for facility-based individual DSD; the definitions and implementation approaches were different in the various studies. Despite the limitations described, this review contributes to the evidence on best practices for HIV service delivery in resource-limited contexts. These limitations highlight gaps that should be addressed in future research studying HIV care delivery models. There is a need for more rigorous studies with stronger methodologies looking at DSD implementation and outcomes, including negative outcomes and challenges, as well as how to prevent and address them. There are also few studies looking at the effect on facility-based individual DSD on viral suppression, therefore, further studies should be conducted to assess the relationship between the care delivery model and viral load outcomes of those enrolled.

Clinical significance

Research in new HIV service delivery models shows great potential and is important for the future of how HIV treatment services are delivered and expanded at the population level, particularly in challenging contexts such as those experiencing high HIV disease burden, low health budgets, and an inadequate healthcare workforce. Healthcare cadres involved in direct HIV treatment, such as nurses, physicians, and other health care providers have the opportunity to assess clients for stability and facilitate the transition of eligible clients into differentiated care models for HIV treatment that would benefit both the client, the healthcare workers, and the healthcare system's ability to expand care. There are clear differentiated care implementation guidelines from the WHO and other national and facility-level agencies that may be used to guide the process. Additionally, being on the frontline of HIV care and treatment provides practitioners the opportunities to develop and engage in research aiming to improve HIV service delivery.

Conclusion

Facility-based individual DSD appears to be a promising model for HIV care and treatment, and it is particularly useful in resource-limited contexts with a high HIV burden. Patients favor this model of care delivery due to its ability to alleviate the constraints associated with multiple and frequent HIV service provider visits, long wait times and transportation costs. It is beneficial to healthcare workers and health systems because it frees up provider time to concentrate on more complicated patients and to enroll more new patients needing HIV treatment. It may also improve adherence to HIV treatment for clinically stable patients. While facility-based individual DSD seems advantageous, potential downsides to consider may include

reduced ART adherence due to reduced follow-up and health systems not having adequate ART supply (stock outs) to last the longer duration between clinical visits. It is important to note that there is no ‘one size fits all’ model for HIV service delivery, thus, future studies should explore the value of customizing approaches to care based on clients’ needs and developing targeted evidence-based strategies to deliver and expand HIV treatment in resource-limited settings.

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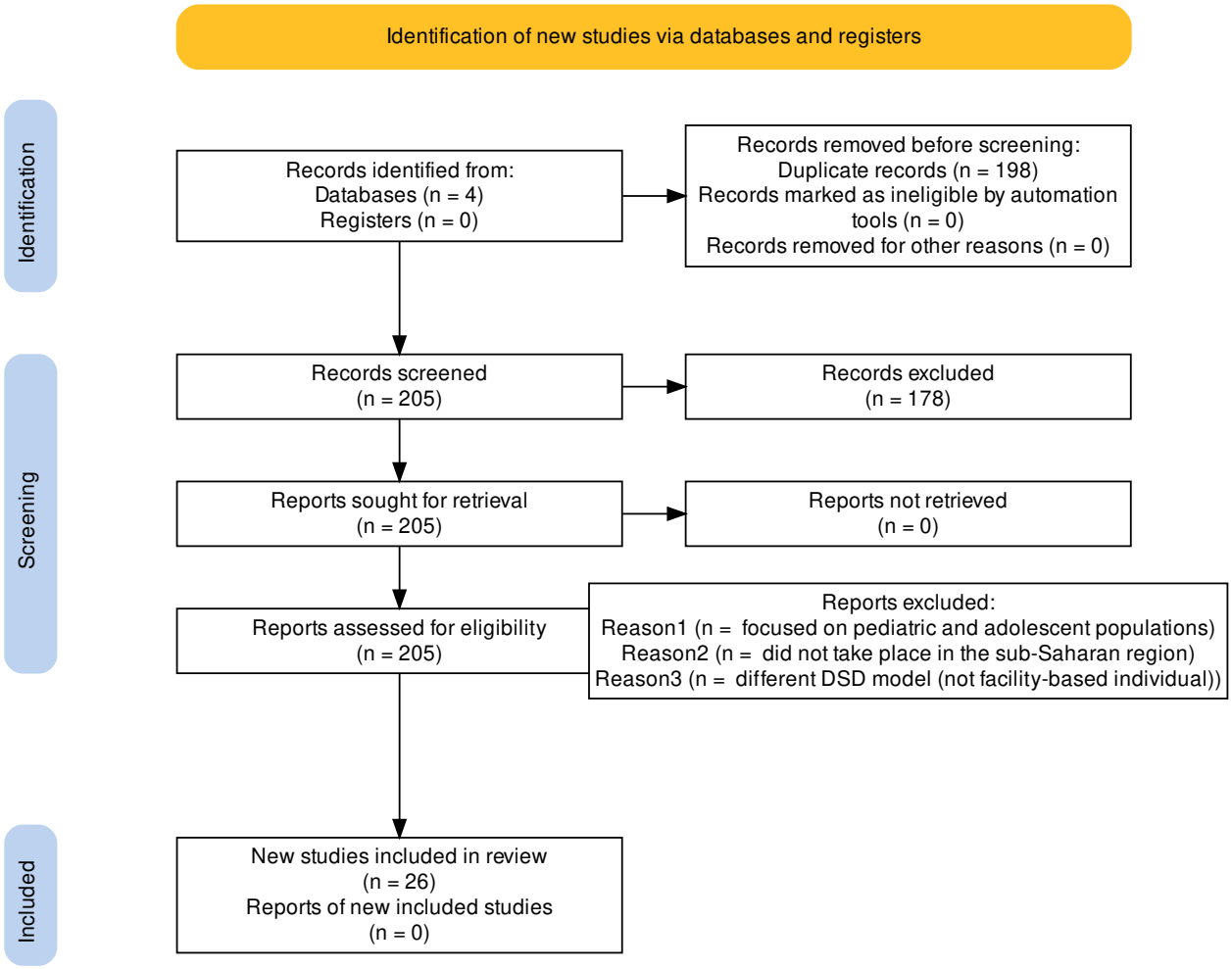

Figure 1: PRISMA Flow Diagram

Table 1

Summary of keywords, databases used, and search yield

Study #	Database	Search terms	Results
#1	PubMed	("differentiated services delivery"[tw] OR "differentiated service delivery"[tw] OR "Differentiated care"[tw] OR "Differentiated Model"[tw] OR "facility-based delivery system"[tw] OR "pharmacy fast-track refill"[tw] OR "extended refill"[tw] OR "multi-month scripting"[tw] OR "multi-month prescriptions"[tw] OR "multi-month prescription"[tw]) AND ("Anti-Retroviral Agents"[Mesh] OR "antiretroviral agent"[tw] OR "antiretroviral drug"[tw] OR "HIV Infections/drug therapy"[Mesh] OR "Antiretroviral Therapy, Highly Active"[Mesh] OR HAART[tw] OR "Anti-Retroviral Agents" [Pharmacological Action]) AND (sub-Saharan Africa OR "Africa South of the Sahara"[Mesh])	110
	Embase	("differentiated services delivery" OR "differentiated service delivery" OR "Differentiated care" OR "Differentiated Model" OR "facility-based delivery system" OR "pharmacy fast-track refill" OR "extended refill" OR "multi-month scripting" OR "multi-month prescriptions" OR "multi-month prescription") AND ("Anti-Retroviral Agents" OR "antiretroviral agent" OR "antiretroviral drug" OR "Highly Active Antiretroviral Therapy" OR "HAART") AND ("sub-Saharan Africa" OR "Africa South of the Sahara")	103
#2	PubMed	("differentiated services delivery"[tw] OR "differentiated service delivery"[tw] OR "Differentiated care"[tw] OR "Differentiated Model"[tw] OR "facility-based delivery system"[tw] OR "pharmacy fast-track refill"[tw] OR "extended refill"[tw] OR "multi-month scripting"[tw] OR "multi-month prescriptions"[tw] OR "multi-month prescription"[tw]) AND (Kenya[tw] OR "Kenya"[Mesh] OR sub-Saharan Africa OR "Africa South of the Sahara")) AND ("viral load"[tw] OR "Viral Load"[Mesh])	36
	Embase	("differentiated services delivery" OR "differentiated service delivery" OR "Differentiated care" OR "Differentiated Model" OR "facility-based delivery system" OR "pharmacy fast-track refill" OR "extended refill" OR "multi-month scripting" OR "multi-month prescriptions" OR "multi-month prescription") AND (Kenya OR sub-Saharan Africa OR "Africa South of the Sahara") AND viral load	60
#3	PubMed	("differentiated services delivery"[tw] OR "differentiated service delivery"[tw] OR "Differentiated care"[tw] OR "Differentiated Model"[tw] OR "facility-based delivery system"[tw] OR "pharmacy fast-track refill"[tw] OR "extended refill"[tw] OR "multi-month scripting"[tw] OR "multi-month prescriptions"[tw] OR "multi-month prescription"[tw]) AND (sub-Saharan Africa OR "Africa South of the Sahara"[Mesh]) AND ((clinician[tw] OR nurse[tw] OR "healthcare worker"[tw] OR pharmacist[tw] OR physician[tw] OR counselor[tw]) AND (experience[tw] OR perception[tw] OR perspective[tw] OR "Attitude of Health Personnel"[MeSH]))	3

	Embase	("differentiated services delivery" OR "differentiated service delivery" OR "Differentiated care" OR "Differentiated Model" OR "facility-based delivery system" OR "pharmacy fast-track refill" OR "extended refill" OR "multi-month scripting" OR "multi-month prescriptions" OR "multi-month prescription") AND (Kenya OR sub-Saharan Africa OR "Africa South of the Sahara") AND ((clinician OR nurse OR "healthcare worker" OR pharmacist OR physician OR counselor) AND (experience OR perception OR perspective OR "Attitude of Health Personnel"))	16
#4	Web of Science		59
#5	CINAHL	("differentiated services delivery" OR "differentiated service delivery" OR "Differentiated care" OR "Differentiated Model" OR "facility-based delivery system" OR "pharmacy fast-track refill" OR "extended refill" OR "multi-month scripting" OR "multi-month prescriptions" OR "multi-month prescription") AND (Kenya OR sub-Saharan Africa OR "Africa South of the Sahara")	8
#6	Grey/ Conference/ Google	The searches google and conference web pages were much more basic: “differentiated services” & one or two words representing the topic of the paper.	8
Total (Before removal of duplicates)			403
Total (After removal of duplicates)			205

Table 2

Summary of literature review for facility-based individual DSD in sub-Saharan Africa

	Objective Reviewed	Author (s)	Region; Sample size	Study Design; Source	Objective	Results/Conclusion
1.	**Outcomes** *Health*	Hickey et al., 2020	Uganda Tanzania *(n=6,190 patients)*	Randomized control trial *(Peer-reviewed journal publication)*	Evaluate the effect of implementing a streamlined care DSD model on viral suppression.	In ART experienced persons, streamlined care was associated with higher viral suppression (67% vs 47%, RR 1.41, 95% CI: 1.05 to 1.91). In ART-naïve persons, viral suppression was not significantly higher with streamlined care (83% vs 79%, RR 1.05, 95% ci:0.95 to 1.16).
2.	**Outcomes** *Health*	Mutasa-Apollo et al., 2017	Uganda, USA, South Africa, Malawi, Spain, Kenya *(n= 11 studies)*	Systematic literature review and analysis. *(Peer-reviewed journal publication)*	Assess the impact of reducing the frequency of clinic visits and drug dispensing.	Comparative analysis of 8 studies showed that reduced clinic visits led to increased retention in care (OR:1.90; 95% CI: 1.21-2.99).
3.	**Outcomes** *Health*	Obua et al., 2014	Uganda *(n= 1,481 patients)*	Pre-post intervention study *(Peer-reviewed journal publication)*	Assess the effects of facility-based interventions on patient clinic attendance and ART adherence.	Implementation of facility-based interventions led to a reduction of missed appointments from 24.4% to 20.3% and a medication gap of 3 days or more (a measure of ART adherence) reduced from 20.2% to 18.4% in the experienced cohort. In the newly treated

						cohort, there were significant reductions in the hazards of experiencing a medication gap of 7 days (44%) and 14 days (38%).
4.	**Outcomes** *Health*	Wringe et al, 2018	Malawi *(n=22,633 patients)*	Retrospective cohort analysis *(Peer-reviewed journal publication)*	Assess the impact of longer intervals between clinic visits; six-monthly clinical consultations (SMCC) with fast-track ART refill every 3 months.	After the implementation of SMCC with three monthly fast track ART refills, the probability of retention at 5 years was higher at 97% (95% CI: 96.7% to 97.3%) than after 1 year at 86% (95% CI: 85% to 87%).
5.	**Outcomes** *Health*	Mody et al, 2018	Zambia *(n=62,084 patients)*	Retrospective cohort analysis *(Peer-reviewed journal publication)*	Examine the association between 6-month scheduled appointment intervals and patient outcomes.	Compared to clients scheduled to return monthly, patients enrolled for the 6-month clinic intervals model had improved retention in care (aOR 0.20; 95% CI 0.17-0.24), ART adherence (aOR 0.47; 95% CI 0.39-0.57), and reduced loss to follow-up (aOR 0.41; 95% CI 0.31-0.54).
6.	**Outcomes** *Health*	Bekolo et al, 2017	Guinea *(n=1,957 patients)*	Retrospective cohort analysis *(Peer-reviewed journal publication)*	Evaluate the implementation of *Rendevouz-de Six Mois* (R6M), a six-monthly appointment interval approach.	When compared to patients enrolled in the standard one to three monthly visits for HIV treatment, patients enrolled in R6M had higher retention in care 90% vs 75%.

