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Improving Retention in Care for Adolescents and Young Adults in Kenya: Implementation
Science to Support Adaptation and Integration of a Stepped Care Intervention

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Abstract

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Adolescents and young adults represent a diverse population. Globally, more than five million are living with HIV. This dissertation comprises three aims with the overall objective to evaluate implementation outcomes of a cluster randomized controlled trial, *Data-informed Stepped Care (DiSC) to Improve Adolescent HIV Outcomes* (UG3/UH3 HD096906; PIs: Kohler, John-Stewart), that tested a Stepped Care intervention across 24 health facilities to improve retention among adolescents and youth living with HIV (AYLHIV) in western Kenya. We use an implementation science approach to understand how to optimize stepped care and provide valuable information about the context necessary for successful scale-up of stepped care interventions for adolescents and young adults within Kenya or scale out to other global settings. We applied three implementation science frameworks to accomplish our overall objective.

In Aim 1, the Framework for Reporting Adaptations and Modifications to Evidence-based interventions (FRAME) was applied to characterize provider-identified adaptations that were made to improve DiSC stepped care intervention fit with context. Providers participated in

continuous quality improvement (CQI) meetings using plan-do-study-act processes to optimize uptake and delivery of the intervention. During the CQI meetings, providers completed surveys to quantify their perceptions of adaptation influence on implementation outcomes of acceptability, appropriateness, and feasibility. A total of 65 adaptations were made, with the majority focused on optimizing the integration of DiSC within the clinic. Primary reasons for adaptations were to increase reach and engagement with AYLHIV and align delivery with their needs and preferences. All adaptations were considered fidelity consistent. Provider perceptions of implementation were consistently high throughout, but on average, slightly improved each month for intervention acceptability ($\beta = 0.011$, 95% CI: 0.002, 0.020, $p = 0.016$), appropriateness ($\beta = 0.012$, 95% CI: 0.007, 0.027, $p < 0.001$) and feasibility ($\beta = 0.013$, 95% CI: 0.004, 0.022, $p = 0.005$).

In Aim 2, the Consolidated Framework for Implementation Research (CFIR) was used to understand key barriers and facilitators that influenced implementation outcomes of adoption, reach, and fidelity of the DiSC stepped care intervention. In this qualitative assessment, focus group discussions (FGDs) were conducted with providers across 12 intervention sites using a semi-structured interview guide grounded in relevant CFIR constructs across five domains, including novel constructs relevant in low- and middle-income country settings. A *Sort and Sift*, *Think and Shift* rapid qualitative analysis approach was used to identify key determinants of implementation. A total of 43 health providers participated in 12 FGDs. Overall, providers described a general positive experience engaging with the DiSC intervention and were enthusiastic about it and quick to adopt. They found the DiSC tool easy to use and felt it provided a relative advantage by improving service delivery efficiency and prioritizing time with higher need AYLHIV. Providers perceived that the DiSC intervention facilitated individualized care to better meet adolescent needs and believed that the design quality and packaging of DiSC supported AYLHIV reach and engagement. Provider collective efficacy was important in consistent implementation of DiSC and was facilitated by CQI meetings, access to knowledge and

information, and perceived intervention effectiveness. Providers identified compatibility with workflows and changing guidelines as the most prominent challenges, and supportive leadership as an important driver of implementation success. As a result of their experiences, providers recommended scale up of the DiSC intervention so that others may benefit but highlighted specific considerations such as modifications to the DiSC tool to inform care and management, strategies to support DiSC integration into routine and workflows, and continued engagement with key stakeholders.

In Aim 3, we use the Reach, Effectiveness, Adoption, Implementation, and Maintenance (RE-AIM) framework to guide evaluation of DiSC intervention performance. We used a mixed methods convergent parallel design with data obtained from diverse sources including medical records, an end-of-trial survey, and in-depth interviews with providers (n=2/facility). Quantitative and qualitative data were compared for concordance. Of 933 AYLHIV screened, 895 were enrolled, representing 96% *reach* overall. There were no significant differences between intervention and control facilities in the primary effectiveness outcome measure defined as number of missed visits (8.5% versus 8.3% respectively; adjusted Relative Risk [aRR] = 1.04 (95% Confidence Interval [CI]: 0.89, 1.20). However, perceived intervention *effectiveness*, including improved retention and viral suppression among AYLHIV, motivated continued implementation throughout the study duration. Forty-nine providers were trained to deliver the DiSC intervention, representing 25% (49/199) of the total health facility workforce. All providers trained, *adopted*, and delivered the intervention. *Implementation* was facilitated by provider-identified adaptations to optimize contextual fit of the DiSC intervention within respective healthcare settings. All adaptations made by providers were fidelity consistent. Key determinants influencing *implementation* were provider collective efficacy, compatibility with clinic workflows, leadership engagement, and alignment with changing national guidelines. Post-trial, providers agreed that the DiSC intervention will be sustainable (*maintenance*) beyond the study period (72% agree/strongly agree) and believed it could be easily integrated into clinic operations (92%

agree/strongly agree). Providers supported continued use of the DiSC intervention (*maintenance*), citing leadership support, training, and material and human resources as key influencers on future sustainment.

This dissertation enriches our understanding of implementation contexts, outcomes, as well as barriers and facilitators, and adds to the knowledge base of evidence-based interventions to support retention in care for AYLHIV to improve their health outcomes. We used implementation science frameworks to close the know-do gap, the gap between what we know and what we do, in order to achieve maximum impact for populations who need it most.

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Dedication

To my family, to resilience.

Chapter 1. Introduction

In sub-Saharan Africa (SSA), adolescents and young people aged 10-24 continue to bear a disproportionate burden of HIV, experiencing high HIV incidence and HIV-related mortality [1, 2]. The UNAIDS 95-95-95 care cascade targets, where 95% of people living with HIV (PLHIV) know their status, 95% of PLHIV diagnosed are linked to care and on antiretroviral therapy (ART), and 95% of PLHIV on ART are virally suppressed, are not attainable without addressing the critical gap in reaching the third 95. This is especially true for adolescents and youth living with HIV (AYLHIV) where less than 30% are virally suppressed after 12 months on treatment [3, 4]. Retention in care is an important first step to achieving viral suppression and prevention of onward HIV transmission.

Currently, about one million adolescents 15-19 are living with HIV globally, with 84% residing in SSA [2]. Kenya, one of the highest HIV burden settings in the world, has an estimated 1.4 million adults and children living with HIV [5]; in 2020, young people aged 15-24 accounted for 35% of new HIV infections [6]. Although Kenya has made significant progress in ensuring those living with HIV are on antiretroviral therapy (ART), gaps remain in reaching viral suppression targets, especially for AYLHIV; with only 67% of children ages 0-14 and 79% aged 15-24 on ART achieving viral suppression [7]. Despite effective treatment, mortality among 15–19-year-old adolescents remains consistently high. Ending the HIV epidemic will not be achievable without targeted interventions for specific age groups, populations, and locations, including AYLHIV in Kenya.

AYLHIV would benefit from new interventions that can improve their outcomes of retention, adherence, and viral suppression. Adolescents and young people experience many challenges to achieving retention and viral suppression [8-10] including fear of disclosure [11], lack of social

support, unaddressed mental health needs [12], and lack of services designed to meet their unique social, interpersonal, and developmental needs [13]. Additionally, AYLHIV needs are not static, and may change with age and development. For example, younger AYLHIV may need caregiver involvement to access services due to consent policies, whereas older AYLHIV may struggle with self-management skills as they transition to independently managing care [14]. Regardless, all AYLHIV need comprehensive mental health services, as recommended by the World Health Organization [15]. To date, few studies have focused on delivering psychosocial interventions specifically tailored to this population; and studies focused on mental health interventions have demonstrated mixed findings [16]. Person-centered approaches, such as differentiation of HIV services, may address the diverse needs of this population by aligning available services with AYLHIV needs to optimize support to maintain life-long antiretroviral therapy (ART).

This dissertation comprises three aims, with the overall objective to evaluate implementation outcomes of a hybrid type 1 cluster randomized controlled trial, *Data-informed (DiSC) Stepped Care (DiSC) to Improve Adolescent HIV Outcomes*, designed to improve retention in care for AYLHIV [17]. Stepped Care [18], where individuals who need additional support are matched to increasing levels of services, is one approach that aligns resources to client needs, resulting in improved health outcomes and health system efficiencies. Use of a Stepped Care model may support health providers in care delivery, increase their efficacy, and address challenges they face, such as high caseloads and resulting limited time spent with each AYLHIV and poor quality of services [19]. Evaluating implementation of the DiSC stepped care intervention alongside evaluating intervention effectiveness is critical to shorten the time it takes to translate and scale-up effective evidence-based interventions into routine practice [20], ensuring that ‘what works’ reaches ALHIV with greater speed and efficiency.

Use of implementation science frameworks enriches our understanding of how to optimize and adapt interventions for maximum impact. Additionally, use of frameworks provides a way to harmonize findings across studies implemented in different settings and populations [21] to provide more generalized knowledge. We applied three implementation science frameworks to accomplish our overall objective of evaluating implementation outcomes of a stepped care intervention for AYLHIV. In Aim 1, the Framework for Reporting Adaptations and Modifications to Evidence-based interventions (FRAME) was applied to characterize provider-identified adaptations that were made to improve DiSC stepped care intervention fit with context. Quantitative surveys were also administered to assess provider perceptions of acceptability, appropriateness, and feasibility. In Aim 2, the Consolidated Framework for Implementation Research (CFIR) was used to understand key barriers and facilitators that influenced implementation outcomes of adoption, reach, and fidelity. In Aim 3, we used the Reach, Effectiveness, Adoption, Implementation, and Maintenance (RE-AIM) framework to guide evaluation of DiSC intervention performance along these key indicators, with the goal of improving understanding of how to optimize HIV service delivery for AYLHIV.

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Chapter 2. Using FRAME to characterize provider-identified adaptations to a stepped care intervention for adolescents and youth living with HIV in Kenya: A mixed methods approach

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Abstract

Introduction: The Data-informed Stepped Care (DiSC) study is a cluster-randomized trial implemented in 24 HIV care clinics in Kenya, aimed at improving retention in care for adolescents and youth living with HIV (AYLHIV). DiSC is a multi-component intervention that assigns AYLHIV to different intensity (steps) of services according to risk. We used the Framework for Reporting Adaptations and Modifications-Expanded (FRAME) to characterize provider-identified adaptations to implementation of DiSC to optimize uptake and delivery, and determine influence on implementation outcomes.

Methods: Between May and December 2022, we conducted continuous quality improvement meetings with providers to optimize DiSC implementation at 12 intervention sites. The meetings were guided by plan-do-study-act processes to identify challenges during early phase implementation and propose targeted adaptations. Meetings were audio-recorded and analyzed using FRAME to categorize the level, context, and content of planned adaptations and determine if adaptations were fidelity consistent. Providers completed surveys to quantify perceptions of DiSC acceptability, appropriateness, and feasibility. Mixed effects linear regression models were used to evaluate these implementation outcomes over time.

Results: Providers participated in 8 CQI meetings per facility over a six-month period. A total of 65 adaptations were included in analysis. The majority focused on optimizing integration of DiSC within the clinic (83%, n=54), and consisted of improving documentation, addressing scheduling challenges, and improving clinic workflow. Primary reasons for adaptation were to align delivery with AYLHIV needs and preferences and to increase reach among AYLHIV: with reminder calls to AYLHIV, collaborating with schools to ensure AYLHIV attended clinic appointments, and addressing transportation challenges. All adaptations to optimize DiSC implementation were fidelity consistent. Provider perceptions of implementation were consistently high throughout the

process, and on average, slightly improved each month for intervention acceptability ($\beta=0.011$, 95% CI: 0.002, 0.020, $p=0.016$), appropriateness ($\beta=0.012$, 95% CI: 0.007, 0.027, $p<0.001$), and feasibility ($\beta=0.013$, 95% CI: 0.004, 0.022, $p=0.005$).

Conclusions: Provider-identified adaptations targeted improved integration into routine clinic practices and aimed to reduce barriers to service access unique to AYLHIV. Characterizing types of adaptations and adaptation rationale may enrich our understanding of implementation context and improve abilities to tailor implementation strategies when scaling to new settings.

Clinical Trial Number: NCT05007717

Introduction

Ending the HIV epidemic requires achieving UNAIDS 95-95-95 HIV care cascade targets [1, 2]. The greatest gap for adolescents and youth living with HIV (AYLHIV) along the care and treatment cascade is achieving the third 95 target, with greater than 30% of AYLHIV not achieving viral suppression after 12 months on treatment [3, 4]. Improving HIV care for AYLHIV requires tailoring interventions [5-9] to their unique social, interpersonal, and developmental needs. Stepped Care is an evidence-based service delivery model, used in mental health to align individual needs with provided services [10], simplifying care for clients who are effectively managing their health and providing more intensive care for clients who need additional support. Stepped care approaches have been utilized in high income and resource-constrained settings, including Kenya [11, 12], to improve health outcomes for adolescent, youth, and adult populations [13, 14].

A stepped care approach was used to deliver services for AYLHIV enrolled in the Data-informed Stepped Care (DiSC) to Improve Adolescent HIV Outcomes study [15]. The DiSC intervention is multi-component and includes a clinical assessment tool that health providers use to assign AYLHIV to “steps” according to their level of need, with each step corresponding to evidence-based interventions aimed at supporting AYLHIV with retention in care. DiSC components include differentiated care [16-19] and psychosocial interventions (enhanced adherence and mental health counseling [20]), which are important patient-level strategies recommended by the World Health Organization for addressing clinical care needs of adolescents and young adults living with HIV.

To ensure evidence-based approaches for AYLHIV can effectively support retention in care, interventions need to be acceptable, appropriate, and feasible for local healthcare settings and practice. Health providers play a critical role in providing HIV care for AYLHIV. Provider-identified

adaptations of interventions may ensure HIV care services align with the needs of AYLHIV while simultaneously optimizing available resources [21, 22]. Adaptations, defined as thoughtful and deliberate changes made to programs or interventions [23, 24] are often made during the dynamic process of implementation. However, the who, when, what, how, and why adaptations are identified and prioritized during implementation are often not well documented, limiting knowledge dissemination from implementation experiences. Sharing of lessons learned is critical to inform integration and future scalability of evidence-based interventions that support AYLHIV with retention in care and to maintain life-long adherence to antiretroviral therapy.

In this paper, we aim to characterize intervention adaptations made by providers during early phase implementation of an ongoing cluster-randomized clinical trial (cRCT) in western Kenya [15] and examine how adaptations influenced intervention acceptability, appropriateness, and feasibility.

Methods

Study setting, population, and design

This analysis was implemented during the DiSC study, conducted from April 2022 to August 2023. DiSC was an effectiveness-implementation hybrid type I cRCT aimed to improve retention in care for AYLHIV in 24 HIV care clinics across Kisumu, Homabay, and Migori counties in western Kenya [15]. Participating HIV care clinics were selected based on client volume (≥ 100 AYLHIV in care), use of electronic medical records (EMR), and facility leadership interest. During early phase implementation, providers participated in continuous quality improvement (CQI) meetings to identify and prioritize adaptations that optimized DiSC implementation. We examined how adaptations influenced acceptability, appropriateness, and feasibility, measures which serve as indicators of the implementation process and are critical preconditions for achieving desired impact on clinical outcomes [25, 26].

The DiSC intervention

DiSC employs a Stepped Care delivery model [14], an evidence-based service delivery strategy, to align the needs of AYLHIV, ages 10-24, with provided services. The overall primary trial outcome measure is retention in care, defined as a missed visit (within a 30-day time period for any visit) and 12-month loss to follow-up [15]. Using a Stepped Care approach, AYLHIV with the highest need receive the highest intensity and frequency of care while allowing those effectively managing their HIV care to benefit from less intensive services. As part of DiSC, a clinical assessment tool is used by providers to identify AYLHIV at risk for loss to follow-up and assign them to four care “steps” (differentiated care, standard of care, individual counseling, or intensive support) [15]. The lowest care step (Step 1) aligns with differentiated service delivery strategies where HIV services include fast-track pharmacy refills and longer visit intervals [16, 27]. AYLHIV in Step 2 receive standard of care with standard visit intervals. As AYLHIV step up, visit frequency and service intensity increases, including provision of cognitive behavioral therapy (CBT) counseling sessions for AYLHIV who screened positive for depression, as determined by the Patient Health Questionnaire 2-item (PHQ-2) depression screening tool (Step 3). In the highest step (Step 4), clients with unsuppressed viral loads receive enhanced adherence counseling sessions and case management services including home visits. Adolescents and youth enrolled from control facilities received standard of care per Government of Kenya guidelines, which did not include the clinical assessment tool and referral approach, though some elements such as enhanced adherence counseling would be implemented for AYLHIV with viral non-suppression [27, 28].

Data collection

Between May and December 2022, health providers participated in twice-monthly CQI meetings using plan-do-study-act (PDSA) processes to make planned adaptations to optimize intervention implementation at their specific HIV care clinic. PDSA cycles consisted of four interrelated

processes: 1) Plan – providers identify a challenge and specific adaptation (change concept) to address the identified challenge, 2) Do – providers implement the proposed adaptation, 3) Study - providers evaluate the effect of the adaptation by reviewing improvement indicators and implementation experiences, and 4) Act – providers make a decision to either accept the adaptation as implemented, continue adaptation to improve implementation, or abandon the adaptation and begin a new cycle [29]; learnings from one cycle guide subsequent cycles. After the initial CQI meeting, the short-term impact of adaptations [30] on implementation outcomes of reach, adoption, and fidelity (correct step assignment and step reassessment) were shared at the subsequent meeting [31], allowing providers to determine if the adaptation resulted in short-term improvement [30], thereby informing their decision to adopt, adapt, or abandon each tested adaptation.

Although 144 CQI meetings were planned (12 per facility), 96 were implemented because providers experienced challenges identifying adaptations to test during subsequent cycles. Providers found the original 2-week interval insufficient to test adaptations and assess effect given AYLHIV return-to-clinic appointment windows. As a result, after the fourth CQI meeting, every other meeting shifted to informal check-ins with DiSC study research assistants (RAs) without identification of new adaptations. At the final CQI, all sites except one opted to use their meeting to discuss overall experiences with CQI meetings, summarize adaptations they tested and which were still being implemented, rather than identifying a final challenge to address.

