

Differentiated service delivery – beyond HIV treatment for integration and other health needs

Guest Editors: Anna Grimsrud, Charles B. Holmes, Linda Sande

Supplement Editor: Camille Gourouvadou



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EDITORIAL

Build, do not dismantle: leveraging a differentiated service delivery approach for broader health impact amidst funding changes

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"It is so easy to break down and destroy. The heroes are those who make peace and build."—Nelson Mandela

We received over 100 abstracts in response to this supplement's call for evidence to advance the scale-up of differentiated service delivery (DSD) beyond HIV treatment. However, since January 2025, the global context for HIV service delivery has shifted dramatically.

A steep, sudden reduction in United States government funding has jeopardised HIV services in many high-burden countries [1]. The closure of United States Agency for International Development (USAID) and termination of President's Emergency Plan for AIDS Relief (PEPFAR) programming delivered through USAID partners [2] marks more than a bureaucratic reshuffle—it signals the potential unravelling of critical components of the global HIV response.

While a State Department waiver was intended to provide clarification to allow for life-saving humanitarian assistance, it failed to deliver, resulting in widespread disruption of HIV services, including life-saving treatment [3]. The punitive choices reflected in the waiver also reveal a fundamental shift in the scope of U.S. support going forward. The cessation of most pre-exposure prophylaxis (PrEP) programmes (except for pregnant and breastfeeding women), removal of earmarked funding for key populations and orphans and vulnerable children, and the elimination of HIV survey, surveillance and community-led monitoring activities underscore the magnitude of the shift. These changes threaten to dismantle the very structures built to make HIV care more efficient, client-centred and resilient. Among them is DSD—an approach that has transformed HIV services and remains key to sustaining and expanding access amid shrinking resources.

Prior to 20 January 2025, DSD had been scaled and integrated into national guidance, especially in Eastern and Southern Africa. Data from the Coverage, Quality and Impact Network (CQUIN) network of 21 countries in Sub-Saharan Africa show that by 2023, a median of 76% of people on antiretroviral therapy (ART) accessed treatment through a less-intensive DSD model [4]. Multi-month dispensing (MMD) of ART, which

expanded during COVID-19 [5], is an enabler of DSD. Scale-up of MMD has continued, with 45% of people on ART supported by PEPFAR outside of South Africa, or 6.67 million people, receiving 6MMD in July–September 2023 (personal communication, Lauren Bailey). The potential savings from DSD include cost and resource savings from less frequent clinic visits, both for clients and the health system [6, 7], and can increase human resource capacity [8].

During COVID-19, the World Health Organization (WHO) recommended DSD components to support uninterrupted access to services: MMD of ART, MMD and prescribing of PrEP, scaled provision of HIV self-testing and ART distribution through community distribution points [9]. While these elements remain relevant, the current trend is moving in the wrong direction—ART refill durations are being shortened [10, 11], community distribution points are dismantled and group models phased out with reduced healthcare worker funding, especially for lay cadres.

This supplement is more timely and relevant than ever. DSD adapts care around client needs—a flexibility that is essential in an era of austerity. In the face of funding cuts, DSD provides not a fallback plan, but a forward-looking strategy. Since its articulation nearly a decade ago [12], DSD has focused on client-centredness, grounded in the assumption that those who are clinically stable and treatment literate can be seen less frequently and will seek care when needed. DSD aligns with self-care principles and ensures that resources are available when intensified care is required.

Crucially, DSD is not HIV-specific. It offers a scalable framework for managing other chronic conditions and comorbidities among people living with HIV [13]. In today's resource-constrained environment, the principles of DSD—client-centredness, efficiency, flexibility—are not just relevant, but essential. Rather than dismantling the DSD framework, we should build upon it to support an integrated HIV service delivery model for the future.

This supplement demonstrates how DSD can go beyond sustaining HIV treatment. It can be a foundation for integrated chronic care, a model for resilience in fragile systems

and a mechanism to safeguard key populations from being left behind. DSD offers a way to keep people at the centre and to build health systems from the ground up—efficiently, equitably and sustainably. The supplement includes research across four key themes.

The first theme is on DSD for HIV treatment alongside the integration of other health needs. Articles in this section explore how DSD can be used to deliver integrated care—for example, combining HIV treatment with hypertension or diabetes management. Three papers—Kiggundu et al. [14], Hickey et al. [15] and Pascoe et al. [16]—highlight the successes of integrating hypertension and HIV care within DSD models. In Uganda, Kiggundu et al. randomised clinics to implement hypertension screening and treatment into their HIV DSD models [14]. There were large numbers of people living with HIV with undiagnosed hypertension, 85% of the 3164 people with HIV and hypertension were newly diagnosed in the study. Presenting a mixed-methods study, integration was concluded to be feasible and adaptable facilitated by the availability of resources and synchronisation of HIV and hypertension visits. In South Africa, Pascoe et al. reviewed the already integrated DSD approach in the country assessing the alignment of medication visits and dispensing intervals for people living with HIV and hypertension from 18 public sector clinics across models of service delivery [16]. The results highlight high degrees of alignment with facility visits and medication pick-ups, 94% and 95%, respectively, and no increase in visit burden for co-morbid clients. In the SEARCH study from Kenya and Uganda, Hickey et al. present an alternative approach to leveraging existing Ministry of Health staff to integrate HIV and non-communicable disease care [15]. They show how Ministry of Health community health workers can effectively deliver integrated HIV and hypertension services at the community level, with active linkages to nearby health facilities. The magnitude of the chronic disease risk among people living with HIV in South Africa was described by Sahu et al. in the Kwa-Zulu Natal province [17]. Among those in a community-based ART model, nearly a quarter of participants smoked (24%), had hypertension (23%) and half (50%) were obese. These data highlight the urgent need to address both the prevention and treatment of chronic conditions among people living with HIV. It is encouraging to see growing opportunities and the increasing feasibility of integrating HIV care alongside common co-morbidities.

The second theme examines how the DSD approach is being applied to other chronic conditions, with two papers on DSD for tuberculosis (TB), drawing lessons from HIV service delivery informing design and scale-up. In a discrete choice experiment (DCE), Strauss et al. found strong preferences for DSD among people with TB in the Eastern Cape province in South Africa, with three classes of preferences—community-based, clinic-based and group-models [18]. In Ferroussier-Davis et al., outcomes among people living with TB accessing care and treatment through different DSD models in Uganda are presented, demonstrating the feasibility of both facility- and community-based DSD models beyond HIV [19].

The need and the practical potential of extending DSD models to often-overlooked populations is the third theme. In Hicks et al., results from implementing a risk assessment tool to adapt care for adolescents and young adults living with HIV

in Kenya demonstrates that low-intensity models can be provided to adolescents and young adults living with HIV without additional loss to follow-up or viral non-suppression [20]. In the low HIV prevalence setting of Cambodia, Yam et al. highlight that a community ART delivery model implemented during COVID-19 was cost-effective in reducing the decline in physical health in people living with HIV [21]. Bothma et al. present experiences of healthcare workers delivering a DSD model to trans clients [22]. They demonstrate the need for tailored transgender services as transgender clients continue to face negative experiences when seeking care in standard service delivery facilities. This evidence is particularly crucial in the current climate of shifting funding priorities that represent a major threat to person-centred services for key populations. Another DCE from Australia assessed preferences among gay, bisexual and other men who have sex with men and highlighted the diverse preferences for the delivery of sexual health and PrEP services [23].

In addition to the work of Ong et al., DSD for PrEP emerged as the final theme of this supplement and is also the focus of Musheke et al. and Owidi et al. [24, 25]. In Zambia, Musheke et al. highlight the extended reach of PrEP for adolescent girls and young women in Zambia with decentralisation of PrEP services [24]. Similarly, Owidi et al. present the perspectives of both clients and providers in a pharmacy-based PrEP programme, another intervention adapting the “where” building block of service delivery to expand access to PrEP [25].

Beyond these themes, Fernández Villalobos et al. present the scale of global ART DSD implementation prior to COVID-19 across 175 facilities, offering a rare and valuable insight into its scope [26]. This information is particularly relevant for decision-makers, especially in the context of limited resources, where there is a continued need to decongest facilities and prioritise care for clients requiring the most provider attention. And finally, in a viewpoint, Wilkinson et al. summarise the need for differentiation at re-engagement, and the policy work done in South Africa and Zimbabwe to develop re-engagement algorithms [27]. In both examples, the algorithms are designed both to support those with increased clinical needs and to enable rapid access to less-intensive DSD models to support sustained engagement.

As we navigate this new era in global health and HIV service delivery, several key questions remain:

- **Will countries embed DSD into their primary care strategies?** In some settings, such as Kenya and Uganda [28–30], integrating HIV into chronic care platforms is seen as an efficient solution in response to cuts in foreign health aid. But will the core elements of DSD – client-centredness, the separation of clinical visits from refill-only visits and access to MMD – be retained? Can successes in DSD for HIV influence the expanded use of DSD models for other chronic conditions addressed in primary care settings?
- **What is the future of out-of-facility DSD models and of community healthcare workers?** Out-of-facility models have been instrumental in improving treatment access and adherence, particularly in rural areas, where travel to clinics is a challenge especially when compounded by

a short supply of chronic medications [31]. Community health workers have been vital in facilitating group models, as well as providing treatment literacy and psychosocial support. Yet, these outreach models and lay cadres have often relied on external funding, and as that diminishes, will governments prioritise and sustain these components of the HIV response?

- **Will DSD be a core element of PrEP delivery going forward?** The COVID-19 pandemic accelerated a DSD approach to PrEP [32], with a more flexible, less medicalised and more user-centred approach—including, and especially for key and vulnerable people. However, with uncertainty in the HIV prevention landscape, will advocates push for a DSD approach for PrEP to be continued?
- **Will DSD support the scale-up of future innovations in HIV drug delivery?** Long-acting HIV prevention and treatment products could reshape the HIV response. In addition, new co-formulations and self-injectable delivery mechanisms will be part of the future response. These innovations will only reach their potential if delivered in a way that puts people first [33]. Will DSD be part of this future?

In the face of a precipitous decline in U.S. funding and an uncertain global funding context, HIV services are being reshaped at an alarming speed. This supplement offers timely, practical evidence to support ministries of health and finance, implementers and advocates in rethinking how HIV services are delivered. Amid this upheaval, DSD—including beyond HIV treatment—remains one of our strongest tools to sustain the impact of HIV response and uphold the premise of people at the centre. In addition, enablers of DSD such as MMD are particularly important now, as they can be cost-saving for clients and resource saving for the health systems [34] during a period of increased resource constraint. We must resist the impulse to retreat and instead build on the innovations already in place. Yet, without deliberate intention and sustained commitment, DSD risks becoming a casualty of the current funding crisis. It is not only worth protecting; it is essential to the future of the HIV response and part of the antidote. We cannot allow short-term decisions to unravel years of progress. Now is the time to build—not dismantle.

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COMPETING INTERESTS

The authors declare no competing interests.

AUTHORS' CONTRIBUTIONS

AG wrote an initial outline of the Editorial and the first draft. CBH and LS reviewed and added content. All authors approved the final version of the manuscript.

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Data sharing is not applicable to this article as no datasets were generated or analysed during the current study.

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RESEARCH ARTICLE

Early findings from the integration of hypertension care into differentiated service delivery models for HIV in Uganda: a mixed-method study

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Abstract

Introduction: Uganda's national guidelines recommend integrated HIV and hypertension care; however, integration of hypertension care into HIV differentiated service delivery (DSD) models has not been extensively described. We aimed to describe trends in DSD models for people living with HIV (PLHIV) with hypertension and to qualitatively describe the experiences of healthcare providers (HCPs) and PLHIV with hypertension after implementing integrated care.

Methods: We conducted a parallel convergent mixed methods study nested in an ongoing stepped wedge cluster randomised trial in Kampala and Wakiso districts. Quantitative data (age, sex, blood pressure, DSD model, medication prescriptions) were collected from routine medical records at eight clinics implementing the enhanced care package between March 2023 and July 2024. Additionally, structured interviews were conducted at two clinics with HCPs ($n = 6$, 3 per clinic) and PLHIV with hypertension ($n = 8$, 4 per clinic). Our quantitative outcome variable was enrolment in intensive DSD models (facility-based individual and group models) versus other DSDs. A generalised estimation equation was used to account for within clinic correlation and repeated measures within participants over time. Inductive thematic analysis was applied to the qualitative data using the Consolidated Framework for Implementation Research.