7.	**Outcomes** *Health*	Kaimal et al, 2017	Uganda *(n=624 patients)*	Cross-sectional analysis *(Conference proceeding)*	Evaluate the implementation of a Pharmacy Refill Plus (PRP) program in Uganda.	83/84 (98.8%) patients who were still enrolled in PRP after 12 months had maintained viral suppression.
8.	**Outcomes** *Health*	Cassidy et al, 2018	South Africa *(n=2,150 patients)* *(Conference proceeding)*	Retrospective cohort analysis *(Conference proceeding)*	Describe patient characteristics and retention in a quick pick-up model (QPUP), which involves direct ART pick-up from the pharmacy, without counselor review.	Compared to clinic patients enrolled in standard care, QPUP patients had higher retention in care.
9.	**Outcomes** *Health*	Bosomprah et al, 2020	Zambia *(n= 87,435 patients)* *(Conference proceeding)*	Retrospective cohort analysis. *(Conference proceeding)*	Estimate the effect of a fast-track DSD model on retention and viral suppression in PLWH.	Patients receiving HIV care under the fast-track model were more likely to be virally suppressed and retained in care ($p<0.001$).
10.	**Outcomes** *Health*	Shigayeva et al., 2020	South Africa *(n= 9,501 patients)*	Retrospective cohort analysis *(Conference proceeding)*	Evaluate and compare the effectiveness of four Differentiated Models of Care (DMOC).	Overall retention for all four DMOCs was 89.1%, 82.5% and 77.8% at 12, 24, and 36 months.
11.	**Outcomes** *Health*	Sanwo et al, (2021)	Nigeria *(n= 40,800 patients)*	Retrospective cohort analysis *(Peer-reviewed journal publication)*	Compare viral suppression and retention among patients enrolled in DSD vs those receiving the standard package of HIV care.	Adults enrolled in DSD were virally suppressed compared to adults in standard care 95.4% vs 91.8% ($p <0.01$). Retention rates at 6 months were higher in the DSD group (96% vs 94%).
12.	**Cost-effectiveness** *Financial Cost*	Roberts et al., 2019	Uganda, South Africa, Ethiopia, Nigeria,	Systematic review *(Peer-reviewed journal publication)*	Assess the cost of differentiated antiretroviral therapy (DART) in sub-Saharan	An analysis of 12 articles reporting costs for DART implementation concluded that DART led to a $67

			Malawi, Kenya *(n=12 articles)*		Africa compared with standard HIV care.	median incremental saving per patient per year.
13.	**Cost-effectiveness** *Financial Cost*	Babigumira et al., 2011	Uganda *(n=829 patients)*	Retrospective cohort analysis *(Peer-reviewed journal publication)*	Conduct a cost-effectiveness analysis comparing a Pharmacy-only Refill Program (PRP) to standard HIV care.	When compared to standard care, PRP was less costly (US$ 520 vs 655 annually).
14.	**Cost-effectiveness** *Financial Cost*	Prust et al., 2017	Malawi *(n=30 facilities)*	Mixed-methods cross-sectional evaluation. *(Peer-reviewed journal publication)*	Assess and describe the characteristics and costs associated with the implementation of differentiated care.	As a result of implementing differentiated models of care, there was a 67% reduction in patient costs, linked to travel and time. There was a 10% reduction in health system costs (commodities and service delivery costs).
15.	**Cost-effectiveness** *Financial Cost*	Shade et al., 2017	Kenya Uganda *(n=17 facilities)*	Cohort analysis *(Conference proceeding)*	Estimate and model the cost of streamlined HIV care incorporating a patient-centered approach, nurse-driven appointments, telephone access to clinicians, VL testing, and counseling every 6 months.	Implementation of streamlined HIV care averaged at $275 per -person-per-year and was less costly or similar to standard care which was estimated to cost $224 to $1089 per -person-per-year.
16.	**Cost-effectiveness** *Time*	Alamo et al., 2013	Uganda *(n= 262 patients)*	Pre-post analysis *(Peer-reviewed journal publication)*	Assess the impact of triage and longer clinic appointment intervals on clinic efficiency.	Overall time spent at the clinic waiting to see a provider and time spent with providers reduced from 206 to 83 minutes per

						patient per visit. (for all patients). Among stable patients, waiting time was reduced from 102 to 20 minutes per visit.
17.	**Cost-effectiveness** *Time*	Jakubowski et al., 2016	Kenya Uganda *(n= 2,819)*	Cohort analysis *(Conference proceeding)*	Examine changes in costs incurred in patients receiving streamlined HIV care incorporating appointment reminders, quarterly clinic visits, patient-centered care.	Results from household surveys of PLWH in 32 communities showed that when compared to the standard care model of care, patients receiving care in the streamlined model had a significant reduction in time spent at the healthcare facility (4.4 hours per month at baseline vs. 1.78 hours per month at follow-up, $p<0.001$).
18.	**Perspectives** *Patient*	Bemelmans et al., 2014	Malawi, South Africa, DRC, Mozambique.	Programmatic evaluation study *(Peer-reviewed journal publication)*	Assess the impact of differentiated care in 4 sub-Saharan countries supported by Médecins Sans Frontières.	Implementation of appointment spacing for clinical visits (every 6 months vs. 1-2 months) and fast-track ART refills in Malawi was perceived by patients to lead to a reduction in clinical visits and less time waiting for ART refills.
19.	**Perspectives** *Patient*	*Roy et al., 2019	Sub-Saharan Africa	Literature review *(Peer-reviewed journal publication)*	Gain a better understanding of the effectiveness, mechanisms of intervention effect, and	An analysis of published evidence on DSD implementation showed that patients perceived that DSD lowers treatment costs and

					generalizability, and reach of DSD models.	decreases the amount of time spent in care
20.	**Perspectives** *Patient*	*Hubbard et al, 2020	Malawi *(n= 17 HCWs, 62 ART patients)*	Qualitative study *(Peer-reviewed journal publication)*	Understand client and provider experiences with multi-month dispensing (MMD) of ART.	After semi-structured interviews with 62 stable adult PLWH on ART, participants expressed that 6-month MMD was beneficial due to decreased transportation costs, decreased lost wages, reduction in time spent traveling to the health facility, and less waiting time at the clinic.
21.	**Perspectives** *Patient*	*Prust et al, 2018	Malawi *(n= 30 facilities; 32 HCWs, 216 ART patients)*	Qualitative study *(Peer-reviewed journal publication)*	Understand challenges and successes of DSD implementation; multi-month scripting (MMS), fast track ART refills (FTRs), and community ART groups (CAGs).	After 30 focus groups with 216 ART patients, participants reported reduced travel costs and time spent during clinic appointments. Challenges associated with DSD implementation included drug stockouts.
22.	**Perspectives** *Patient*	*Jere et al., 2018	Malawi	Qualitative study *(Conference proceeding)*	Understand the experiences of health workers and patients of the Fast-Track model after six months of implementation	After 6 focus group discussions with patients, participants perceived the model to decongest the clinic and reduce waiting time to see a provider.
23.	**Perspectives** *Patient*	Mantell et al., 2020	Ethiopia *(n=93)*	Qualitative study *(Conference proceeding)*	Explore why some patients who are eligible for care under an appointment spacing	After convening 12 focus group discussions (6 with participants enrolled and 6 not enrolled in ASM),

					model (ASM) decline enrollment.	participants enrolled in ASM expressed being satisfied with the model. Those not enrolled expressed concerns regarding medication storage, reduced clinic frequency visits, and misunderstandings about the care delivery model.
24.	**Perspectives** *Patient*	Assefa et al., (2018)	Ethiopia (n=6 facilities; 24,657 ART patients)	Mixed-methods study *(Conference proceeding)*	Understand the successes and challenges associated with the implementation of a DSD six-month appointment spacing model (ASM) in Ethiopia at 6 health care facilities.	51% of patients who were eligible for enrollment in the ASM declined to participate. Reasons for declining to participate included fear of inadvertent disclosure due to having a large volume of ART and concerns regarding safety and storage of ART at home.
25.	**Perspectives** *Patient*	*Rabkin et al., (2020)	Zimbabwe (n= 35 HCWs, 54 PLWH	Mixed-methods study *(Peer-reviewed journal publication)*	Understand differentiated antiretroviral treatment model (DART) preferences among patients and HCWs in Zimbabwe.	Out of the 5 DART models implemented, patients preferred health facility-based the fast-track model because it is perceived to offer privacy and efficiency (less frequent appointments and shorter waiting times).
26.	**Perspectives** *Health worker*	*Roy et al., 2019	Sub-Saharan Africa	*Literature review* (Peer-reviewed journal publication)	Gain a better understanding of the effectiveness, mechanisms of	An analysis of published evidence on DSD implementation showed that health workers perceived

					intervention effect, and generalizability, and reach of DSD models.	that DSD leads to a reduction in workload and improved retention in care for patients.
27.	**Perspectives** *Health worker*	*Hubbard et al, 2020	Malawi *(n= 17 HCWs, 62 ART patients)*	Qualitative study *(Peer-reviewed journal publication)*	Understand client and provider experiences with multi-month dispensing (MMD) of 6 months of ART.	After semi-structured interviews with 17 ART providers, participants expressed that MMD led to reduced workload and alleviated clinic congestion.
28.	**Perspectives** *Health worker s*	Phiri et al, 2021	Zambia *(n=18)*	Qualitative study *(Peer-reviewed journal publication)*	Explore Zambian HIV care providers' experiences with multi-month dispensing (3 versus 6-month dispensing)	After 18 in-depth interviews with clinical officers and nurses, the providers expressed a preference for 6-months ART dispensing over 3-months ART dispensing, citing that it was beneficial for both clients and providers because it reduced client burden and led to a reduction in workload and congestion at the clinic.
29.	**Perspectives** *Health worker*	*Prust et al., 2018	Malawi *(n= 30 facilities; 32 HCWs, 216 ART patients)*	Qualitative study *(Peer-reviewed journal publication)*	Understand challenges and successes of DSD implementation; multi-month scripting (MMS), fast track ART refills (FTRs), and community ART groups (CAGs).	After in-depth, semi-structured interviews with 32 health workers, participants reported that DSD models were beneficial in reducing patients' travel and clinic visit time, facility decongestion, and improved adherence and retention.

						Challenges associated with DSD implementation included drug stockouts.
30.	**Perspectives** *Health worker*	*Jere et al., 2018	Malawi	Conference proceeding *(Qualitative study)*	Understand the experiences of health workers and patients of the Fast-Track model after six months of implementation.	After 8 in-depth interviews with health care workers, participants perceived the fast-track model to decongest the clinic and reduce waiting time to see a provider.
31.	**Perspectives** *Health worker*	*Rabkin et al., (2020)	Zimbabwe (n= 35 HCWs, 54 PLWH	Mixed-methods study *(Peer-reviewed journal publication)*	Understand differentiated antiretroviral treatment model (DART) preferences among patients and HCWs in Zimbabwe.	Healthcare workers preferred health-facility based models which they perceived as helpful in decongesting clinics and reducing their workload.

*Denotes a study covered more than one of the categories.

CHAPTER 3: IMPACT OF FACILITY-BASED INDIVIDUAL DIFFERENTIATED SERVICE DELIVERY ON VIRAL SUPPRESSION OF HIV-INFECTED PERSONS IN NAIROBI, KENYA

Abstract

Introduction: The prevalence of HIV infection in sub-Saharan Africa remains disproportionally high. The region also suffers from a chronic shortage of healthcare workers, which makes provision of comprehensive HIV care and treatment challenging. This has warranted exploring strategies to ensure access to HIV care and antiretroviral therapy for viral suppression, a marker of HIV treatment success in persons living with HIV (PLWH). To address the high HIV burden and healthcare workforce shortages experienced in regions such as sub-Saharan Africa, the World Health Organization (WHO) recommends implementation of efficient models such as facility-based individual differentiated service delivery (DSD). Through a mechanism of extending the time between clinical visits which frees up providers to see new and more complex patients, DSD results in increased access to HIV treatment services. There are efforts to scale-up implementation of this HIV service delivery model, as it has the capability of lowering the care burden of the healthcare system. As DSD becomes more common, there is a need to determine how it impacts health outcomes. Out of the four types of DSD, the facility-based model is the least complex to implement and most patient-preferred. This research sought to assess the effect of facility-based individual DSD implementation on viral suppression among individuals already established on antiretroviral therapy. The main research question explores whether there are differences in viral load detection among DSD-eligible patients who chose to enroll in facility-based individual DSD versus those remained in standard HIV care.

Methods: A retrospective study was conducted using data abstracted from electronic medical records at a large antiretroviral treatment center located in Nairobi, Kenya. From the universal population of patients already enrolled in care at the facility, 407 patients met the study inclusion

criteria for the exposure group (i.e., those enrolled in DSD). 1-1 case matching was conducted based on age, gender, year of enrollment, and marital status to create a sample of 407 patients for the control group who were also eligible for DSD but remained in standard HIV care. Descriptive statistics were conducted to gain an understanding of the characteristics of the study sample. Bivariate analysis using McNemar's test was conducted to compare viral load detection (detectable vs. undetectable) between two groups of DSD-eligible patients who were enrolled in either facility-based individual DSD or standard HIV care for at least 1 year.

Results: Of the 814 patients in the study, there were more females than males (58.5% vs. 41.5%). The majority of the patients were between 40-49 (37.3%) and 50-59 (38.3%) years of age. More than half (56.5%) were married. Among those who were eligible and enrolled in DSD, 94.6% were initially undetectable and maintained an undetectable viral load (<200 copies/ml) after 1 year, 3.8% transitioned from detectable to undetectable, 1.5% transitioned from undetectable to detectable, and 0.3% were detectable at both the pre and post visit. We found no significant difference between the pre-enrollment status of DSD patients and their post follow-up period (p= 0.078; McNemar's test). A second McNemar's test examining whether or not there was a difference between DSD and matched controls with regard to post-enrollment viral load detection. This analysis was conducted on 388 eligible matched pairs for whom viral load was initially undetectable. All individuals maintained viral suppression (<1000 copies/mL) according to WHO guidelines at the post visit, with only 6 (1.5%) of the DSD patients versus 3 (0.8%) of the non-DSD patients transitioning to detectable viral load at the post visit (p= 0.508; McNemar's test).

Conclusion: The results indicate that eligible PLWH on long-term therapy who enrolled into facility-based individual DSD had comparable viral suppression outcomes to eligible PLWH who receive standard care.

Keywords: HIV, ART, viral suppression, viral load, antiretroviral therapy, differentiated care, models of care.

Introduction

Viral load is a crucial universal measure of HIV antiretroviral therapy (ART) adherence and response to treatment in people living with HIV (PLWH) (AIDSinfo, 2017). So much so that it is one of the three 90-90-90 targets set in 2014 by United Nations Programme on HIV/AIDS (UNAIDS) to end the AIDS epidemic by 2020. The UNAIDS 90-90-90 targets aim for 90% of all PLWH knowing their HIV status, 90% of diagnosed persons receiving treatment with ART, and 90% of individuals on ART achieving viral suppression (Joint United Nations Programme on HIV/AIDS, 2014; UNAIDS, 2016). Impressive advances in HIV/AIDS research and achievement of these goals have been made globally; however, gaps remain and the ambitious targets were not met in 2020 (UNAIDS, 2020d). In the continued endeavor to fight HIV/AIDS, UNAIDS set higher targets (95-95-95) to fast-track ending the epidemic by 2030 (Joint United Nations Programme on HIV/AIDS, 2020c). Unfortunately, recent data show that only 68% adults and 53% children have access to life-saving ART (Joint United Nations Programme on HIV/AIDS, 2020b), therefore, an even lower proportion are virally suppressed.