CQI meetings were audio-recorded and facilitated by RAs. RAs were trained nurses or clinical officers. RAs used standardized PDSA worksheets to record highlights from each CQI discussion. During CQI meetings, providers identified challenges experienced during implementation and proposed targeted adaptations to intervention materials, procedures, or delivery to specifically address each identified challenge. Data were collected and managed using REDCap (Research

Electronic Data Capture), a web-based software platform hosted at the University of Washington [32, 33].

Prior to each CQI meeting, providers completed individual surveys that quantified their perceptions of intervention acceptability, appropriateness, and feasibility measures over time using a Likert scale from 1 – 5 (1=strong disagreement; 5=strong agreement) [25]. The survey was first administered April 2022 post-training but prior to starting the cRCT, and subsequently repeated every 2-weeks for 6 months for a total of 13 survey timepoints.

Data processing

CQI adaptations were analyzed by two primary analysts (NC and DO) using the Framework for Reporting Adaptations and Modifications to Evidence-based interventions (FRAME). FRAME allowed systematic evaluation of provider-identified planned adaptations over time to understand how and why health providers adapted delivery of DiSC [24]. Analysts reviewed PDSA worksheets and listened to CQI meeting audio recordings to identify key challenges experienced, adaptations planned, and rationale for selecting specific adaptations. Data informed development of CQI meeting summaries. At the conclusion of the adaptation period, one primary analyst (NC) extracted adaptation data from CQI meeting summaries and PDSA worksheets into an excel matrix containing FRAME constructs to categorize the level, context, and content of planned adaptations and determine if adaptations were fidelity consistent. The matrix also tracked whether adaptations were carried out as planned, and the final decision providers made on the proposed adaptation (i.e., adopt, adapt, or abandon). Adaptations were also categorized based on whether they represented one change idea or comprised multiple changes proposed as a single adaptation.

Analysts reviewed the adaptation matrix [34] independently and resolved differences in FRAME construct classification through discussion, referring to the audio files as needed, until reaching an agreement.

Statistical analysis

SankeyMATIC was used to develop a Sankey Diagram that illustrated the application of FRAME constructs [35]. Facility-specific trends in provider perceptions of intervention acceptability, appropriateness, and feasibility over time were visually displayed using scatterplots. Mixed effects linear regression models were used to evaluate provider perceptions of acceptability, appropriateness, and feasibility of the intervention over time (measured at monthly intervals) with random effects for provider and facility (p -value <0.05 was considered significant). Analysis was conducted using a complete case analysis approach and it was determined a priori that missing provider data was missing at random. Analyses were performed using the R statistical computing environment [36].

Ethical considerations

Research ethics approval was received from Maseno University Ethical Review Committee (MUERC/00917/20), the Kenya National Commission for Science, Technology and Innovation (444824), and the University of Washington Institutional Review Board (STUDY00011096). All health providers gave written informed consent.

Results

Health providers included nurses ($n=16$) and clinical officers ($n=38$; Table 1). The majority of providers were female (52%) and were a median age of 34 years (interquartile range [IQR]: 31-38). Providers reported a median of 5 years (IQR: 2-8) at their clinic, a median of 7 years (IQR:

5-9) providing care to people living with HIV of all ages, and a median of 6 years (IQR: 5-9) providing care and treatment specifically to AYLHIV.

Providers participated in a total of 96 CQI meetings, with each site completing at least eight PDSA cycles. Each CQI meeting included a median of 3 providers (IQR: 2-4) and lasted a median duration of 33 minutes (IQR: 20-44). CQI meetings where providers did not identify an adaptation (n=13), or where adaptations were research related (n=18), were excluded, leaving a total of 65 CQI meetings included in this analysis. Research related adaptations usually occurred during earlier CQI sessions (i.e., meetings 1-3) and involved initial study activities such as consenting and enrollment, whereas later adaptations were related to implementation.

Adaptation characteristics

Provider-identified adaptations were characterized using FRAME (Table 2). Of the 65 adaptations analyzed, 26 were unique. Adaptations based on one change concept (55%, n=36) were as common as adaptations that represented multiple change concepts proposed as a single adaptation (45%, n=29).

Contextual adaptations

The majority of proposed adaptations were related to context (83%, n=54), with 51 (78%) identified as exclusively context adaptations, and 3 bundled with content-related adaptations (Figure 1A). Context adaptations were made to format (76%, n=41), personnel (28%, n=15), and setting (9%, n=5) to optimize how DiSC was implemented at each facility (Figure 1B). Format-related context adaptations focused on integration of DiSC within the clinic and consisted of: 1) improving clinic workflows to identify AYLHIV needing step reassessment at visit follow-up, 2) decreasing AYLHIV waiting time at the clinic, 3) accommodating AYLHIV showing up for unscheduled visits, and 4) prioritizing specific clinic days for AYLHIV who need enhanced

adherence counseling. Adaptations were also made to remind providers to use the paper-based clinical assessment tool because majority of facilities were using an EMR system. Adaptations also focused on improving documentation to ensure updated AYLHIV contact information for reachability for appointment reminders and mobile delivery of counseling sessions. Additionally, improving documentation facilitated AYLHIV attendance at clinic visits (rather than medication pick-up by caregivers) by harmonizing visit schedules with school breaks.

Personnel-related context adaptations included sensitizing other providers (ex: peer mentors, lab staff, adherence counselors) to DiSC-related service needs to streamline clinic flow and ensure access to data (e.g., uploading latest viral load to the EMR to support step reassessment, updating AYLHIV contact information in the EMR). Setting-related context adaptations were made to provide space, such as a tent or room, so that mental health screening and counseling sessions could be conducted in a confidential and private environment.

Content-related adaptations

There were few targeted content-specific adaptations (9%, n=6; with three (5%) bundled with context related adaptations) given the focus on improving implementation rather than effectiveness. Content changes involved lengthening, shortening, and tailoring/tweaking/refining AYLHIV return to clinic appointment schedules, even though this meant visit intervals were not aligned with the DiSC clinical assessment tool. These adaptations were made to harmonize clinic appointments with the school calendar, address safety concerns post-presidential election results in 2022, address AYLHIV transportation challenges, and meet AYLHIV needs and preferences to have caregivers present during clinic appointments.

Training and evaluation adaptations

Adaptations related to training and evaluation (12%, n=8) focused on improving documentation, and best practices regarding tracking and follow-up of AYLHIV who were referred to mental health services to ensure receipt of motivational interviewing and CBT sessions, as recommended for AYLHIV assigned to the individual counselling “step”.

Adaptation rationale

Adaptations were primarily made to align intervention delivery with AYLHIV needs and preferences, prioritizing adaptations that improved the ability to meet the needs of specific groups of AYLHIV, such as those in boarding school or aged <15 years (46%, n=30; Figure 1C). These findings align with the main goals of the adaptations which were to improve fidelity (step reassessment: 28%, n=18; service exposure: 23%, n=15; step assignment: 2%, n=1), improve fit with AYLHIV (20%, n=13), increase reach/engagement (17%, n=11), and to improve clinical effectiveness (5%, n=3; Figure 1D).

Adaptations most frequently targeted the organizational level (38%, n=25; Figure 1E) and addressed resource availability (60%, n=15) and service delivery structure (32%, n=8; Figure 1F). For adaptations targeting the recipient level (28%, n=18), the most frequent determinant was related to motivation and readiness (94%, n=17). Adaptations targeted to the provider level (20%, n=13) were mainly due to provider’s previous training and skills (46%, n=6) and perception of the intervention (38%, n=5). Finally, adaptations targeting the sociopolitical level (17%, n=11) were predominantly motivated by societal/cultural norms (82%, n=9).

Relationship to fidelity

None of the proposed adaptations impacted the core elements of the intervention (i.e., step assignment, and step re-assessment), therefore all adaptations made by providers to optimize DiSC implementation at their facility were considered fidelity consistent.

Decision on adaptation implementation

Eighty-three percent of adaptations were carried out as planned, with providers making the final decision to adopt (63%), adapt (35%), and abandon (2%) proposed adaptations. Only one adaptation, related to improving workflow by applying stickers to client files to make it easier to identify AYLHIV enrolled in the study, was abandoned. This adaptation was abandoned due to lack of supplies.

Implementation outcomes: acceptability, appropriateness, and feasibility

Overall provider perceptions of acceptability, appropriateness, and feasibility were high; trends were consistent across facilities and across early-stage implementation outcome measures (Figures 2-4). Excluding pre-trial scores, intervention acceptability, appropriateness and feasibility measures were consistently high throughout the implementation process (acceptability mean (SD): 4.89 (0.35), median (IQR): 5 (5, 5); appropriateness mean (SD): 4.85 (0.41), median (IQR): 5 (5,5); feasibility mean (SD): 4.87 (0.38), median (IQR): 5 (5,5)). However, provider perception did slightly improve over time. Average monthly change over time was statistically significantly higher across all implementation outcome measures (acceptability $\beta=0.011$, 95% CI: 0.002, 0.020, $p=0.016$; appropriateness $\beta=0.012$, 95% CI: 0.007, 0.027, $p<0.001$; feasibility $\beta=0.013$, 95% CI: 0.004, 0.022, $p=0.005$) (Table 3).

Discussion

Intervention adaptability is a potential facilitator of implementation success and determinant informing strategies for scale-up and scale-out to new settings and populations [37]. Our analysis characterized provider-identified adaptations across 12 HIV care clinics in western Kenya using FRAME, an adaptation framework previously applied across multiple disciplines, populations, and settings [38-51]. FRAME uses a systematic approach to understand how adaptations improve contextual fit, and improve relevance of intervention content. In our study, systematic tracking of adaptations enabled better understanding of adaptation rationale and how to optimize intervention fit. Providers identified and made adaptations that addressed the challenges they experienced during implementation, such as incorporating the stepping tool into existing workflows. A key finding was that despite differences between clinic settings and organizational structures, providers made similar types of adaptations to improve intervention fit. With time, providers identified fewer challenges to address, and adaptations made had less impact on implementation outcomes since previous adaptations had already partially optimized fit of DiSC to their setting. Understanding context during implementation informs applicability across settings by improving our knowledge of what is generalizable and what is not. We found that the majority of adaptations providers made were context specific, addressing clinic workflow and documentation challenges. A few adaptations focused on content, specifically adjusting for the school calendar.

The majority of provider adaptations were intended to align DiSC delivery to better meet AYLHIV needs and preferences, with minimal disruption to routine service provision. During implementation, context adaptations were made to ensure that administration of the PHQ-2 depression screening tool, and adherence or CBT counseling sessions, were done in settings that provided privacy and confidentiality. For younger AYLHIV, providers adapted delivery to accommodate caregiver involvement as needed. Some AYLHIV preferred having caregivers

present during clinic visits. Especially for younger AYLHIV (ages 10-14), providers found that caregiver involvement made it easier to explain the importance of keeping scheduled clinic appointments and deliver some components of DiSC, including CBT counseling sessions. Many adaptations were related to aligning clinic visit schedules to accommodate AYLHIV who were in boarding schools, common for adolescents and young adults in Kenya. We found that Step 1 of the DiSC intervention, differentiated care, was best aligned with the school calendar, which may be a motivating factor for AYLHIV to adhere to medications and routinely attend scheduled clinic visits in order to qualify for differentiated care visit schedules.

Adaptations that optimize intervention fit in real-world settings can impact fidelity [26]. All adaptations made by providers during implementation were fidelity consistent and did not impact “core” components of the DiSC intervention, which included initial stepping with the clinical assessment tool, re-stepping with the tool at each subsequent visit, or receiving services aligned with the four care “steps” (differentiated care, standard of care, individual counseling, or intensive support). The main content change made to the DiSC intervention was related to visit frequencies for different steps.

FRAME was originally designed and applied within the US-based healthcare system with psychosocial interventions focused on mental health, substance abuse, sexual risk prevention and HIV prevention [24, 52]. As FRAME is used for different types of evidence-based interventions and in different health systems contexts, it may need minor modifications. A potential future refinement of FRAME could be to connect the goal of an adaptation to service, client, or implementation science outcomes [23]. Additionally, although FRAME categorizes the goal of an adaptation, it does not identify the potential relationship between an adaptation and the potential mechanism of action (and mediating or moderating effects) [53, 54] that brings about the desired outcome. Understanding potential mechanisms of action may inform identification of

implementation strategies to overcome challenges experienced during early phase implementation as well as future scale-up.

Our study had several strengths. We collected quantitative measures of provider perceptions of acceptability, appropriateness, and feasibility of the DiSC intervention over time [25]. These implementation outcome measures are important for monitoring successful implementation efforts. Giving providers support to identify challenges of importance to them and develop their own strategies to address them, may have contributed to improved perceptions of these measures over time. To our knowledge, simultaneously quantifying and tracking implementation outcomes alongside characterization of adaptations is an innovation unique to our study.

Our analysis has limitations. Given our focus on adaptations to address intervention delivery, our analysis did not include evaluation of client reported outcomes. Although including quantitative measures of acceptability, appropriateness, and feasibility was a strength of our study, it was also a limitation because these scores were consistently high throughout implementation. However, we demonstrated in the mixed effects linear model that provider perceptions slightly increased over time. We are not aware of alternative measures for these constructs that have evidence of reliability and validity. We note that facility 7, in comparison to other sites, showed a decrease in these measures over time. We did not identify any differences in participation in the CQI meetings related to cadres, numbers of meetings, and types of adaptations made at this site. Overall, because providers made single or multiple adaptations at a time, it was challenging to link short-term impact on improvement indicators of reach, adoption, and fidelity with the adaptation being tested. It was also unclear whether observed impacts on outcomes are due to a single adaptation or the cumulative effect of several adaptations implemented sequentially. Additionally, reach and adoption may be a result of AYLHIV return to clinic schedule, and providers on leave or transferred out respectively, rather than a result of the adaptation being tested. However, using a framework

to unify adaptation descriptions is a first step towards understanding how adaptations impact implementation outcomes and success.

Conclusion

We used FRAME as a systematic way to track and categorize adaptations made to a multi-component intervention supporting AYLHIV with retention in care. Adaptations identified by providers targeted improved integration into routine clinic practices and better meeting the needs of AYLHIV. Our study successfully adapted the elements of FRAME to capture adaptations to intervention delivery in HIV clinics in Kenya. Understanding adaptations within this framework was critical in identifying implementation challenges that were unique for AYLHIV services, such as the school calendar. The lessons learned during early phase implementation may inform Kenya Ministry of Health best practices for engaging youth and supporting them along the treatment and care continuum, ultimately informing future scalability of youth-centered interventions [20] in HIV care clinics across Kenya.

Competing interests

The authors have no competing interests to disclose.

Author's contributions

PKK, GJS, and KA serve as principal investigators of the study. JB, JK, WJ, and KA contributed to data collection and management. DO provided support supervision for the quality improvement meetings. NC and DO categorized the adaptations data. NC analyzed data with support from DO, KBS, WJ, and BAR. NC drafted the initial manuscript; KBS, DIM, PKK, KA, BAR, and GJS critically reviewed and revised the manuscript. All authors have reviewed and approved the final manuscript.

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Data availability statement

Data available upon reasonable request.

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Table 1. Demographic characteristics of health providers across intervention facilities

Characteristic*	N (%) or Median [IQR]
Primary work location	
Comprehensive Care Clinic	48 (89)
Other ¹	6 (11)
Sex	
Male	26 (48)
Female	28 (52)
Age (years)	34 [31, 38]
Highest level of education: University/college	54 (100)
Healthcare Provider Classification	
Clinical Officer	38 (70)
Nurse/Nurse Counselor	16 (30)
No. of years at current clinic	5 [2, 8]
No. of years providing HIV care to PLHIV (all ages)	7 [5, 9]
No. of years providing HIV care to AYLHIV (ages 10-24 years)	6 [5, 9]

*N=54; The majority of health providers filled out a demographic survey prior to the start of DiSC trial implementation, with 5 providers filling out demographic information when continuous quality improvement meetings concluded; 4 providers are missing demographic information and not included in this table; ¹Other category includes: Prevention of Mother-to-Child Transmission, Maternal Child Health, and Outpatient Departments. Abbreviations: PLHIV=People living with HIV; AYLHIV=Adolescents and youth living with HIV

Table 2. Framework for Reporting Adaptations and Modifications-Expanded (FRAME) classification system¹ to characterize provider-identified adaptations

Constructs	Coding categories
WHEN was the adaptation made? ²	- During early implementation phase (initial 6 months)
Were adaptations PLANNED ? ²	- Planned/proactive with continuous quality improvement (CQI) using Plan-Do-Study-Act (PDSA) cycles
BY WHOM are adaptations made? ²	- Health providers (nurses and clinical officers) at intervention facilities
Consisted of ONE CHANGE IDEA or MULTIPLE CHANGE IDEAS proposed as one adaptation? ³	- Single/Simple - Bundled/Complex
WHAT was modified?	- Context (changes made to where, when, what, or how) - Content (changes made to content itself or impact how aspects of intervention are delivered) - Training and evaluation (changes made to the way that staff are trained or how intervention is evaluated)
At what LEVEL OF DELIVERY (for whom/what are modifications made)	- Individual Recipient Level - Target Intervention Group: all individuals with the problem that is being targeted - Cohort/individuals that share a particular characteristic - Individual Practitioner - Specific Group of Practitioners - Clinic/unit level (HIV clinic) - Organization (entire Facility impacted) - Network System/Community (outside Facility)
If CONTEXT changes, modifications are made to which of the following?	- Format - Setting - Personnel - Population
If CONTENT changes, what was nature of modification?	- Tailoring/tweaking/refining - Changes in packaging or materials - Adding elements - Removing/skipping elements - Shortening/condensing (pacing/timing) - Lengthening/extending (pacing/timing) - Substituting - Reordering of intervention modules or segments - Spreading (breaking up session content over multiple sessions) - Integrating the intervention into another framework - Integrating another treatment into EBP - Repeating elements or modules - Loosening structure - Departing from the intervention (“drift”) followed by a return to protocol within the encounter - Drift from protocol without returning