Results: Overall, 3164 PLHIV with hypertension accessed care at the eight clinics. Median age was 46 years (IQR 38–56); more than two-thirds were female. There was considerable heterogeneity across clinics in the use of DSD models during the study period. Overall, use of intensive models increased over time (OR 1.127 [1.059–1.199] per month). However, two clinics showed significant time interaction effects (Wald test $\chi^2(7) = 69.94$, $p < 0.001$), with a decrease in the intensive models over time. HCPs and PLHIV observed that integrating hypertension care was easily adaptable in some models, while more challenging in others. The availability of resources and synchronisation of HIV and hypertension visits facilitated the integration of hypertension care within the HIV DSD models.

Conclusions: The integration of hypertension management into HIV DSD models is both feasible and adaptable; however, it requires transitioning PLHIV between various models based on clinical needs. To facilitate this process, comprehensive client education by the HCPs is necessary.

Clinical Trial Number: [clinicaltrials.gov # NCT05609513](https://clinicaltrials.gov/ct2/show/study/NCT05609513)

Keywords: differentiated service delivery; HIV; hypertension; implementation; integrated care; people living with HIV

Additional information may be found under the Supporting Information tab of this article.

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1 | INTRODUCTION

Differentiated service delivery (DSD) models of care are defined as “client-centered approaches that simplify and adapt HIV services across the cascade, in ways that both serve the needs of people living with HIV (PLHIV) better and reduce unnecessary burdens on the health system” [1]. Uganda adopted and began to scale up DSD models in 2017 [2]. By 2023, approximately 1.4 million adult PLHIV were receiving care through one of the six DSD models, experiencing well-documented benefits such as fewer clinic visits, reduced waiting time and lower transportation costs [1, 3, 4]. From the health system’s perspective, healthcare providers (HCPs) experience decreased client load and reduced workload, while the system provides more efficient care at lower cost [4, 5].

Like many other sub-Saharan African countries, Uganda faces a significant burden of both infectious and non-communicable diseases (NCDs) [6, 7]. Up to 20–32% of adult PLHIV have hypertension, a leading preventable risk factor for cardiovascular diseases (CVDs) [8–11]. PLHIV with hypertension have a higher risk of CVD and all-cause mortality compared to people without HIV [12, 13]. For these reasons, inclusive, person-centred hypertension treatment should be a top priority within HIV DSD models.

With the increasing burden of hypertension among PLHIV, some countries in Africa including Uganda have recommended the integration of hypertension in HIV care across all DSD models [14]. For example, the Uganda guidelines for HIV treatment recommend that PLHIV with controlled hypertension receive care through both less intensive and intensive models, while those with uncontrolled hypertension should receive care through intensive models, such as facility-based individual management (FBIM) and facility-based group (FBG) care, or HCP-managed less intensive models, including community drug distribution points (CDDPs) and fast track drug refill (FTDR) models [15, 16].

Although prior implementation and programmatic reports have demonstrated improved hypertension cascade metrics following the integration of HIV hypertension care, most of these studies have focused on integrating hypertension in intensive models [17, 18]. Given that nearly 80% of PLHIV in Uganda receive care through less intensive models [19], PLHIV with hypertension are likely to receive suboptimal hypertension care if integration is not expanded to all models. Several groups have proposed expanding DSD models to offer more comprehensive and person-centred care, including hypertension services [20–23]. However, there is limited evidence to show how the implementation of hypertension services in less intensive models can be done. In addition, there is little information detailing the experiences of PLHIV receiving HIV and hypertension care through these models.

The Strengthening Blood Pressure Care and Treatment Cascade for Ugandans Living with HIV—Implementation Strategies to Save Lives (PULESA-Uganda) study is an implementation trial aimed at improving hypertension care cascades among PLHIV [24, 25]. The ongoing PULESA-Uganda trial leverages existing HIV platforms to expand care for hypertension across public and private not-for-profit clinics. In this paper, we document trends in the utilisation of the var-

ious DSD models for PLHIV with hypertension following the integration of HIV hypertension care at these clinics. We also explore the experiences of HCPs in delivering, and PLHIV with hypertension in receiving, hypertension care within DSD models using the updated Consolidated Framework for Implementation Research (CFIR) [26].

2 | METHODS

2.1 | Study design

We conducted a parallel convergent mixed methods study nested in PULESA-Uganda, a stepped wedge cluster randomised trial evaluating two strategies for integrating HIV hypertension care in 16 HIV clinics in Wakiso and Kampala districts [25]. Eight clinics were randomly assigned to “Hypertension PLUS” or “Hypertension BASIC.”

Clinics assigned to “Hypertension BASIC” receive a consistent supply of guideline-recommended anti-hypertensive medications (amlodipine 10 mg, valsartan 160 mg and hydrochlorothiazide 25 mg), basic training on hypertension treatment and blood pressure (BP) devices (*Welch Allyn ProBP 2000 digital*). In addition to the components of “Hypertension BASIC,” clinics randomised to the “Hypertension PLUS” arm of the study receive: (1) training of HCPs on hypertension care; (2) quarterly performance audit and feedback; (3) remote patient monitoring of BP in the community; and (4) integration of HIV hypertension care in all existing HIV DSD models while aligning both HIV hypertension services and allowing multi-month dispensing (MMD) for both anti-retroviral therapy (ART) and anti-hypertensive medications (Supporting information File S1).

2.2 | Study sites

Although 16 clinics are participating in the trial, this paper presents initial findings from the eight clinics assigned to the “Hypertension PLUS” intervention who are more intentionally working to integrate hypertension care into existing DSD models as one of the package components. These clinics were assigned random unique identifiers (C12, C01, C14, C08, C03, C10, C05, C15) and are subsequently referred to by these numbers in our manuscript (Supporting information File S2).

All the HIV clinics are supported by a local implementing partner with funding from the US President’s Emergency Fund for AIDS Relief to provide HIV care and treatment services. PLHIV receive care and treatment services under the six DSD models; FBIM, FBG, Fast Track Drug Refill, Community Client-Led ART Delivery, Outreach HCP-led Community Drug Distribution Point (CDDP-outreach) and Community Retail Pharmacy Drug Distribution Point (CRPDDP) [15] (Supporting information File S3).

2.3 | Participant selection

For the quantitative component, we gathered routine clinical data from PLHIV aged 18 years and above who received HIV and hypertension care at the “Hypertension PLUS” clinics. Using the Uganda guidelines, participants were classified as having hypertension if they had at least two BP readings

$\geq 140/90$ mmHg from separate clinic visits a week apart or were on anti-hypertensive treatment [15]. Although we did not have a predetermined sample size, the power calculations for the primary outcomes were based on an estimated sample size of 5000 PLHIV with hypertension across all 16 clinics.

We purposively selected a sub-sample of eight PLHIV with hypertension ($n = 4$ per clinic) aged 18 years and above and provided informed consent to participate in in-depth interviews (IDIs). We excluded those with cognitive impairment or using anti-hypertensive medications for purposes other than treating hypertension (e.g. systolic heart failure). Our purposive approach to sampling sought to balance the representation of natal sex as well as participants diagnosed with hypertension either prior to or during the intervention rollout.

For key informant interviews (KIIs), we purposively selected six HCPs ($n = 3$ per clinic) who provided integrated HIV and hypertension care. We excluded HCPs not engaged in direct client care or planning to leave the clinics during the study period.

2.4 | Data collection

2.4.1 | Quantitative data

From March 2023 to July 2024, trained research assistants extracted data from paper-based medical records of adult PLHIV at each clinic on every clinic visit during the implementation phase. Due to the stepped-wedge design, follow-up time ranges from 2 to 16 months (Supporting information File S4). We collected age, sex, BP measurements, chart diagnosis of hypertension, anti-hypertensive medications, DSD model and place of prescription. These data were entered in a pre-designed instrument developed in Research electronic data capture [27, 28]. The study data manager conducted weekly data quality checks to ensure that all metrics were correctly entered.

2.4.2 | Qualitative data

We conducted interviews at two clinics (C14 and C08), 6 months after each clinic's transition into the intervention phase. Data collection occurred between January and April 2024. Trained research assistants, (JK—male and JA—female), conducted IDIs with people living with HIV and hypertension. The PLHIV client interviews were conducted in Luganda, a widely spoken language in the Kampala and Wakiso districts. Additionally, FA (female), a social scientist with extensive expertise in the subject matter, conducted KIIs with HCPs. The HCP interviews were conducted in English. Each interview lasted approximately 30–45 minutes. Two interview guides were used: one for IDIs, and another for KIIs. The questions explored issues such as how easy or challenging it was to integrate hypertension care into the existing DSD models, clients' experiences in receiving hypertension care, barriers or challenges they encountered and how beneficial they found the integration of hypertension care into these models.

2.5 | Data analysis

2.5.1 | Quantitative analysis

We conducted univariate analyses to describe the socio-demographic characteristics of the cohort. We summarised

continuous variables using medians and interquartile ranges and presented categorical variables as percentages and frequencies.

A generalised estimation equation (GEE) model was used to account for repeated measures within participants over time. The binary outcome variable was enrolment in intensive DSD models (FBIM and FBG) versus the other DSDs. A logit link function was used, with clinic (categorised: 1–8), time from start of intervention (continuous) and the clinic*time interaction term as predictors. Clinic C12, the first to implement the intervention and the clinic with the longest follow-up duration, served as the reference. An exchangeable correlation structure was assumed, and robust standard errors were used. Clusters were defined by participant ID where the repeated measures were assumed to be correlated, with 3164 clients making 6575 visits (range 1–11) with a mean of two observations. Comparisons were made with the exchangeable correlation structure which showed consistent results. Wald tests were used to establish overall clinic effects and those of each clinic*time interaction. Clinic-level margin plots were made to check the consistency of predictive margins for being in intensive DSDs. Analyses were performed in Stata 18.5 and $p < 0.05$ was considered statistically significant.

2.5.2 | Qualitative analysis

All interviews were audio recorded and transcribed verbatim by an external consultant. The updated CFIR guided our qualitative data analysis. Two social scientists (FA and CK) reviewed the 14 transcripts and conducted rapid thematic analysis, manually coding the transcripts to identify preliminary codes which were then synthesised into emerging themes related to integrating hypertension care within DSD models. We held team meetings (ARK, FA, CK, JBK and FCS) to discuss the codes and emerging themes, and resolve any disagreements until a final codebook was agreed upon. This analysis examined PLHIV's and HCP's experiences with the integration of hypertension care within DSD models. We present the results of this analysis using the CFIR domains and constructs [26], along with themes and illustrative quotes from the participants.

2.6 | Conceptual framework

We utilised the updated CFIR to identify key domains influencing implementation [26]—we sought to identify domains and constructs that supported or hindered the integration of hypertension care in DSD models. We identified the updated CFIR constructs (innovation domain and inner setting) as being relevant to understanding how the innovation was received and delivered by PLHIV and HCPs, respectively. We were interested in understanding how the intervention was beneficial to both PLHIV and HCPs, whether it was adaptable or not with existing DSD models and how easy or difficult it was to integrate hypertension care into DSD models of care. Following our analysis, we mapped our themes onto the identified CFIR domains and constructs.

Table 1. Characteristics of PLHIV diagnosed with hypertension

Variable	Previously diagnosed n = 476	Newly diagnosed n = 2688	All N = 3164
Age (years)	44 (38–52)	47 (39–54)	46 (38–54)
Age category			
18–35 years	92 (19.3)	460 (17.1)	552 (17.4)
36–49 years	228 (47.9)	1123 (41.8)	1351 (42.7)
50+ years	156 (32.8)	1105 (41.1)	1261 (39.9)
Sex			
Female	326 (68.5)	1842 (68.5)	2168 (68.5)
Male	150 (31.5)	846 (31.5)	996 (31.5)
District			
Kampala	417 (87.6)	2131 (79.3)	2548 (80.5)
Wakiso	59 (12.4)	557 (20.7)	616 (19.5)
Clinic type			
Private not for profit	62 (13.0)	313 (11.6)	375 (11.9)
Public	414 (87.0)	2375 (88.4)	2789 (88.1)

Note: Data expressed as median (interquartile range) for continuous variables and number (%) for categorical variables.
 Abbreviation: PLHIV, people living with HIV.

2.7 | Data integration

We utilised the narrative approach in which qualitative findings provided a more in-depth understanding and context to the quantitative results, even though they are presented separately in the results [29].