According to the 2016 World Health Organization (WHO) *Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection*, viral suppression is defined as <1000 copies/mL (World Health Organization, 2016a). A growing body of evidence confirms that viral suppression is indicative of optimal health in PLWH; thus, it is the goal of treatment in PLWH (AIDSinfo, 2017). Viral suppression is achieved through access to and adherence to ART. Attaining viral suppression is crucial because it improves the health outcomes and quality of life among PLWH (Farnham et al., 2013; Samji et al., 2013) .Viral load, which is a measure for viral suppression is classified as either undetectable (<=200 copies/ml according to Centers for Disease Control and Prevention (CDC) or detectable (>200 copies/ml) (Centers for

Disease Control and Prevention, 2022). Having an undetectable viral load is beneficial not only for achieving optimal health outcomes, but also for prevention of disease transmission. Several studies have demonstrated that having an undetectable viral load also eliminates the risk of transmission of HIV(Centers for Disease Control and Prevention, 2019; Cohen et al., 2016; Cohen et al., 2020; Cohen et al., 2012). The results of these studies prompted the launch of the undetectable equals untransmissible (U=U) campaign, which raises awareness on viral suppression and its role in preventing HIV sexual transmission (Eisinger et al., 2019).

It can, however, be difficult to access HIV treatment and attain viral suppression in the context of population-level high HIV burden and healthcare worker (HCW) shortages. Sub-Saharan Africa, for example, carries the greatest HIV burden, with about two-thirds of all global HIV cases (UNAIDS, 2020c); yet it also suffers one of the greatest health workforce shortages (World Health Organization, 2016b). The double burden of high HIV rates coupled with HCW shortages makes it difficult to access HIV treatment services for newly diagnosed individuals and those already established in care. Therefore, there is a need to explore approaches that will facilitate the expansion of HIV treatment in resource-limited settings with high HIV burden.

These obstacles have prompted development and implementation of more efficient HIV service delivery models which, despite limited resources, still facilitate and ensure access to ART. Facility-based individual differentiated service delivery (DSD) is one such patient-centered approach that is recommended by the WHO. Facility-based individual DSD prolongs the duration between clinical visits for PLWH who are established on ART and virally suppressed, for up to 6 months, versus every 1-3 months in the regular standard package of HIV services. Through this mechanism of prolonging the intervals between clinical visits with a healthcare provider, DSD alleviates crowding in healthcare facilities, which improves quality of

care and allows healthcare workers to focus on complex cases that require more attention (World Health Organization, 2016a). For patients, facility-based individual DSD potentially alleviates care fatigue and other stressors associated with frequent clinic visits e.g., financial costs (transportation) and time (commuting to the clinic and waiting to see a care provider) (Croome et al., 2017; Mukudu et al., 2016).

According to the WHO *Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection recommendations,* clients are defined as established on ART (previously referred to as 'stable') and thus eligible for enrollment in DSD if they meet the following criteria: "received ART for at least one year and have no adverse drug reactions that require regular monitoring, no current illnesses or pregnancy, are not currently breastfeeding and have good understanding of lifelong adherence and evidence of treatment success (i.e. two consecutive viral load measurements below 1000 copies/mL)" (World Health Organization, 2016a).

In an effort to improve HIV service delivery and increase access to ART and HIV care in Kenya, the Kenya Ministry of Health's National AIDS and STI Control Program (NASCOP) rolled-out DSD implementation nationally in 2017. To facilitate implementation, NASCOP developed several resources to serve as guides and to assist with familiarization of DSD. Using the WHO *Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection recommendations* as a framework, NASCOP developed: i) *Differenitated Care: Operational Guide* (National AIDS and STI Control Programme, 2016a) and ii) *Improving the Quality and Efficiency of Health Services in Kenya: A practical Handbook for HIV Managers and Service Providers on Differentiated Care (National AIDS and STI Control Programme,*

2016b). Both of these resources served and continue to serve as a resource for DSD implementation in Kenya.

All four models of DSD have been implemented in Kenya as necessary and they include: i) facility-based fast track system for ART refills, ii) community ART groups for ART refills, iii) facility ART groups, and iv) community ART distribution points. Because majority of HIV service is facility-based (Joint United Nations Programme on HIV/AIDS, 2014), the facilty-based fast track system for ART refills model is the most popular among PLWH and the least complex to implement at the health faciltity level (National AIDS and STI Control Programme, 2016a; Rabkin et al., 2020). Per the Kenya DSD guidelines (National AIDS and STI Control Programme, 2016a), the facility-based fast track for ART refill (also known as facility-based individual DSD) uses the WHO model of prolonging the interval between clinic visits up to 6 months, with an expedited ART refill visit at the midway point (3 months) which includes a quick assessment for continued DSD eligibility by a DSD-trained nurse and/or pharmacist. The Kenya DSD operation guide recommends that PLWH be given the option to enroll in DSD if they meet the eligibility criteria, however, it is not mandatory and DSD-eligible PLWH may opt to remain in standard HIV care even if they qualify for DSD.

While it is hypothesized that fewer clinical visits could alleviate patient burden, thus promoting retention in HIV care and adherence to life saving ART, it can also be argued that less engagement with the health system could lead to decreased adherence to treatment due to infrequent monitoring. Therefore, it is crucial to ensure that more efficient forms of care delivery do not result in negative outcomes. Several studies looking at facility-based individual DSD have been conducted to assess its cost-effectiveness (Babigumira et al., 2011; Prust et al., 2017; Roberts et al., 2019), effect on retention in HIV care and adherence to ART (Mutasa-Apollo et

al., 2017; Obua et al., 2014; Wringe et al., 2018), and patient perspectives regarding the model (Prust et al., 2018; Roy et al., 2019b). However, only a few studies (Bosomprah et al., 2020; Hickey et al., 2020; Sanwo et al., 2021) have examined how DSD models versus the standard package of HIV care impact viral suppression in PLWH. None of the studies have specifically focused on facility-based individual DSD alone. To address this gap, this study investigated the effect of facility-based individual DSD implementation on viral load detection among DSD-eligible patients who opted for the care model compared to those who were eligible but remained in standard HIV care. Our hypothesis was that there would be no difference between the pre-enrollment and at least 1-year post -enrollment viral load detection status in the two patient groups, demonstrating that the two approaches are equivalent. With efforts in place to scale-up DSD (Ehrenkranz et al., 2019), it is essential to gain a comprehensive understanding of how its implementation impacts the health outcomes of PLWH.

Methods

Study setting/ Source of data

In July 2020, patients' clinical and demographic data for this study were obtained from a large antiretroviral treatment center located in Nairobi, the capital and largest city of Kenya. The facility is a U.S. President's Emergency Plan for AIDS Relief (PEPFAR) funded initiative. It provides HIV care and treatment services to over 10,000 men, women, and children. Facility-based individual DSD has been implemented at the HIV care center since August 1, 2017. For this retrospective study, patient data were extracted from an electronic medical record (EMR) system by a staff data manager at the HIV treatment facility. The EMR data is intended to be used for clinical decision-making by healthcare providers during clinical visits, quality

improvement, and other approved programmatic monitoring and evaluation activities as required by facility leadership, Kenya Ministry of Health, and funders. Reports generated from these data facilitate the development of approaches to improve HIV service delivery and health outcomes in the facility and in Kenya. The data manager at the facility provided the abstracted records to the study team as de-identified data.

Study design and participants

This is a 2.5-year retrospective cohort design study of all DSD-eligible patients enrolled in the DSD model of care and 1:1 matched DSD-eligible patients who remained in standard HIV care. Subjects for this study included all facility-based DSD-eligible adult (18 years and older) patients who were enrolled in HIV care at the facility for a minimum of 12 months, who received HIV care at the study facility between December 1, 2017 (5 months post-commencement of DSD implementation) and July 31, 2020 (approximately 3 years post-DSD implementation), and who had at least 2 records of viral load data >=12 months apart during the study period. Exclusion criteria were patients with records missing data pertinent to this study, including viral load, date viral load was recorded, gender, age, years enrolled in care, and records with inaccurate (such as an improbable viral load value) or inconsistent data (such as a remarkably different value from previously recorded viral load values). To obtain all the desired variables, 9 individual datasets that were part of the EMR, were merged.

Variables and Definitions

According to the WHO definition, successful HIV treatment is defined as viral suppression (viral load <1000 copies/ml) and this cut off is also used to define DSD eligibility

(World Health Organization, 2016a). However, the current goal of treatment and non-transmissibility is undetectable viral load defined as <200 copies/ml; thus, the outcome variable used for this study was viral detection status maintained at the end of the study period. Follow up viral load measurements were performed at 12 months up to 3 years post-enrollment.

Statistical Analysis

Descriptive statistics were used to summarize key demographic and clinical variables across the patient sample of 814 (407 exposure/DSD and 407 matched controls) used for this study. Further analysis was then conducted via McNemar's test for paired binary data to examine transitions from detectable to undetectable viral load (and vice versa) during the follow up period, separately for DSD and the non-DSD patient groups. McNemar's test was also used to determine whether there was a statistically significant difference in viral load detection at the post (after at least 1 year of enrollment) visit among subjects who were enrolled in facility-based individual DSD, versus pair-matched subjects who were not enrolled and continued to receive the standard HIV care package. All statistical analyses were performed using SPSS software (version 28).

Human Subjects Consideration

The Emory University Institutional Review Board (IRB) in Atlanta, GA and The Aga Khan University IRB approved exempt status for the study and protocol numbers were assigned (Emory: STUDY00000050 & Aga Khan: IERC-125). Approval to conduct research in Kenya was obtained from the Kenya National Commission for Science, Technology, and Innovation (NACOSTI) and from the study site. Approval to use the de-identified data was obtained from

facility leadership and data were abstracted and stripped of identifiers by hospital informatics staff. Confidentiality of data was maintained at all times by ensuring that the EMR data extracted for the study did not have any personally identified information present in the analysis data set. All extracted data for the final dataset was encrypted and stored in password protected files on institutionally maintained servers with limited access to the study team only.

Results

Of the 11,204 total adult patients with records in the EMR, 4,997 (44.6%) were enrolled in DSD at the time the data was abstracted from the EMR and 6,207 (55.4%) remained in standard care. Among the 4,497 patients enrolled in DSD, 407 (9.05%) met the previously described study eligibility criteria for the exposure group (DSD). Most importantly, they should have been enrolled in the DSD care delivery model for a minimum of 12 months and have a minimum of 2 records of viral load data recorded during pre-enrollment into DSD and >= 12 months apart during the study period. For the control group (standard care), 1-1 case matching was conducted based on age (+/- 5 years), gender, year of initial enrollment in care at the facility (+/- 12 months), and marital status to create a sample of 407 patients for a total study population of 814 patients.

While the study subjects included in our study were adequate for analysis, it is important to note that out of the 4,997 patients who were enrolled in DSD at the time the data was abstracted from the EMR, only 407 (9.05%) met the study inclusion criteria. This low proportion of eligibility could be attributed to a significant change in the Kenya HIV treatment optimization guidelines, which prompted an alteration in the prescribed ART regimen for some patients. The updated guidelines resulted in a major reduction in the number of patients who were enrolled in

DSD. This reduction was primarily due to the fact that previously enrolled DSD patients were considered to be ineligible to remain in the care model until their response to the newly prescribed regimen was monitored closely and deemed to be appropriate by a healthcare provider before re-entry into DSD. Therefore, in our dataset, a large number of DSD patients were not enrolled in the model of care for at least 12 months during the study period, thus not eligible for inclusion in the study.

Characteristics of the Study Population

Table 1 presents the demographic and descriptive characteristics of study subjects. Due to matching criteria for the two groups, there were no differences between DSD-enrolled patients and standard care patients for age, number of years enrolled in treatment, gender, and marital status variables. DSD-enrolled patients were more likely to be female [238 (58.5%)] vs male [169 (41.5%)]. The mean age was 39.94 years for subjects enrolled in DSD and 40.2 years for those enrolled in standard care. The majority of subjects were in the 40-49 years and 50-59 years age groups, accounting for 37.3% and 38.3% of the total sample respectively. Most (56.5%) of the participants were married for both study groups. The mean number of years since the time of HIV diagnosis was 9.87 years for the DSD group and 9.27 years for the standard care group. For both groups, patients were enrolled in HIV care at the treatment center for a similar time period (9.64 years for the DSD patients and 9.65 years for the standard care group).

Table 2 presents a summary of the clinical characteristics of subjects in the two study groups. The clinical characteristics of patients in the two groups were fairly similar. Most were staged to be in either stage 1 or 2 of the WHO HIV disease classification. Majority had disclosed their HIV status to their partners; 245 (60.5%) in the DSD group and 244 (60.2%) in the standard

care group. Most were also on a first line regimen for ART (88.4% and 88.7% for the DSD and standard care groups respectively.

Table 1. Demographic and descriptive characteristics of subjects in the two study groups.

Characteristics	Enrolled in DSD (*n*=407)		Enrolled in Standard Care (*n*=407)	
	N	%	N	%
*Gender				
Male	169	41.5%	169	41.5%
Female	238	58.5%	238	58.5%
*Age				
20-29	3	0.7%	5	1.2%
30-39	42	10.3%	40	9.8%
40-49	156	38.3%	152	37.3%
50-59	157	38.6%	156	38.3%
60-69	41	10.1%	48	11.8%
70-79	8	2.0%	6	1.5%
*Marital status				
Married	230	56.5%	230	56.5%
Cohabiting	2	0.5%	2	0.5%
Divorce/separated	46	11.3%	46	11.3%
Widowed	54	13.3%	54	13.3%
Single	72	17.7%	72	17.7%
Unmarried with a child	3	0.7%	3	0.7%
Mean age (at enrollment in HIV care at facility)	39.94 (std. deviation 8.76)	-	40.2 (std. deviation 8.96)	-
Mean age (at time of study)	50.15 (std. deviation 8.55)	-	50.42 (std. deviation 8.79)	-
Mean #. of years enrolled in HIV care at facility	9.64 (std. deviation 3.65)	-	9.65 (std. deviation 3.64)	-
Mean # of years since HIV diagnosis	9.87 (std. deviation 4.3)	-	9.27 (std. deviation 3.97)	-
Currently sexually active	229	56.3%	224	55.0%
Uses condoms	273	88.9%	265	84.4%

* Indicates a variable used in the 1-1 case matching.

Table 2. Clinical characteristics of subjects in the two study groups.