WHY? What was the goal of the adaptation?	- Increase reach (number of AYLHIV exposed or engaged with the intervention) - Improve clinical effectiveness (improve clinical outcomes of AYLHIV) - Increase adoption (number of providers using the DiSC tool/delivering intervention) - Increase acceptability, appropriateness, or feasibility (summed up as fit) - Decrease costs of implementation - Improve fidelity (correct step assignment) - Improve fidelity (correct service exposure) - Improve fidelity (re-assessment of correct step assignment at subsequent visits) - Improve fit with recipients - Improve sustainability of EBP - To address cultural factors
LEVEL of Rationale (Reasons for making the adaptation)	- Sociopolitical - Organization/Setting - Provider - Recipient/client
FACTORS that influenced level of rationale	- Sociopolitical (existing laws, mandates, policies, and regulations; political climate; societal/cultural norms) - Organization/Setting (service structure; available resources; location/accessibility; time constraints) - Provider (preferences; previous training and skills; perception of intervention) - Recipient/client (motivation and readiness; access to resources)
Relationship to FIDELITY	- Fidelity Consistent/Core elements or functions preserved - Fidelity Inconsistent/Core elements or functions changed - Unknown
Adaptation DECISION ³	- Adopt - Adapt - Abandon

¹Compiled from Stirman et al., 2019, FRAME coding manual, and Rabin et al., 2018, Table 2;

²Not coded because no changes were made to these constructs during early phase implementation;

³Additions to FRAME

Table 3. Mixed effects linear regression model of health provider perception of acceptability, appropriateness, and feasibility measures over time

	Acceptability			Appropriateness			Feasibility		
	β	95% CI	p-value	β	95% CI	p-value	β	95% CI	p-value
Intercept	4.82	4.71, 4.93	-	4.75	4.60, 4.90	-	4.79	4.66, 4.93	-
Time (months)	0.011	0.002, 0.020	0.016	0.012	0.007, 0.027	<0.001	0.013	0.004, 0.022	0.005

CI=Confidence Interval

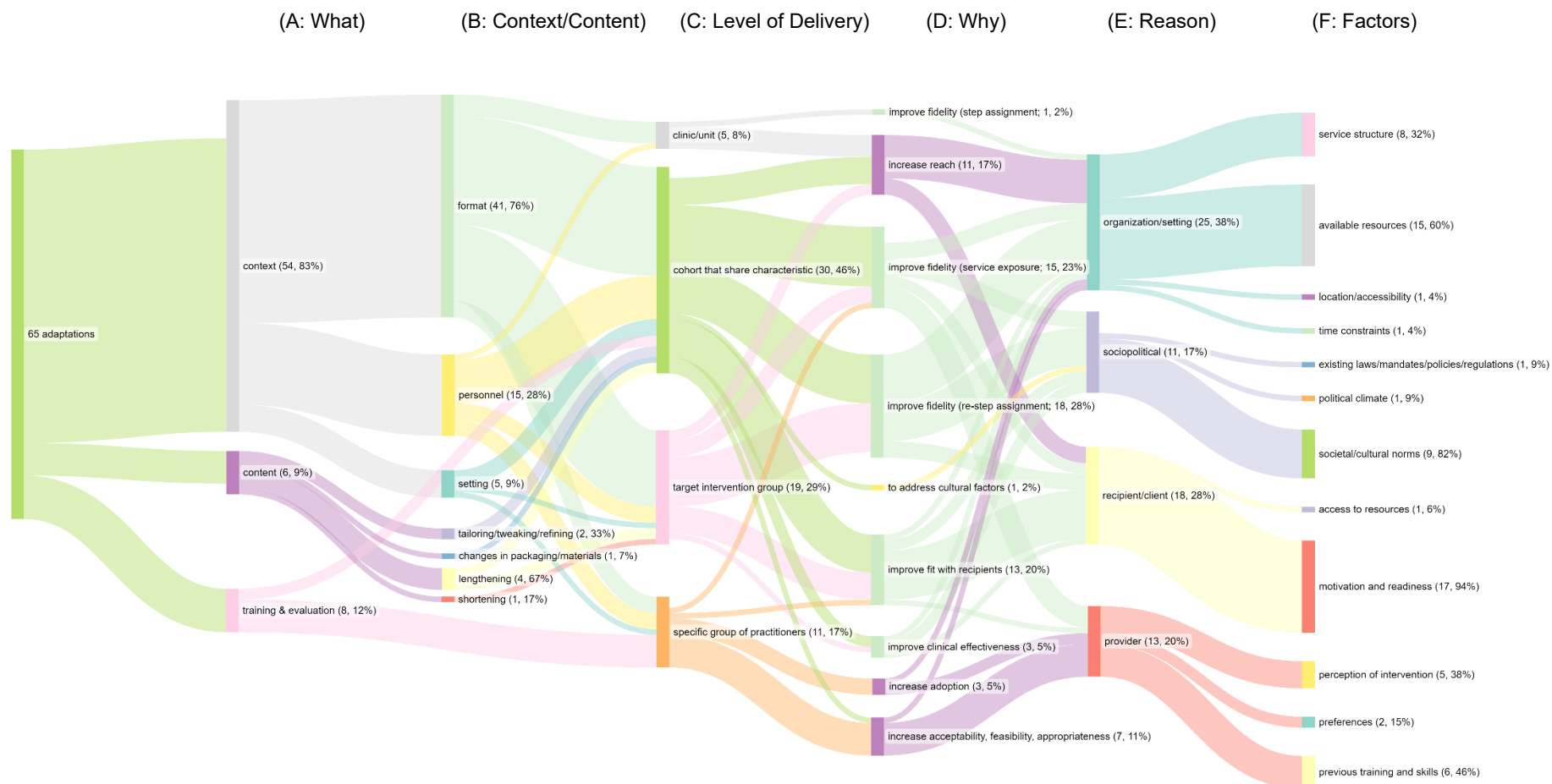


Figure 1. Sankey Diagram for Framework for Reporting Adaptations and Modifications Expanded. (A) **WHAT** was modified? (B) If **context** or **content** changes, modifications are made to which of the following? (C) At **what LEVEL of delivery**?; (D) **WHY**? Goal of the adaptation; (E) **LEVEL** of rationale (reasons for making the adaptation); (F) **FACTORS** that influenced level of rationale; Adaptations may cover multiple categories, therefore, percentages may total more than 100 percent; Width of flow lines are related to percentage.

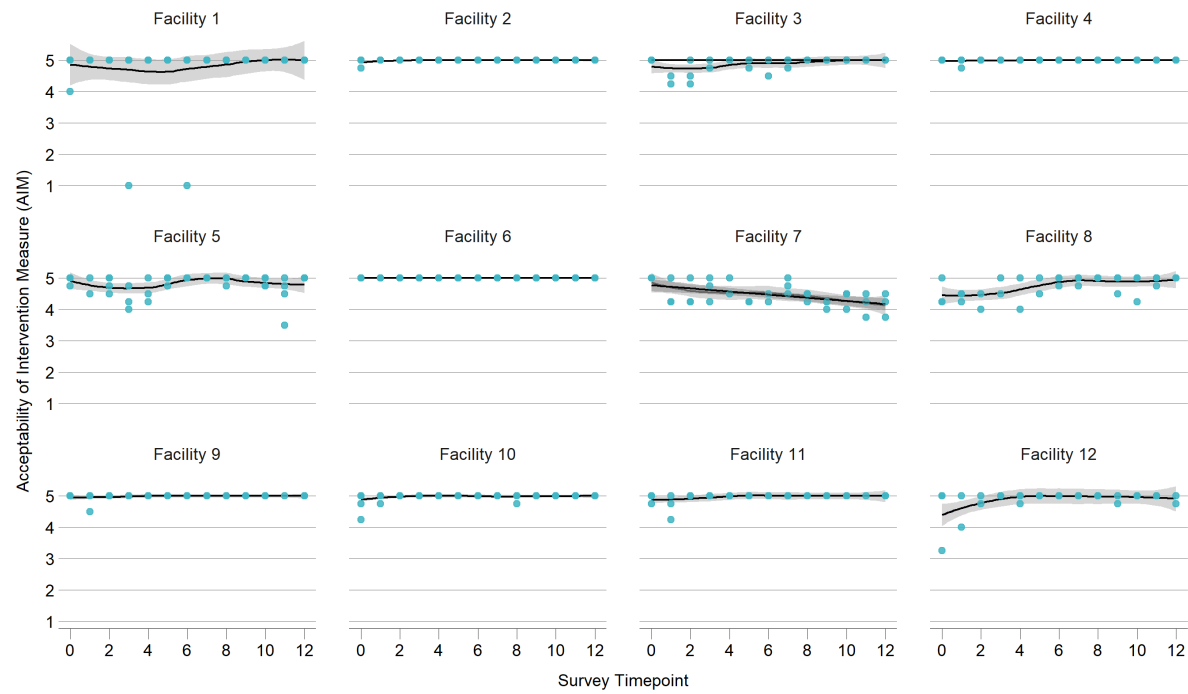


Figure 2. Acceptability of Intervention Measure (AIM). Provider perceptions of acceptability during Stepped Care early implementation phase, including pre-trial survey timepoint (April – December 2022).

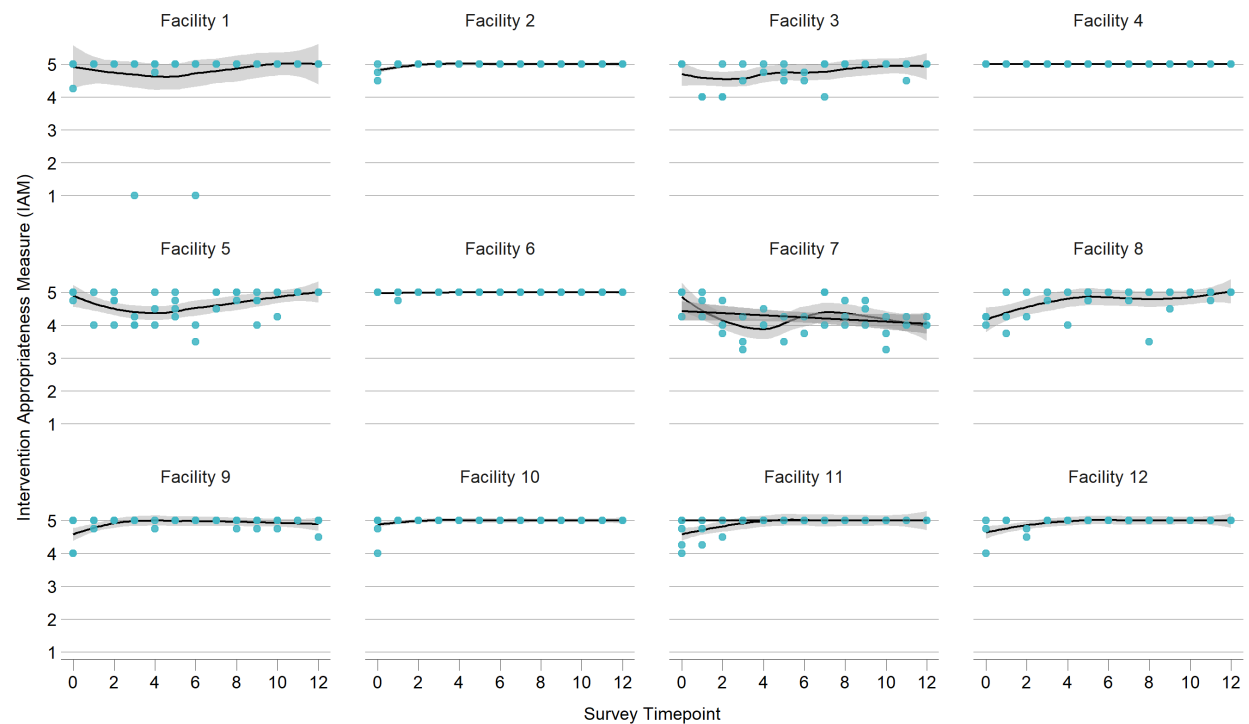


Figure 3. Intervention Appropriateness Measure (IAM). Provider perceptions of appropriateness during Stepped Care early implementation phase, including pre-trial survey timepoint (April – December 2022).

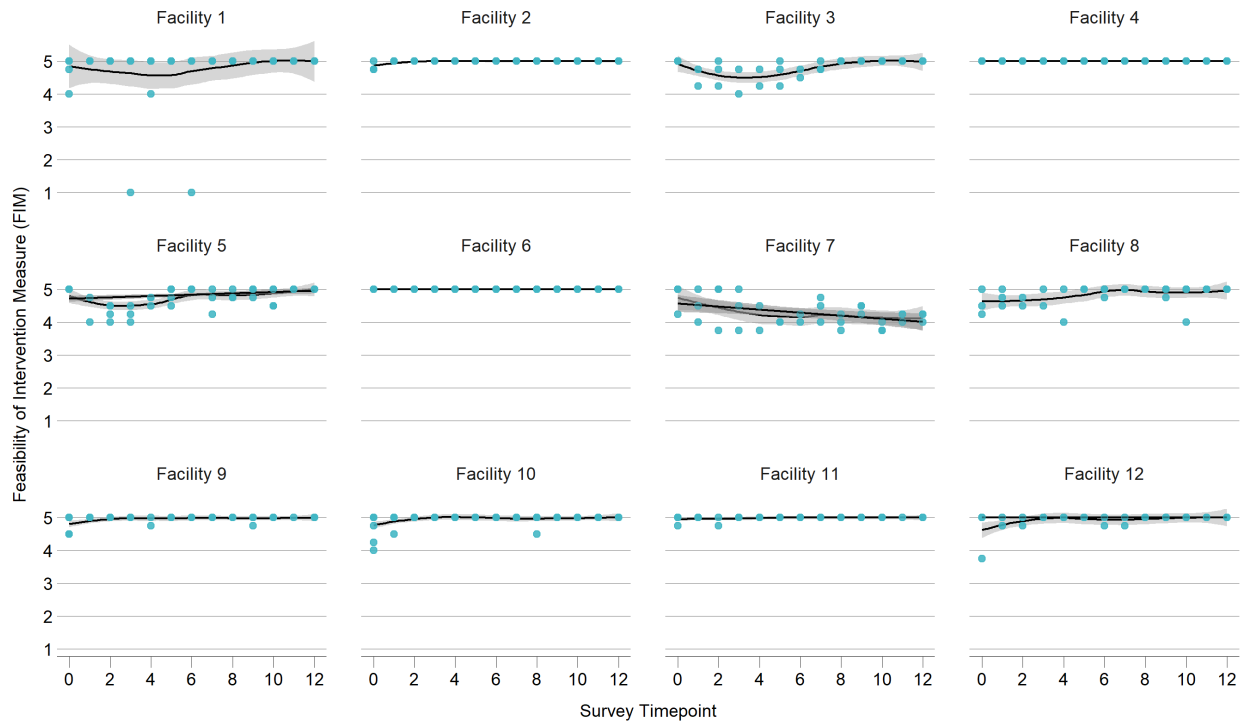


Figure 4. Feasibility of Intervention Measure (FIM). Provider perceptions of feasibility during Stepped Care early implementation phase, including pre-trial survey timepoint (April – December 2022).

Chapter 3. Determinants of implementation of a stepped care intervention for adolescents and youth living with HIV in Kenya: A qualitative evaluation

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Abstract

Background: Differentiation of HIV services, a client-centered strategy, may improve care outcomes among adolescents and youth living with HIV (AYLHIV). Understanding health provider perceptions of barriers and facilitators that influence implementation can optimize adoption and sustainment of health systems interventions.

Methods: The Data-informed Stepped Care (DiSC) study was a cluster randomized controlled trial of a stepped care intervention in 24 HIV care facilities in Kenya. At each visit, providers used an assessment tool to allocate AYLHIV to services according to level of need. Stable clients were allocated to differentiated service delivery (DSD) with less frequent visits. Intensified services, including behavioral counseling, were provided for those with greater likelihood of loss to follow-up, mental health issues, or viral non-suppression. We conducted focus group discussions (FGDs) with providers across 12 intervention sites between January-February 2023. FGDs used a semi-structured interview guide, grounded in the Consolidated Framework for Implementation Research, were audio-recorded and transcribed. Transcripts were analyzed using a team-based rapid turnaround approach to characterize key determinants influencing adoption, reach, and fidelity.

Results: Providers were enthusiastic about, and quick to adopt, the DiSC intervention. They found the DiSC tool easy to use and felt it provided a relative advantage by improving service delivery efficiency and prioritizing time with higher need AYLHIV. Providers noted the importance of tool flexibility to align with changing national guidelines. They expressed concerns about compatibility with existing workflows at facilities exclusively using electronic medical record (EMR) systems, suggesting EMR integration will be needed for intervention sustainment. AYLHIV eligible for DSD benefited from clinic visit intervals that aligned with the school calendar, which posed a

challenge for reaching AYLHIV in more intensive steps. Provider collective efficacy was important in consistent implementation of DiSC and was facilitated by continuous quality improvement meetings, access to knowledge and information, and perceived intervention effectiveness. Supportive leadership was an important driver of implementation success, through availing space for mental health counseling sessions and time for client-provider interactions outside standard operating hours.

Conclusions: Consideration of alignment with national policy, integration into clinic workflows, school schedules, and leadership engagement, will be important for sustained use of differentiated care interventions.

Trial Registration: ClinicalTrials.gov, NCT05007717.

Keywords: Consolidated framework for implementation research (CFIR), implementation determinants, implementation science, HIV, adolescents and young adults, differentiated service delivery, Kenya

Contributions to the literature

- By studying the impact of expanded service delivery strategies alongside revised guidelines for differentiated service delivery (DSD), we are generating timely and critical knowledge to support implementation of DSD for adolescents and youth living with HIV (AYLHIV).
- We identified that provider participation in continuous quality improvement meetings was important for promoting collective efficacy and facilitated implementation of DiSC aligned to real-world healthcare settings and practice.
- Differentiation of HIV care services improves outcomes; providers perceived that AYLHIV are maintaining their adherence, clinic appointments, and viral suppression.
- Providers recognized and valued the importance of psychosocial interventions for AYLHIV experiencing mental health challenges.