2.8 | Ethics approval and consent to participate

The Makerere University School of Medicine Research and Ethics Committee (Mak-SOMREC-2022-40) and the Uganda National Council for Science and Technology (HS2398ES) approved the study. We also obtained administrative clearance from the leadership of the Uganda Ministry of Health, Kampala and Wakiso districts. We received a waiver of consent to collect routine clinical data while participants provided informed consent to participate in qualitative interviews.

3 | RESULTS

3.1 | Quantitative results

3.1.1 | Participant characteristics

Overall, across the eight “Hypertension PLUS” clinics, 29,316 sought HIV care from the clinics. Of whom, 26,800 (91%) had at least one BP measurement, and 3164 (12%) PLHIV had hypertension; 2688 (85%) of whom were diagnosed during the intervention, which included higher rates of BP screening with newly available and functioning BP cuffs. Over two-thirds of the participants were females with a median age of 44 years (IQR: 38–52). The participants were predominantly getting care from urban public clinics in Kampala (Table 1 and Figure 1).

3.1.2 | Trends in DSD models for PLHIV and hypertension following implementation of hypertension PLUS

There was considerable heterogeneity in DSD model use across the eight sites. Except for C10, all other clinics had significantly lower odds of using the intensive models ($p < 0.001$) relative to the reference clinic. The Wald test revealed a significant overall clinic effect ($\chi^2 (7) = 1276.82$, $p < 0.001$). The time from the start of the intervention also showed a statistically significant main effect (OR 1.127 [95% CI 1.059–1.199], $p < 0.001$), indicating that uptake increased significantly over time across all clinics.

Most clinics had relatively stable use of more versus less intensive DSD models over time; however, some clinics saw considerable changes (Supporting information File S5). Overall, the Wald test showed the interaction between clinic and time was statistically significant ($\chi^2 (7) = 69.94$, $p < 0.001$). The predictive model plot shows that some clinics favoured intensive models for PLHIV with hypertension, while others kept these participants in less intensive models. Both clinics that contributed qualitative data to this analysis (C08 and C14) showed statistically significant clinic*time interactions ($p < 0.001$), demonstrating a shift towards less intensive models over time after implementation. One clinic—C15—showed a non-statistically significant ($p = 0.827$) trend towards intensive model use over time, possibly an artifact of the short 2-month period of observation at this clinic since it was the last site to implement hypertension PLUS (Table 2 and Figure 2).

3.2 | Qualitative results

3.2.1 | Participant characteristics

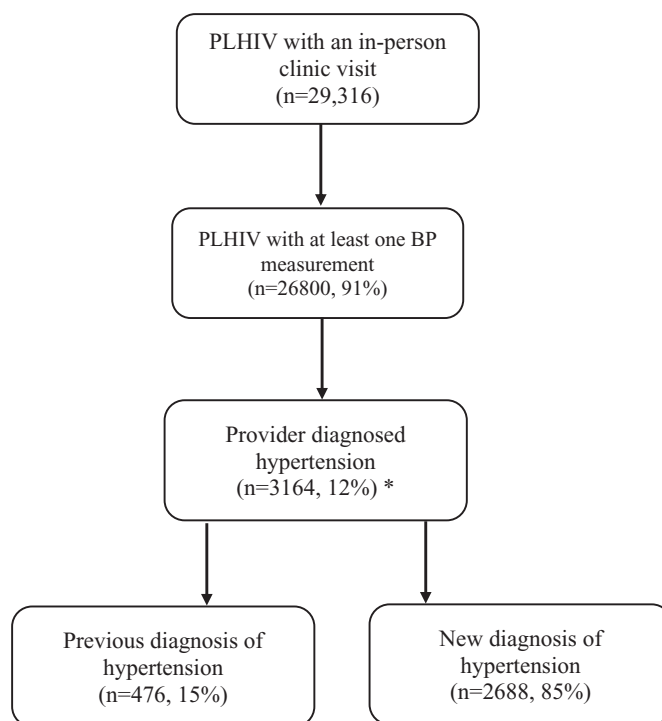
Six HCPs participated in the KIIs, half of whom were males with a median age of 34 years (IQR: 27–40). Of the eight PLHIV with hypertension who were interviewed, 50% were males and the median age was 56 (IQR: 52–61) (Table 3).

The following CFIR domains were dominant determinants of hypertension care implementation into existing DSD models. Some were barriers (–), while others were facilitators (+) (Table 4).

3.2.2 | Innovation adaptability (degree to which intervention can be adapted, tailored, refined, reinvented to meet local needs)

Fast track drug refill model adaptable to integration (±). HCPs generally expressed that the integration of hypertension in DSD models was easily adaptable. They highlighted that models such as the fast track drug refill were particularly amenable to adaptation, especially for PLHIV who had controlled BP and suppressed viral load (Supporting information File S6). PLHIV with controlled BP continued to receive both HIV and hypertension care in this model, as illustrated in the following excerpt:

“If they [PLHIV] have controlled BP, they qualify for fast track drug refill so they will get three months of ART and even the anti-hypertensives [medications] they will get three



*Healthcare providers were trained to diagnose hypertension if a client had at least two BP readings $\geq 140/90$ mmHg from separate clinic visits a week apart or were on antihypertensive treatment as per Uganda national guidelines. This analysis includes only health provider made diagnosis of hypertension.

Figure 1. Diagram showing hypertension screening and diagnosis cascades. Abbreviations: BP, blood pressure; PLHIV, people living with HIV.

Table 2. Odds of enrolment into intensive DSD models compared to the reference clinic (C12; representing the first clinic to rollout the intervention)

More intensive DSDs	OR	Robust SE	p
Clinic			
C12	1.000		
C05	0.035 (0.015–0.084)	0.016	$p < 0.001$
C14	0.058 (0.033–0.100)	0.016	$p < 0.001$
C03	0.040 (0.020–0.080)	0.014	$p < 0.001$
C15	0.201 (0.092–0.438)	0.080	$p < 0.001$
C10	0.759 (0.431–1.338)	0.220	0.341
C01	0.018 (0.005–0.072)	0.013	$p < 0.001$
C08	0.182 (0.096–0.345)	0.060	$p < 0.001$
Time from intervention start	1.127 (1.059–1.199)	0.036	$p < 0.001$

Abbreviations: DSD, differentiated service delivery; OR, odds ratio; SE, standard error.

months [refills] because the stock [hypertensive medication] is there... (Medical officer, C14)

HCPs re-organised client flow at the fast track drug refill point to incorporate routine BP measurement and triage.

As described in the excerpt below, PLHIV with uncontrolled hypertension were reassigned to FBIM for more comprehensive care, while those who had controlled hypertension continued to receive hypertension medication refills through this model.

“Fast track drug refill clients did not want to be removed from their models. They are used to getting six months of ART refills now you want to bring them down [routine clinic] and give few months, they were not happy but we try, we counsel and explain. And now with a BP machine at the FTDR desk at least we can still measure them before we give them a refill...” (Nurse, C14)

Reassignment across DSD models (–). In the early stages of implementation of the integrated care, HCPs tended to reassign PLHIV with uncontrolled BPs from a less intensive model such as fast track drug refill to an intensive model like FBIM.

HCPs also noted that within facility-based less intensive DSD models, clients valued the convenience of receiving 6-month ART refills and expressed a desire for a similar approach to anti-hypertensive medication refills. Challenges were noted, mainly when clients were newly diagnosed with hypertension as elaborated by a medical officer in the excerpt below:

“If a client is diagnosed with hypertension during a previous visit, the best option is to take them off the fast track drug refill point. But, for those diagnosed with

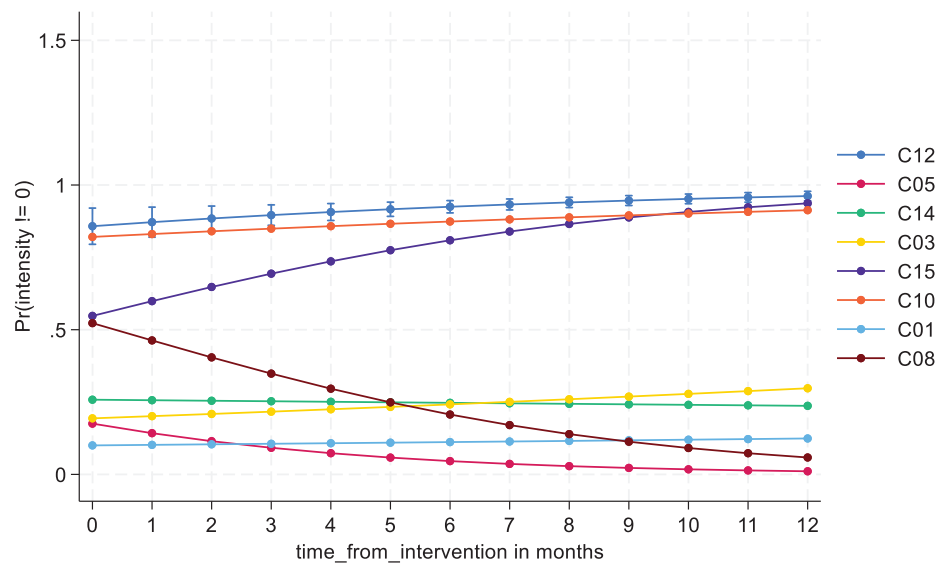


Figure 2. Model predicted clinic-level trends of differentiated service delivery (DSD) enrolment into intensive DSD models over time.

Table 3. Characteristics of participants who participated in the qualitative interviews

	Healthcare providers n = 6	PLHIV with hypertension n = 8
Age	34 (27, 40)	56 (52–60.5)
Sex		
Male	3 (50)	4 (50)
Female	3 (50)	4 (50)
Cadre		
Medical doctor	2 (33.3)	–
Nurse	2 (33.3)	–
Clinical officer	1 (16.7)	–
Pharmacy technician	1 (16.7)	–
Years of practice	8.5 (2–16)	–
Hypertension status		
Newly diagnosed	–	4 (50)
Previously diagnosed	–	4 (50)

Note: Data expressed as median (interquartile range) for continuous variables and number (%) for categorical variables.
Abbreviation: PLHIV, people living with HIV.

hypertension at the fast track drug refill point after missing an earlier appointment, it becomes inconvenient—they have to go back to the clinic and start regular visits again. ...it involves a long line.....” (Medical officer, C14)

Adaptation of integration in CDDP models (±). HCPs reported that integrating hypertension care into outreach HCP-led CDDP models was straightforward. To seamlessly integrate hypertension within this model, HCPs ensured that they carried supplies (BP devices, medications, treatment algorithm

and dispensing logs) needed for the provision of hypertension care. HCPs sought to align hypertension and ART services. HCPs tried not to disrupt ART services by providing additional counselling and MMD for hypertension.

“Usually, they [community drug distribution point-outreach team] also have an algorithm for hypertension treatment; those who go for outreach, we give them an [hypertension treatment] algorithm. They have a dispensing log. They go with [ART and antihypertensive] medications. They have to make sure that they have to check the appointment book and see those ones who need [hypertension medications] refill on different appointments. So, they can know, they have to make sure that they go with hypertension medications because they have clients there.” (Medical officer, C08)

3.2.3 | Innovation relative advantage (the innovation is better than other available innovations or current practice)

Perceived benefits of integration of hypertension in DSD models (±). PLHIV emphasised that receiving treatment and medication for both HIV and hypertension during a single visit was extremely beneficial, convenient and reduced the need for multiple clinic visits. This addressed the challenge of seeking care at multiple locations, as illustrated in the excerpt below.