Characteristics	Enrolled in DSD (*n*=407)		Enrolled in Standard Care (*n*=407)	
	N	%	N	%
WHO HIV disease stage				
Stage 1	150	37.2%	137	33.7%
Stage 2	123	30.5%	131	32.3%
Stage 3	111	27.5%	115	28.3%
Stage 4	19	4.7%	23	5.7%
Missing (not recorded in EMR)	4	1.0%	1	0.2%
HIV Disclosure status to partner				
Disclosed to partner	245	60.5%	244	60.2%
Not disclosed to partner	7	1.7%	4	1.0%
Has no partner	153	37.8%	157	38.8%
Missing (not recorded in EMR)	2	0.5%	2	0.5%
Partner testing status				
Partner tested	232	57.3%	230	56.8%
Partner not tested	20	4.9%	17	4.2%
Has no partner	153	37.8%	158	39.0%
Missing (not recorded in EMR)	2	0.5%	2	0.5%
Family planning				
Yes	126	31.0%	103	25.3%
No	69	17.0%	90	22.1%
Missing (not recorded in EMR)	212	52%	214	52.6%
Tuberculosis (TB) screening result				
Presumed TB (positive tuberculin skin test)	43	10.6%	25	6.1%
Negative TB screening	350	86.0%	374	91.9%
Missing (not recorded in EMR)	14	3.4%	8	2.0%
ART line of regimen*				
1st line	357	88.4%	360	88.7%
1st line alternative	5	1.2%	3	0.7%
2nd line	41	10.1%	41	10.1%
2nd line alternative	1	0.2%	1	0.2%
3rd line	0	0%	1	0.2%
Missing (not recorded in EMR)	3	0.7%	1	0.2%

*ART line of regimen refers to the ART regimen that the patient is currently on. First-line is the initial treatment. Second-line treatment is used if the initial treatment fails or is not tolerated by the patient. Third-line is used when the initial and second lines of treatment fail or stop working.

Analysis of Viral Load Detection Status

Table 3 presents data underlying the results of McNemar's test conducted to assess the difference in pre vs post enrollment viral load detection status (<200 copies/ml) among patients in the DSD group. Of the 407 DSD-enrolled patients, 1 (0.2%) patient had a detectable viral load (>200 copies/mL) during DSD pre-enrollment and remained detectable after a year of enrollment in DSD. In the same group, there were 15 (3.7%) patients who had detectable viral loads between 200 and 1000 copies/ml during pre-enrollment but converted to an undetectable viral load during the study period. There were 385 (94.6%) DSD patients who maintained their undetectable viral load detection status after being enrolled in DSD. However, 6 (1.5%) patients who started off as undetectable converted to detectable status. We note that the transitions from detectable to undetectable were more common than those from undetectable to detectable (15 vs. 6), although this trend was not statistically significant (p= 0.078; McNemar's test).

Table 3. McNemar's Pre-Post Viral Load Detection Results for Patients Enrolled in DSD.

				Viral load detection (post)		
				Detectable	Not Detectable	Total
	Viral load detection (pre)	Detectable	Count (%)	1 (0.2%)	15 (3.7%)	16 (3.9%)
		Not Detectable	Count (%)	6 (1.5%)	385 (94.6%)	391 (96.1%)
	Total		Count (%)	7 (1.7%)	400 (98.3%)	407 (100%)

Note. The p-value = 0.078 (not statistically significant at the p<0.05 level)

Among DSD-eligible patients who were enrolled in the standard package of HIV care, there were no patients who had a detectable viral load during DSD pre-enrollment who remained detectable after a year of enrollment in DSD. In the same group, there were 3 (0.7%) patients who had a detectable viral load during pre-enrollment but converted to undetectable viral load. There were 401 (98.5%) patients who maintained their undetectable viral load detection status

after being enrolled in DSD. However, 3 (0.7%) patients who started off as undetectable converted to detectable status. Among this non-DSD control group, there was no significant difference in pre-post viral load detection status (p=1; McNemar's test). See Table 4.

Table 4. McNemar's Pre-Post Viral Load Detection Results for Patients Enrolled in Standard HIV Care

				Viral load detection (post)		
				Detectable	Not Detectable	Total
	Viral load detection (pre)	Detectable	Count (%)	0 (0.0%)	3 (0.7%)	3 (0.7%)
		Not Detectable	Count (%)	3 (0.7%)	401 (98.5%)	404 (99.3%)
	Total		Count (%)	3(0.7%)	404 (99.3%)	407 (100%)

Note. The p-value = 1(not statistically significant at the p<0.05 level)

It is important to note that although a small proportion of patients converted from detectable to undetectable and vice versa, all DSD-enrolled patients, as well as their 1-1 matched non-DSD counterparts remained virally suppressed as defined by WHO at <1000 copies/ml during the study period and did not lose their eligibility to be enrolled or remain enrolled in DSD.

Table 5 presents the data underlying a McNemar's test conducted to compare viral load detection status at the end of the study period (post) for DSD versus non-DSD standard care patients., accounting for the matching. This test examines whether there was a tendency toward more discordant matched pairs where it is the DSD member who was more likely to have transitioned from undetectable to detectable post viral load vs the control member. Patients who had a detectable viral load during the pre-enrollment period were filtered out (16 DSD and 3 controls (tables 3 and 4). Thus, for this analysis we focused on those patients and controls who

were undetectable pre-enrollment to examine transitions to detectable viral load during the study. This analysis then also required that all individual cases that did not have a match due to dropping the pre-enrollment detectable viral load cases were also filtered out of the analysis. This resulted in the removal of 19 matched pairs, leaving 388 matched pairs (776 individual patients, all initially non-detectable) for analysis. Table 5 indicates that out of the 388 matched pairs, 379 (97.7%) pairs had an undetectable viral load for both members (DSD and non-DSD) in the post enrollment period. Only 6 (1.5%) of the DSD patients were detectable at the post visit, compared to only 3 (0.8%) of the matched non-DSD members (p=0.508; McNemar's test). Thus, detectable viral load was very uncommon in both groups, and there was no trend toward a significant difference with regard to post-enrollment viral load detection among DSD enrolled patients and their matched non-DSD counterparts.

Table 5. McNemar's Matched Pairs Viral Load Status Results at Post-Visit for DSD and Non-DSD Patients.

				Viral Load Detection (post)		
				Non-DSD member of matched pair		
				Detectable	Not Detectable	Total
DSD member of matched pair	Viral Load Detection (post)	Detectable	Count (%)	0 (0.0%)	6 (1.5%)	6 (1.5%)
		Not Detectable	Count (%)	3(0.8%)	379 (97.7%)	382 (98.5%)
		Total	Count (%)	3 (0.8%)	385 (99.2%)	388 (100%)

Note. The p-value = 0.588 (not statistically significant at the p<0.05 level)

Discussion

Our study found that both DSD and standard care controls maintained viral suppression per WHO's definition (<1000 copies/ml) for at least 12 months during the follow-up period. In

addition, we found no statistically significant difference when comparing DSD patients who converted from undetectable to detectable viral load vs their matched pair control. Our findings indicate that spacing out of clinical visits does not result in increased viral load detection during follow up in this group of patients who have been in long term treatment. Despite concerns that patients enrolled in facility-based individual DSD could result in treatment default due to lack of contact with the health system, the study results indicate that those fears may be unfounded for those who chose to enroll in DSD for patient populations similar to ours.

These findings are consistent with the results of the few previously conducted studies, which examined how DSD models versus the standard package of HIV care impact viral suppression in PLWH (Bosomprah et al., 2020; Hickey et al., 2020; Sanwo et al., 2021). These studies demonstrated that DSD models are effective in maintaining viral suppression. However, unlike our study, these studies didn't specifically focus on the facility-based individual DSD model only; in some cases they examined other DSD and included additional patient engagement strategies. The Hickey et al (2020) study also included patients who were not established on ART (described as ART-naïve), thus, not eligible for differentiated care per the WHO DSD guidelines.

Findings from this study in one clinic in Kenya illustrates the potential for healthcare providers to transition eligible and willing patients to the DSD care delivery model. This has the potential to alleviate patient and health worker burden and increase access to HIV treatment for patients who have difficulty accessing overburdened, under-resourced health systems.

Limitations and Strengths

While the findings are reassuring, the study is not without limitations. The findings are limited to patient data from one single health system, thus limiting the generalizability of the study results to other settings. Additionally, this was a retrospective study, therefore the opportunity to customize the data was not an option. In our study, patient enrollment in DSD was voluntary (not random assignment) and utilized available data. It was not possible to determine the exact reason eligible patients were not enrolled including whether or not patients who did not enroll in DSD were offered the opportunity to enroll. Future prospective studies should be designed to ensure that all eligible patients are offered DSD enrollment, and for those who decline, data should be collected on reasons for declining. We also did not have access to data on other factors that might have influenced decisions to enroll in DSD such as travel time to the health facility for patients or the exact number of provider visits. Providing estimates on the cost-effectiveness of DSD would also be helpful in further understanding the benefit of the DSD model.

Finally, a study bias to consider is that the patients included in this study had been in long-term treatment. In our study population, DSD-enrolled patients had been in HIV care and receiving treatment for a mean of almost 10 years. WHO only requires 12 months on treatment with viral loads <1000 copies/mL for DSD eligibility. Thus, our data may not be generalizable to patients who have not been in more long-term treatment. Our study also only included those DSD patients who remained in follow-up care. We were not able to examine possible differences in lost to follow-up between care models.

Despite these limitations, this study has several important strengths. The data was obtained from a large health system that provides HIV care to about 10,000 patients, and we

were able to sample a large study population for the study. This study is unique in that it is one of few to explore viral load detection outcomes in patients after continuous enrollment in facility-based individual DSD for patients who have been established in care for years and virally suppressed.

Conclusion

In our study population findings demonstrate that facility-based individual DSD is an effective care delivery model and did not result in an increased percentage of DSD patients reverting to detectable viral load when compared to those who remained in standard care. These findings support the agenda to implement and scale up facility based-individual DSD to increase access to HIV treatment services in contexts with high HIV burden and health workforce shortages.

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CHAPTER 4: USING RE-AIM TO EXAMINE HEALTHCARE WORKERS' PERSPECTIVES OF FACILITY-BASED INDIVIDUAL DIFFERENTIATED SERVICE DELIVERY IN NAIROBI, KENYA

Abstract

Background: Sub-Saharan Africa suffers from disproportionally high rates of HIV and chronic healthcare workforce shortages. Facility-based individual differentiated service delivery (DSD) is a model of care recommended by the World Health Organization to address challenges associated with access to antiretroviral therapy in regions with high HIV burden and limited resources. Because DSD is both more feasible and efficient than traditional HIV services, countries in the region are developing plans for scale-up. However, much remains unknown about this model from the perspectives of those who implement it. The purpose of this study was therefore to understand healthcare workers' perceptions of and experiences with DSD, ultimately to identify opportunities to improve it.

Methods: A qualitative research study was conducted at a large HIV treatment facility in Nairobi, Kenya. A total of 30 in-depth interviews were conducted with healthcare workers. Interview questions focused on the 5 dimensions of the RE-AIM evaluation framework: reach, efficacy, adoption, implementation, and maintenance of facility-based individual DSD. Interview transcripts were evaluated using a content analysis approach, which involved code identification, cross-code comparison, code abstraction, and theme development.

Results: Medical staff (n=10), allied health (n=9), administrative staff (n=7), and community health workers (n=4) were interviewed. Among the healthcare workers, the perceived benefits of this model of care outweighed the challenges. Participants largely favored implementation of facility-based individual DSD because of its ability to reduce patient volume and workload, which enabled them to provide higher quality of care. Perceived patient benefits (from the

healthcare worker perspective) included reduced costs, less time spent commuting to the clinic and waiting to see a provider, improved medication adherence and retention in care, and decreased HIV stigma. Challenges that participants described centered around concerns regarding inadequate DSD education (for both patients and care providers), discontinuation in care, medication supply disruption, and fear of losing their jobs. Potential strategies to address these challenges involved additional and targeted DSD education for staff, patient follow-up to prevent discontinuation in care, ensuring adequate medication supply, and DSD sensitization for patients.

Conclusion: Facility-based individual DSD is a promising approach in this context because it addresses challenges associated with healthcare workforce shortages and yields favorable outcomes for patients. Opportunities to improve the care model should be explored further and implemented.

Keywords: HIV, ART, PLWH, antiretroviral therapy, models of care, health workers, human resources for health, qualitative research, sub-Saharan Africa

Introduction

The global scale-up of antiretroviral therapy (ART) for HIV treatment over the past three decades has been moderately successful in treating HIV, ensuring effective pre-exposure prophylaxis (PrEP) for HIV prevention, and prevention of mother-to-child transmission of HIV (PMTCT). However, per the United Nations Programme on HIV/AIDS (UNAIDS) 90-90-90 targets, this effort continues to lag in the fight to end the AIDS epidemic. Out of the estimated 38.0 million people living with HIV (PLWH) globally, only 68% adults (15 years or older) and 53% children (0-14 years) have access to life-saving ART (Joint United Nations Programme on HIV/AIDS, 2020b). These numbers fall significantly below the UNAIDS targets, which aim to have 90% of all PLWH know their HIV status, 90% of diagnosed persons receiving treatment with antiretroviral therapy (ART), and 90% of individuals on ART achieving viral suppression (UNAIDS, 2016). A growing body of evidence confirms that high levels of ART adherence is key to achieving and maintaining viral suppression, which reduces HIV-related morbidity and mortality for PLWH (Hogg et al., 1998; Palella et al., 1998; Staszewski et al., 1999). In addition to health benefits for PLWH, several studies have demonstrated that viral suppression with ART prevents sexual transmission of HIV (Cohen et al., 2016; Cohen et al., 2020; Cohen et al., 2012). These results prompted the launch of the undetectable equals untransmissible (U=U) campaign, which raises awareness about preventing HIV sexual transmission (Eisinger et al., 2019).

HIV treatment and prevention interventions are particularly crucial in sub-Saharan Africa, which carries a disproportionate proportion of the global HIV burden and HIV/AIDS remains a leading cause of death in the region (Collaborators, 2018). The majority of all new HIV infections and about two-thirds of all HIV cases are in sub-Saharan Africa(UNAIDS, 2020c) . In addition to carrying most of the global HIV burden, this region also confronts a

chronic shortage of health care workers (HCWs). Per the World Health Organization's (WHO) recommendation, a minimum workforce density index of 4.45 doctors, nurses, and midwives per 1,000 population is necessary for the delivery of essential health services; however, Sub-Saharan Africa operates significantly below this threshold, with a shortage of 4.2 million HCWs in 2013(World Health Organization, 2016b). Unlike other regions which are predicted to experience an improvement in the needs-based shortage of HCWs, the situation is expected to worsen in much of the region, where the shortage of health professionals is predicted to increase to 6.1 million (World Health Organization, 2016b).