Background

Adolescents and youth living with HIV (AYLHIV) continue to bear a disproportionate HIV burden with lower retention and viral suppression rates when compared to adults [1-3]. A critical gap remains in reaching viral suppression targets for AYLHIV [4], with greater than 30% not virally suppressed after 12 months on treatment [5]. Achieving the UNAIDS 95-95-95 targets for AYLHIV will require interventions designed to meet their unique social, interpersonal, and developmental needs [6]. Client-centered strategies that have proven effective for adult populations, such as differentiation of HIV services [7], may also benefit adolescents and young adults.

Differentiated service delivery (DSD) models of care have been used in a variety of settings to improve treatment adherence, retention in care, and viral suppression [8, 9]. Recently updated World Health Organization (WHO) guidelines include adolescents and young adults as eligible for DSD [10]. In alignment with updated WHO recommendations, the Kenya Ministry of Health revised their HIV Prevention and Treatment guidelines to expand differentiated care services to AYLHIV in August 2022 [11]. As a result, AYLHIV are now eligible for services for which they did not previously qualify, such as multi-month refills or longer visit intervals between clinic appointments. As DSD services continue to expand to new populations, it will be important to evaluate strategies for implementing DSD alongside evaluation of the impact of DSD on HIV care and treatment outcomes [12-14].

The “Data-Informed Stepped Care (DiSC) to improve adolescent HIV outcomes” study was a hybrid type 1 cluster randomized controlled trial testing provision of a stepped care program including DSD and intensified services across 24 HIV care facilities in Kenya. Using routinely available data, a clinical assessment tool, and a stepped care service delivery approach [15], DiSC included intensified services (e.g., motivational interviewing, cognitive behavioral therapy sessions, enhanced adherence counseling) for higher need AYLHIV, in addition to differentiated

services for AYLHIV who are effectively managing their care [16]. Examining the implementation of expanded service delivery strategies can provide timely and critical knowledge about how to optimize HIV care tailored for AYLHIV needs [6, 10].

In this qualitative assessment we aim to identify key barriers and facilitators that influenced adoption, reach, and fidelity of DiSC during early phase implementation. Additionally, we characterize providers' experience delivering differentiated care services for AYLHIV and highlight recommendations for DiSC integration and scale-up across HIV care clinics in western Kenya.

Methods

Study design, setting, and population

DiSC is a multi-component intervention where health providers use a clinical assessment tool, informed by routinely available data, to assign AYLHIV to different intensity (steps) of services (differentiated care, standard of care, individual counseling, or intensive support) aligned to their needs (Figure 1). Services offered for those in Step 1 are aligned with DSD, with less frequent scheduled visits and fast-track pharmacy visits. In Step 2, AYLHIV are assigned to standard of care and receive standard visit intervals per Government of Kenya guidelines [11]. Intensity and frequency of services increase as AYLHIV step up; those in Step 3 receive cognitive behavioral therapy (CBT) counseling sessions if mental health support is needed. Lastly, clients with unsuppressed viral loads are assigned to Step 4 and receive enhanced adherence counseling sessions, transportation support to attend clinic appointments, or home visits. A more detailed description of DiSC has been previously published [16].

The DiSC study was conducted in 24 HIV care facilities across Kisumu, Homabay, and Migori counties from April 2022 to August 2023 [16]. The healthcare facilities located in the three counties

represented a mix of urban, rural, and fishing communities. HIV prevalence reported for these counties was 18.5% for Homabay, 17.5% for Kisumu, and 11.8% for Migori, compared to the national average of 4.5% reported in 2020 for adults aged 15-49 years old [17]. The highest rates of HIV acquisitions among youth ages 15-24 years is concentrated in these high prevalence counties in western Kenya [17].

Theoretical framework

We used the Consolidated Framework for Implementation Research (CFIR) [18, 19] to examine barriers and facilitators experienced during early phase implementation of DiSC. The semi-structured interview guide used during discussions with providers was grounded in relevant CFIR constructs across five domains: intervention characteristics (e.g., complexity, relative advantage), inner setting (e.g., compatibility, access to knowledge and information), outer setting (e.g., patient needs and resources, external policies and incentives), characteristics of individuals (e.g., knowledge and beliefs about the intervention), and process (e.g., engaging, executing), with an additional domain (characteristics of systems) and novel constructs (e.g., resource continuity, collective efficacy, team characteristics, community characteristics) relevant in low- and middle-income settings [19].

Data collection

Between January and February 2023, we conducted 12 focus group discussions (FGDs) with providers from DiSC intervention sites (Kisumu n=3, Homabay n=4, Migori n=5). All health providers from intervention sites who participated in continuous quality improvement (CQI) meetings to optimize DiSC implementation at their HIV care clinic [20] were purposely recruited for participation in FGDs. Providers were ≥18 years old and were nurses or clinical officers with experience delivering HIV care services to adolescents and young adults.

Discussions were facilitated by an experienced Kenyan social scientist (WAO) who was not involved in study implementation and did not know the participants prior to the FGDs. FGDs were also supported by two additional research team members, who were not involved in providing support supervision during the CQI meetings (JK and NC). Discussions were primarily conducted in English, but providers were also encouraged to use Kiswahili to describe their experiences if preferred. FGDs had a median of 3 providers (interquartile range [IQR]: 3, 4), lasted a median of 75 minutes (IQR: 60-86 minutes) and were audio recorded, translated as needed, and transcribed verbatim. Structured debrief reports were generated by the notetaker (NC) within 48 hours to summarize key information from each FGD.

Data Analysis

A *Sort and Sift, Think and Shift* rapid qualitative analysis approach [21-23] was used to identify barriers and facilitators of DiSC intervention implementation, and provide recommendations on integration and scale-up. Transcripts were analyzed using the following adapted team-based rapid turnaround qualitative analysis approach. First, an FGD summary template was developed using the CFIR constructs and implementation outcome measures organized by three main headings: facilitators, barriers, and recommendations. Three team members (NC, DIM, KBS) summarized one common transcript using the summary template to ensure consistency in capturing key themes and constructs influencing DiSC adoption, reach, and fidelity during the early implementation phase. Team members discussed and compared summary styles and revised the transcript summary to improve usability. Afterwards, two team members (NC, DIM) summarized an additional common transcript using the revised template summary, which was then reviewed by a third team member (KBS). Once consistency was established, the remaining transcripts were divided between two team members (NC, DIM) and each transcript was summarized by one team member and the transcript summary reviewed by another member. During transcript summary review, disagreements in identified constructs were noted and

resolved through group discussion with the larger qualitative analysis team. One primary analyst (NC) abstracted data from final versions of transcript summaries into an excel matrix that displayed the data by site, CFIR constructs, and barriers and facilitators to adoption, reach, and fidelity. Identified constructs were compared between sites to summarize their overall influence on implementation. The matrix and preliminary results were shared and discussed with local research team members (WAO and JK) who were present during the FGDs to ensure agreement with main findings and overall synthesis.

Descriptive characteristics of providers were summarized using counts, proportions, medians and interquartile ranges (IQR) using the R statistical computing environment [24].

Results

A total of 43 health providers participated in 12 FGDs. The majority of providers were clinical officers (72%), male (51%), with a median age of 34 years (Interquartile range [IQR]: 31-37). Providers reported a median of 4 years (IQR: 1-7) working at their respective clinic, and a median of 6 years (IQR 5-9) engaged in providing care and treatment for AYLHIV (Table 1). Overall, providers described high acceptability and a general positive experience engaging with the DiSC intervention. They were enthusiastic about how the clinical assessment tool guided service provision, perceiving an improvement in client satisfaction by using this service delivery strategy.

“I really like using the tool, because it's really guiding whether to step up, step down or maintain the client on the current care that the client is [receiving]. And even our clients, actually, when we offer them these services using the tool, they're getting satisfied. And when you serve a client and the client is satisfied, you as a healthcare provider also feel satisfied. I say it has really helped us and our clients.” [P2, Facility 4]

An overview of barriers and facilitators influencing adoption, reach, and fidelity during early phase implementation of DiSC are presented in Table 2. Key determinants were predominantly related to intervention characteristics, inner setting, and outer setting CFIR domains.

Implementation Outcome: Adoption

Primary drivers of adoption included health provider access to knowledge and information, perceived complexity of implementation, and shared belief in their collective efficacy. Providers perceived that their readiness for implementation was facilitated by the quality of training they received prior to DiSC implementation. The majority of health providers felt that the training was informative and gave them the knowledge needed to do what was “right” for their clients.

“The training was sufficient so that it prepared us to face the challenges directly from the clients. If it were that we were not trained, then it will be difficult to lend information to the clients because it’s me and my colleagues the clients were questioning. So, if we’re not trained, then it could be difficult to respond. So, the training was sufficient, it prepared us to face the work.” – [P5, Facility 4]

In contrast, some providers reported gaps in the quality of the training sessions noting that the training was too short for them to absorb all of the information or led them to mistakenly believe that the DiSC tool would be complicated to implement. Additionally, although providers were trained on *how* to use the tools, some felt they did not leave the training with an understanding of *why* they were assessing and assigning AYLHIV using the DiSC tool. However, once they began using the tool, they found it to be valuable in addition to decreasing their workload.

“[A]t first, it was like this is another difficult one... we were saying why are these people adding us more jobs, we have a lot of work and you are adding more. So, the fact still

remains that at the beginning we were not interested... which I think as time goes, that one faded out and we noted that in fact, it even lessened the work at the end of the day.”

– [P2, Facility 3]

With time, providers' perceived complexity of the intervention improved, it became easier to implement, and they found the overall design and service delivery approach beneficial. They described the DiSC intervention as providing a relative advantage when compared to existing service delivery strategies because it improved efficiency by prioritizing time with higher need AYLHIV while simultaneously reducing time spent with AYLHIV who were doing well. This perceived advantage further facilitated provider adoption.

[T]he tool has really reduced our work; once the clients who are categorized as established; we will now give them a longer TCAs [clinic appointments] so we don't see so many clients with their specific day..... Initially we used to see more than 70 clients in one week, but currently with the Step [1] we can give very long TCAs so we see like 30, 20, it has really reduced our workload.” – [P2, Facility 12]

Providers were motivated to continue implementing DiSC due to perceived intervention effectiveness. They noticed the impact of DiSC on clinical outcomes and recognized that AYLHIV can benefit from the differentiated service delivery model.

“I think our intention was to see, can it really work? And I can see that it is working. Because when we are saying to them, Step 1, and they're still adhering, they're still keeping their TCAs [clinic appointments] and they're still virally suppressed. We've not seen any challenge by putting them in Step 1.” – [P2, Facility 4]

Providers at one facility were so enthusiastic about their experience during implementation that they integrated DiSC into their workflow for all AYLHIV at their clinic, irrespective of enrollment in the clinical trial, and considered the tool a routine “part of their practice.”

“[W]e decided now, despite the fact that the number which the study wanted is over, but our clients were not over, remember we are offering services to clients, so we took initiative as [a] facility and now we are using it at our desk, that is the clinician desk, so he is able to step at that point.” – [P2, Facility 3]

Providers’ participation in continuous quality improvement meetings promoted their adoption of DiSC. During these meetings, providers identified the challenges they experienced during early phase implementation and the targeted adaptations they made to optimize DiSC implementation to their context, thereby increasing their shared belief in the collective capacity to use the clinical assessment tool and deliver the best services to AYLHIV. Further supporting their collective efficacy was the culture of teamwork and leadership engagement at their respective facilities. Providers felt that the relationships across departments, and collaboration among a diverse team of staff and other health cadres helped them to achieve implementation goals.

Implementation Outcome: Reach

Patient needs and resources, design quality and packaging, adaptability, and community factors influenced AYLHIV reach and engagement with the DiSC intervention. Providers perceived that DiSC facilitated individualized adolescent care to better meet adolescent needs.

“[T]his DiSC tool has assisted us in attending to adolescents individually and not as a group as we used to do. With the introduction of this tool, we were able to identify those who had specific needs...At first, we lacked confidentiality and privacy. We had no specific

room for that. With the introduction of the tool, we were able to create a room for that. And now more adolescents were able to open up. And through that we were able to get a lot of problems which these adolescents go through, and we were able to advise them accordingly. Though we were not able to manage them all because some were beyond us, but at least those that were within us, within our reach, we were able to tackle them. So, I can say that this tool has really helped us.” – [P3, Facility 2]

Providers observed that the design quality and packaging of DiSC supported client reach and engagement. Providers found that the longer appointment intervals relieved the transportation burden for adolescents who were located further away from clinics, allowing them to more consistently make scheduled appointments. For example, AYLHIV eligible for Step 1 differentiated care services benefited from clinic visit intervals that were aligned with the school calendar, which had been identified by providers as a primary reason why AYLHIV in boarding schools missed appointments in the past or sent their treatment supporters or caregivers to the clinic instead.

“...if you really go through the DiSC tool, it provides a kind of patient centered support. Because by stepping the clients, it's not just about assigning them TCAs [clinic appointments] because it makes you realize each and every adolescent is unique in their own way... So even if they're going to boarding school, and the majority of the boarding schools nowadays, they don't go past three months, so if I give them drugs for three months, what will make them miss their appointments? They will not have a reason. And then it tends...it works as a kind of motivation for them.” – [P1, Facility 8]

The adaptability of DiSC made it possible for providers to vary implementation approaches to maximize reach and engagement for AYLHIV. Providers described situations where leadership

supported the changes in workflow necessary to meet AYLHIV needs, including accommodating visits that were outside of regular hours.

“[T]here are some occasions where maybe you’ve realized that the client or the adolescent or the caregiver is not able to make it maybe during the weekdays. So, you’ve realized that maybe through a local arrangement, maybe this client can get time during the weekend? So, by this, I want to say that the administration did come and supported us because without them giving us that opportunity to be here on a non-working day then it means that it could not work. So that administration did support us because we could come even during the weekend and attend to those one or two unique cases.” – [P2, Facility 11]

Provider experience during DiSC implementation led to their recommendation of age-specific strategies to support AYLHIV with retention in care. Providers felt that younger AYLHIV need interventions focused on caregiver engagement whereas older AYLHIV need interventions focused on client motivation to support them with independently managing their care as the role of caregiver engagement changes.

“... [W]hen our adolescents come for their scheduled clinic, what we used to tell them is that the support will not continue, probably it might not be there in the near future. So, the issue here is just a matter of preparedness for the sustainability, the support might not be there. So, they get prepared.” – [P2, Facility 7]

For clients who were unable to come to clinic for various reasons, providers had the option to deliver intervention components, such as mental health counselling, over the phone, which reduced clients’ need to travel to the clinic for more intensive services in Steps 3 and 4. Despite

options for alternative delivery, most providers preferred in-person interactions and believed their clients also preferred in-person services. Providers noted that delivery by phone was not ideal and did not allow them to observe AYLHIV responses and emotional state.

“....[T]he hard cases we have to meet the client face to face the reason being sometimes we are doing over the phone you know other people may be in school. Yeah, they may be in a place that they may not have privacy now to talk things so you may not know whether you are dealing with the real thing or they’re just saying things to please you so that you understand.” – [P1, Facility 5]

Providers found it challenging to implement some of the mental health components given the lack of community recognition of the importance of mental health as a health issue. Lack of information and awareness made it hard to engage and follow-up with adolescents who were stepped to receive cognitive behavioral therapy sessions.

“The mental issues thing in our African setting. They don’t believe it’s an illness. So it is you to fix time with this client. In most cases, they are like, you are bothering them a lot.....The issue is getting this client, like for the client, I’m supposed to do “think in a different way part two,” [a session in the mental health counseling series] now she’s even not within, I’m still tracing her.” – [P1, Facility 3]

Implementation Outcome: Fidelity

Consistent implementation of DiSC per protocol was driven by stakeholder engagement, perceived intervention effectiveness, workflow and guideline compatibility, and existing human and material resources. Multiple levels of stakeholders were identified that had key roles in

supporting implementation, including AYLHIV, and their caregivers, providers, and facility leadership. Providers described how leadership support was important during implementation.

“Administration support, because of the time we take, you know, sometimes, you're not supposed to take long with those clients, because of ABCD. But now through the administration, and you explain to the clients, they allow those clients to be here fully. And then maybe sometimes you need to be here longer you'll be supported to be here. And then maybe you want to be with that client. And there's another thing that you should be doing. So, you are allowed to do, to continue with the stepping, and then another person takes over what you're supposed to do.” – [P4, Facility 11]

In addition to their influence on adoption, providers' perception of intervention effectiveness and collective efficacy facilitated consistent implementation of DiSC throughout the early implementation phase. Perceived positive impact on AYLHIV outcomes encouraged consistent intervention use. While they reported consistently using the DiSC stepping tool with all AYLHIV, providers recognized that it was challenging to assess mental health among younger clients using the Patient Health Questionnaire (PHQ-2) [25], potentially leading to inaccurate stepping and misalignment of service provision with identified need for younger AYLHIV. As a result, they recommended the tool be revised to capture caregiver input as a way to better assess the mental health needs of younger AYHLIV.

“I felt they were not the right indicators to assess mental health for that age... One, that children will never lose interest or will never have interest because they're directed to do the normal activity, be it learning. Like in our context in Kenya we don't develop interest in doing things even fetching water, cooking. We don't develop interest; we are instructed, we are given direction. So, they have never developed interest to maybe in any of those

activities you want to assess, they're always instructed So those indicators I found them not age appropriate to assess for mental health....That's why maybe we did not get much of mental health when those cases are there. We missed them because of the questions.” – [P6, Facility 6]

Related to implementation fidelity, providers identified compatibility with guidelines and workflows as the most influential challenge experienced. HIV care clinics were either fully paperless and using electronic medical records (EMR) or were in the process of transitioning. As a result, providers would sometimes forget to use the paper-based clinical assessment tool. However, they were able to collectively identify solutions to ensure that clients were being exposed to the tool and assigned to the correct ‘step’ when they returned to clinic.