“I choose to get the integrated service because if you say you get for hypertension and HIV on separate days you will get inconvenienced like me who stays very far it means you will have to travel two times as compared to the integrated service where you will have to come once and you go back with all the medications at once.” (female 50 years, Community drug distribution point, C08)

Table 4. Summary of key themes, interview questions and quotes on integration of hypertension in DSD models

CFIR domain/construct	Interview questions	Qualitative data
Innovation relative advantage (+) Integration of hypertension into differentiated service delivery (DSD) models addresses clients' needs, reduces frequency of visits to clinic, transportation costs, improves medication adherence	<u>PLHIV and healthcare providers</u> What have been the benefits of the intervention? <u>PLHIV</u> If you were given a choice to receive hypertension services separately from HIV services or combined services at the same time and with the same provider, which option would you choose and why?	"I choose to get the integrated service because if you say you get hypertension and HIV services on separate days you will get inconvenienced. Like me who lives faraway I will have to travel two times as compared to integrated services where you come once and get all your medicines at once" (Female, 50 years, Community drug distribution point, C08)
Innovation adaptability (+) - Integration of HIV hypertension in facility models is possible due to the availability of hypertension medicines - Possible to adapt to existing models of care and may not disrupt services for PLHIV - Synchronisation of HIV hypertension refills is possible for PLHIV receiving care through fast track drug refill	<u>Healthcare providers</u> How easy or difficult has it been to integrate hypertension care into HIV DSD models? What changes have you made within the clinic to accommodate implementation of hypertension-HIV integration?	"If they [PLHIV] have controlled blood pressure, they qualify for fast track drug refill (FTDR) so they will get three months of ART and even the anti-hypertensives [medications] they will get three months [refills] because the stock [hypertensive medication] is there. If they [PLHIV] have uncontrolled BP, they're returned to the facility based individual management where they have to be seen by a clinician" (Medical officer, C14) "When staff go for community outreach, they carry their drugs with the dispensing log. The dispenser who is part of the team is tasked with recording whatever has been done during the community outreach" (Pharmacy staff, C14)
Innovation design (+) Positive perception of integration of hypertension care into DSD models, it encourages client centred care, ensures holistic care, de-fragmentation of services, comprehensive care, more effective client management, alignment of hypertension/HIV services	<u>Healthcare providers</u> What are your thoughts about integrating hypertension care within HIV services? How well is the clinic integrating hypertension into HIV services? <u>PLHIV</u> Tell me about your experience receiving both HIV and hypertension services at this facility under the new approach where services are combined.	"According to the new guidelines, we were told to give them [PLHIV with hypertension] their [multi] month [refills] and they [PLHIV] just come back here for refills and medication because when they come back we take their blood pressure and refill their medication; initially we were not supposed to give them those refills for hypertension medications, but now with the new guidelines as of 2022 we give them [multi month dispensing] for hypertension" (Nurse, C14) "I just want to get the combined services because traveling tires me out; if you come one month and get the antiretroviral therapy and come back another month to get a blood pressure medication that is an inconvenience for me to travel. With [integrated services] it's easier for me because I come at one and I don't have to worry about coming back". (74-year-old Male, C08)
Innovation complexity (–) Negative perception if integrating hypertension services in some of the DSD models like retail pharmacy model which are run privately, misalignment of clinic visits	<u>Healthcare providers</u> What challenges or barriers have you experienced receiving or delivering hypertension and HIV services? <u>PLHIV</u> What, if any are the challenges you may have encountered while accessing HIV and hypertension services in a combined manner at this facility	"If a client is diagnosed with hypertension during a previous visit, the best option is to take them off the FTDR point. But, for those diagnosed with hypertension at the FTDR table after missing an earlier appointment, it becomes inconvenient—they have to go back to the clinic and start regular visits again. ...it involves a long line....." (Medical officer, C14) "Some of us receive services from the community clinic so when we come here to see the doctor but the blood pressure medicine is not available in the community—so I would ask that in the community too we should be able to get the BP medicine" (PLHIV, C14)

(Continued)

Table 4. (Continued)

CFIR inner setting domain		
Available resources, materials and equipment (+)	Healthcare providers	
Availability of hypertension treatment protocol, functional blood pressure devices and anti-hypertensive medicines have supported intervention	What kind of support, materials have facilitated integration? How adequate has the support been to integrate hypertension services into differentiated service delivery models?	"What I would say has facilitated integration, the additional blood pressure machines, the trainings, and then the drugs, those have helped us with the integration (Nurse, C14) They [health care providers] ask about how I feel, they come and health educate us here and tell us how to behave when taking medicine and taking it on time; the health care provider comes and teaches us. When you ask questions, they are answered well. I don't see anything missing because if I've got my antiretroviral therapy, and I've got my blood pressure medication then what more am I asking for? (74-year-old Male, C08)
Access to knowledge and information (+)	PLHIV	
Availability of training and health education on hypertension management positively impacts the intervention	What kind of support have you received from staff at this facility on managing both HIV and hypertension conditions?	
	Healthcare providers	
	How has the training and support received impacted or influenced your practice of providing integrated hypertension and HIV services?	"Training in hypertension management has influenced us, given us more knowledge of how to handle hypertension cases in PLHIV" (Clinical officer, C08)

Abbreviations: CFIR, consolidated framework for implementation research; DSD, differentiated service delivery; FTDR, fast track drug refill; HIV, human immunodeficiency virus; MMD, multi-month dispensing; PLHIV, people living with HIV.

3.2.4 | Innovation complexity (the innovation is complicated, which may be reflected by its scope and/or the nature and number of connections and steps)

Lack of integration in the CRPDDP model (–). Integrating hypertension care into this model was not possible because community retail private pharmacies lacked free hypertension services. Interviews with PLHIV revealed that community retail pharmacies lacked hypertension services and they expressed the need for BP devices and medications to facilitate the provision of hypertension care within this model. HCPs also noted the lack of integrated HIV and hypertension services and often advised PLHIV with hypertension in this model to return to the clinic to receive hypertension care, as illustrated by the following HCP's account:

"Clients in the community retail pharmacy drug distribution point model are not screened for hypertension. The government is still working on that. For those already on hypertension treatment, they always come back to the facility... they come back here, we rescreen them, and then provide the refill."

Interviewer (I): "So, in the community, they only receive the ART?"
 Respondent (R): "Yes, they only receive ART." (Nurse, C14)

Participants were often advised to purchase the medications from nearby pharmacies if they preferred not to return to the clinics, as described in the excerpt below.

"For the community retail pharmacy drug distribution point, many of them [PLHIV] who were known [to have] hyperten-

sion were buying their own [anti-hypertensive] medications, they would not come to the HIV clinic for hypertension services but now some of them are coming to the clinic for hypertension only and then [get] ART refills at the community retail pharmacy drug distribution point." (Nurse, C14)

3.2.5 | Innovation design (innovation is well designed and packaged including how it is assembled, bundled and presented)

Integration consistent with the Ministry of Health (MoH) guidelines (±). HCPs explained that integrating hypertension care into the DSD models involved aligning hypertension and HIV care. This approach aligns with the MoH guidelines, which recommend providing MMD for both HIV and hypertension medications to clients with controlled viral load and BP.

"According to the new guidelines, we were told to give them [PLHIV with hypertension] their [multi] month [refills] and they [PLHIV] just come back here for refills and medication because when they come back we take their BP and refill their medication; initially we were not supposed to give them those refills for hypertension medications, but now with the new guidelines as of 2022 we give them [MMD] for hypertension." (Nurse, H1401)

Appreciation of the synchronisation of services (±). PLHIV appreciated the alignment of hypertension and HIV visits, which enabled them to receive synchronised HIV and hypertension care and reduced the need for disjointed clinic visits and associated travel expenses as described below.

"What I benefit from this, is being helped because when I come on the day I was told to come back, it is all done at once because that up and about movement inconveniences me in terms of transportation ...if they give me about a month, when I come back after that period they check my BP or if it is three months, they do it all after those months but they don't tell me to either wait three days or after a week and I come back, no; if they give me one month to come back to give me the antiretroviral therapy, even the BP medication shall be for one month." (PLHIV, 68 Male, Community drug distribution point, C08)

3.2.6 | Available resources (resources are available to implement and deliver the innovation)

Availability of BP devices to integrate hypertension care in community outreaches (+). HCPs reported that the availability of BP devices and medications were facilitators for the integration of hypertension care into existing DSD models.

"What I would say has facilitated integration, the additional BP machines, the trainings, and then the medicines, those have helped us with the integration." (Nurse, C14)

3.2.7 | Access to knowledge and information (guidance/training is accessible to implement and deliver the innovation)

Training on hypertension care facilitated its integration in DSD models ($\pm$). HCPs reported training on hypertension was greatly beneficial and improved their confidence to manage hypertension. They explained that training in hypertension management expanded their knowledge and competency to diagnose, monitor and treat PLHIV with hypertension.

"The trainings have helped very much-for me as a clinician it added to my knowledge on how to prescribe because now, I can confidently prescribe, I know what I am doing because of the training we received." (Nurse, C14)

4 | DISCUSSION

This study assessed the effect of integrating hypertension care into HIV care on the enrolment of PLHIV with hypertension in various DSD models, using interrupted time series analysis. We also explored the experiences of HCPs in delivering, and PLHIV with hypertension in receiving, hypertension care within these models using the updated CFIR. Our findings showed an increased likelihood of enrolment of PLHIV with hypertension into intensive DSD models, especially in the initial phases of the study (2–16 months); however, there was significant variation across the clinics with two clinics demonstrating a statistically significant trend towards less intensive models over time. Qualitative findings revealed that integration of hypertension care into HCP-managed less intensive models was feasible, beneficial, adaptable and enhanced person-centred care. To integrate HIV hypertension care in DSD models, HCPs temporarily transitioned clients into intensive models until the desired clinical status was achieved. Although clients initially resisted the transition, those who

achieved BP control were eventually reassigned back to less intensive models during the course of the intervention. Integrating hypertension care into the community retail pharmacy model proved challenging, resulting in fragmented HIV and hypertension care.

As opposed to client-led versions of less intensive models (e.g. CRPDDP), less intensive models managed by HCPs (e.g. FTDR and CDDP-outreach) were easily adapted for hypertension care integration. In contrast, integrating hypertension services into the less intensive client-led models was limited, resulting in fragmented care for hypertension and HIV. The integration of hypertension care into a less intensive model was largely attributed to HCP-initiated modifications. These included implementing BP measurement and triage at fast track drug refill points, as well as carrying anti-hypertensive medications, BP devices and treatment algorithms to community outreach points. Clients receiving care through the community retail pharmacy model were often encouraged to purchase their medications or receive fragmented hypertension medication refills from pharmacy points.

Transitioning clients with uncontrolled hypertension into intensive facility-based models such as FBIM and FBGs was a common strategy for ensuring clients received medically appropriate care. However, qualitative findings revealed that some clients initially resisted transition and opted to receive disjointed care. With time, clients were transitioned back to less intensive models as they achieved controlled BP, or good adherence to anti-hypertensive medication.

The use of the CFIR enabled the identification of key factors influencing the integration of hypertension care into DSD models. Specifically, the interplay between innovation, access to knowledge and availability of resources emerged as critical determinants of success. At the two clinics (C08 and C14) showing the greatest adaptability over time, the integration of hypertension care into HCP-managed less intensive models, such as FTDR and CDDP-outreach, was possible due to the availability of resources (e.g. medications and BP devices) and access to hypertension training for HCPs. HCPs implemented several innovations to support integration. These included conducting BP monitoring at fast track drug refill points, identifying clients with uncontrolled hypertension and redirecting them to clinics for enhanced management. HCPs also transported BP machines, medications and treatment algorithms to community settings, ensuring the delivery of integrated HIV and hypertension care directly to clients. However, despite the availability of medications and BP devices at clinics, HCPs viewed it as not feasible to extend these services to the small number of clients receiving HIV medication refills from community retail pharmacies. This limitation resulted in fragmented care for these clients with comorbid hypertension, highlighting a significant challenge to achieving comprehensive integration.

Consistent with findings from other studies [17, 30], availability of resources (BP devices and medications), training of HIV HCPs, task shifting and use of simplified protocols enhanced the integration of hypertension care into HIV services, as evidenced by the markedly high hypertension screening and detection rates. However, the high prevalence of hypertension presents new and unique demands for the

integration of hypertension care into an already mature HIV service delivery programme, potentially necessitating adjustments to client flow and re-allocation to various DSD models. For example, PLHIV with uncontrolled hypertension might require a transition to an intensive model, while clients who have achieved control of both HIV and hypertension may be transitioned to less intensive models. The national guidelines need to be more explicit on the eligibility for transition from one model to another based on HIV and hypertension control status as well as the clients' preferences.

The CRPDDP model was described as less adaptable for hypertension services. Operationalising this model by ensuring consistent availability of resources (BP medications and devices) and training of the community pharmacy staff are needed to integrate hypertension care into the CRPDDP model, but require considerable resources, planning, and alignment of public health and business incentives. The benefits of receiving pharmacy-based hypertension services such as adherence counselling, BP monitoring and optimising hypertension management have been documented in the African region [31]. To increase the client-centeredness of integrated care, hypertension care for PLHIV should be expanded to pharmacy-based models. Furthermore, insights from South Africa's Central Chronic Medicine Dispensing and Distribution programme could be modelled into Uganda's CRPDDP and expanded to provide hypertension medication refills, BP monitoring, counselling on side effects not only to PLHIV with hypertension but also to individuals with NCDs [32].