The HIV burden coupled with the critical HCW shortage in sub-Saharan Africa limits access to life-saving ART, which is essential for HIV care and treatment and achieving viral suppression. To achieve viral suppression, it is recommended that PLWH maintain high adherence and remain fully engaged in care (Cohen et al., 2011; Giordano et al., 2003; Sethi et al., 2003). Depending on the country's HIV treatment guidelines and the HCW's clinical judgment, PLWH are advised to attend primary care HIV clinic appointments regularly; typically, between every 1-3 months(Bemelmans et al., 2014; McGuire, 2016). This high level of engagement may be challenging for most patients in Africa due to the high HIV disease burden and HCW shortages. Additionally, engagement in care is challenging due to factors such as poverty, transportation challenges and expenses, distance and access to health facilities, stigma and discrimination, food insecurity, and competing priorities (Croome et al., 2017; Kagee et al., 2011; Mesic et al., 2019; Rachlis et al., 2016).

To address the above-described challenges, WHO updated the HIV treatment guidelines to recommend evidence-based approaches that attain high ART adherence and retention in HIV care by implementing longer durations between clinical visits while still achieving optimal

outcomes. In the *Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection*, WHO recommends less frequent clinical visits (3-6 months) and medication pick-ups (3-6 months) for patients established on ART (World Health Organization, 2016a). This approach aligns with the practices of a service delivery model that WHO is recommending for implementation in the context of high HIV burden and limited resources including HCW shortages. The new model, titled "facility-based individual differentiated service delivery" (DSD), is a patient-centered approach to delivering HIV care and treatment services.

DSD extends the interval between clinical visits for stable PLWH up to 6 months versus the standard 1-3 months, and is based on WHO recommendations (World Health Organization, 2016a). The model allows patients to receive an ART prescription for half the duration of the interval between clinical visits, requiring patients to utilize fast-track ART refill where a quick assessment is conducted by a HCW, often a nurse and/or pharmacist. The ART refill appointments are expedited and take significantly less time than clinical provider visits (Prust et al., 2017). This approach alleviates the patient burden associated with multiple clinical visits such as financial costs associated with frequent travel to the clinic, income loss, and long wait times (Alamo et al., 2013; Prust et al., 2017). It is also believed to relieve workforce burden and fatigue associated with high patient volumes in healthcare facilities (Hubbard et al., 2020; Rabkin et al., 2020). Implementing DSD decongests health care facilities, thus, freeing-up healthcare providers' time to focus on more complex patients (World Health Organization, 2016a). DSD implementation could also allow healthcare systems to enroll more new patients, expanding the treatment capacity and providing greater access.

As potentially beneficial as this model may be, the introduction of any new approach or intervention should incorporate perspectives of all parties receiving and providing care. Patient

perspectives regarding longer intervals between clinic visits and ART refills have been fairly well-documented (Adjetey et al., 2019; Keene et al., 2020; Prust et al., 2018); however, there is a lack of evidence specifically describing HCWs' perspectives of facility-based individual DSD as it is formally defined by the WHO. As such, we expanded our review of evidence to include studies that explored HCWs perceptions and experiences with HIV care models that include characteristics of DSD; e.g. multi-month scripting and fast-track refills (Adjetey et al., 2019; Hagey et al., 2018; Hubbard et al., 2020; Phiri et al., 2021; Prust et al., 2018; Rabkin et al., 2020). The findings of these studies are consistent with the benefits of the fast-track ART refill approach described previously as well as challenges such as patient fears of stigma, inadvertent disclosure of HIV status, and drug stock-outs. However, none of the available studies occurred in East Africa and none explored opportunities for improvement. With national scale-up of DSD being on the current agenda in much of East Africa (Ehrenkranz et al., 2019); it is critically important to seek the perspectives of the people providing this service so as to strengthen its delivery.

The purpose of this study was therefore to explore HCWs' perspectives and experiences of DSD, including the factors that influence its implementation as well as potential opportunities for improvement. The RE-AIM model for planning and evaluation of health programs (Glasgow et al., 1999) was used to guide this research overall. The RE-AIM framework is a useful tool in implementation science, and it can be used to "understand complex situations and results, why and how outcomes were obtained, and contextual factors not easily assessed using quantitative measures"(Holtrop et al., 2018). The RE-AIM model focuses on 5 dimensions, including reach, efficacy, adoption, implementation, and maintenance (Glasgow et al., 1999). As will be

described further in the following section, each dimension was evaluated to gain a better understanding of DSD implementation and how to improve the care delivery model.

Methods

Study Setting

The study was conducted at one of the largest single-site antiretroviral treatment facilities in Nairobi, Kenya. The facility was established in 2004 after receiving funding from the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) initiative to provide comprehensive HIV/AIDS care and treatment services. It provides care to almost 10,000 men, women, and children, approximately 90% of whom are adults. The facility has been implementing DSD since August 1, 2017, when DSD was rolled-out nationally by the Kenya Ministry of Health. Per the Kenya DSD country guidelines, DSD-eligible PLWH meeting the pre-established eligibility criteria listed in the operational guide(National AIDS and STI Control Programme, 2016a) have the option to reduce the number of clinical visits and extend the duration between ART refills. Unlike the standard HIV package of care that requires clinical visits every 3 months, DSD requires clinical visits every 6 months and in some cases up to 1 year. DSD is offered on an opt-in basis, therefore, despite meeting eligibility criteria, it is not mandatory that a patient enroll. However, the healthcare providers encourage all eligible patients to join the DSD care delivery model.

Participants

The study population included health administrators, staff, and health personnel working at the study site. Inclusion criteria included HCWs who were involved in DSD, able and willing

to participate in individual interviews, worked at the facility for a minimum of 6 months, and able to speak and understand English or Swahili. Individuals unable to schedule a time to participate in individual interviews were excluded. Purposive sampling was used to select participants who were grouped into 4 categories by cadre/primary role: medical staff (doctors, clinical officers, nurses, and pharmacists), allied health (social workers, counselors, nutritionists), administrative staff (facility leadership, monitoring and evaluation staff, financial officers, receptionists), and community health workers, peer mentors, mentor mothers). To recruit participants, the facility director and heads of departments were requested to share the study information with staff using an IRB-approved flyer, and direct interested participants to the study team. Interested participants were then screened for eligibility and if they met the criteria, they were verbally consented. Enrollment continued until there were adequate representatives (at least 2) from each of the cadres listed above.

Data Collection

Interviews were conducted in June of 2020. An open-ended interview guide was used during semi-structured individual interviews. The RE-AIM framework(Glasgow et al., 1999) was used to structure the interview questions around reach, efficacy, adoption, implementation, and maintenance of DSD. See Table 1 for example questions. Participants were also asked to provide suggestions on how to improve the model and its implementation. Participants were offered a choice of conducting the interview in English or Swahili, and all elected to proceed in English. Interviews occurred in a private office space at the facility during a time that was convenient for the participant and each interviews took approximately 1 hour. Participants received KSH 1000 (approx. USD $10) for their time. The interviews were digitally audio-recorded and transcribed verbatim by a professional transcription service. All personally

identifying information (PII) was removed from the audio-recordings, transcripts, and analyzed data. All study-related data was imported into a designated password-protected and HIPAA-compliant server accessible only to the study team.

Table 1. RE-AIM Interview Guide

RE-AIM Dimension	Example questions (probes not included)
Reach	• What do you think are some of the factors that contribute to the participation of DSD-eligible patients at the [healthcare facility] • What might have been done to get more DSD-eligible patients to participate/opt-in to differentiated service delivery
Effectiveness	• Did the implementation of DSD as an intervention work to effect outcomes noted?
Adoption	• What factors contributed to the [healthcare facility] and its individuals taking up the intervention [DSD]?
Implementation	• How is DSD implemented at the [healthcare facility]?
Maintenance	• What components of the differentiated care program have changed/adapted since implementation?

Data Analysis

A content analysis approach as described by Hsieh and Shannon (Hsieh & Shannon, 2005) was used for this study. In preparation for analysis, transcripts were uploaded to and organized in the NVivo software (version 12) (QSR International Pty Ltd, 2020). An iterative process, which included informal data analysis (reviewing interview notes and listening to recorded audio) was conducted during the interviewing process to detect data saturation. The initial step of formal data analysis (once all interviews had been conducted) consisted of reading and re-reading all transcripts to achieve immersion. The next step involved assigning rough codes to the text by highlighting and labeling all concepts that appeared to be related to the

research questions (either directly or indirectly); i.e., HCWs' perceptions of and experiences with DSD. At the same time, memos were created to help develop working theory as well as account for researcher bias (reflexivity) and to keep track of analytic decision making. Codes were then compared and refined before being abstracted into broader categories based on apparent relationships to the 5 RE-AIM concepts. Finally, the most salient categories identified were developed into meaningful themes and detailed descriptions were written.

Human Subjects Consideration

The Emory University Institutional Review Board (IRB) and the Aga Khan University IRB approved expedited review status for the study, and protocol numbers were assigned (Emory: STUDY00000050 & Aga Khan: IERC-125). Approval to conduct research in Kenya was obtained from the National Commission for Science, Technology, and Innovation (NACOSTI) and from the study site. After a full explanation of the study purpose and procedures, verbal consent to participate was obtained from all participants enrolled in the study (waiver of written/signed consent was approved by the IRBs).

Results

A total of 30 participants (12 male and 18 female) were interviewed. All the potential participants invited agreed to take part in an interview and all consented to be audio recorded. Study participants represented the following cadres: medical staff (*n*=10), allied health (*n*=9), administrative staff (*n*=7), and community health workers (*n*=4). A more detailed description of the sample is not provided in order to protect participants' identities. The findings presented in this section are organized into two broad categories; the first category describes specific themes

involving perceived benefits and challenges of DSD as they relate to each of the 5 RE-AIM concepts (reach, efficacy, adoption, implementation, maintenance)- see Table 2 for a summary of results. The second category describes participants' ideas regarding how to strengthen DSD delivery.

Reach

For this study, "reach" pertained to whether the targeted population (DSD-eligible patients) enrolled in DSD. To assess this component of the model, we therefore explored various factors that the participants believed influences this enrollment. Participants noted several benefits that would facilitate reach by encouraging patients to enroll (if DSD-eligible) or motivate patients who are not eligible to be more engaged in their care and become eligible to join and reap the perceived benefits. Perceived patient benefits (from a HCW lens) that would facilitate reach included improved ART adherence and retention in care, cost savings (for the patient), and reduced stigma. Although enrollment in DSD is appealing to most patients, some HCWs shared factors that could discourage patients from enrolling in DSD; thus, hindering reach. Challenges identified included difficulty storing large amounts of ART/non-disclosure and reassurance of seeing a healthcare provider frequently.

Effectiveness

Effectiveness was assessed by exploring whether DSD implementation was perceived as successful by HCWs at the facility. Success was measured both in terms of organizational and individual successes. The consensus among the HCWs who were interviewed was that DSD was a success. Some of the measures of success described by HCWs included reduced clinic

crowding, meeting donor/funder targets, fewer missed appointments for patients, and improved adherence and viral suppression. Improved adherence and retention are benefits for both HCWs/the health system and for patients. As a grant-funded infectious disease center, it is beneficial for the health facility to report favorable indicators and demonstrate cost savings because having good adherence and retention rates promotes sustainability of grant funded HIV programs. HCWs interviewed also identified challenges that they perceived to hinder the effectiveness of DSD implementation. A major factor included lack of adequate in-service education for staff

Adoption

Adoption was assessed by seeking to understand the process and factors that influenced adoption of DSD. Reduced workload and providing improved quality of care were identified by HCWs as benefits that facilitated the adoption of DSD. Participants shared that most of the HCWs embraced implementation of DSD due to the perceived benefits (for HCWs and patients). However, there were some who viewed it as a setback. HCW perceived challenges that are linked to the adoption of DSD included fear of job loss, fear of care discontinuation, and inadequate DSD education for patients.

Implementation

Implementation was assessed by looking at the extent to which DSD was implemented as intended and factors that influenced the process. Participants noted that in addition to having the WHO and country DSD guidelines as a resource, having opportunities for continuous medical education (CME) and access to internal standard operating procedures (SOPs) at the facility was

beneficial for implementation. HCW perceived challenges that are linked to DSD implementation included countrywide changes in treatment optimization guidelines from the Ministry of Health and drug stock-outs.

Maintenance

Maintenance was assessed by examining the extent to which DSD was sustained over time. We asked what elements of the program have changed or been adapted since program implementation. HCWs stated that they view DSD as beneficial for patients and HCWs and hope that implementation will be sustained especially after the recommended improvements (below) are made. One major change that has taken place was the amount of medication dispensed- from a 3-month supply to a 6-month supply.