“[W]hile you are using the step tool, we need to work within the guideline that is universal in the entire country. So that was the biggest thing that we were seeing...also another thing that we see is we're using the Kenya EMR [electronic medical record]; we are paperless but now the step tool was in paper form so you could easily forget once you've cleared the clients now you want to come and write on the papers.” – [P2, Facility 12]

Providers found implementing the tool as designed difficult because viral load assessment cut-off measures were not aligned with updated MoH guidelines, a change which occurred during the study implementation timeframe. Furthermore, when viral load information needed for stepping was not available, providers were not able to assign AYLHIV to their correct ‘step’ which prevented AYLHIV from receiving services aligned to their needs. For example, AYLHIV who may have qualified for a lower step assignment, continued to receive more intensive services (e.g. Step 4 adherence counseling) placing a burden on the AYLHIV as well as reducing efficiency in prioritization of provider time and resources.

“Like maybe when the viral load is not being done, like the experience we had; see like the whole [of] Kenya, the viral loads were not there. Now we’ll keep on stepping this person like maybe the previous viral load was just more than 50. So, this client will be always step four, step four...” – [P4, Facility 11]

Additional challenges to fidelity were related to available resources. Once viral load results were available, there were delays in uploading results into the EMR, making them unavailable for point of care use. To overcome this challenge, providers described working as a team to update viral load information in the EMR themselves so that “at each and every time we have the current viral load,” to assign AYLHIV their correct step assignment.

“...just to add on the viral load, another challenge we had was that given the long period that we’re not taking viral load, there was a backlog also, and in our facility, we only have one lab man. So, downloading of the results and keying them in the EMR [electronic medical record] used to take quite some time. So, at times also we had cases whereby the adolescents are seen with the previous viral loads yet there was a current one but has not been keyed in yet.” – [P4, Facility 4]

Recommendations for Scale-up

Based on their experiences with delivery, providers recommended expanding implementation of the DiSC intervention in HIV care clinics across Kenya.

“Let me say that whoever came up with this idea, it was a good thing. And for your information, it’s going to save quite a lot of adolescents. It’s going to save lives. So, something which is saving lives, what are you going to do about it? You roll it out, you expand it so that it captures a wider area of many youths to benefit.” – [P3, Facility 3]

When considering scale-up within Kenya, providers outlined specific considerations to improve implementation and effectiveness (Table 3). First, providers recommended modifications to the DiSC clinical assessment tool that would inform care and management, such as categorizing AYLHIV by age groups to address differences among those moving into adolescence and those who are aging out.

“I’d wish that the tool can be categorized to capture some of the uniqueness in those who are just stepping into adolescence and those people who are mature, almost getting out of adolescence... I would wish that we categorize them, so we have a tool specifically for maybe 15 to 24. And maybe 10 to 14. With some relevant questions in each age group to enable us to capture almost everything.” – [P2, Facility 3]

Second, providers identified strategies to support DiSC integration into routine care and workflows that addressed modifiable barriers experienced during implementation. These included aligning viral suppression cut-off criteria with changing Kenya national guidelines and incorporating the paper-based DiSC clinical assessment tool into the EMR system and integrating it with the Green Card, a Ministry of Health Clinical Encounter form that providers currently fill out at every visit. Recommendations also centered around building technical capacity to support scale-up, including expanding access to knowledge and information by training additional healthcare worker cadres, including peer mentors, community health workers, and lab technicians, because “everybody at one point is involved.”

To ensure resource continuity during scale-up, providers supported cascading mental health training to other colleagues. This would address challenges experienced during DiSC implementation when providers who were trained to deliver the mental health sessions were transferred out to another facility.

[N]owadays mental health is at a high rate and maybe what if the one who has been trained is not around. It will mean the client will not even get quality services.” – [P4, Facility 5]

Lastly providers highlighted the importance of continued engagement with multiple key stakeholders, including AYLHIV, caregivers, health facility leadership, educators, external partnerships, networks and organizations, the community, and the Ministry of Health, for successful scale-up.

Discussion

This qualitative evaluation aimed to identify key facilitators and barriers that influenced implementation outcomes of adoption, reach, and fidelity during early phase implementation of DiSC, a stepped care intervention for AYLHIV that was delivered in 12 intervention sites in western Kenya. We applied the CFIR, a determinants framework, to organize our understanding of key influences impacting implementation. Providers perceived that in Kenya, differentiation of HIV services was aligned with the school calendar for those in boarding school, and clients were able to manage their care with less provider interaction. Providers also perceived that under the DSD model available in the study, AYLHIV were maintaining their adherence, clinic appointments, and viral suppression. Our findings spotlight opportunities for strategy development to optimize integration of new interventions, such as DiSC that incorporate elements of DSD and other client-centered HIV services like psychosocial interventions for addressing AYLHIV mental health needs. Our intervention is novel in that the stepped care approach targets AYLHIV established in care, and those vulnerable to loss to follow up, by aligning available services to their individual needs.

Implementation of DiSC occurred against a background of policy recommendations that expanded DSD to adolescent and young adult populations. Alignment of DiSC study implementation timelines with changing guidelines offered an opportunity to assess how DSD for AYLHIV could be implemented in practice by providers, e.g., screening for eligibility and delivery of DSD services. Our study highlights the benefit of job aids and other tools that support providers in delivering care aligned to client needs. In our study, providers used the clinical assessment tool to guide use of routinely available data to place eligible AYLHIV in less-intensive differentiated services like longer visit intervals or pharmacy fast-track visits, while identifying those that need more targeted support. In research settings, various differentiated models of care have been successful in improving outcomes for AYHLIV, including retention in care [26, 27] and viral suppression [28]. An example of one approach to DSD in Kenya that has proven effective is the “Red Carpet Program,” where clients are fast-tracked to receive health services within a clinic setting [27, 29].

The perceived effectiveness of the DiSC intervention had a cascading impact on provider adoption of the clinical assessment tool and their consistent implementation of DiSC for supporting the care and management of AYLHIV. Provider recognition of improved service efficiencies as a result of the DiSC intervention also facilitated their adoption. Providers found that the longer visit intervals and fast-track ART refills that were part of DSD model used in DiSC, lessened their workload by staggering client return to clinic schedules and optimized time with clients who needed more support to stay in care. This finding corroborates evidence that differentiation of care enables health system reallocation of resources to better serve client needs [30, 31].

Fostering positive perceptions of the intervention was provider participation in CQI meetings during early phase implementation to support fit of the intervention with the complex ‘real-world’

context of the healthcare facility in which it was being implemented. As a result, a team-based learning environment may have promoted collective efficacy, a shared belief in provider capacity to achieve implementation goals. This finding is aligned with existing literature demonstrating that team-driven approaches, such as CQI, improve health service provision as well as client outcomes [32, 33].

Provider recommendations for expansion of DiSC to other healthcare facilities in Kenya were informed by their experiences during implementation. Providers indicated that their readiness for implementation was facilitated by the training they received and recommended that mental health training be expanded to additional healthcare providers not trained during DiSC implementation. Although providers recognized the benefit of psychosocial interventions (i.e. cognitive behavioral therapy) for adolescents and young adults experiencing mental health challenges, an important barrier that emerged from the analysis was community attitude that mental health was not an issue, which may impact AYLHIV demand for and experience with mental health service. Further research is needed to address community perceptions of mental health to promote environments that can support the overall well-being of AYLHIV.

Our study had several strengths. We used a team-based rapid turnaround data analysis approach to summarize and synthesize DiSC implementation experiences across different HIV care facilities in Kenya. Our application of CFIR to a low-middle-income country (LMIC) setting further expands the use of this determinants framework in global health settings and supports comparison with findings from other studies conducted in LMICs. Our study generated timely information about how to screen AYLHIV for DSD eligibility and deliver differentiated care using a data-informed approach. Lessons learned from our experience are generalizable to other settings interested in routinizing DSD for AYLHIV, now that policy barriers are no longer in place, and DSD is available outside of a research environment.

Our analysis has limitations. While the CFIR framework elucidated multiple determinants that affect implementation outcomes, it was difficult to characterize the influence of one determinant on another and map the synergistic relationships among determinants that impact implementation [34]. Additionally, this qualitative evaluation of early phase implementation is assessed from the perspectives of health care providers delivering the intervention and does not include recipient experiences. However, a planned future analysis will provide insights about AYLHIV experiences with the DiSC intervention from a client perspective.

Conclusion

Given recent policy changes expanding eligibility of DSD to ALHIV, there is limited description of factors impacting implementation of differentiated services for AYLHIV in real world settings. Identifying key facilitators and barriers to implementation of new interventions that incorporate elements of DSD for AYLHIV can inform strategies about how to support risk assessment and service frequency for ALHIV at HIV care facilities across Kenya. Consideration of resource continuity challenges, leadership engagement at multiple levels, integration into clinic workflows, and alignment with changing national guidelines will be important for sustained use and scale-up of the DiSC intervention.

List of abbreviations

AYLHIV: Adolescents and young adults living with HIV

CFIR: Consolidated Framework for Implementation Research

CQI: Continuous Quality Improvement

DiSC: Data-informed Stepped Care to Improve Adolescent Outcomes Study

DSD: Differentiated Service Delivery

EMR: Electronic Medical Record

FGD: Focus Group Discussion

TCAs: To Come Again (Clinic appointments)

WHO: World Health Organization

Declarations

Ethics approval and consent to participate

Study procedures were approved by Maseno University Ethical Review Committee (MUERC/00917/20), the Kenya National Commission for Science, Technology and Innovation (444824) and the University of Washington Institutional Review Board (STUDY00011096). All participants provided written informed consent.

Consent for publication

Not applicable

Availability of data and materials

Data cannot be shared publicly because of the sensitive nature of qualitative data. The data are available from the University of Washington for researchers who meet criteria for access to qualitative data.

Competing interests

The authors have no competing interests to disclose.

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Author's contributions

PKK, GJS, and KA serve as principal investigators of the study. KA, WAO, JK, NC, JB, JKK contributed to data collection and management. WAO, JK, NC participated in focus group discussions; WAO as facilitator, JK as coordinator, and NC as notetaker. NC, DIM, KBS analyzed the qualitative data using a team-based rapid analysis approach. NC drafted the initial manuscript; KBS, DIM, PKK, KA, and GJS critically reviewed and revised the manuscript. All authors have reviewed and approved the final manuscript.

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Table 1. Demographic characteristics of focus group discussion (FGD) participants (N=43)

Characteristic*	N (%) or Median [IQR]
Primary work location	
Comprehensive Care Clinic	39 (91)
Other ¹	4 (9)
Sex	
Male	22 (51)
Female	21 (49)
Age (years)	34 [31, 37]
Highest level of education: University/college	43 (100)
Healthcare provider classification	
Clinical Officer	31 (72)
Nurse	11 (26)
Nurse Counselor	1 (2)
No. of years at current clinic	4 [1, 7]
No. of years providing HIV care to PLHIV (all ages)	7 [5, 9]
No. of years providing HIV care to AYLHIV (ages 10-24 years)	6 [5, 9]

*Majority of health providers filled out a demographic survey prior to the start of DiSC trial implementation, with 6 providers filling out demographic information post-FGD;

¹Other work location includes vertical transmission, maternal child health, and outpatient departments; Abbreviations: PLHIV=People living with HIV; AYLHIV=Adolescents and youth living with HIV.

Table 2. Health provider perceptions of determinants influencing adoption, reach, and fidelity of a stepped care tool to support service delivery for adolescents and youth living with HIV

CFIR* domain	CFIR Construct	Description	Illustrative Quotes
Facilitators			
Adoption			
Intervention characteristic	Design quality and packaging	The tool is comprehensive and designed to cover relevant topics	"[T]he tool is short and precise. And it has touched like everything. Because there [are] elements of depression here. There's [the] element of opportunistic infections, and there are elements of breastfeeding or pregnant mother[s]. And then there's this step that the client is supposed to be assigned to... So you can't miss, you can't miss anything." – [P3, Facility 12]
Intervention characteristic	Complexity	The tool is easy to use and provides guidance on what to do during the client visit	"[W]e want to appreciate the tool because the tool is not that complicated. Actually, the experience that we got from the first time is that it even made our work easier. It was more simplified, because without the tool we could just talk and ask anything but at least the tool is guiding us." – [P2, Facility 11]
Inner setting	Readiness for implementation: Access to knowledge & information	Training provided information needed to implement the tool	"[T]he training was good generally and it helped us to do the right thing. Yeah, so currently we don't have any challenge in stepping our clients. Yeah, it was excellent is what I can say." – [P3, Facility 7]
Inner setting	Collective efficacy	CQI meetings facilitated collaborative problem solving to address challenges	"[W]hen we started using the tools, that's why we were evaluating every two weeks to see where we have had the gap or the challenges and at each point we were giving suggestions and then implementing them... we sat, as a team in our discussions..." – [P4, Facility 4]
Reach			
Intervention characteristic	Adaptability	Providers were able to adapt the intervention to meet client needs	"It depends, it depends on case-by-case, one-on-one... Yes, I did both. Some will come here to date, some might call, depending on the distance; like the other one I'm managing is in [location], the other one is a form 3 class, so I can't allow him to be coming here, so sometimes they come over the weekend, sometimes we talk over the phones." – [P6, Facility 10]
Outer setting	Patient needs and resources	Providers were able to adjust the clinic appointment schedule to accommodate the school calendar	"[T]he dates we were giving were not matching with their school calendars... So, we realized that and we were able to change. Now we are ... we were giving dates according to school calendars. This helps us because we could now not get missed appointments." – [P1, Facility 2]
Fidelity			
Intervention characteristic	Perceived intervention effectiveness	Providers observed a positive impact of the intervention on clients	"The adolescents, like at first they were not opening up, but through knowledge we got on how to probe the client, you probe, you be friendly with them, then you talk to them well. You are in that age of theirs. And then they just open up and now be your friend tell you everything.... Now when they come, now they want to see you, because the way you are talking to them. I think that it has helped a lot." – [P1, Facility 2]
Inner setting	Collective efficacy	Providers problem solved to optimize their ability to provide services	"[A]t some point we had some adolescents which had no valid viral loads. We had to request the office and they tried their level best and provided us with some viral load tubes, which they brought, and we were able to draw blood for the missing adolescents. Yeah. And through that we got at least we had ... we managed to get some valid results for those adolescents which helped us in managing them." – [P3, Facility 2]

Barriers			
Adoption			
Intervention characteristic	Design quality & packaging	Language in the tool was complicated, which made it challenging for providers to explain to clients	"So, my concern for the tool is about the step three; over the last two weeks, how often have you been bothered by the following problems? So, the question can be posed very well in English to a patient, but now level of understanding is a problem. So, you need to translate this to either Kiswahili or Luo for the patient to understand. So, I find it quite challenging even to translate it for someone to understand...." – [P2, Facility 6]
Inner setting	Readiness for implementation: Access to knowledge & information	Some providers felt that refresher trainings would have been beneficial	"It is a good thing and even as we proceed even refreshers are needed so that we can really be sure that whatever that we are doing on the ground are the real thing..., yeah so because these are real clients and it needs frequent practice. Yeah, it needs frequent practice for you to master so that you are able to handle. – [P1, Facility 5]
Reach			
Intervention characteristic	Design quality & packaging	Availability of training tools in another language will support providers in assessing mental health	"[I]n the training, it is in English but now it is upon you now to translate to the local language that the client can understand so now as you are transferring you may miss and say something totally different than was meant there. ... those clients maybe they are not up to date like if you start putting, talking in English they may not understand well or maybe they may not respond well so it is upon you to turn into another language, Kiswahili or any other language that you can fit in." – [P1, Facility 5]
Outer setting	Community characteristics	Challenges with assessing mental health for younger AYLVHIV	"[T]he younger ones, you have to interrogate probe them. That's why mostly we want the younger adolescents to come with their guardian or parents. Because for example, if your child has lost some interest or depressed with him or her, she will not know, but the parent or guardian will know. Or the teacher will know, because maybe the patient or the client was doing well in class." – [P2, Facility 2]
Fidelity			
Intervention characteristic	Design quality & packaging	Availability of training tools in another language will support providers in assessing mental health	"[T]he aspect of mental assessment can only apply on those older adolescents. For those very young adolescents like let's say, below 15 years, for that matter, they may not understand so well. So, the issue of mental assessment. I don't know how it can be simplified so that also the very young adolescents can understand...." – [P3, Facility 1]
Inner setting	Compatibility	Not aligned with ART guidelines	"There is need to, like as we are designing this tool, the designers are up to date with the guideline because you see for us the guidelines reign supreme, yeah, should there be a conflict between any document and the guideline the guideline carries the day [Laughter] Yeah so that may create a bit of friction because now you don't know whether to proceed with the tool or revert back to the guideline yah so the default setting is the guideline. So, the designers should just, make it in a way that it does not contradict or be seen to be antagonizing the guideline." – [P6, Facility 9]
Inner setting	Readiness for implementation: Available resources	Viral loads needed for step assignment were not readily available	"[T]he tool came about at a season when the facility was also not able to take samples for viral loads. So being able to administer the tool, because majority of them could not be assigned properly because of the missing key interventions that would inform the tool." – [P1, Facility 8]

* Consolidated Framework for Implementation Research (CFIR)

Table 3. Recommendations for scale-up and optimization of DiSC implementation across HIV care clinics in Kenya