One of our study's strengths is the mixed-methods design, which revealed the nuances in perceptions in receiving and experiences of delivering and receiving integrated HIV hypertension care across the intensive and less intensive DSD models. Second, the study applied selected CFIR constructs to explore how integrated care was received by PLHIV and delivered by HCP. Third, by interviewing both HCPs and PLHIV, the study identified demand-side and supply-side challenges affecting the integration of hypertension care within DSD models. Finally, the GEE model illustrated changes over time in the pooled sample as well as by individual clinic.

One of the limitations of this paper is it does not address the effect of integration on clinical outcomes, such as BP control and so on, so as not to interfere with reporting of the primary results of the clinical trial. In future analyses, we will aim to evaluate the effect of providing hypertension care in various DSD models on these clinical outcomes. The study provided free medications and BP devices and implemented a human resource-intensive strategy. However, the scope of this paper does not include an assessment of the cost-effectiveness of integrating hypertension care into DSD models. A cost-effectiveness analysis is planned after trial completion to provide further insights into the financial feasibility of this approach. Due to time limitations, the qualitative data was obtained from two clinics. This may have resulted in missing insights from other clinics, particularly those with a higher proportion of clients enrolled in intensive models of care. Lastly, for brevity, we focused on two CFIR domains—Innovation and Inner setting—to explain the most important barriers and facilitators of care emerging from our qualita-

tive data; however, other CFIR domains could be considered in future work.

5 | CONCLUSIONS

Integrating hypertension care into DSD models is feasible and adaptable in peri-urban and urban settings in Uganda. However, it requires transitioning PLHIV between models based on clinical needs. This approach enhances person-centred care and allows for more comprehensive management of hypertension; however, careful planning is needed to address challenges related to resource availability, client preferences and staff training. There is a need to facilitate client transition with clear education. This approach will enhance client education on the importance of transitioning to intensive DSD models when needed for better hypertension management, which will mitigate resistance and improve adherence to care protocols. Additionally, strengthening community DSD models through the provision of adequate resources (medications, BP devices and tools) and training of non-physician HCPs is essential for the delivery of integrated HIV hypertension care in Ugandan settings.

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COMPETING INTERESTS

The authors have no competing interests to declare.

AUTHORS' CONTRIBUTIONS

FCS, CTL, ARK, JIS, MM, IS, JK and DS designed the research study and secured the funding for this research. JBK, FCS, CTL and ARK conceptualised the manuscript. JBK drafted the manuscript. ENM, FA, CFL and CK participated in data collection. FA, CK, ENM and CFL analysed qualitative results. LG analysed quantitative data and FA, CK, ENM and CFL analysed qualitative results. ARK, FCS and CTL provided a detailed review of the initial drafts. All authors reviewed and contributed to the final manuscript.

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DISCLAIMER

The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Heart, Lung, and Blood Institute, the National Institutes of Health or the U.S. Department of Health and Human Services.

DATA AVAILABILITY STATEMENT

The datasets utilised in this study can be obtained from the corresponding author upon reasonable request.

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SUPPORTING INFORMATION

Additional information may be found under the Supporting Information tab for this article:

Supplemental file 1: PULESA-Uganda study intervention components.

Supplemental file 2: Characteristics of HIV clinics participating in the Hypertension PLUS arm of the PULESA-Uganda study.

Supplemental file 3: Differentiated service delivery models in Uganda.

Supplemental file 4: Stepped wedge cluster randomised trial design schematic.

Supplemental file 5: Staked bar graphs showing the distribution of study visits by DSD model over time at the eight Hypertension PLUS clinic sites.

Supplemental file 6: Comparing PLHIV level versus provider-level themes.

RESEARCH ARTICLE

A prospective cohort study of the SEARCH integrated HIV/hypertension community health worker-led intervention in rural Kenya and Uganda

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Abstract

Introduction: Clinic-based hypertension screening and treatment for people with and without HIV depends on consistent clinic engagement. Retention is challenging in rural areas, especially for people with severe hypertension, which typically requires more frequent visits than clinically stable HIV. We hypothesised that Ministry of Health (MoH) community health workers (CHWs) could improve severe hypertension detection and treatment through an integrated hypertension/HIV intervention.

Methods: In rural Uganda and Kenya, we added HIV testing and a status-neutral hypertension intervention to CHW workflow in an ongoing cluster-randomised population-level study (SEARCH:NCT05768763). Data spans March 2023–August 2024. Trained CHWs screened all adults aged ≥ 40 years in intervention communities for hypertension, referring those with blood pressure (BP) $\geq 140/90$ mmHg to MoH HIV/primary care clinics. After initial in-clinic evaluation, adults with BP $\geq 160/100$ mmHg were offered choice of clinic-based or telehealth (CHW home visit, clinician telehealth evaluation, medication delivery) follow-up care. Telehealth used a MoH-compatible CHW smartphone app that syncs with electronic clinic records, prompts CHW follow-up visits and facilitates clinician telehealth assessment/medication prescribing. We report hypertension control achieved through the implementation of CHW-supported screening and telehealth and used targeted minimum loss-based estimation to estimate the change in population prevalence of uncontrolled hypertension from baseline to 1 year.

Results: Across eight communities, 198 CHWs measured BP in 14,378/15,879 adults aged ≥ 40 years at baseline (91%) and 13,334/15,879 after 1 year (84%); 55% were female and 19% living with HIV. Estimated population prevalence of BP $\geq 140/90$ mmHg decreased from 16.0% at baseline to 6.4% at year 1 (9.6% absolute decrease, 95% CI 8.6%, 10.6%). Among people with HIV aged ≥ 40 years ($n = 3036$), the prevalence of BP $\geq 140/90$ mmHg decreased from 10.5% to 4.7% (5.9% absolute decrease, 95% CI 3.0%, 8.8%). In the subset with BP $\geq 160/100$ who enrolled in the intervention ($n = 919$), 96% received antihypertensive medication, 81% were retained in care at 1 year and 79% achieved BP control; people with HIV ($n = 120$) had similar retention (80%) and BP control (80%).

Conclusions: Within the context of a pragmatic trial, leveraging existing CHWs in an integrated HIV/hypertension model reduced the population-level prevalence of uncontrolled hypertension by 60% among people with and without HIV, extending health services into the community at scale.

Keywords: community health worker; HIV; hypertension; integrated care; telehealth; telemedicine

Additional information may be found under the Supporting Information tab of this article.

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1 | INTRODUCTION

Hypertension is the leading modifiable cause of cardiovascular disease (CVD) globally and an increasingly common cause of morbidity and mortality in low- and middle-income countries in Africa [1, 2]. In Kenya and Uganda, hypertension prevalence ranges from 13% to 27%, with higher prevalence observed among older adults, who face the greatest risk of CVD [3–6]. Diagnosis, treatment and control are lower in Africa compared to other regions [7], including Kenya and Uganda, where fewer than one-quarter of people with hypertension are diagnosed and fewer than 10% have controlled hypertension [5, 8–10].

People living with HIV are at increased risk of CVD due to a higher prevalence of traditional risk factors, as well as chronic inflammation associated with viral replication and exposure to antiretroviral therapy (ART) [11–19]. With the expansion of ART and the decline of AIDS-associated morbidity and mortality, people living with HIV are living longer, and the burden of disease has shifted towards non-communicable diseases and CVD in particular [11, 12]. The rising burden of CVD among people with HIV has prompted a frameshift: high-quality HIV care can no longer be limited to ART delivery and prevention and treatment of opportunistic infections. CVD prevention must be included as part of routine HIV care—both to improve overall health and sustain gains made by the HIV response [20].

At the same time, the increasing burden of CVD across settings such as East Africa impacts both people with HIV and people without HIV. Care models must serve all people at risk of CVD to ensure effective, equitable and population-level impact. Clinic-based care models can provide HIV status-neutral hypertension treatment, though are limited by either low levels of community reach, or by low retention in care. In the recent INTE-AFRICA study, the integration of HIV, hypertension and diabetes treatment in Uganda and Tanzania resulted in high levels of retention in care over 1 year [21]. However, the INTE-AFRICA study was conducted among people already engaged in care and thus was not designed to reach people with undiagnosed hypertension or those not currently in care. We previously showed in the SEARCH study that population-level multi-disease (HIV, hypertension, diabetes screening) community health campaigns can improve hypertension diagnosis through community screening and improve hypertension control and all-cause mortality through integrated patient-centred clinic-based care [4]. Despite these improvements, linkage to care and long-term retention were sub-optimal, with only 53% maintaining hypertension control after 3 years.

People with hypertension face multiple barriers to accessing hypertension screening and chronic hypertension care, including transportation challenges, competing priorities, medication availability and costs, and knowledge limitations [22]. These barriers are compounded when hypertension is severe or poorly controlled and requires frequent clinic visits to adjust medications and dosages. Community-based approaches to hypertension diagnosis and treatment could help address many of these barriers to hypertension diagnosis and ongoing management.

Community health worker (CHW)-facilitated hypertension screening outside of a clinic setting has been shown to improve hypertension diagnosis [23–28]. The addition of CHW-facilitated hypertension treatment could address multiple barriers to ongoing care engagement in hypertension care for both people with and without HIV. We previously conducted a pilot randomised trial of a CHW-facilitated hypertension telehealth intervention where CHWs conducted home visits for blood pressure (BP) measurement, facilitated a telehealth call with a clinician and delivered clinician-prescribed medications [29]. This intervention led to a nearly two-fold improvement in hypertension control at 48 weeks compared to integrated clinic-based care (86% vs. 44% hypertension control). We now seek to understand the effectiveness of this CHW telehealth intervention at scale. In the present study, we evaluated the implementation of HIV and hypertension CHW screening plus the CHW hypertension telehealth intervention at a community-based population level in eight communities in Kenya and Uganda as part of an ongoing cluster randomised controlled trial.

2 | METHODS

2.1 | Study setting, design and participants

This prospective cohort study was nested within the intervention arm of an ongoing cluster-randomised population-level study in rural southwestern Uganda and western Kenya (SEARCH: NCT05768763). Intervention communities received a community-based integrated HIV/hypertension intervention that included CHW hypertension screening, referral to clinic and CHW-facilitated home-based telehealth visits for those with moderate to severe hypertension. We evaluated changes in hypertension outcomes over 1 year among all adults aged ≥ 40 years residing in the eight intervention communities at baseline. Baseline hypertension screening began on 29 March 2023. The study is ongoing, and we report data through 27 August 2024 (the conclusion of year 1 follow-up screening). The study received ethical approval from the Makerere University School of Medicine Research and Ethics Committee in Uganda (Mak-SOMREC-2023-566); the Kenya Medical Research Institute in Kenya (P00151-4173); and the University of California San Francisco in the United States of America (20-32144).