Table 2: Results by RE-AIM Dimension

RE-AIM Dimension	Themes	
Reach	**Benefits/Opportunities**	**Challenges/Fears**
	• ***Improved ART Adherence and Retention in Care*** HCWs recognized that DSD results in improved ART adherence (as evidenced by improved viral load suppression) for patients already enrolled in DSD and those who would like to enroll due to the perceived benefits. Participants shared that those patients who are already enrolled are less likely to miss appointments because they have fewer visits to attend. Additionally, they are likely to maintain good ART adherence because they do not want to lose their DSD privileges: *"Clients know, if my adherence is poor, I'll be forced to come back maybe monthly, I'll be given monthly appointments or three-monthly appointments". But, when their adherence is enhanced, that is indicated by a low viral load…it means they're doing well. So, when they get such motivations, like when I go to the lab and my results are good, I'll get six months…that is a motivation for good adherence."* (Nurse)	• ***Medication Storage/Non-Disclosure*** HCWs shared that among patients who have not disclosed their HIV status to partners or family members, enrolling in DSD would be a challenge due to the large amounts of medications that are dispensed. Rather than deal with where to store the medications to avoid disclosure of their HIV status, some patients opt to not enroll in DSD and instead attend more appointments and receive less medication. *"The ones who opt out are fewer, and it's because of confidentiality, disclosure – people who have not disclosed. So, they'll always ask you, "Why would I carry all these tins? I don't have anywhere to keep them." So, they find it a burden carrying the tins to their houses."* (Nurse)
	• ***Reduced Financial Costs*** All participants identified cost-savings associated with HIV care and treatment as a motivation for patients to enroll in facility-based individual DSD. Such costs may include transportation to the facility and accommodation costs for those residing out of the county, and country:	• ***Reassurance from Provider*** Participants stated that few DSD-eligible patients opt not to enroll into the care delivery model; however, for the few who choose to opt out, the psychological satisfaction of seeing their healthcare provide is a major contributing factor. Study participants stated

	"Sometimes, also, the patients that we serve come from outside Nairobi, and they have to cover a bit of a distance coming to the facility. And that costs money. And so, financial reasons are part of the reason that they would want to get into differentiated care, just to save the coin." (Clinical Officer) A reduction in the amount of time patients spend either commuting to the facility every 6 months versus the standard 1-3 months or waiting to be seen by a healthcare provider for a regular appointment (not fast-tracked refill) is a benefit that HCWs recognize and actually use as a way to bargain with patients to encourage them to achieve and maintain DSD eligibility. They explain to patients that: *"It [DSD] is timesaving, and there is the convenience of just coming and within the shortest time possible you've already left."* (Nurse)	that many patients are accustomed to receiving the standard package of HIV care which requires more visits but provides reassurance to patients who still believe that their HIV diagnosis must be monitored very closely: *"They feel safer. I think it's the psychological satisfaction of having to see your healthcare provider every other time. They feel like the six months will be too long a time without them having to come to health facility. So, there are some who kind of feel safe when they come more frequently."* (Clinical Officer)
Effectiveness	**Benefits/Opportunities**	**Challenges/Fears**
	• ***Health system cost savings/Sustainability*** Given that the health facility is donor funded, saving on healthcare cost is a priority: *"In the past we would support them[patients] in terms of reimbursing the transport…you see it has also reduced that expenditure, so from a financial aspect, it has reduced that burden. And also, in line with what the donor expects in terms of finally being able to just sustain ourselves*	• ***Lack of In-Service Education for HCWs*** Because DSD is a new approach to HIV service delivery, some of the participants expressed that it would have been beneficial for all staff to receive DSD-specific training to allow them to address patients' questions and/or concerns confidently; thus promoting program effectiveness: *"Unfortunately, us being a private implementing partner, we are not always trained as much as the public facilities are*

	without depending on the funds". (Financial Officer)	*trained. What happens is, we have to outsource for ourselves, and we have to make sure that we are doing the best we can to sensitize our healthcare workers. Even if we are trained – you are trained, like two or three of you, or one person if you're lucky, and now you have to go down and streamline and make sure there's capacity building in your health facility."* (Clinical Officer)
Adoption	**Benefits/Opportunities**	**Challenges/Fears**
	• ***Reduced Workload*** HCWs interviewed for this study described that since the implementation of facility-based individual DSD, they have noted a reduction in workload and other associated benefits: *"It's beneficial both to us, and to the clients, and the facility because we have less to do… Those times when we were seeing them every month, it used to be very hectic… So, the staff have also seen now we [have] more time to review the charts of the patient, see the files… be involved in more disciplinary teams – I mean to review patient files and all that, and also maybe be able to learn other things – you can get into a learning program because there is some time now, especially in the afternoons, when you can do other things apart from seeing the patients*." (Clinical Officer)	• ***Fear of Job Loss*** Some participants expressed that there was an initial fear that implementation of facility-based individual DSD would lead to a reduced workload which could be used as a justification to reduce the number of HCWs at the facility. While the model was efficient enough to reduce workload, it wasn't significant enough to require lay-offs. The initial fear of loss of jobs was dispelled after HCWs received reassurance from leadership and upon realizing that they were still needed because the facility continues to enroll patients daily: *"To some extent, I would hear some people saying this has come to reduce the number of staff. They thought it would come with negative impacts to staffing, which did not happen."* (Social Worker)
	• ***Improved Quality of Care***	• ***Fear of Care Discontinuation***

	Study participants stated that reduced workload for HCWs as described above has contributed to improved quality of care because medical errors and oversights that may be associated with work fatigue are lessened. Additionally, the model allows care providers to focus on the more complex patients: *"I like that ever since we started DC [DSD], even from the feedback that we're getting from patients, our interactions have significantly improved. As compared to times where we used to clear the line, now you get more into it. We actually take time with our patients…. a consult now can go for an average of between 15 and 30 minutes, depending what type of patient we have. So, this has improved all services that we give to the patient, in terms of diagnosis and treatment. So, for me it's a huge plus, seeing that I don't have a clear line, but now I have to give quality care."* (Clinical Officer)	HCWs were concerned that due to the long intervals between clinical visits, patients may think the providers are abandoning or getting rid of them. Some study participants feared that this could contribute to discontinuation in care due to patients feeling unwanted in the health facility: *"There are people who tend to think that us giving them drugs for six months is us sending them away. That we don't want to see them as frequent as before."* (Clinical Officer)
		Inadequate DSD Education for Patients Because DSD is different from what established patients are accustomed to, some HCWs worried that patients would default out of treatment because they did not fully understand the rationale for enrolling in DSD: *"We need to make them understand why, also because when it was starting, I think patients were being told we're giving you six months, but actually, they don't understand why. So, a few of them, I used to explain to them on the criteria. Actually, some even don't know the criteria."* (Clinical Nutritionist)

Implementation	**Benefits/Opportunities**	**Challenges/Fears**
	• ***Standard Operating Procedures*** Interviewed HCWs stated that while it was useful to have the general guidelines, having access to procedures that were developed specifically for the facility made it easier to implement DSD and gain buy-in from patients: *"The fact that there are standardized operating procedures makes it even easier to implement this. So, it actually helps and guides us a lot. For patients who will not take your word for it, actually showing them something that's standardized actually makes it much easier to even now convince them. So, the SOPs have actually come in handy."* (Clinical Officer)	• ***Change in Treatment Optimization Guidelines*** During DSD implementation, treatment guidelines changed and this prompted changes in regimens for some patients, which made a large number of patients who were already enrolled in DSD to become ineligible for a period of time; thus, disrupting the process. Previously enrolled patients had to have their response to the new treatment assessed before re-enrollment into DSD. In addition to confusion among providers and patients, this led to a significant drop in the proportion of patients enrolled DSD which reflected poorly on the reportable targets. *"I generally say that the numbers have been fluctuating because, if we compare what we reported last quarter with the previous quarters, you realize that, I think in the previous quarter, we reported a high percent as compared to the last quarter. I think a major reason is due to regimen change, because I understand there's a regimen which was introduced so that, for all the clients who are on that regimen, they are supposed to see a clinician, meaning they tend to be ineligible from being in DSD."* (Monitoring and Evaluation Staff)
		• ***Potential Medication Supply Disruption*** Study participants identified that a significant challenge to proper DSD implementation is a

		disruption of ART supply or prophylaxis agents to the facilities. These medications are supplied by the government and are free for patients; however, unfortunately there are instances where the facility runs out of ART or/and prophylaxis drugs: *"As a country, we have been experiencing drug stockouts. So, that in itself has been a huge challenge that we're still grappling with. As it is presently, we have patients taking a combination of Zidovudine and Lamivudine. This is in short supply. Apart from that, you also have a lack of Septrin as it is right now. So, that is a huge hinderance and actually interrupts the cycle…one of the biggest challenges would have to be that definitely. Episodic lapse and failures of systems, that can always be there, but it's not as frequent and major…because there are patients who actually had their scripts for six months, but due to this stockout, they have to come here every week or two just to get their supplies… so that was a huge interruption we're still grappling with this but it's getting better."* (Clinical Officer) In cases where the supply of ART or prophylaxis agents is delayed or disrupted, patients who could otherwise have a prolonged interval between visits to the facility have to return to the clinic frequently if they cannot afford to purchase the drugs elsewhere. This disruption in medication supply may lead DSD to lose its essence and appeal to patients. The disruption in supply could also lead to ART

		interruption in patients which increases the risk of drug resistance and treatment failure (Jiamsakul et al., 2016).
Maintenance	**Benefits/Opportunities**	**Challenges/Fears**
	• ***Elimination of 3-month ART refill visit*** Participants noted that at the beginning of the COVID-19 pandemic in 2020, many patients travelled from Nairobi to upcountry regions. Due to the pandemic-related uncertainties, providers were concerned that some patients would run out of ART which would lead to negative outcomes. In addition to exploring how to deliver medications to individuals who had traveled, facility leadership (with approval from the Ministry of Health) eliminated the 3-month ART refill visit and dispensed 6 months of ART. This change which was prompted by the COVID-19 pandemic demonstrated that the 3-month DSD visit for fast-track ART refill was not necessary for all DSD patients. Participants shared that they hope this will be a sustained change. *Right now, due to the COVID pandemic, since it started at about March, we are now giving everybody who is willing and who qualifies six months at a go. (Clinical Officer)*	

Opportunities to improve facility-based individual DSD

Participants were requested to provide recommendations to improve DSD implementation. Suggestions included follow-up communication with patients, additional DSD education for HCWs, prescription flexibility, ensuring adequate medication supply, and more DSD marketing and sensitization for patients.

Follow-Up Communication. As previously described, some HCWs had concerns regarding facility-based individual DSD, fearing loss of adherence during the prolonged timeframe between clinical visits. Participants identified that one way to improve the model and alleviate HCWs' hesitations regarding the implementation of DSD for fear of decreased ART adherence would be to identify alternative ways to engage patients in-between provider visits. Suggestions included a follow-up phone call(s) to speak with patients and assess medication adherence. Other suggestions included using short message service (SMS) for patients who requested not to be called. However, a follow-up call seemed to be more favorable as it offers a more personal touch to care, especially considering that HIV is a very sensitive subject. Some felt that an SMS may be viewed as impersonal and response rate to SMS may be lower:

> *"For a DC [DSD] client who's been given maybe six months…a phone call… between the sessions, maybe after two months or three months, just to follow up on them and check, how are you doing? Are you taking your drugs? Are there any challenges?...We are dealing better with patients who are getting to a point whereby they are stopping to take medication because they are experiencing med fatigue. And those are some of the things that we can do to help so that they cope better with the challenges that they are having."* (Clinical Officer)

DSD Education. To address challenges regarding lack of familiarity with the model, some participants proposed additional and targeted DSD education for HCWs based on cadre and primary roles. Education of HCWs currently takes place as needed during staff meetings where continuous medical education (CME) credits are awarded. There was a suggestion to include it in the orientation curriculum for new hires:

> *"If you're offering DC, orient your staff properly in an intense training of what DC entails and everything just to avoid some mistakes that you can make along the way. So, I think I could have benefitted more if there was comprehensive training."* (Counselor)

Prescription Flexibility. Some participants described flexibility with prescriptions as a way to improve facility-based individual DSD. This option would be available only to specific patients who need additional supply of their prescribed ART regimen (e.g., patients who live in distant counties or reside outside the country). Providing these patients with ART supply to last a longer duration may help to rescue the risk of ART interruption/non-adherence due to running out of medications.

> *"Suggestions that we're getting from patients is if we can do two bi-annual visits, why can't we make it one? So, if there can be space and wiggle room for us, now instead of using six months, we can go up to a year, considering we do viral load monitoring after every other year."* (Clinical Officer)

Ensuring Medication Supply. Participants shared that while ensuring an adequate stock of medications is not within their control, facilities could advocate on behalf of clients to ensure that the government adequately stocks needed medications:

> *"Sometimes even the antiretrovirals…like, we had a case with lamivudine, we had a shortage. We find that the medications are ordered, the government doesn't have it… So, I'm just recommending that if the government can be efficient in supplying all the medications so that we don't find — you know, sometimes if you tell a patient to go and buy medication, but maybe he doesn't have money to eat."* (Pharmacist)

DSD Marketing and Sensitization. Participants suggested it may be worthwhile exploring ways to increase DSD awareness for patients through brochures, posters, banners, and televised infomercials in the waiting areas and patient rooms:

> *"If they have brochures about differentiated care…as they wait, they can be reading it".* (Clinical Nutritionist)

Discussion

The RE-AIM framework guided the evaluation of DSD from the HCW's lens and as it pertains to an organization and the patients who participate in DSD. Overall, the HCWs felt that DSD was a favorable approach to traditional HIV service delivery. In particular, they expressed the benefit of alleviating the HIV workforce burden, thus allowing HCWs to focus on more complex patients – which may translate to the provision of improved quality of care and improved health outcomes. Participants felt that patients also benefited from the implementation of DSD because it relieves constraints associated with standard HIV care, such as transportation costs, travel time, long wait times at the clinic, taking time off from work, and managing stigma of living with an HIV diagnosis. While mostly seen as beneficial, participants also expressed some areas of concern, such as insufficient ART supply that would require patients to frequently return to the clinic frequently, thus counteracting the desired benefit of fewer visits to the healthcare facility. Addressing medication supply shortages would likely improve the implementation of this model of care.

The findings of this study are consistent with the previous limited literature exploring HCWs' perceptions of DSD or models of care that incorporate characteristics of DSD. Similar to this study, previous studies conducted in other regions of sub-Saharan Africa reported that facility-based individual DSD and other DSD-type models are perceived as useful in reducing the cost of care for the patient and the health care system and alleviating challenges linked to standard HIV care (multiple clinical visits) such as frequent travel to the health facility, income loss due to taking time off for work to attend clinical visits, and long wait times at the clinic (Alamo et al., 2013; Prust et al., 2017). HCWs in previous studies also described that DSD relieves healthcare workforce burden linked to overwhelming patient loads (Hubbard et al., 2020; Rabkin et al., 2020). A previous study also identified drug stock-outs as a major challenge

associated with DSDCOM implementation(Prust et al., 2018). Distinguishing itself from other published studies on this topic, this study elicited new perspectives not mentioned in previous DSD-related studies, most notably the recommendation for comprehensive DSD training for HCWs. It also includes specific recommendations from HCWs on how to improve the care delivery model. This study is also the only one that has explored HCWs perspectives in the East African region to date.

This study highlights factors associated with the implementation of DSD in high HIV burden contexts with limited human resources for health and identifies opportunities to enhance the care delivery model so it may yield added benefits for HCWs, health systems, and patients. A strength of the study is its inclusion of a wide variety of providers representing various cadres in medicine, allied health, administrative, and community health workers. This variability provided a comprehensive outlook of HCWs' experiences. Participants' perceptions across the various cadres were consistent. Patients were not interviewed for this study because patients' perceptions and experiences with DSD are already well-documented across various regions in sub-Saharan (Assefa et al., 2018; Bemelmans et al., 2014; Hubbard et al., 2020; Jere et al., 2018; Mantell et al., 2020; Prust et al., 2018; Rabkin et al., 2020; Roy et al., 2019a). This study aimed to provide an extensive overview from multiple health facilities; however, it was only feasible to conduct the study at a single site due to budgetary and time constraints. Therefore, the findings are limited to HCWs' perspectives of DSD implementation in a single health system; thus, the findings may not necessarily be transferable to other similar contexts.

Despite being a single-site, this research adds to the literature of qualitative studies using an implementation science framework (RE-AIM) and facilitates the adoption and integration of DSD into community and clinical settings. This study also contributes to the limited literature on HCW experiences and perceptions of DSD implementation. To obtain a comprehensive

understanding of DSD and obtain additional data to inform the improvement of the HIV care delivery model, it will be important to engage patients and incorporate their perspectives of the model as well as how to improve it. Such an approach may empower participants and encourage engagement in their HIV care and treatment. Research findings provide one impetus for scale-up of DSD nationally, and the perspectives of HCWs and patients are critical to successful adoption, implementation, and maintenance of DSD programs. Future studies engaging HCWs and conducted in other contexts within East Africa will be important for shedding light on additional benefits, challenges, and opportunities associated with the implementation of DSD. Such studies could also provide a better understanding as to whether factors associated with the adoption, implementation and maintenance of the care delivery model vary by location.