Themes	Description	Illustrative Quotes
Modifying the DiSC clinical assessment tool	• Categorize AYLHIV by age groups in order to address differences among those stepping into adolescence and those stepping out • Include missed doses as an indicator of adherence rather than a missed visit • Categorize opportunistic infections by level of severity to inform care management	<i>“[W]e have opportunistic infection. They’re staged, we have stage one, stage two, stage three, stage four. So, if you generalize it like the opportunistic infection, ideally it doesn’t bring the picture because even with us, if we see a client with maybe herpes, we stage that one as stage two, we are not much concerned too much to this client like a client with cancer, or a TB client.”</i> – [P1, Facility 1]
Implementing strategies to support DiSC integration into routine care and workflows	• Align criteria for step assignment with Kenya Ministry of Health National Guidelines • Incorporate paper-based DiSC clinical assessment tool into the electronic medical record (EMR) system • Integrate the DiSC clinical assessment tool with the Clinical Encounter Green Card, a form that is available in the EMR • Replace PHQ-2 mental health assessment questions with the PHQ-9 because it is what clinics are currently using • Develop reporting tools to monitor progress and track key milestones and outcomes	<i>“I think the tool needs to be updated as per the guideline so that it makes it easy for, for the clinicians and even the nurses who are implementing the tool as you roll it out to be able to not have two contradicting messages in the file. So that, you know, if the cut off for high viral load is 200, then it’s uniform regardless if it’s the tool, because the tool is supposed to support to give patients centered care. So, changes should be made same as in the guideline.”</i> – [P1, Facility 8] <i>“[S]taffing for the ministry if the tool is not integrated within the tools that are being used, they might find it difficult to implement...[W]e have the green card that is used to most of the government facilities. So, if it is added in the green card, then it will be easy for them to use because now, they’ll be going step by step.”</i> – [P4, Facility 4]
Building technical capacity to support scale-up and implementation	• Invest in human resources • Expand training to additional healthcare worker cadres, including adherence counselors, peer mentors, community health workers, and lab technicians • Provide support supervision • Cascade mental health training to all providers • Utilize train-the-trainer mentorship model	<i>It’s about sensitization, and the training and all that and I think that tool is so easy and it can be used by any other person after they undergo some kind of training.”</i> – [P2, Facility 11] <i>“[A]s we are going to escalate this thing into other facilities for us who have been trained you can make as a mentor we mentor other people so that if we mentor other people from other facilities the tool will be used optimally.”</i> – [P2, Facility 12]
Engaging stakeholders to ensure sustainability and scalability	• Preserve institutional knowledge in the face of turnover by involving and sharing information across all levels of the organization • Engage facility leadership • Engage clients in their own care • Involve caregivers in the care of AYLHIV • Involve external partners who are involved in HIV care and management • Engage multiple stakeholders at the subcounty and county levels during scale up • Engage with networks and organizations involved with AYLHIV, for example, teacher networks and organizations that advocate for individuals living with HIV • Foster community engagement	<i>“[Y]ou know, these adolescents, they come from the communities, and in our communities, we have allocated them, community health workers, who also works closely with them at the households, so maybe they would have also been involved, because they also do adherence monitoring at the households.”</i> – [P4, Facility 4]

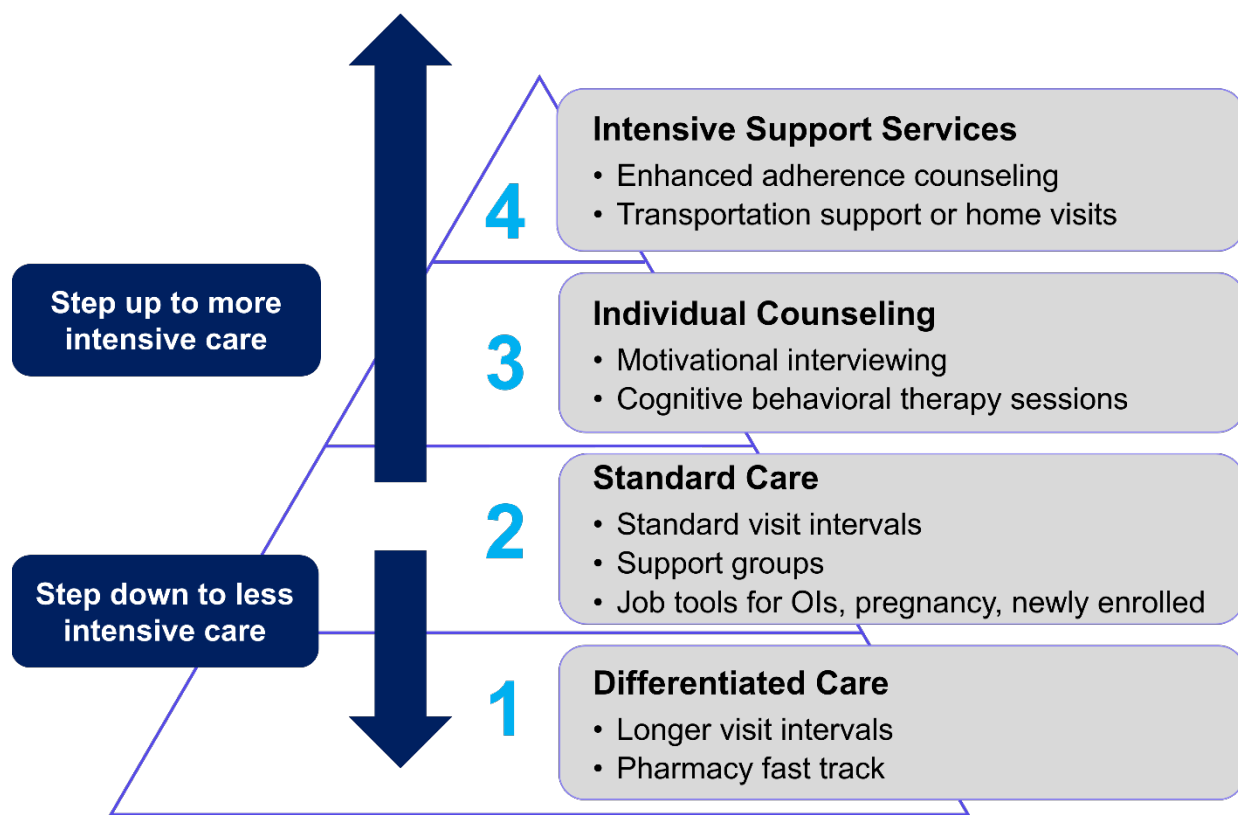


Figure 1. Data-informed stepped care (DiSC) intervention. DiSC is a multi-component intervention that uses a Stepped Care delivery approach along with a clinical assessment tool to assign adolescents and youth living with HIV to different steps of services aligned to their needs. OI, opportunistic infections.

Chapter 4. Application of the RE-AIM framework to evaluate a stepped care intervention for adolescents and youth living with HIV in Kenya: a mixed methods approach

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ABSTRACT

Background: Recently expanded WHO guidelines on differentiated service delivery (DSD) include expanded eligibility for adolescents and youth living with HIV (AYLHIV). We evaluated implementation of a stepped care program that included DSD for stable AYLHIV, and intensified services for AYLHIV with viral non-suppression, depression, or with greater likelihood of non-retention.

Methods: We used the Reach, Effectiveness, Adoption, Implementation, and Maintenance (RE-AIM) framework to guide evaluation of the Data-informed Stepped Care (DiSC) study, a hybrid type I cluster randomized controlled trial implemented from April 2022 to August 2023 in 12 intervention HIV care facilities in Kenya. We used a mixed methods convergent parallel design to evaluate performance indicators across RE-AIM dimensions. Data were obtained from medical records, an end-of-trial survey, and in-depth interviews with health providers (n=2/facility). Surveys were analyzed using descriptive statistics and qualitative data using directed content analysis.

Findings: Of 933 AYLHIV screened, 895 were enrolled, representing 96% *reach* of the intervention. Distribution by age groups were (10–14 years: 28% [252/888]; 15–19 years: 48% [428/888]; 20–24 years: 23% [208/888]). There were no significant differences between intervention and control facilities in the primary effectiveness outcome measure defined as number of missed visits (8.5% versus 8.3% respectively; adjusted Relative Risk [aRR] = 1.04 (95% Confidence Interval [CI]: 0.89, 1.20). However, perceived intervention *effectiveness*, including improved retention and viral suppression among AYLHIV, motivated continued implementation throughout the study. Prior to implementation, 49 health providers at 12 intervention sites were trained to deliver the DiSC intervention, representing 25% (49/199) of the total facility workforce, 95% of clinical officers (35/37), and 56% of nurses (14/25). All providers

trained, *adopted*, and delivered the intervention. *Implementation* was facilitated by provider-identified adaptations to optimize contextual fit of the DiSC intervention. All adaptations were considered fidelity consistent. Key determinants influencing *implementation* were provider collective efficacy, compatibility with clinic workflows, leadership engagement, and alignment with changing national guidelines. Post-trial, providers supported continued use of the DiSC intervention (*maintenance*), citing leadership support, training, and material and human resources as key influencers on future sustainment.

Conclusion: Applying RE-AIM to evaluate performance indicators of a stepped care program for AYLHIV identified high adoption and perceived effectiveness, and key influences on implementation and maintenance. Use of RE-AIM during planning and evaluation can inform how to increase reach, adoption, and integration of programs that may benefit AYLHIV.

Trial Registration: ClinicalTrials.gov, NCT05007717

Keywords: RE-AIM, implementation science, Kenya, adolescent and youth, stepped care

Introduction

Adolescents and youth ages 10-24 living with HIV (AYLHIV) continue to experience high HIV incidence and HIV-related mortality [1-3]. In sub-Saharan Africa, where 84% of AYLHIV aged 15-19 reside [2], AYLHIV have greater likelihood of disengaging from HIV care when compared to older adults [4, 5]. Evidence-based interventions that can improve outcomes among AYLHIV are needed to achieve the UNAIDS 95-95-95 targets for this priority population. Interventions are specifically needed to address the critical gap in reaching the third 95 target, with retention in care crucial for achieving viral suppression [4].

Adolescents and youth represent a diverse population, with unique influences on their ability to remain in care. Interventions should be tailored to better meet individual health needs for HIV care and management and personal experiences living with HIV. Stepped care models have been utilized in health care settings to improve health outcomes by matching available services to need [6-8]. This service delivery approach improves health system efficiencies by allocating resources to individuals who need more intensive services to manage their health while maintaining or simplifying care for those we are doing well. In resource constrained settings experiencing a high burden of youth living with HIV and a health care workforce shortage, stepped care approaches ensure health systems are not overburdened, and AYLHIV are receiving the support they need to maintain their life-long engagement in care. In Kenya, stepped care has already been applied to support adolescents and young people with information about HIV and sexual reproductive health [6, 9]. Using a digital platform, youth are referred to services tailored to their needs, with increasing amounts of intensity in management, ranging from an online forum to a telephone support line. A stepped care approach may also be an effective strategy for addressing retention and viral suppression among AYLHIV.

In contrast to more intensified services, differentiated service delivery (DSD) has afforded workforce optimization through allowing those with lower support needs to access health services less frequently. The recent change in World Health Organization guidelines expanding DSD eligibility to AYLHIV offers an opportunity to examine the potential for DSD to improve both AYLHIV health outcomes and workforce efficiencies. The Data-informed Stepped Care (DiSC) study was a cluster randomized controlled trial implemented from April 2022 to August 2023 in 24 HIV care facilities in western Kenya. DiSC was a health systems intervention delivered by health providers who used a clinical assessment tool, along with routinely available data, and a stepped care service delivery approach to place AYLHIV into appropriate levels of care (differentiated care, standard of care, individual counselling, and intensive support services). Using this stepped care approach, providers aligned intensity and frequency of services with AYLHIV needs. AYLHIV who needed higher levels of support received more intensive services, such as cognitive behavioral therapy and enhanced adherence counseling sessions. In contrast, AYLHIV who were stable benefitted from differentiated care elements including fast-track pharmacy refills and longer visit intervals.

Although DSD models were available for AYLHIV in the context of research settings, information about adoption, reach, implementation, and integration into HIV care programs is limited. Implementation information is important for understanding how to effectively translate research [10, 11] to practice and ensure sustainment of programs that improve AYLHIV clinical outcomes. Using a mixed methods approach, we evaluated implementation of the DiSC stepped care intervention to increase knowledge about whether matching AYLHIV needs to services could simultaneously improve workforce efficiencies alongside health outcomes among this priority population.

Materials and Methods

HIV care clinic setting

The DiSC study was implemented in 12 intervention HIV care facilities in Kisumu (n=3), Homabay (n=4) and Migori (n=5) counties in western Kenya. The facilities ranged from a level 2 to level 4 designation and were classified as dispensaries and clinics, health centers, or sub-county hospitals, respectively [12]. Participating intervention facilities were 83% (10/12) public and 20% (2/12) faith-based organizations. Eligibility criteria for participating facilities included use of electronic medical records (EMR), client volume (≥ 100 AYLHIV ages 10-24 years old enrolled in care), and facility leadership interest in participation [13].

Study design and theoretical framework

We used a mixed methods convergent parallel design to evaluate DiSC stepped care intervention implementation, using varied sources of data collected from October 2021 to November 2023. Using this mixed methods approach, we collected quantitative and qualitative data concurrently and compared results for concordance.

Theoretical framework

We used the Reach, Effectiveness, Adoption, Implementation, and Maintenance (RE-AIM) framework [11] to guide our evaluation of DiSC intervention performance (Table 1). Within our study, implementation outcome measures were defined as follows: 1) *Reach* - participation and representativeness of the target population for the intervention, 2) *Effectiveness* – actual and perceived impact on health-specific outcomes. We expand the definition to include perceived effectiveness because at the time of data collection, providers were not aware of actual trial outcomes, therefore their responses were based on their perception of intervention effectiveness, 3) *Adoption* - uptake of the intervention by health providers, 4) *Implementation* - consistent

delivery of the intervention as intended, adaptations made to optimize delivery, and barriers and facilitators experienced, and 5) *Maintenance* – sustained use of the intervention and its benefits over time [11, 14]. Given the 12-month timeframe of the clinical trial, we were not able to assess longer term maintenance. As a result, we report determinants of future sustainment. We previously reported findings focused on effectiveness [15] and implementation [16, 17] dimensions of RE-AIM; however, we summarize previous findings where relevant to present a fuller description of how RE-AIM was applied to evaluate the *who, what, where, when, and how* performance indicators of the DiSC stepped care program across all framework dimensions.

Data collection

Quantitative data

Electronic medical record data abstraction

Data to evaluate the representativeness of our target population were abstracted from the electronic medical records (EMR) in October 2021, prior to the start of DiSC trial enrollment in April 2022. To assess reach of the total clinic population, we defined the denominator for our target population as the total number of AYLHIV ages 10-24 years old attending care at intervention facilities. The EMR was also used to abstract data on the primary outcome measure for *effectiveness*, which was retention in care, defined as a missed visit (within a 30-day time period for any visit) and 12-month loss to follow-up [13]. A secondary measure, viral suppression, was abstracted from the Kenya National AIDS & STI Control Program database.

Case report forms

Study case report forms were used to assess the number of clinical officers and nurses who participated in DiSC implementation training; a subset of these providers, in addition to adherence counselors at the facility (who were not part of DiSC implementation training) were trained to deliver the mental health components that were part of the Step 3 services offered during the trial.

The mental health training consisted of didactic instruction, systematic feedback, and mentored counseling of providers delivering mental health sessions to AYLHIV. *Adoption* was calculated as the proportion of clinical officers and nurses trained to deliver the DiSC intervention, out of the total number of health providers in these cadres, as well as the overall number of healthcare workforce at the facilities.

End-of-trial surveys

The DiSC study is part of the *Prevention and Treatment through a Comprehensive Care Continuum for HIV-affected Adolescents in Resource Constrained Settings* (PATC³H) consortium. All health providers from intervention facilities completed surveys that included evaluation of adoption, implementation, and maintenance dimensions of RE-AIM using standardized questions adopted by all PATC³H consortium teams to ensure data harmonization across studies in this network [18, 19]. The quantitative survey was administered to 37 providers from July to November 2023 and assessed provider perceptions of the intervention, the training they received, whether providers consistently implemented the DiSC intervention as intended, and the extent to which the DiSC intervention would be sustained over time.

Qualitative data

In-depth interviews (IDIs) were conducted with 2 health providers from each intervention facility in August 2023. The interviews were conducted by a team of experienced Kenyan social scientists (WAO, NAO, OAO, OLA, POO, VAS) using a semi-structured discussion guide covering the following topics: (1) provider experience delivering the DiSC intervention, both the clinical assessment tool and services; (2) provider perception of intervention adaptability during implementation; (3) perceived impact of the intervention on health-related outcomes; and (4) likelihood of continued use of the DiSC clinical assessment tool and perception of resources needed to ensure sustainability. Providers were ≥18 years old, clinical officers or nurses, and

were purposely selected for participation in the IDIs to reflect a range of experiences during implementation. IDIs were conducted in English, but providers were also encouraged to use Kiswahili if preferred. Discussions lasted a median of 67 minutes (interquartile range [IQR]: 58, 75), and were audio-recorded, translated as needed, and transcribed verbatim (WAO).

Quantitative data analysis

Descriptive statistics were used to summarize counts, proportions, means, standard deviations, medians, and interquartile ranges. Provider perceptions of quantitative measures of adoption, implementation, and maintenance dimensions were measured on a Likert scale and visually displayed using diverging bar charts. All quantitative analyses were performed using the R statistical computing environment [20].

Qualitative data analysis

Health provider interview data were analyzed using a directed content analysis approach [21], and an initial codebook was developed (NC). The codebook was organized around the RE-AIM dimensions with specific code constructs within each dimension [22]. The codebook was further refined through group discussion (NC, DIM, KBS). Two team members (NC, DIM) tested the codebook by coding a common transcript and resolved differences in code application through discussion until consensus was reached. The remaining transcripts were divided for independent coding by one member of the team, code application evaluated by another team member, and discrepancies discussed to achieve group consensus (NC, DIM). Queries and code co-occurrence tables were generated to summarize findings within RE-AIM dimensions. *ATLAS.ti* software (version 24) was used to facilitate data management and analysis. Qualitative and quantitative approaches were used to achieve triangulation, convergence, and expansion of findings.

Ethical considerations

Ethical approval was received from Maseno University Ethical Review Committee (MUERC/00917/20), the Kenya National Commission for Science, Technology and Innovation (444824) and the University of Washington Institutional Review Board (STUDY00011096). All health providers who participated in the post-trial survey and the qualitative interviews provided written informed consent prior to conducting study procedures.