2.2 | Intervention and study procedures

Ministry of Health (MoH) CHWs received initial training on HIV counselling and testing, BP measurement, hypertension basics (overview of diagnostic criteria, medication names and purpose), and use of a CHW-facing smartphone app to guide screening and subsequent hypertension treatment support with clinician telehealth evaluation. Following training, each CHW had 1:1 coaching for 1–5 days until proficient with intervention delivery. The integrated HIV/hypertension intervention consisted of two major components: (1) population-level screening of all adults aged ≥ 15 years for HIV and aged ≥ 18 years for hypertension and (2) hypertension follow-up home visits with clinician telehealth for adults aged ≥ 40 years with baseline moderate to severe hypertension (BP

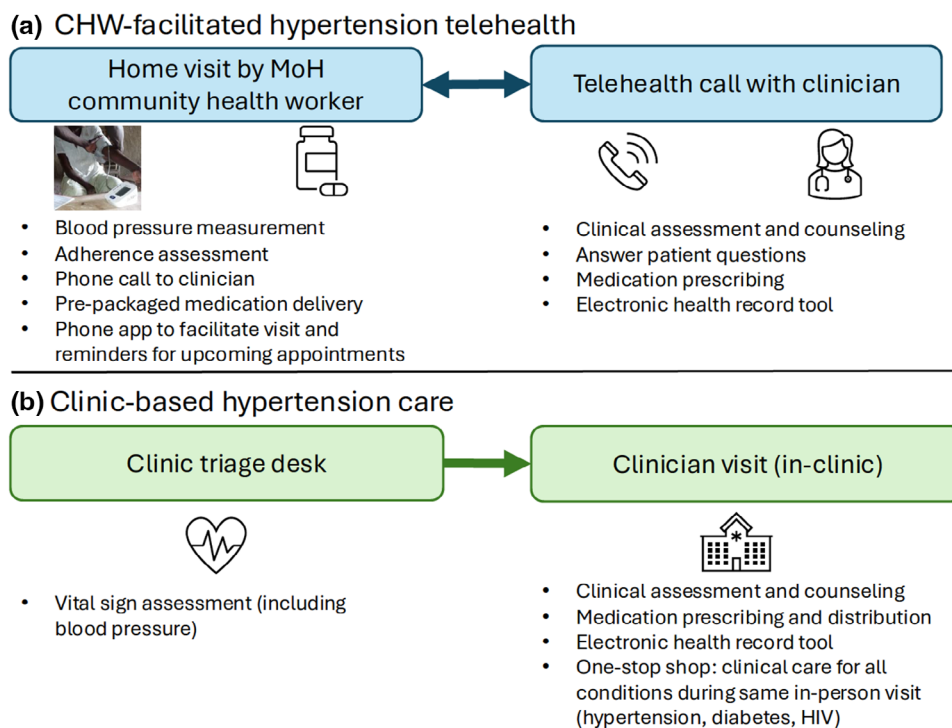


Figure 1. Hypertension care models. Participants were offered choice between CHW-facilitated hypertension telehealth **(a)** or clinic-based hypertension care **(b)**, with option for participants or clinicians to dynamically change choice over time based on preference or clinical need. In both care models, participants received free hypertension medications based on country-specific treatment algorithms. Medication refill duration and follow-up were scheduled every 4 weeks if blood pressure was uncontrolled ($\geq 140/90$ mmHg) or every 12 weeks if blood pressure was controlled ($< 140/90$ mmHg). Abbreviations: CHW, community health worker; MoH, Ministry of Health.

$\geq 160/100$ mmHg). CHWs obtained verbal consent before baseline screening. Baseline screening included an offer of home-based HIV testing to all adults not known to be living with HIV. People living with HIV who reported being off HIV treatment, were pregnant or who had a newly positive HIV antibody test were referred to the nearest government HIV clinic. For those with a negative HIV test, CHWs asked about self-assessed HIV risk and referred those reporting risk to the nearest government primary health centre for enrolment in a nested Dynamic Choice HIV prevention intervention [30–34]. At household visits, CHWs conducted BP measurements using a standardised protocol, with a single BP measurement taken after 5 minutes of rest and two additional measures separated by at least 1 minute of rest for those with an initial BP ≥ 140 mmHg systolic or ≥ 90 mmHg diastolic [35]. Using the average of the second and third BP measure, everyone with BP $\geq 140/90$ mmHg was referred to the nearest government primary health centre; those with BP $\geq 160/100$ mmHg were given a transportation voucher redeemable for the equivalent of approximately \$5 US Dollars upon linkage to hypertension care, based on our prior work [25]. CHWs called the study clinician for anyone with possible hypertensive urgency/emergency (defined as average BP $\geq 180/110$ mmHg with possibly related symptoms or average BP $\geq 200/120$ mmHg regardless of symptoms) for phone triage and arrangement of immediate referral to the clinic.

Upon linkage to the health facility, study clinicians repeated BP measurements using the same procedures. Participants

were eligible for the embedded CHW-facilitated hypertension telehealth intervention if BP was moderate-severely elevated at community- or clinic-based screening (≥ 160 mmHg systolic or ≥ 100 mmHg diastolic) and remained elevated to at least $\geq 140/90$ mmHg at the time of clinic evaluation. Community residents (aged ≥ 40 years) who were screened at the clinic without prior CHW measurement were also eligible if their BP was ≥ 160 mmHg systolic or ≥ 100 mmHg diastolic. Participants with hypertensive urgency/emergency received immediate evaluation and treatment following country guidelines within the MoH clinic before the initiation of any study procedures. Participants completed written informed consent before enrolment. Hypertension treatment at the initial visit and all follow-up visits was provided using a hypertension treatment algorithm developed based on country guidelines using locally available antihypertensive medications.

Following the initial visit, participants receiving the hypertension telehealth intervention were offered a choice of the next follow-up location, either at the clinic or at home with a CHW facilitating clinician evaluation via telehealth as depicted in Figure 1. Table S1 provides additional details of both care models and, for reference, standard hypertension care that existed prior to the introduction of study interventions. Follow-up visits were scheduled every 4 weeks if hypertension was uncontrolled and every 12 weeks if hypertension was controlled (defined as BP $< 140/90$ mmHg, based on country guidelines).

Hypertension telehealth visits consisted of a CHW home visit where CHWs assessed adherence, provided counselling on adherence and lifestyle changes to improve BP (e.g. salt reduction, physical activity), and measured BP using the standardised protocol described above. CHWs then called the study clinician who was stationed at the primary health centre in their community for a telehealth clinician visit. The clinician reviewed the data with the CHW, talked directly with the participant for clinical assessment and counselling, and prescribed medications which the CHWs delivered using pre-packaged medication sets based on treatment algorithm steps.

CHWs used a smartphone app to enter all screening and follow-up data. The app was built on the open-source Medic Mobile platform [36] and was designed to walk CHWs through procedures for screening and telehealth follow-up visits. The CHW app features two-way synchronisation with the study electronic medical record available to clinic-based clinicians: CHW-entered data are available to clinicians, and the clinic database pushes upcoming appointment reminders and prompts for CHWs to conduct tracing for participants who missed hypertension, HIV or HIV prevention visits.

2.3 | Measurements

CHWs entered baseline census data on community members residing in their assigned households and updated information on births, deaths and moves in/out of the community over the course of the study. One year following the initial screening, CHWs repeated population-level HIV and hypertension screening among all adults residing in study communities using the same procedures described above. To assess HIV status, CHWs asked all residents about their HIV status at the time of screening. Those who reported negative or unknown status were offered rapid HIV testing, with positive or indeterminant tests leading to referral to the clinic for additional testing and, if diagnosed with HIV, linkage to care. We supplemented CHW assessment with linkage to the clinic medical record to identify people who were in HIV care but missed by community screening.

2.4 | Analysis

We used targeted minimum loss-based estimation (TMLE) to estimate the prevalence of uncontrolled hypertension (BP $\geq 140/90$ mmHg) and moderate-severe hypertension (BP $\geq 160/100$ mmHg) at baseline and year 1 as well as evaluate changes over time. We accounted for differences between participants with and without BP measures. At baseline, we assumed that within all values of country, community, sex, age and HIV status, persons who screened at baseline were representative of persons who did not. We made a similar assumption at year 1, but expanded our adjustment set to include baseline screening. Within TMLE, we used Super Learner, an ensemble machine learning method, to minimise modelling assumptions and combine estimates from main terms regression, multivariate adaptive regression splines and the mean. We conducted several sensitivity analyses to examine the robustness of this approach (Table S5). We repeated these analyses within strata defined by HIV status (known vs. not known to have HIV), country and sex.

Among the subset who enrolled in the embedded CHW-facilitated hypertension telehealth intervention, we describe participant characteristics and report care delivery, engagement, retention (defined as not late for a follow-up visit by more than 7 days at the time of 1-year population-level screening) and achievement of hypertension control (defined as BP $< 140/90$ mmHg on average of three measures at any follow-up visit for clinical hypertension care during the 1 year follow-up period).

2.5 | Role of the funding source

The funder of the study had no role in study design, data collection, data analysis, data interpretation or writing of the report.

3 | RESULTS

3.1 | Baseline screening

Of 42,121 adults aged ≥ 18 years in eight intervention communities, 15,879 were aged ≥ 40 years at baseline. Among adults aged ≥ 40 years, 198 CHWs measured BP in 14,378/15,879 (91%) at baseline (Figure 2). Among those screened, 55% were female and 19% were living with HIV (Table 1). Baseline BP measurement during community-based screening was similar among people with HIV (90% screened for hypertension).

3.2 | Hypertension telehealth

Nine hundred and nineteen were eligible and enrolled in the CHW-facilitated hypertension telehealth intervention: 598 were first identified with moderate-severe hypertension (BP $\geq 160/100$ mmHg) on community screening; 150 had mild hypertension (BP 140–159/90–99 mmHg) in the community and were identified with moderate-severe hypertension upon clinic linkage, and 171 had normal or no community BP screening but were identified with moderate-severe hypertension on clinic screening (Figure 3). Enrolled participants had a mean age of 62 years (SD 14 years); 66% were female sex, and 13% were living with HIV. At the initial clinic visit, 77% had BP $\geq 160/100$ mmHg, and 19% had BP $\geq 180/110$ mmHg (Table 2).

Over the first year of implementation, 96% ($n = 881/919$) of participants who were enrolled in the CHW-facilitated telehealth intervention received ≥ 1 antihypertensive medication; 94% ($n = 860/919$) had ≥ 1 follow-up visit; 82% ($n = 757/919$) had at least one follow-up visit by telehealth; 80% ($n = 736/919$) were retained in care at 1 year; and 79% ($n = 730/919$) achieved BP control during at least one follow-up visit; people with HIV ($n = 115$) had a similar proportion who received ≥ 1 visit by telehealth (83%; $n = 95/115$), were retained in care (80%; $n = 92/115$) and achieved BP control (80%; $n = 95/115$) (Table 3 and Table S2).

3.3 | Year 1 screening

CHWs measured BP in 13,334/15,879 adults aged ≥ 40 after 1 year (84%). BP measurement completion at year 1 was

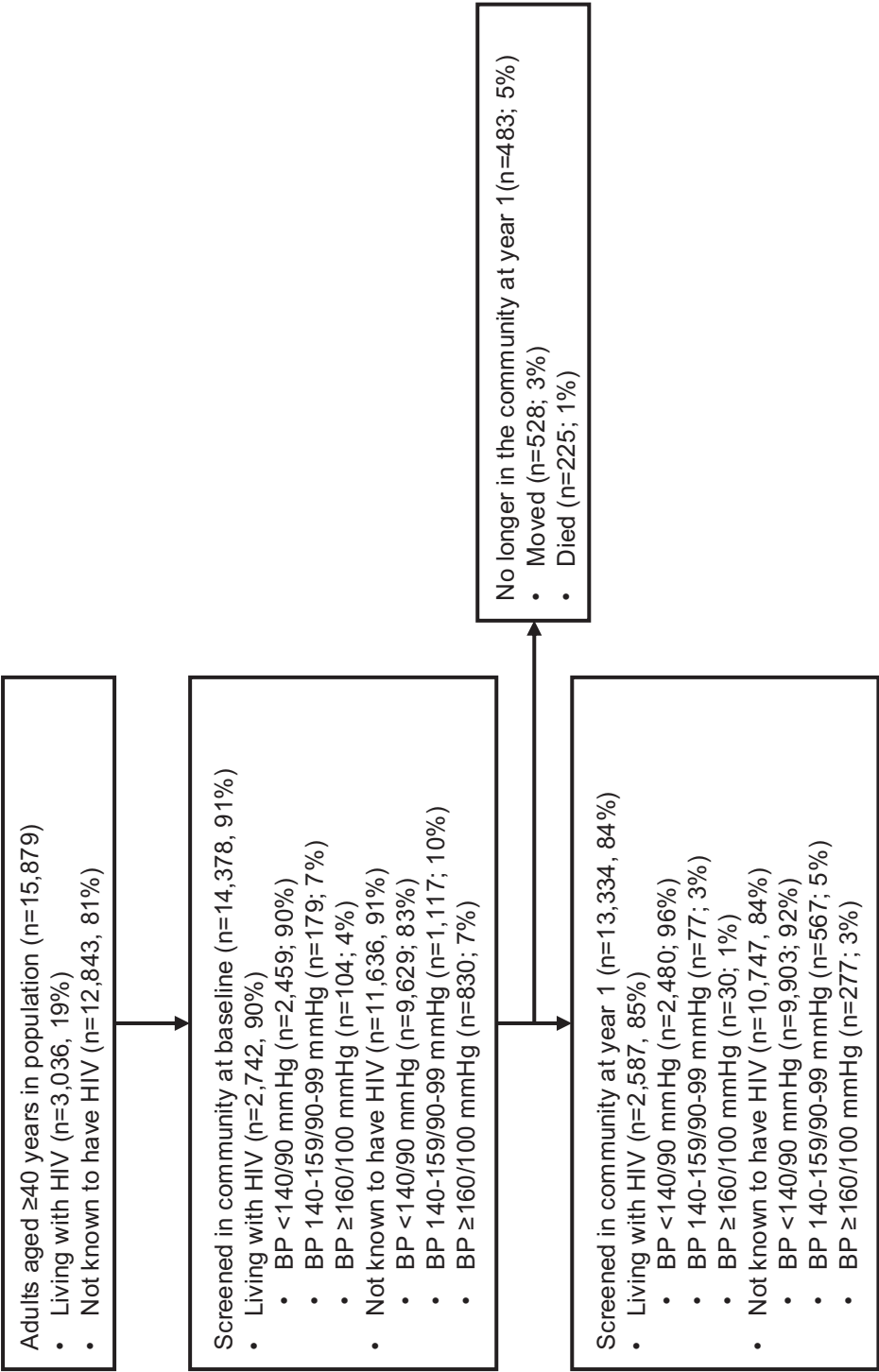


Figure 2. Consort diagram for community health worker hypertension screening at baseline and year 1.
Abbreviations: BP, blood pressure; mmHg, millimetres of mercury.