Conclusions

This study contributes to knowledge on HCWs' perceptions and experiences with HIV service delivery models implemented in regions with high HIV burden and limited resources. The findings suggest that increasing the intervals between clinical visits is beneficial for HCWs/health systems and patients. Implementing DSD reduces patient burden and helps to alleviate HCWs' burden which in turn contributes to improved access to ART for newly diagnosed patients and patients who would otherwise have difficulty accessing HIV care. Scaling up DSD implementation may help to accelerate progress towards the universal goal of viral suppression. To end the AIDS epidemic by 2030 and reach the recently updated UNAIDS 95-95-95 targets (Joint United Nations Programme on HIV/AIDS, 2015), it will be essential to identify opportunities to improve access to HIV care and treatment services, particularly in contexts such as sub-Saharan Africa which carries the greatest HIV burden and the greatest shortage of HCWs.

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CHAPTER 5: SUMMARY AND CONCLUSIONS

Summary of Results

In response to global workforce shortages impacting access to HIV care in low to middle income countries (LMICs), the World Health Organization (WHO) recommends the implementation of differentiated service delivery (DSD); a patient-centered approach to delivering HIV care and improving access to ART. Theoretically, extending the time in between provider visits for PLWH who are established on ART and do not require frequent provider follow-up, DSD improves access to HIV care and frees up more time for providers to see other individuals with a HIV diagnosis who otherwise might have difficulty accessing care. DSD also allows health workers to provide more attention to more complex cases that need closer monitoring.

To maximize the capacity of health care systems in resource-limited settings experiencing high HIV burden, this study sought to better understand the impact of the implementation of facility-based individual DSD as a HIV care delivery model in contexts with a high HIV burden and limited resources. The specific aims of the study were: 1) to determine the effectiveness of facility-based individual DSD implementation on viral load detection among PLWH, and 2) to explore perceptions and experiences of health care workers regarding facility-based individual differentiated service delivery. The Social Ecological Model (McLeroy et al., 1988) and the RE-AIM model (Glasgow et al., 1999) were used as the guiding frameworks for the evaluation of facility-based DSD implementation.

For Aim 1, a retrospective research design was used to describe characteristics of facility-based individual DSD-eligible patients who enroll in the care delivery model vs. those who do not enroll (receive standard package of care) and to compare viral load detection outcomes of facility-based individual DSD-eligible patients who enroll in the care delivery model vs those who do not enroll (receive standard package of care). For Aim 2, a qualitative descriptive design

was used to explore health workers' perspectives of the care delivery model. For Aim 1, de-identified retrospectively collected demographic and clinical data recorded on routine basis during clinical care encounters were collected via electronic medical record (EMR) abstraction. A sample of 814 subjects meeting DSD-eligibility criteria were analyzed for this study. There were 407 subjects in the intervention group (DSD-enrolled patients) and an additional 407 subjects were case-matched for the control group (DSD-eligible patients who were enrolled in standard care). For Aim 2, a purposive sample of 30 healthcare workers representing various cadres were recruited and interviewed for this study.

Chapter 2 describes the findings of a literature review conducted to explore the current state of science in facility based- individual DSD in sub-Saharan Africa. Studies suggest that facility-based care for individuals is most popular among patients and the least complex DSD model to implement (National AIDS and STI Control Programme, 2016a; Rabkin et al., 2020). While facility-based individual DSD is formally described as a new concept in the literature, this approach shares similarities with multi-months prescriptions (MMS) and fast-track antiretroviral therapy (ART) refill models, which have been implemented in sub-Saharan Africa for decades. To gain a more comprehensive yet focused understanding of the model, the literature review was centered around: 1) health outcomes, 2) cost-effectiveness and 3) provider/patient perspectives of facility-based DSD. Results of this literature search indicated that facility-based individual DSD and similar mechanisms such as fast-track ART refill and multi-month ART prescriptions are linked to: 1) improved ART adherence, retention in HIV care, and viral suppression for PLWH (Bekolo et al., 2017; Bosomprah et al., 2020; Cassidy et al., 2018; Hickey et al., 2020; Kaimal et al., 2017; Mody et al., 2018; Mutasa-Apollo et al., 2017; Obua et al., 2014; Sanwo et al., 2021; Shigayeva et al., 2020; Wringe et al., 2018); 2) improved financial and time cost-effectiveness for patients and the health system (Alamo et al., 2013; Babigumira et al., 2011; Jakubowski et

al., 2016; Prust et al., 2017; Roberts et al., 2019; Shade et al., 2017); and 3) positive patient perceptions regarding how helpful it is in alleviating patient burden related to transportation costs, lost wages, and time spent travelling and waiting at the health facility (Assefa et al., 2018; Bemelmans et al., 2014; Hubbard et al., 2020; Jere et al., 2018; Mantell et al., 2020; Prust et al., 2018; Rabkin et al., 2020; Roy et al., 2019b) and positive healthcare worker perceptions regarding how efficient the care delivery model is in reducing health care workforce burden by reducing patient volumes, saving healthcare costs, improving adherence and retention in care (Hubbard et al., 2020; Jere et al., 2018; Phiri et al., 2021; Prust et al., 2018; Rabkin et al., 2020; Roy et al., 2019b). The present study extends the previous research findings by addressing gaps related to assessing long-term health outcomes of PLWH who enrolled in DSD and health workers' comprehensive perspectives of the model.

Chapter 3 describes the effect of facility-based DSD implementation on viral load detection status. To analyze change in viral detection status for DSD-eligible patients who enrolled in DSD and those who enrolled in standard HIV care, the viral load variable (obtained from viral load lab results) was dichotomized as: 'undetectable' (<200 copies/mL) and 'detectable' (>200 copies/mL). There were no subjects classified as unsuppressed (>1000 copies/mL); an unsuppressed viral load status automatically disqualified a patient's eligibility for enrollment into facility-based individual DSD. The viral load detection status before and at least 1 year after enrollment in DSD (for the intervention group) and a similar period in standard care (for control group) were compared.

Because the values are non-parametric, McNemar's test was conducted to compare viral load detection status among subjects who chose to be enrolled for facility-based individual DSD for a minimum of 1 year versus those who chose not to enroll but remain in standard HIV care for 1 year. The pre-post McNemar's test results showed that in the group that enrolled for DSD,

6 subjects (1.5%) converted from undetectable to detectable viral load suppression status and 15 subjects (3.7%) converted from detectable to undetectable viral load suppression status. In the group that did not enroll for DSD, 3 subjects (0.7%) converted from undetectable to detectable viral load suppression status and similarly 3 subjects (0.7%) converted from detectable to undetectable viral load suppression status. These results indicate that among subjects who enrolled in DSD, a greater proportion (3.7% vs 0.7%) had improved viral load detection after 1 year. The pre-post McNemar's test also determined that among patients who were eligible and enrolled in DSD, 94.6% maintained viral suppression after 1 year compared to 98.5% in the group that was eligible but was not enrolled in DSD (p= 0.078; McNemar's test). It's important to note that in both groups, all patients maintained their viral suppression status. To compare the viral load status at the end of the study period (post) in DSD and standard care patients McNemar's matched pairs test was also conducted. Results indicated that 379 (97.7%) out of the eligible 388 matched pairs, 379 (97.7%) pairs had an undetectable viral load for both members at the end of the study period. Only 6 (1.5%) of the DSD patients were detectable at the post visit, compared to only 3 (0.8%) of the matched non-DSD members (p=0.508; McNemar's test). Overall, these results demonstrate the hypothesis that implementation of facility-based individual DSD produces viral load detection outcomes that are at least equivalent to the standard package of care.

Chapter 4 describes the qualitative findings of health workers' perceptions and experiences of health care workers regarding facility-based individual DSD. A total of 30 HWs were interviewed and overall, study participants expressed their preference for facility-based DSD over standard care, citing that it was beneficial for patients, health workers, and the health system. Patient benefits as perceived by health workers included decreased costs associated with transportation to the clinic, reduced waiting time at the clinic, motivation to maintain viral

suppression, and reduced stigma. Health worker benefits linked to facility-based DSD implementation included reduced workload and during the interviews, several health workers attributed improved ART adherence and retention in care at the facility to DSD implementation. General studies have shown that manageable healthcare provider workloads facilitate proper patient monitoring, which, translate to improved quality of care (Mohr et al., 2013). Excessive workloads are also linked to negative patient outcomes and burnout in healthcare workers (Carayon & Gurses, 2008; Dubale et al., 2019; Havaei & MacPhee, 2020). Healthcare workers noted that the benefits of DSD implementation in their health system included improved quality of care (as evidenced by improved adherence and viral load suppression) and cost savings associated with ability to function with less staff. As a result of DSD implementation, the study site reported improved target measures to the Ministry of Health and to funding agencies.

However, DSD implementation is also perceived to have some challenges; there were medication stock outs which reduced the efficiency of the care delivery model. Also, some healthcare workers feared losing their jobs because they were concerned that the new model was put into place to allow the healthcare system to reduce staffing levels. Additionally, some healthcare workers feared that the long duration between patient visits might contribute to poor adherence and loss of viral suppression among established patients.

Recommendations to strengthen facility-based DSD included placing follow-up calls with patients in between clinical visits to mitigate decreased ART adherence, providing more patient education about the new care model, and marketing and sensitization via brochures, posters, and banners to increase patients' awareness and understanding of DSD.

Strengths and Limitations

This study is unique and one of the few to study the effectiveness of facility-based DSD in maintaining viral suppression in stable PLWH. The study demonstrates that the care delivery model does not result in loss of viral suppression when compared to standard of care; this model is effective in alleviating challenges associated with chronic healthcare workforce shortages. These results provide sufficient evidence to support the scale up of facility-based individual DSD and also highlight the importance of conducting additional intervention research to strengthen the care delivery model. The qualitative study also provided insights into possible ways to improve the model which can be further attempted and evaluated.

The study was conducted in one private HIV comprehensive care center in one geographic location which may not be representative of all HIV comprehensive clinics, especially those in the public sector, in Kenya or other African countries. Therefore, generalizability may be limited. However, the study site provides diversity in participants and practices that will contribute to the generalizability of the findings. Another limitation includes using retrospectively collected data from the electronic medical record, which meant there was no opportunity to customize the data collected and there were a lot of missing data. Additionally, the cost-savings aspects of this model were not ascertained because the existing data didn't contain information such as patient travel time and cost of care per visit, which could be used to analyze cost savings. Assessing this is important and more future studies ought to include the cost-saving aspects of facility-based individual DSD. Despite these limitations, this study contributes to science and to evidence on best practices for HIV service delivery in high burden regions with limited human resources for health.

Research, Policy, and Clinical Implications

Ultimately, the goal of health systems providing HIV care should be to transition all DSD eligible patients to this stream-lined care delivery model. However, at this time, DSD is offered on an opt-in basis and not all patients are opting in to receive this service model. In order to further free-up human resources for health and reduce patient and clinic costs incurred in the provision of care, it is essential that healthcare providers continuously assess, educate and encourage patients to opt for DSD. Additionally, in order to make it more effective, it may be worth considering offering DSD on an opt-out basis; meaning that all patients are automatically transitioned to the model (recommended to the patient by their provider) unless the care provider determines it is not ideal or if the patient makes a reasonable justification for opting out. The demographic descriptive results of this study also provide information about specific populations to target for enrollment; for example, results from this study indicated that females enroll in DSD more than men and majority are in the 40-49 and 50-59 age groups. This should inform providers to target enrollment of more men and other ages not falling in the majority age group.

There are additional clinical implications that arise from the results of this study. Several participants in the qualitative component of this study expressed fears about loss to follow-up and concerns about patients converting from virally suppressed to virally unsuppressed due to the risk of poor-adherence linked to longer durations between provider visits. To avoid adherence and follow-up issues, health providers, therefore, should focus more effort to providing patient education to all clients. Additionally, continuous assessments should be conducted to mitigate the risks associated with defaulting out of HIV care and ensure that patients enrolled in DSD maintain their eligibility-criteria and remain enrolled.

The review of the current literature showed there are limited studies looking at long-term health outcomes of continued enrollment in facility-based DSD among stable PLWH, thus

warranting the need for additional research in this area. This study, therefore, informs the direction of future research in HIV service delivery. Strategies to address provider concerns should be explored. Further studies employing health workers' recommendations to strengthen facility-based DSD should also be conducted.

Conclusions

While advances have been made in the HIV sector, out of the 38.0 million PLWH, only 68% adults (15 years or older) and 53% children (0-14 years) have access to ART (Joint United Nations Programme on HIV/AIDS, 2020b). Access to ART relies heavily on having an adequate healthcare workforce, however critical healthcare workforce shortages is a global concern. It is even more challenging in sub-Saharan Africa which operates significantly below the WHO recommended health workforce density of 44.5 doctors, nurses and midwives per 10,000 population (World Health Organization, 2016b). Given the current state of the global HIV burden coupled with a critical workforce shortage, it is important to explore creative evidence-based interventions to deliver effective and efficient HIV care, using existing resources. Additionally, with increasing reductions in budget cuts and donor funding, health systems in regions with limited resources are encouraged to become cost-effective, if not self-reliant. DSD is cost-effective, both for patients and health care systems, and requires minimal upfront investment. Thus, it is a promising model to address the challenges of healthcare systems in resource-limited settings with high HIV burden.

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Appendix A

Emory University IRB Approval

IRB EXPEDITED APPROVAL

March 11, 2020

Rosemary Kinuthia, MPH RN

rkinuth@emory.edu

Title:	Tailoring HIV Care to End AIDS: An Evaluation of Differentiated Service Delivery in Kenya.
Principal Investigator:	Rosemary Kinuthia
IRB ID:	STUDY00000050
Funding:	Name: NIH FOGARTY INTERNATIONAL CENTER
Documents Reviewed:	• Coptic Site Permission Letter, Category: Other; • Fogarty Application, Category: Sponsor Attachment; • Fogarty Award Letter, Category: Sponsor Attachment; • Interview Guide, Category: Surveys, Questionnaires, Interview Guides; • Protocol 02/15/20, Category: IRB Protocol; • Revised Verbal Consent, Category: Consent Form; • Study Flyer, Category: Recruitment Materials

Dear Ms. Kinuthia:

On 3/7/2020 the Emory IRB reviewed the above-referenced study by expedited process. This research is eligible for expedited review under 45 CFR.46.110 and/or 21 CFR 56.110 because it poses minimal risk and fits expedited review categories F5 and F7 as set forth in the Federal Register.