Results

Twenty-four in-person interviews were conducted with health providers. The majority of providers were clinical officers (74%), identified as female (52%), and had a median age of 35 years (IQR: 32, 41). Providers reported a median 5 years (IQR: 3, 8) at their current clinic, and a median of 8 years (IQR: 6, 12) engaged in AYLHIV care and treatment. Respondent characteristics of providers who participated in the post-trial survey were similar (Table 2).

Reach

Prior to trial start, a total of 3945 AYLHIV ages 10-24 attended routine HIV care at intervention facilities, of whom, 895 were enrolled in the clinical trial [15], representing 23% of the total clinic population. Within the context of a clinical trial, we report a reach of 96%, which is the proportion of AYLHIV enrolled among those screened (n=933). When stratified by age, reach was 28% (252/888) for AYLHIV 10–14 years, 48% (428/888) for AYLHIV 15–19 years, and 23% (208/888) for AYLHIV 20–24 years; among those attending care, the age distributions were 29%, 30%, and 41% respectively.

When discussing representativeness of enrolled AYLHIV, providers acknowledged that the DiSC intervention was part of a research study with an enrollment target, which limited the number of AYLHIV able to participate from each site.

“[T]he challenge was that, during the enrollment, when we were doing the study, we were given a maximum number to reach in enrolling the client. So some of our clients missed, because we have a bigger number, a bigger adolescents. But I think we were given up to around 50, something like that. And some of them missed the study. And to us we thought that all of them would benefit during this time. That is one of the challenges we had. That one disadvantaged some of our clients.” – [P2, Facility 3]

Reaching AYLHIV aged 10-14 years required additional coordination by providers to ensure involvement of parents/caregivers. Providers highlight how Kenyan parental/caregiver consent guidelines for research participation for AYLHIV <18 years made it challenging to enroll younger AYLHIV, even though this population is accurately represented.

“[W]hen we were starting to implement the tool. We needed to have a guardian sign that they have agreed that the adolescent should participate in this study. So, you find some guardians, they don't accompany their children to the hospital. So, you cannot start stepping such a kid if a consent form has not been signed. It has been a challenge at some point.” – [P3, Facility 1]

While the DSD service delivery model of 3-month visit intervals appealed to younger AYLHIV, providers perceived that already existing eligibility for differentiated services with longer 6-month visit interval negatively affected willingness to enroll in DiSC among older AYLHIV (ages 20—24),

as evidenced by the lower reach in this age group (representing 23% of those enrolled vs. 41% of those attending care).

“... for the 20 to 24, sometimes we now book them... they have to only come to clinic twice in a year so in between they can be coming for the refill. But for the tool... the maximum that you can give them is now that three months... they'll tell you, "Doctor, the three months will inconvenience me. I'm working in Nairobi. So if you give me that, the transport is not there.” – [P1, Facility 5]

Effectiveness

Clinical trial effectiveness dimension have been previously reported [15]. In summary, a total of 1911 AYLHIV were enrolled from intervention and control facilities. Overall, the majority of AYLHIV were retained in care, attending 92% of their scheduled clinic appointments. There were no significant differences between intervention and control facilities in the number of missed visits (8.5% versus 8.3% respectively; adjusted Relative Risk [aRR] = 1.04 (95% Confidence Interval [CI]: 0.89, 1.20). Viral suppression was also similar between arms (aRR = 0.78, 95%CI: 0.49, 1.23) [15].

Despite absence of observed impact on retention and viral suppression outcomes, at the time of the interviews and in the absence of clinical trial outcome data, providers perceived that the intervention was effective in supporting AYLHIV with retention in care, viral suppression, and adherence. Providers felt this benefit was especially helpful for AYLHIV who received enhanced services offered in response to viral non-suppression or mental health screening.

“Suppression has been good. Like I’m saying it’s 99% as at now. It has really enabled us to categorize our mental health participants into their clinics and cater for their needs.”

– [P3, Facility 12]

Providers also noted improvement in overall provider-client relationships, describing more openness from AYLHIV during clinic visits.

“They feel comfortable in our clinics, they feel that at least they’re served well in our clinics. So, when you take time with them, talking to them using the DiSC tool, asking them questions, they feel like they’re loved. They feel so protected in our clinic, they feel like the next time they want to come back, you know, so it helped us in retaining them. And also, management of the high viral loads, those with high viral loads. It helped us to follow them closely, giving them shorter TCAs [clinic appointments], counselling them, so it also helped us.” – [P3, Facility 8]

Providers recognized the burden of mental health and described how AYLHIV poor health outcomes are related to their mental health status, with recognition of how both disclosure and transition impact mental health outcomes.

“That issue of mental health and by this tool bringing that tool where you can screen for depression; it was a major milestone because when you...these adolescents face so many issues, yes both at home, at school and also during the transitions. When they are transitioning from child to adolescent then to adulthood. So the issue of mental health when it came with this tool, it helped a lot. Because you find even the issues how disclosure is done the issue of when an adolescent wants to transition to a boarding school. So this things were affecting their adherence and it’s because of that issue of the

mental part; the mental health issue. So, by this form bringing that part it was a good step, yes, towards also helping these adolescents who have mental issues.” – [P2, Facility 1]

While providers perceived that the DiSC intervention was effective and improved health outcomes overall, they noted some unintended consequences as a result of the way the intervention was designed. Providers perceived that AYLHIV with a justified reason for a missed visit, whether they are in school or were unable to go due to transportation support, should not be stepped up to receive more intensive services. Providers noted that the intensified services provided by stepping up would not address the reasons why they had a missed visit. Furthermore, provider time and resources would be diverted to AYLHIV who are otherwise successfully managing their care.

“So, you find maybe they missed a clinic once, yes, but it was maybe due to unavoidable or something. Maybe they were in school doing exam.....[it] could be this child is stable but just because they have missed this clinic once now, they have to go to Step 3. Which for me, I felt like maybe we could get another way to address that.” – [P1, Facility 7]

Adoption

Prior to implementation, 49 health providers across participating intervention facilities were trained to deliver the DiSC intervention. This represented 25% (49/199) of the total health facility workforce, 95% of facility-based clinical officers (35/37), and 56% of facility-based nurses (14/25). Additionally, nine clinical officers, two nurses, and 22 adherence counselors (total n=33) were trained to deliver the cognitive behavioral therapy sessions for AYLHIV assigned to Step 3; 88% completing training (n=29). Due to study oversight during implementation of the clinical trial, all facilities implemented the intervention, we did not have non-adopting or partially adopting sites.

The end-of-trial survey highlighted providers' perception that the DiSC intervention was easily adaptable to fit the needs of clinics who may implement it (92% agree/strongly agree; Figure 1A). In response to the statement that the DiSC intervention was too complex, too expensive, or would require too many human resources to implement, 98%, 97%, and 92% disagreed/strongly disagreed respectively. Qualitatively, providers supported their survey responses noting that the clinical assessment tool allowed them to deliver services targeted to AYLHIV needs while decreasing their workload at the same time. Ability to align services to meet AYLHIV needs while improving service efficiencies was a major factor in influencing adoption of DiSC.

"I would first like to appreciate the introduction of the DiSC tool actually, because through the DiSC tool, we managed to provide services to our adolescents as individuals. It really helped us even identify our gaps as healthcare workers, because we were now able to approach the needs of those adolescents as individuals and not as a group. Because initially, we would just brush over some issues without thinking further, even without knowing the specific needs of some of the adolescents who were in the study. So, through the DiSC tool, I can say we've managed to provide appropriate care to our adolescents."

– [P3, Facility 2]

"[W]ith this tool we are able to give longer TCAs [clinic appointments] for the children. So, you'll find maybe an adolescent who is maybe in the university and is going for a longer way, at least if they're stable and if they're suppressed and they have no issues, I'm able to give a longer TCA. Then it has also reduced our workload in that instead of having all the adolescents and just coming for drug refill, we give a longer TCA to the ones who are stable...established and then we remain with the few who might need more care and more time to handle them." – [P1, Facility 7]

Implementation

Adaptations providers made during early phase implementation (May – December 2022) to optimize uptake and delivery of the DiSC intervention have been previously described [16]. In summary, the Framework for Reporting Adaptations and Modifications Expanded [23] was applied to characterize planned adaptations, which providers identified during the continuous quality improvement meetings. The majority of adaptations were made to improve integration into routine clinic practices, such as improving documentation, clinic workflows, and addressing scheduling challenges. Primary reasons for adaptations were to align delivery with AYLHIV needs and preferences and address barriers to service access unique to AYLHIV, such as boarding school. All adaptations to optimize DiSC implementation were determined to be fidelity-consistent because none impacted core elements of the intervention, which was step assignment and step reassessment at subsequent visits. Providers also quantified their perceptions of DiSC intervention acceptability, appropriateness, and feasibility using a Likert scale from 1 to 5 (1 = strong disagreement; 5 = strong agreement). Provider perceptions of these three measures were consistently high but did significantly improve over time [24].

Key barriers and facilitators experienced during early phase implementation have also been previously reported in a qualitative assessment [17]. In summary, the Consolidated Framework for Implementation Research was used to examine key determinants influencing implementation. Factors impacting implementation were predominantly from the inner setting, outer setting, and intervention characteristic CFIR domains. Provider collective efficacy was important in consistent implementation of DiSC and was facilitated by the previously described continuous quality improvement meetings, access to knowledge and information as a result of the training they received, and perceived intervention effectiveness. Providers highlighted that leadership involvement was an important driver of implementation success; leadership examples included

availing space for mental health counseling sessions and time for client-provider interactions outside standard operating hours.

In the end-of-trial survey, providers continued to report that they perceived the DiSC intervention was implemented with high fidelity. Although 51% of providers (19/37) believed that health providers were similarly motivated at the beginning and end of the intervention period, 30% (11/37) believed that providers were more motivated at the beginning of the intervention. Providers reported that their motivation for continued, consistent use was partially driven by the positive impact the tool had on their work environment.

“When we're using it [DiSC tool], we're not using it for the sake of only the client. We're using it for the sake of both of us. Because it has helped us in the management of our young adolescent, in that we do the right stepping. We do give the right things when they're supposed to be given those. And what can I add? I feel that is enough.” – [P6, Facility 10]

When asked to rate their preparedness, on a scale of 1 to 10, to deliver the DiSC intervention, providers perceived that the training was adequate (median = 10, IQR: 9, 10). During interviews, providers highlighted the importance of training if the intervention were to be expanded to other facilities.

“[T]hey have to be trained on the DiSC, so that they understand the tool. The staff or the people who will be taking care of the client, first of all, must understand the tool. They are the people who will be able to talk to the client, to register or to enroll to the tool. So they must understand the tool. That one requires that they must be trained. And they need to appreciate the goodness of the tool, because the tool is definitely designed to make us improve on our indicators.” – [P2, Facility 3]

The majority of providers agreed that they followed study standard operating procedures (98% well/very well; Figure 1B). In addition, their level of agreement with the statements about whether they were assigning AYLHIV to the correct step (94% well/very well), and if not whether they were able to course correct in real time (95% well/very well), demonstrated high collective efficacy during implementation.

“We the CQI team, the continuous quality improvement team. If you see that these interventions are not working, then the team will sit down and there's something called the brainstorming. So, when people for brainstorming, then people will come with the different opinions and we see which one can work if it doesn't work, we'll take the gaps to the CQI team, and the team will sit down, I think they will come with the change ideas which can work.” – (P6, Facility 9)

Maintenance

Providers identified leadership support, training, and material and human resources as key influencers on future sustainment. Providers perceived that leadership engagement was high and they supported implementation of DiSC (91% agree/strongly agree; Figure 2C). Additionally, providers agreed that leadership were involved with the DiSC intervention (90% agree/strongly agree) and efficiently managed staff and other resources to support implementation (86% agree/strongly agree). Most providers agreed that the DiSC intervention will be sustainable beyond the study period (72% agree/strongly agree; Figure 2D) and believed there was strong clinic support for the intervention (92% agree/strongly agree), which could be easily integrated into clinic operations (92% agree/strongly agree). Providers identified potential barriers to sustaining the intervention that were related to material and human resource availability.

“[T]he key thing would be personnel. Yeah, because without the personnel, it can't kick off. And also the facilities, making sure that the offices are friendly, and the confidentiality of the same, and also just the way I said it that they should be adolescent friendly clinics where they don't feel stigmatized. Much more training, of course, needs to be done on the DiSC tool more so when there's changes, here and there. There need to be [refresher] trainings. Yes. And the other resources, of course, would be the tools and the requirements that are needed, the stepping tool, the DiSC tool, and all those. Those ones are the most important resources that a facility need to consider before having the intervention.” – [P2, Facility 11]

Providers believed they would continue using the tool because of perceived effectiveness and improved guidance on how to optimize AYLHIV care.

“I think using the tool is something we can continue with, because we really saw how it impacted on the lives of our adolescents and even me as a clinician, I'm able to feel the weight it took in terms of offering services, and also making it easy for me as a clinician to be able to know what do I need to offer to this adolescent for them to be able to maybe achieve suppression, address their mental health barriers, and also just change the overall thought process of our adolescents.” – [P1, Facility 8]

In order to support continued use of the tool, providers recommended a process for continued updates to ensure evaluation criteria in the stepping tool align with changing national guidelines, highlighting the importance of continued adaptation to optimize tool relevance to contextual setting.

“Changes, I think we said earlier, maybe some indicators need to align to the new guideline...then nowadays we are doing viral load at three months. So, Step 3, I said

should read enrolled within the last three months. And Step 1 on ART for more than 12 months, so it should read on ART for more than six months because at six months... we categorize them as stable and unstable at six months.” – [P1, Facility 6]

Finally, providers felt that sustained use of the DiSC intervention would require leadership support at the national level. Providers recognized policies and policymakers as key influences on standardizing health practices at the facility level, as well as streamlining trainings on DiSC tool use and mental health.

“The good thing in Kenya, usually the policies are usually standard, they are standardized when it comes from NASCOP, the national AIDS Control Program. It is mandated... So, at policy making level, if you are able convince NASCOP and also if us, we can be given a chance to tell our experiences about the tools because we participated in the study, it can be very good.....But I don’t think you’ll face resistance because the tool was simple very straightforward” – [P2, Facility 1]

Discussion

Using a mixed methods approach, we evaluated the DiSC stepped care intervention to better understand how matching AYLHIV needs to service delivery using a standardized assessment tool could improve workforce efficiencies and AYLHIV health outcomes. Triangulating qualitative and quantitative data enhanced our understanding of DiSC performance indicators along all five dimensions of the RE-AIM framework. We found that providers were motivated to adopt and sustain use of the DiSC intervention because they perceived a positive impact on AYLHIV outcomes and optimization of their time and effort. Additionally, providers felt that integrating

mental health into HIV care programs may support improved outcomes in this population by providing support during challenging times, such as disclosure and transition.

Adolescents and young adults represent a diverse group, with varied characteristics such as age, gender, sexual orientation, marital status, as well as how and when they acquired HIV. As a result, their access to care as well as the barriers experienced are similarly varied depending on engagement with the healthcare system. We found that the majority of AYLHIV participating in the DiSC trial were in the 15-19 age group, therefore it is not surprising that for those in boarding school, it was important that the intervention was adaptable to meet their needs and align their clinic visit intervals with the school calendar. Younger adolescents face barriers to participation as a result of age of consent laws. Without caregiver consent, adolescents are not able to take part in research, and their lack of representation may limit the development of interventions that are tailored to their needs. This finding is similar to prior studies that identified legal requirements for caregiver consent as a barrier to AYLHIV accessing quality health services [25-27].

DiSC is a health systems intervention delivered by health providers using routinely available data to deliver services aligned to the level of support AYLHIV needed to stay engaged in care. Even though the intervention did not impact the primary effectiveness outcome of retention in care, providers perceived that the intervention improved their client's health outcomes. Providers noted the DiSC tool focused their time and resources on AYLHIV who needed more intensive support to manage their care, thereby improving health system efficiencies and resources. This adds to the literature demonstrating that differentiation of services reallocates resources to where it is most needed, thereby improving efficiencies of health systems [28, 29].

In order to ensure that the DiSC tool remains relevant, additional adaptations may be needed, such as the flexibility to change content to reflect changes in national guidelines, such as the

definition of an established client. Also, as AYLHIV become candidates for other models of differentiated care not available as part of this research, such as community-based ART refills, or qualify for new therapies, such as long-acting injectables, the tool will need to be revised to screen AYLHIV and align them to services previously not available to them. Interventions that are adaptable and can respond dynamically to changing real-world contexts are more likely to be sustained over time [30].

Our study had several strengths. We utilized both quantitative and qualitative data to explore each dimension of RE-AIM. Use of qualitative methods helped contextualize quantitative findings to describe not only *what* provider's thought about the DiSC tool, but *why* they supported implementation and *how* implementation might be adapted to promote sustained use. For example, within the context of a cluster randomized clinical trial, knowing the percent reach of AYLHIV as a proportion of those attending care at participating intervention facilities is not informative due to constraints of enrollment targets. However, qualitative data enhanced understanding of whether or not AYLHIV participating in the research were representative of the population for whom the intervention was intended to benefit and why certain populations of AYLHIV are not represented. Our evaluation adds to the limited published literature that applies qualitative methods to each dimension of RE-AIM.

Our analysis has limitations. As a result of having an enrollment target, reach was parameterized as the proportion of those enrolled among those screened. Therefore, we cannot anticipate whether reach in clinical programs would reflect the high reach we found given that our assessment was done in a clinical trial context. We summarize the effectiveness and implementation dimensions from previously published work. Although this enables us to describe how all five dimension of RE-AIM was used in our evaluation, the richness of the implementation experience, such as the adaptations made and provider perceptions of key determinants

influencing implementation are limited. Furthermore, this evaluation was assessed from the perspectives of health providers who delivered the intervention, with in-depth interviews conducted prior to analysis of the effectiveness outcomes. Therefore, although providers supported continued use of the DiSC intervention, their responses may have differed if we were able to share at that time that there were no differences in the primary outcome of retention in care between intervention and control facilities. Additionally, we were not able to include AYLHIV experience with the intervention or share their perspectives. This information is part of an ongoing analysis that will be reported in a future publication.