Table 1. Characteristics of participants at baseline

	Screened for hypertension at baseline (<i>n</i> = 14,378)	Not screened for hypertension at baseline (<i>n</i> = 1501)	Overall (<i>N</i> = 15,879)
Age			
Mean (SD)	55.5 (12.6)	53.4 (11.6)	55.3 (12.5)
Median [Q1, Q3]	52 [45, 63]	51 [44, 60]	52 [45, 63]
Sex			
Female	8084 (56.2%)	645 (43.0%)	8729 (55.0%)
Male	6294 (43.8%)	856 (57.0%)	7150 (45.0%)
Country			
Kenya	8098 (56.3%)	508 (33.8%)	8606 (54.2%)
Uganda	6280 (43.7%)	993 (66.2%)	7273 (45.8%)
Living with HIV	2742 (19.1%)	294 (19.6%)	3036 (19.1%)

Note: Characteristics of participants identified as members of the eight study communities during baseline census, stratified by completion of hypertension screening by community health worker at baseline.

Abbreviations: HIV, human immunodeficiency virus; SD, standard deviation.

similar among people living with HIV (85%; *n* = 2587/3306) (Figure 2 and Supporting information Tables S3 and S4).

3.4 | Changes in population-level hypertension over 1 year

In pre-post comparison, the estimated population-level prevalence of BP $\geq$ 140/90 mmHg decreased from 16.0% at baseline (95% confidence interval [CI] 15.7%, 16.4%) to 6.4% at year 1 (95% CI 5.4%, 7.4%), a decrease of 9.6% (95% CI 8.6%, 10.6%). Estimated population-level prevalence of BP $\geq$ 160/100 mmHg decreased from 6.5% at baseline (95% CI 6.3%, 6.8%) to 2.1% at year 1 (95% CI 1.5%, 2.7%), a 4.4% absolute decrease (95% CI 3.8%, 5.1%; Figures 4 and 5, and Table 4). These results were robust to the handling of missing data (Table S5).

Among people with HIV aged $\geq$ 40 years (*n* = 3306), estimated prevalence of BP $\geq$ 140/90 mmHg decreased from 10.5% at baseline (95% CI 9.9%, 11.2%) to 4.7% at year 1 (95% CI 1.8%, 7.5%), a decline of 5.9% (95% CI 3.0%, 8.8%). The prevalence of BP $\geq$ 160/100 mmHg decreased from 3.9% at baseline (95% CI 3.5%, 4.3%) to 1.4% at year 1 (95% CI 0%, 2.8%), a 2.5% absolute decrease (95% CI 1.1%, 3.9%).

Baseline prevalence of uncontrolled hypertension was greater in Uganda (21.8%; 95% CI 21.2%, 22.4%) compared to Kenya (11.1%; 95% CI 10.8%, 11.5%), among people not known to have HIV (17.3%, 95% CI 16.9%, 17.7%) compared to people living with HIV (10.5%, 95% CI 9.9%, 11.2%) and among females (19.1%, 95% CI 18.6%, 19.6%) compared to males (12.2%, 95% CI 11.7%, 12.7%). Despite baseline differences, there were similar relative declines in prevalence of uncontrolled hypertension over the 1-year intervention across all sub-groups.

4 | DISCUSSION

In this population-level study, we showed that combined CHW multi-disease screening and CHW-facilitated hypertension telehealth intervention led to a 60% reduction in the population prevalence of uncontrolled hypertension over 1 year (from 16.0% to 6.4%) among adults aged $\geq$ 40 years across eight rural communities in Kenya and Uganda. We observed reductions in population-level uncontrolled hypertension across all sub-groups, including among people with HIV.

We also demonstrated that MoH CHWs can achieve a high level of hypertension screening coverage through a multi-disease HIV, HIV risk and hypertension screening package. Other studies have shown that CHWs can successfully conduct community-based hypertension screening; we add to this literature by demonstrating a high uptake of hypertension screening at scale across multiple communities in rural East Africa [23–28].

Despite high levels of HIV care engagement among people with HIV, with Kenya exceeding UNAIDS 95-95-95 targets and Uganda nearing 90-90-90 targets [37], we identified a high prevalence of uncontrolled hypertension at baseline among people living with HIV suggesting missed opportunities for hypertension diagnosis and treatment during routine HIV care. People living with HIV experienced large reductions in uncontrolled hypertension by year 1, suggesting that our CHW screening and facilitated telehealth intervention successfully extended traditionally clinic-based services to the community for people living with HIV. As efforts expand to integrate hypertension and other non-communicable disease services into HIV clinics, CHW-facilitated telehealth provides an alternative that reduces the need for all services to be delivered within a single integrated visit. Further, telehealth avoids requiring people to come to the clinic for frequent visits for hypertension medication titration that occur more frequently than visits for stable HIV care which may be only twice yearly.

Among people with moderate to severe baseline hypertension regardless of HIV status, our CHW-facilitated hypertension telehealth intervention resulted in high levels of retention in care and hypertension control over the 1-year study period. People with moderate to severe hypertension are at greatest risk of near-term morbidity and mortality from CVD and stand to benefit most from achieving hypertension control [38–40]. We previously showed that population-level hypertension screening and clinic-based integrated care reduced all-cause mortality among people with hypertension in rural Kenya and Uganda, with the greatest benefits among those with moderate to severe hypertension [4]. In our present study, CHW-facilitated telehealth resulted in greater retention in care than prior clinic-based care models and has the potential to further reduce CVD morbidity and mortality in this high-risk population.

Our study adds to a growing body of literature showing the effectiveness of CHW-based interventions for hypertension treatment outside of a traditional clinic setting. Two trials in middle-income countries (Colombia, Malaysia, Argentina) showed that home-based hypertension treatment that was CHW-led and primary care physician supervised improved

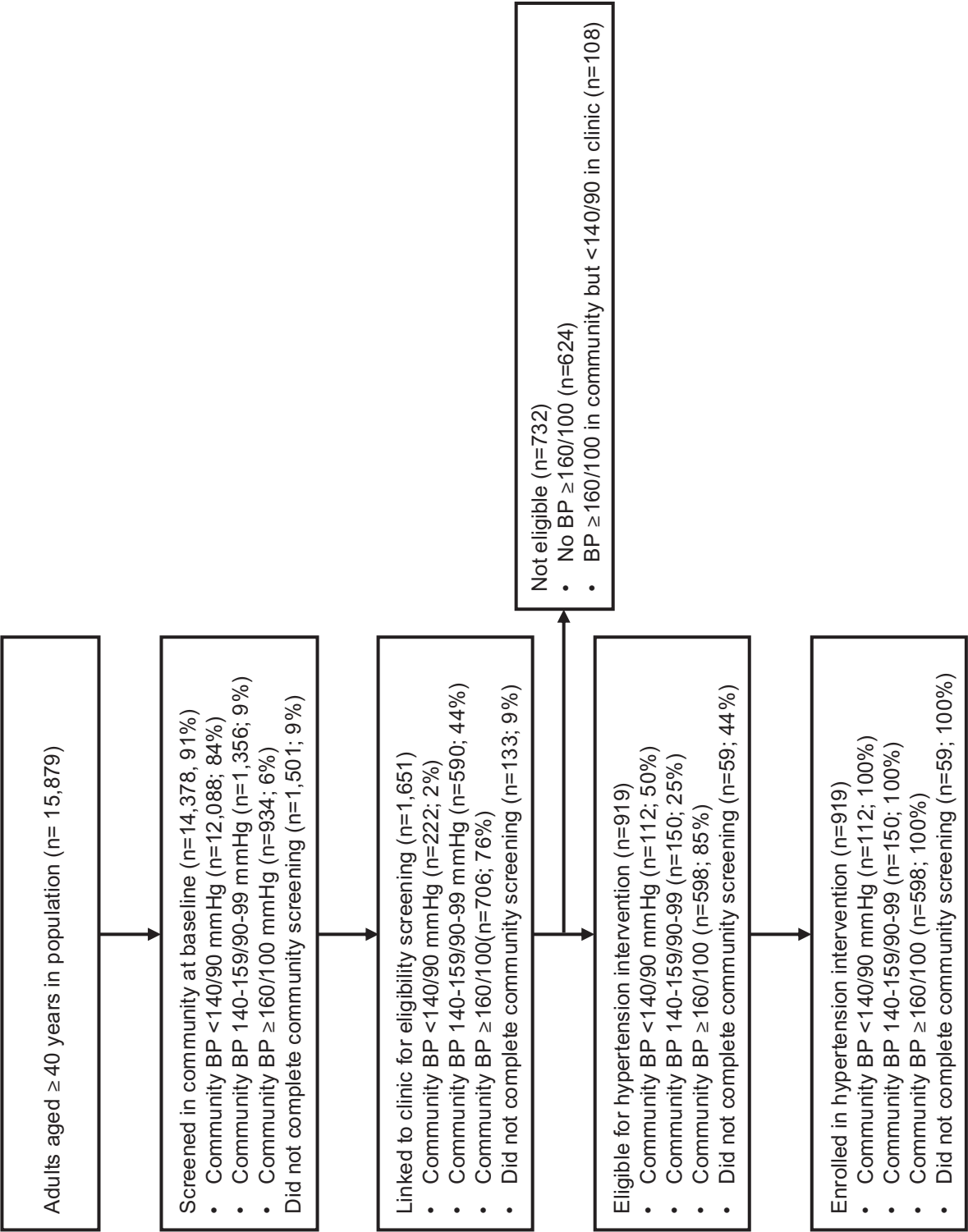


Figure 3. Consort diagram for enrolment in CHW-facilitated hypertension telehealth intervention.

Note: Participants could enrol in the CHW-facilitated hypertension telehealth intervention if they had BP $\geq 160/100$ mmHg on community screening and persistently elevated BP of at least $\geq 140/90$ mmHg upon presentation to the clinic, or if they had BP $\geq 160/100$ mmHg upon presentation to the clinic regardless of BP measurement in the community. Abbreviations: BP, blood pressure; CHW, community health worker.

Table 2. Characteristics of participants in telehealth intervention

	Living with HIV (n = 115)	Without known HIV (n = 804)	Overall (N = 919)
Age			
Mean (SD)	55.8 (9.1)	62.9 (13.4)	62.0 (13.2)
Median [Q1, Q3]	54 [48, 62]	62 [51, 72]	61 [51, 71]
Sex			
Female	82 (71.3%)	528 (65.7%)	610 (66.4%)
Male	33 (28.7%)	276 (34.3%)	309 (33.6%)
Country			
Kenya	69 (60.0%)	355 (44.2%)	424 (46.1%)
Uganda	46 (40.0%)	449 (55.8%)	495 (53.9%)
Living with HIV	115 (100%)	—	115 (12.5%)
SBP at enrolment			
Mean (SD)	154.9 (14.9)	161.6 (16.7)	160.8 (16.6)
Median [Q1, Q3]	156 [142, 166]	160 [150, 172]	160 [150, 170]
DBP at enrolment			
Mean (SD)	100.7 (8.1)	99.3 (10.6)	99.5 (10.4)
Median [Q1, Q3]	100 [96, 106]	100 [93, 105]	100 [94, 105]
BP at enrolment (mmHg)			
140–159/90–99	27 (23.5%)	182 (22.6%)	209 (22.7%)
160–179/100–109	73 (63.5%)	466 (58.0%)	539 (58.7%)
≥ 180/110	15 (13.0%)	156 (19.4%)	171 (18.6%)

Abbreviations: BP, blood pressure; DBP, diastolic blood pressure; mmHg, millimetres of mercury; Q1, first quartile; Q3, third quartile; SBP, systolic blood pressure; SD, standard deviation.