No annual IRB review is required, as permitted under the 2018 Common Rule.

Please note carefully the following items with respect to this approval:

- THIS IS A CONDITIONAL APPROVAL. In-country study activities may not commence until local IRB approval of this study is secure.
- Attached are stamped approved consent documents. Use copies of these documents to document consent.

- A request to waive documentation of informed consent (i.e. signature) has been approved for enrollment of interviewees. Please note that you are required to consent subjects with the verbal consent script approved with this submission and document this consent process. Informed consent has not been waived; only the requirement for subject signature has been waived.
- A request to waive informed consent from patients whose medical records you will abstract has been reviewed and approved under 45 CFR 46.116(d).

In conducting this protocol, you are required to follow the requirements listed in the Emory Policies and Procedures, which can be found at our IRB website.

Sincerely,

Sam Roberts, BA CIP
Research Protocol Analyst, Sr.

Your stamped consent form is available under the "Documents" tab.

Now that your submission has been approved, please take a few moments to complete the Emory IRB Satisfaction Survey. We will use your responses to improve our service to the Emory research community. We appreciate your feedback!

Appendix B

Aga Khan University IRB Approval

THE AGA KHAN UNIVERSITY

Ref: 2019/IERC-125 (v2) **Date:** 23.03.2020

Prof Michael Chung
Site Supervisor and Faculty,
Aga Khan University, Nairobi Kenya

Dr. Rosemary Kinuthia– PhD Candidate, Emory University

Dear Prof Chung and Team,

RE: Tailoring HIV Care to End AIDS: An Evaluation of Differentiated Service Delivery in Kenya.

The Aga Khan University, Nairobi Institutional Ethics Review Committee (IERC), is in receipt of your protocol resubmitted to the Research Office on March 12, 2020. With reference to the IERC letter 2019/IERC-125 (v1), the IERC reviewed and conditionally approved this project {*as per attached official stamped protocol and attachments - version 2019/IERC-125 (v2)*}. You are authorized to conduct this study from **March 24, 2020**. This approval is valid until **March 23, 2021.**

This approval is subject to compliance with the following requirements;

1. The study should be conducted in full accordance with all the applicable sections of the IERC guidelines and you should notify the IERC immediately of any changes that may affect your research project (amendments, deviations, and violations)
2. Prior to commencing the study, you will be expected to ensure compliance with relevant AKU institutional administrative regulations, including obtaining a research license from the National Commission for Science, Technology and Innovation (NACOSTI) and a site approval from Coptic Hope Centre for Infectious Diseases.
3. As applicable, prior to export of biological specimens, ensure an MTA is in place as well as seek shipment authority/permit from the relevant government ministry.
   Copies of approvals of 2 and 3 above, should be submitted to the Research Office for records purpose.
4. As applicable, all Serious Adverse Events (SAEs) and the interventions undertaken should be reported as soon as they occur but not later than 48 hours. A report from the Hospital Patient Safety Committee should also be submitted.
5. All consent forms must be filed in the study binder.
6. Further, you must provide an interim report **60 days before expiration** of the validity of this approval and request extension if additional time is required for study completion.
7. You must advise the IERC when this study is completed or discontinued and a final report submitted to the Research Office for record purposes.

If you have any questions, please contact Research Office at research.supportea@aku.edu or 020-366 2148/1136.

With best wishes,

Dr. Wangari Waweru-Siika,
Chair - Institutional Ethics Review Committee (IERC)
Aga Khan University, (Kenya)

3rd Floor, Park Place Building, 2nd Parklands Avenue, Off Limuru Road
P. O. Box 30270, GPO 00100, Nairobi, Kenya
Tel: +254 20 366 1200; Website: www.aku.edu

Appendix C

NACOSTI Research Permit

REPUBLIC OF KENYA

NATIONAL COMMISSION FOR SCIENCE,TECHNOLOGY & INNOVATION

Ref No: **177310**

Date of Issue: **02/April/2020**

RESEARCH LICENSE

This is to Certify that Dr.. Rosemary Gichiru Kinuthia of Emory University, has been licensed to conduct research in Nairobi on the topic: Tailoring HIV Care to End AIDS: An Evaluation of Differentiated Service Delivery in Kenya. for the period ending : 02/April/2021.

License No: **NACOSTI/P/20/4687**

177310

Applicant Identification Number

Director General
NATIONAL COMMISSION FOR SCIENCE,TECHNOLOGY & INNOVATION

Verification QR Code

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THE SCIENCE, TECHNOLOGY AND INNOVATION ACT, 2013

The Grant of Research Licenses is Guided by the Science, Technology and Innovation (Research Licensing) Regulations, 2014

CONDITIONS

1. The License is valid for the proposed research, location and specified period
2. The License any rights thereunder are non-transferable
3. The Licensee shall inform the relevant County Director of Education, County Commissioner and County Governor before commencement of the research
4. Excavation, filming and collection of specimens are subject to further necessary clearence from relevant Government Agencies
5. The License does not give authority to tranfer research materials
6. NACOSTI may monitor and evaluate the licensed research project
7. The Licensee shall submit one hard copy and upload a soft copy of their final report (thesis) within one of completion of the research
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Appendix D

Interview Guide

****Note: This guide may change due to the iterative nature of qualitative research****

Participants:

- Health administrators, staff, and health personnel including physicians, clinical officers, nurses, midwives, counsellors, social workers, & healthcare assistants working in the Coptic Hope Centre
- Involved in HIV service delivery using facility-based individual DSD.
- Be able and willing to participate in individual interviews
- Worked at the facility for a minimum of 6 months.
- Speak and understand English or Swahili.

Scheduled Site:

- Coptic Infectious Disease Centre, Ngong Rd, Nairobi, Kenya

Contact:

- Rosemary Kinuthia (PhD Candidate)

Materials:

- Digital audio recorder
- Notebook
- Incentive money (USD 10/ KSH 1000 per person)
- Sign-in sheet
- Verbal consent forms

Introduction (5 minutes)

Good morning/afternoon evening, my name is Rosemary Kinuthia. I am a PhD in Nursing Student Investigator from Emory University. Thank you for agreeing to participate in this study about understanding your experience with differentiated service delivery implementation at the Coptic Hope Centre. This interview is completely confidential (your name will not be used) and your participation is voluntary. You don't have to answer any questions that you don't want to answer. If it's OK with you, I'd like to audio record this interview so we can accurately record your comments. Once the audio recording is transcribed, it will be destroyed and your name and any identifying information about you will be removed from the transcript. This interview should last about 1 hour. There are no wrong or right answers during our conversation today. You have the right to stop participating in the interview any time. Do you have any questions before we get started? Is it ok with you if I record the interview? (If yes, turn on the recorder).

Questionnaire ID Number_____

**Note- Probes indicate areas that for asking follow-up questions that I can use to motivate participants to elaborate further about the topic of DSD implementation at Coptic.

Warm-up

Good morning again. Thanks for joining me for this interview.

- How are you doing today?
- Tell me about yourself
- What is your primary role here at the Coptic Hope Centre?
- How long have you been working at the Coptic Hope Centre?

Thank you for sharing a little about yourself. Let's go ahead and get started with the interview. Our interview today will focus on taking your experience with differentiated service delivery (DSD) at Coptic Hope Centre, you may also include any other DSD experiences you have had at other facilities.

Reach:

1. What do you think are some of the factors contribute to the participation of DSD eligible patients at Coptic?

2. What might have been done to get more DSD-eligible patients to participate/opt-in to differentiated service delivery?

    a. What do you think is currently being done? *(probe)*

Efficacy:

3. Did the implementation of DSD as intervention work to effect the outcomes noted?

    a. *Tell me about what other factors contributed to the results? (probe)*

    b. *Are the outcomes found accurate? (probe)*

    c. *Are the results meaningful? (probe)*

Adoption:

4. What factors contributed to the Coptic Hope Centre and its individuals taking up the intervention?

    a. *What barriers interacted with the implementation of DSD to prevent adoption? (probe)*

    b. *Was there partial or complete adoption? (probe)*

c. *Why did some staff members at the Coptic Hope Centre participate/are more pro-active about differentiated care and others were not? (probe)*

Implementation:

5. How is differentiated service delivery implemented at the Coptic Hope Centre?

    a. *By whom and when? (probe)*

    b. *What factors influenced implementation of facility-based differentiated DSD or lack of (proper) implementation? (probe)*

    c. *What combination of implementation effects affected the outcome results? (probe)*

    d. *How has the differentiated care program or policy adapted or modified over time? (probe)*

    e. *Why has the differentiated care program or policy adapted or modified over time? (probe)*

Maintenance:

6. What components of the differentiated care program have changed/adapted since implementation?

    a. *What is sustained- and why? (probe)*

    b. *What discontinued- and why? (probe)*

DSD guideline and facility-level recommendations:

I would like to get your feedback about strategies that you think would improve differentiated service delivery guidelines.

7. What are some suggestions you have regarding the current DSD operational guidelines?

FINAL QUESTION:

8. Is there anything I did not ask you that you think we should know about differentiated service delivery?

You have completed the interview. I want to thank you for your time and willingness to talk about your experience with differentiated service delivery. If you have any questions about this project, please do not hesitate to call one of the contacts listed on your consent form.

Appendix E

Consent Form

Emory University Oral Consent Script For a Research Study

Study Title: Tailoring HIV Care to End AIDS: An Evaluation of Differentiated Service Delivery in Kenya
Principal Investigator: Rosemary Kinuthia, Nell Hodgson Woodruff School of Nursing
Funding Source: National Institutes of Health, Fogarty International Center

Introduction and Study Overview

Thank you for your interest in Differentiated Service Delivery research study. We would like to tell you everything you need to think about before you decide whether or not to join the study. It is entirely your choice. If you decide to take part, you can change your mind later on and withdraw from the research study.

The purpose of this study is to understand health workers' perceptions and experiences with differentiated service delivery. We also want to understand what factors are associated with implementation of the care delivery model. The study is funded by the National Institutes of Health, Fogarty International Center. This study will take about 1 hour to complete.

If you join, you will be asked questions on what you think about differentiated service delivery, as well as information on any opportunities or challenges encountered. You may refuse to answer any questions that you do not wish to answer. Also, you can stop participating in the interview at any time. All interviews will be digitally recorded and transcribed. We will not use your name and all information gained will be kept on protected and restricted to study staff members working directly with the data. Recordings will be transcribed without any personal identifiers you give during the responses, and audio recordings will be destroyed, once the data has been transferred to a protected electronic format. Participants will receive KES 1000 (approximately USD 10) for participation in the study to compensate you for your time and assist with transportation.

Though unlikely, the main risk to your taking part in this study is a loss of confidentiality. To protect from this risk, all data collected for this work will be stored in a password-protected and encrypted electronic database located in the principal investigator's office and recordings will be transcribed without any information that can identify who you are. Any paper records will be kept in a locked file cabinet accessible only to the principal investigator and IRB approved study staff. All of the information collected during the study will be kept strictly confidential. It is also possible that discussion of your honest perceptions and experiences at your place of employment may cause some you to be uncomfortable or experience emotional distress.

This study is not intended to benefit you directly, but we hope this will help to identify opportunities to improve the health of future HIV/AIDS patients receiving care at the Coptic Hope Centre for Infectious Diseases and other similar settings. We also hope that other individuals with HIV/AIDS and care providers may benefit from the research through a greater understanding of health worker perspectives of facility-based individual DSD and how DSD as a care delivery model impacts health outcome of persons living with HIV in high HIV burden regions suffering from health workforce shortages. This information will help us lay the groundwork for the development and evaluation of HIV service delivery models.

Certain offices and people other than the researchers may look at study records. Government agencies and Emory employees overseeing proper study conduct may look at your study records. These offices include the Office for Human Research Protections, the funder(s), the Emory Institutional Review Board, the Emory Office of Compliance, the Aga

Khan University Kenya Institutional Ethics Review Committee (IERC). Study funders may also look at your study records. Emory will keep any research records we create private to the extent we are required to do so by law. A study number rather than your name will be used on study records wherever possible. Your name and other facts that might point to you will not appear when we present this study or publish its results.

Your data from this study will not be shared with anyone outside this study, even if we take out all the information that can identify you.

We will use your data only for research. We will not sell them. However, the results of this research might someday lead to the development of further research.

In general, we will not give you any results from the study based on the information you share with us. Should you wish to review the findings of the study, contact the Principle Investigator at the contact listed below to request any published materials arising from this research.

Contact Information

If you have questions about this study, your part in it, your rights as a research participant, or if you have questions, concerns or complaints about the research you may contact the following:
Dr. Rosemary Kinuthia, Principal Investigator: +254 723 539705 or by email at rkinuth@emory.edu
Emory Institutional Review Board: +1 404-712-0720 or by email at irb@emory.edu
Aga Khan University Kenya Institutional Ethics Review Committee (IERC) office via email at AKUKenya.ResearchOffice@aku.edu

Consent

Do you have any questions about anything I just said? Were there any parts that

seemed unclear? Do you agree to take part in the study?

Participant agrees to participate: Yes No

If Yes:

_____
Name of Participant

_____ _____
Signature of Person Conducting Informed Consent Discussion Date Time

_____
Name of Person Conducting Informed Consent Discussion

Appendix F

Recruitment Flyer

Are you involved in Differentiated Service Delivery for HIV Treatment?

If you are a healthcare worker at the Coptic Hope Center for Infectious Diseases, this study may be for you.

Study for healthcare workers involved in differentiated service delivery implementation.

We're looking for healthcare workers who are involved in differentiated service delivery at the Coptic Hope Center.

The purpose of this study is to understand health workers' perceptions and experiences with differentiated service delivery. We also want to understand what factors are associated with implementation of the care delivery model.

Participants will be asked to participate in:

- 1 face-to-face interview, lasting approximately 1 hour.

Participants will receive:

- KSH 1000 (approx. USD 10) at the conclusion of the interview.

Location

- Interviews will take place in a private office space at the Coptic Hope Center for Infectious Diseases during a time that is convenient for the participant.

Are you eligible?

You are eligible to participate if you:

- Are a health administrator, staff, or health personnel (including: physicians, clinical officers, nurses, midwives, counsellors, social workers, or health assistants working at the Coptic Hope Center)
- Are involved in HIV service delivery
- Are able and willing to participate in individual interviews
- Have worked at the Coptic Hope Center for a minimum of 6 months
- Speak and understand English or Swahili

If you're interested or unsure if you meet the requirements, email a member of the study team:

- Dr. Rosemary Kinuthia
- rkinuth@emory.edu

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