Conclusion

Applying RE-AIM to evaluate performance indicators of a stepped care program for AYLHIV identified high adoption and perceived effectiveness, and key influences on implementation and maintenance. We found that having a tool that used routinely available data to match AYLHIV needs to services did simultaneously improve workforce efficiencies and improve their health outcomes. Future studies could explore strategies to improve reach among all 10–24-year-old AYLHIV attending care as well as strategies that build provider capacity to deliver youth-centered interventions. As other models of differentiated care are made available to AYLHIV, use of RE-AIM during planning and evaluation can inform how to increase reach, adoption, and integration of these programs that may benefit AYLHIV.

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Table 1. RE-AIM Evaluation framework dimensions, description, and data sources*

Dimension and definition	Description	Level	Data Sources
Reach: Representativeness of the target population (10-24 years old) for the DiSC intervention	Question: What was the percent of the target population reached by the intervention? Why did/didn't someone participate? Was there adequate participation across all age categories (10-14, 15-19, 20-24)? Evaluation strategy: Use of qualitative methods to understand reach and engagement with the target population.	Client Provider	Facility electronic medical record (EMR) DiSC study case report forms End of DiSC study in-depth interviews with health providers from intervention sites
Effectiveness: Effects of the DiSC intervention, both positive and negative, including unintended consequences	Question: Was there any intervention impact on the primary outcome measure for effectiveness? Evaluation strategy: Use of qualitative methods to understand effects of the DiSC intervention on health-specific outcomes, including unintended consequences.	Client Provider	Primary RCT outcomes reported elsewhere Provider interviews
Adoption: The number and proportion of providers trained to deliver the DiSC intervention	Question: What percentage of facility workforce participated in training on the DiSC intervention? How many were trained on mental health? Evaluation strategy: Use of qualitative methods to understand factors influencing adoption of the DiSC intervention.	Provider	DiSC study case report forms End-of-trial survey Provider interviews
Implementation: Extent to which the DiSC intervention was implemented as intended, adaptations made, and barriers and facilitators	Question: What percentage of facilities made adaptations? What were the adaptations made? What were the barriers and facilitators that impacted implementation? Evaluation strategy: Use of qualitative methods to understand implementation (what multi-level contextual determinants matter for implementation? What factors influenced consistent delivery?)	Provider	Adaptations and determinants reported elsewhere End-of-trial survey Provider interviews
Maintenance: Extent to which the DiSC intervention and its benefits is sustained over time	Question: What is the likelihood of continued use of the DiSC intervention by providers? What are key influencers of future sustainment? Evaluation strategy: Use of qualitative methods to understand facility-level institutionalization of the DiSC intervention.	Provider	End-of-trial survey Provider interviews

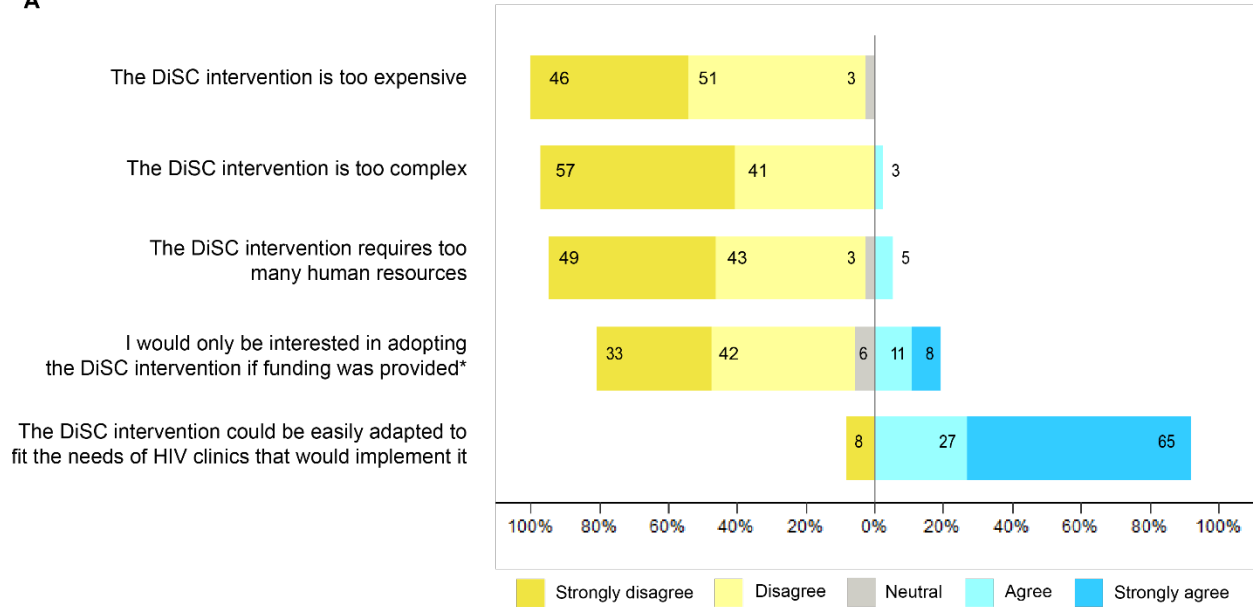
*Data sources do not include those previously reported for Effectiveness and Implementation dimensions.

Table 2. Demographic characteristics of health providers across DiSC trial intervention facilities

Characteristic	Survey (N=37)	Interview (N=23)*
	N (%) or Median [IQR]	N (%) or Median [IQR]
Primary work location		
Comprehensive care clinic	27 (73)	18 (78)
Other ¹	10 (27)	5 (22)
Gender		
Male	14 (38)	11 (48)
Female	23 (62)	12 (52)
Age (years)	34 [31, 39]	35 [32, 41]
Highest level of education: university/college	37 (100)	23 (100)
Healthcare provider classification		
Clinical officer	25 (68)	17 (74)
Nurse Counselor	4 (11)	3 (13)
Nurse	8 (22)	3 (13)
No. of years at current clinic	5 [3, 8]	5 [3, 8]
No. of years providing HIV care to PLHIV (all ages)	8 [6, 10]	8 [6, 13]
No. of years providing HIV care to AYLHIV (ages 10-24 years)	8 [6, 10]	8 [6, 12]

Note: *Information for five providers were abstracted from a demographic survey administered prior to the start of DiSC trial implementation, one provider missing demographic information and not included in this table; ¹Other category includes prevention of vertical transmission, antenatal care, maternal child health, and outpatient departments. Due to rounding percentages may not equal 100 percent. Abbreviations: AYLHIV=adolescents and youth living with HIV; PLHIV=People living with HIV

A



B

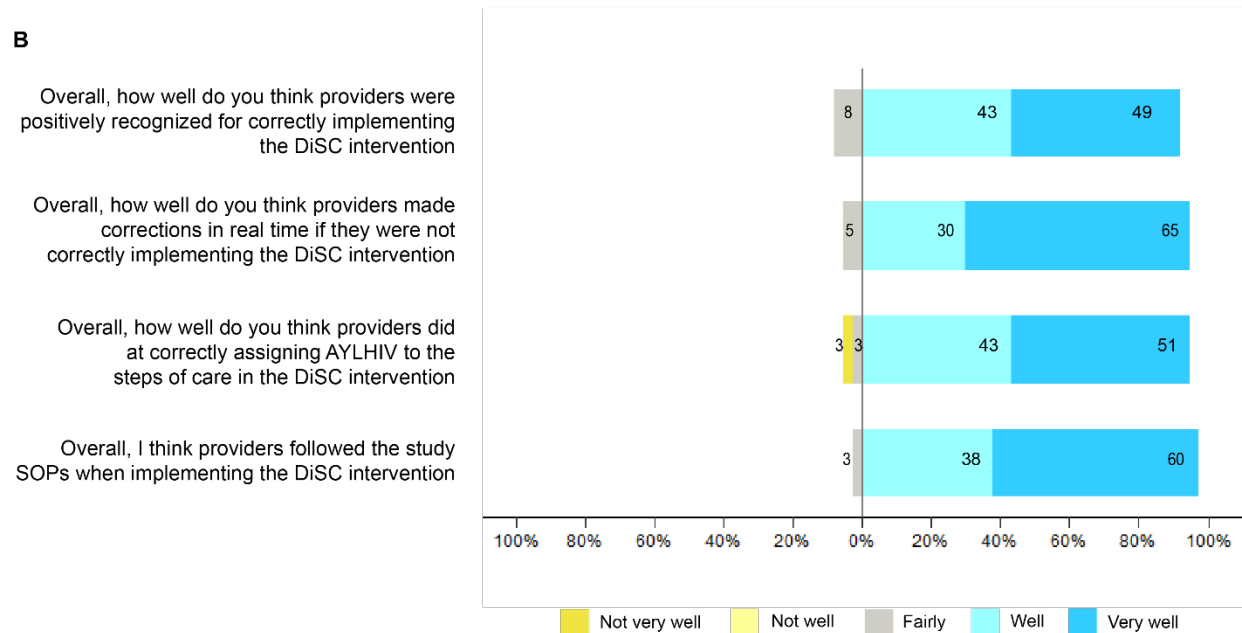


Figure 1. Provider level of agreement with the following statements about factors influencing (A) *adoption* measured on a Likert scale of 1 to 5 (with 1 = strong disagreement and 5 = strong agreement) and (B) *implementation* measured on a Likert scale of 1 to 5 (with 1 = not very well and 5 = very well), collected from the end-of-trial evaluation survey. Total n=37 unless otherwise noted, *n=36. Percentages may not add up to 100 because of rounding. AYLHIV = adolescents and youth living with HIV, SOPs = standard operating procedures.

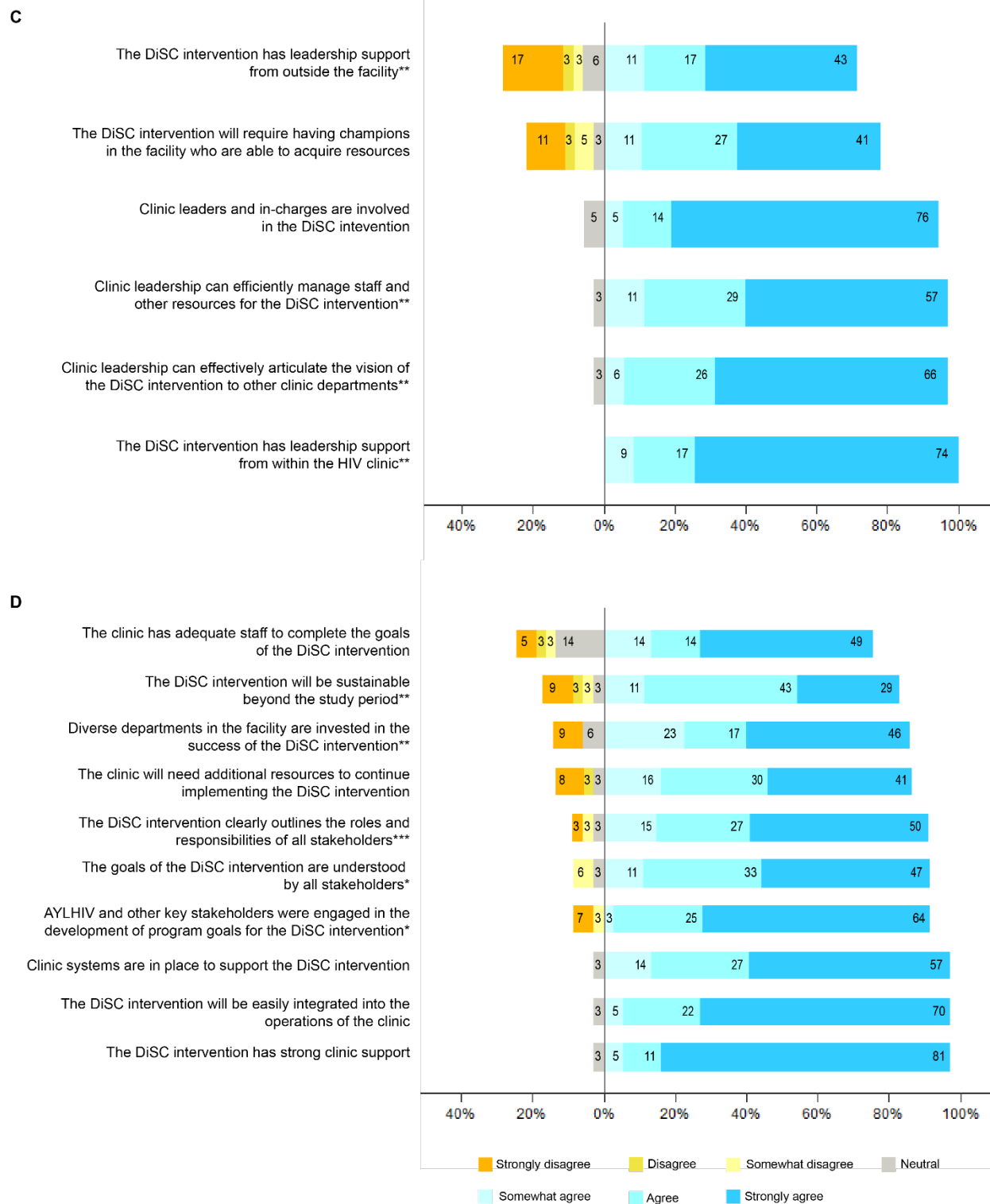


Figure 2. Provider level of agreement with the following statements about factors influencing *maintenance* (C and D), measured on a Likert scale of 1 to 7 (with 1 = strong disagreement and 5 = strong agreement) collected from the end-of-trial evaluation survey. Total n=37 unless otherwise noted, *n=36, **n=35, ***n=34. Percentages may not add up to 100 because of rounding. AYLHIV = adolescents and youth living with HIV.

Chapter 5. Conclusions

This dissertation comprises three chapters that address our overall objective to evaluate implementation outcomes of a stepped care intervention for AYLHIV. Qualitative and quantitative approaches utilizing three implementation science frameworks provided important contextual information about how best to optimize delivery of the DiSC stepped care intervention. Lessons learned may inform Kenya Ministry of Health about how to reach and engage AYLHIV along the treatment and care continuum, ultimately informing future scalability of youth-centered interventions in health facilities across Kenya.

In Chapter 2, we found that provider-identified adaptations improved integration into routine clinic practices. Provider participation in CQI meetings to identify challenges and propose their own solutions during implementation may have contributed to improved perceptions of acceptability, appropriateness, and feasibility measures over time. Adaptations identified during CQI meetings focused on optimizing how DiSC was implemented to better meet AYLHIV needs and preferences with minimal disruption to routine service provision. Using FRAME to characterize adaptations allowed a systematic approach to understand how adaptations improved contextual fit and relevance of intervention content. Understanding context during implementation improves our knowledge of what is generalizable and what is not. We identified barriers to service access unique to AYLHIV; many adaptations were related to aligning clinic visit schedules to accommodate AYLHIV who were in boarding schools, common for adolescents and young adults in Kenya. We found that Step 1, differentiated care, was best aligned with the school calendar, and may be a motivating factor for AYLHIV to adhere to medications and routinely attend scheduled clinic visits in order to qualify for differentiated care visit schedules.

In Chapter 3, we sought to understand provider perceptions of barriers and facilitators that influenced implementation of the DiSC intervention. We applied the CFIR, a determinants framework, to organize our understanding of key influences impacting implementation outcomes of adoption, reach, and fidelity. Provider recognition of improved service efficiencies because of the DiSC intervention facilitated their adoption. Providers found that the longer visit intervals and fast-track ART refills that were part of DSD model used in DiSC, lessened their workload by staggering AYLHIV return to clinic schedules and optimized time with AYLHIV who needed more support to be retained in care. Providers recognized and valued the importance of psychosocial interventions for AYLHIV experiencing mental health challenges. An important barrier that emerged from the analysis was community attitude that mental health was not an issue, which may impact AYLHIV demand for and experience with mental health services. Further research is needed to address community perceptions of mental health to promote environments that can support the overall well-being of AYLHIV. Providers recommended scale-up but had specific suggestions, such as modifying the DiSC clinical assessment tool to better inform care and management, integrating the tool into the electronic medical record system, and building technical capacity to support scale-up by expanding training to other healthcare cadres. Identifying key facilitators and barriers to implementation of new interventions that incorporate elements of DSD for AYLHIV can inform strategies about how to support risk assessment and service frequency for ALHIV at HIV care facilities across Kenya.

In Chapter 4, we applied the Reach, Effectiveness, Adoption, Implementation, and Maintenance (RE-AIM) framework to guide evaluation of the DiSC intervention. We identified high adoption and perceived effectiveness, and key influences on implementation and maintenance. While the program had the highest reach of AYLHIV in the 15–19-year-old category, future studies should explore strategies to improve reach among all 10–24-year-old AYLHIV attending care. Within the context of a clinical trial, our overall reach was 96%. Distribution when broken down by age was

(10–14 years: 28% [252/888]; 15–19 years: 48% [428/888]; 20–24 years: 23% [208/888]). This distribution may explain why during implementation adaptations were related to aligning clinic visit schedules to accommodate AYLHIV who were in boarding schools, common in Kenya among the 15–19-year-old age group. At the end of the trial, providers supported continued use of the DiSC intervention, citing leadership support, training, and human resources as key influences on future sustainment.

With the trial completed, next steps for our work will be to conduct a dissemination and consensus building workshop with diverse stakeholders. During a two-day user-centered design workshop, our goal will be to use Nominal Group Technique (NGT), a consensus building collaborative implementation science approach, to identify and prioritize implementation strategies to optimize integration and sustainment of the DiSC intervention in Kenya. Data generated from the NGT approach will inform a shared vision of how best to integrate the DiSC intervention into routine practice.

In conclusion, we hope this work will inform the design of programs that support AYLHIV with engagement in care. Characterizing adaptations and their rationale improves our understanding of implementation contexts and enables better tailoring of strategies to improve fit. Understanding barriers and facilitators that influence implementation can optimize adoption and sustainment of health systems interventions. By aligning services to AYLHIV need, we can positively impact their health outcomes and improve service delivery efficiencies.