Table 3. Hypertension intervention delivery, stratified by HIV status

	Living with HIV (n = 115)	Without known HIV (n = 804)	Overall (N = 919)
Number of visits for hypertension care (including enrolment), median [Q1, Q3]	5 [3, 7]	5 [4, 7]	5 [4, 7]
Telehealth visits, median [Q1, Q3]	3 [1, 5]	3 [1, 5]	3 [1, 5]
Clinic visits, median [Q1, Q3]	1 [1, 2]	1 [1, 2]	1 [1, 2]
Attended at least one post-enrolment follow-up visit	109 (94.8%)	751 (93.4%)	860 (93.6%)
Attended at least one post-enrolment follow-up visit by telehealth	95 (82.6%)	662 (82.3%)	757 (82.4%)
Received ≥ 1 hypertension medication	107 (93.0%)	774 (96.3%)	881 (95.9%)
Achieved BP control < 140/90 mmHg during at least one follow-up visit	95 (82.6%)	635 (79.0%)	730 (79.4%)
Retained in care at 1 year	92 (80.0%)	644 (80.1%)	736 (80.1%)

Abbreviations: BP, blood pressure; mmHg, millimetres of mercury; Q1, first quartile; Q3, third quartile.

BP control compared to standard clinic-based care (achieving 69–73% hypertension control in home-based CHW intervention arms compared to 30–52% in clinic-based care) [41, 42]. Another small study in Uganda showed that in-person visits by a clinician and a CHW in the community improved access to care and reduced BP more effectively than district hospital-based care [43]. Our study builds on this literature by incorporating primary care clinician supervision and clinical

evaluation by telehealth into CHW home visits at a population level. Our CHW-facilitated, clinician-supervised telehealth model has the potential for scalability across different settings where CHWs are present, including Kenya and Uganda. A future study is planned to understand the implementation strategies needed to facilitate embedding and sustaining this care model within routine care and cost and cost-effectiveness of this approach.

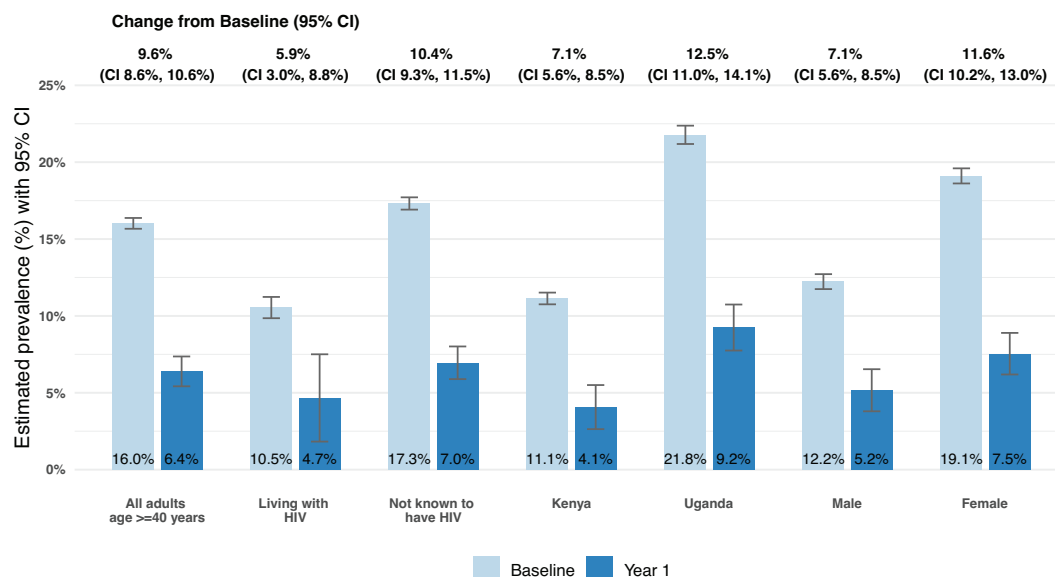


Figure 4. Pre-post comparison of population-level uncontrolled hypertension from baseline to year 1.

Note: Estimated community-wide, population-level prevalence of uncontrolled hypertension (blood pressure $\geq 140/90$ mmHg) at baseline and 1 year after introduction of intervention. Prevalence at both time points and change from baseline to 1 year estimated using targeted minimum loss-based estimation (TMLE). Abbreviation: CI, confidence interval.

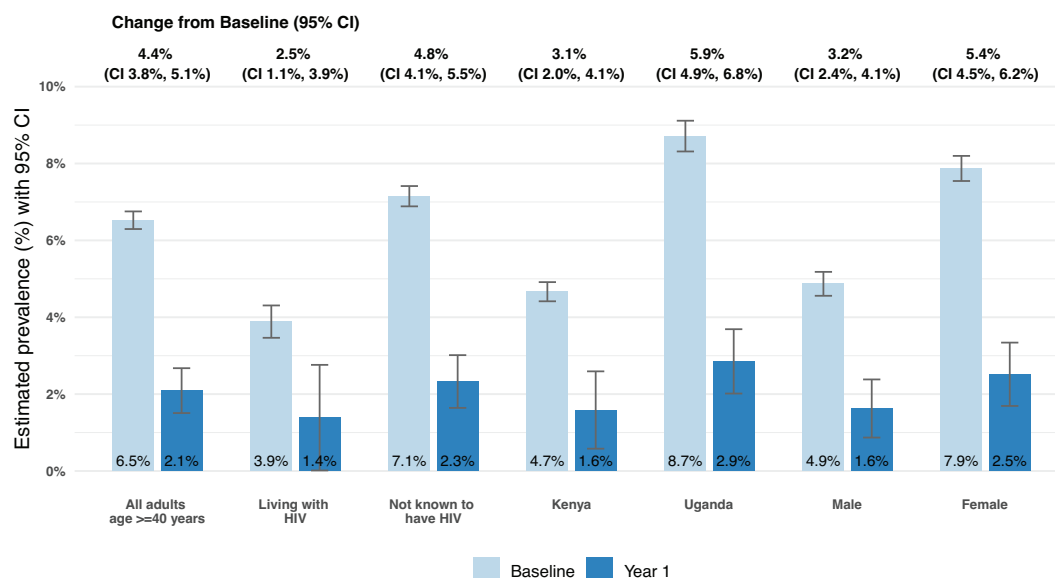


Figure 5. Pre-post comparison of population-level uncontrolled moderate-severe hypertension from baseline to year 1.

Note: Estimated community-wide, population-level prevalence of uncontrolled moderate-severe hypertension (blood pressure $\geq 160/100$ mmHg) at baseline and 1 year after introduction of intervention. Prevalence at both time points and change from baseline to 1 year estimated using targeted minimum loss-based estimation (TMLE). Abbreviation: CI, confidence interval.

Our study has several limitations. First, our single-arm analysis lacks a contemporary comparison group, so we cannot rule out temporal trends as the explanation for our observed reductions in population-level hypertension prevalence. However, it is unlikely that such large reductions would occur due to temporal changes, given the slow uptake of hyper-

tension treatment in primary health centres in our setting to date. Following the completion of the cluster randomised trial, we will be able to compare population-level hypertension outcomes between trial arms. Second, our study was conducted within a controlled research environment with study clinicians and financing for CHW stipends. While this

Table 4. Pre-post comparison of population-level uncontrolled hypertension after 1 year

	Prevalence of BP $\geq$ 140/90			Prevalence of BP $\geq$ 160/90		
	Baseline	Year 1	Change	Baseline	Year 1	Change
All adults aged $\geq$ 40 years	16.0% (95% CI 15.7%, 16.4%)	6.4% (95% CI 5.4%, 7.4%)	9.6% (95% CI 8.6%, 10.6%)	6.5% (95% CI 6.3%, 6.8%)	2.1% (95% CI 1.5%, 2.7%)	4.4% (95% CI 3.8%, 5.1%)
By HIV status						
Living with HIV	10.5% (95% CI 9.9%, 11.2%)	4.7% (95% CI 1.8%, 7.5%)	5.9% (95% CI 3.0%, 8.8%)	3.9% (95% CI 3.5%, 4.3%)	1.4% (95% CI 0.0%, 2.8%)	2.5% (95% CI 1.1%, 3.9%)
Not known to have HIV	17.3% (95% CI 16.9%, 17.7%)	7.0% (95% CI 5.9%, 8.0%)	10.4% (95% CI 9.3%, 11.5%)	7.1% (95% CI 6.9%, 7.4%)	2.3% (95% CI 1.6%, 3.0%)	4.8% (95% CI 4.1%, 5.5%)
By country						
Kenya	11.1% (95% CI 10.8%, 11.5%)	4.1% (95% CI 2.6%, 5.5%)	7.1% (95% CI 5.6%, 8.5%)	4.7% (95% CI 4.4%, 4.9%)	1.6% (95% CI 0.6%, 2.6%)	3.1% (95% CI 2.0%, 4.1%)
Uganda	21.8% (95% CI 21.2%, 22.4%)	9.2% (95% CI 7.7%, 10.7%)	12.5% (95% CI 11.0%, 14.1%)	8.7% (95% CI 8.3%, 9.1%)	2.9% (95% CI 2.0%, 3.7%)	5.9% (95% CI 4.9%, 6.8%)
By sex						
Male	12.2% (95% CI 11.7%, 12.7%)	5.2% (95% CI 3.8%, 6.5%)	7.1% (95% CI 5.6%, 8.5%)	4.9% (95% CI 4.6%, 5.2%)	1.6% (95% CI 0.9%, 2.4%)	3.2% (95% CI 2.4%, 4.1%)
Female	19.1% (95% CI 18.6%, 19.6%)	7.5% (95% CI 6.2%, 8.9%)	11.6% (95% CI 10.2%, 13.0%)	7.9% (95% CI 7.5%, 8.2%)	2.5% (95% CI 1.7%, 3.3%)	5.4% (95% CI 4.5%, 6.2%)

Note: Estimated prevalence of uncontrolled hypertension (BP $\geq$ 140/90 mmHg) and uncontrolled moderate-severe hypertension (BP $\geq$ 160/100 mmHg) using targeted minimum loss-based estimation with adjustment for missing blood pressure measurements.

Abbreviations: BP, blood pressure; CI, confidence interval.

provides evidence for effectiveness at scale, further studies are needed to understand implementation strategies to facilitate implementation of CHW-facilitated hypertension telehealth within routine MoH primary health centres. Third, as a large population-level study, we have limited individual measures of patient experience with the CHW-facilitated hypertension telehealth model. We previously reported additional information on potential mechanisms for how CHW-facilitated hypertension telehealth likely functions to improve outcomes in the pilot study that informed the larger trial [29] and will also further explore mechanisms through nested qualitative studies. Fourth, although we achieved high coverage of BP measurements at both baseline and year 1, we were unable to measure BP in everyone. While this high coverage limits the impact of missing data on our estimates, we further adjusted for differences between those with and without measurements using TMLE. Our results were robust to this approach and several sensitivity analyses, strengthening our inferences.

5 | CONCLUSIONS

Population-level uncontrolled hypertension was reduced over the first year of a CHW multi-disease screening and facilitated hypertension telehealth intervention in Kenya and Uganda. By extending care to the community, this approach may be an effective strategy for improving hypertension outcomes and preventing CVD for both People living with and without HIV.

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COMPETING INTERESTS

The authors have declared that no competing interests exist.

AUTHORS' CONTRIBUTIONS

MDH: Initial drafting of the manuscript. MDH, EWM, JS and LBB: Data management and analysis. MDH, AO, SO, HS, CA, NS, GA, JK, EK, NS, DB, AM, GC, DVH, MRK and MLP: Study management and data collection.

DVH, MLP and MRK: Acquisition of funding and study oversight. All authors reviewed and approved the final manuscript.

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DATA AVAILABILITY STATEMENT

A complete de-identified patient dataset sufficient to reproduce the study findings will be made available approximately 1 year after completion of the ongoing trial (NCT04810650), following approval of a concept sheet summarising the analyses to be performed. Further inquiries can be directed to the SEARCH Scientific Committee at douglas.black@ucsf.edu

PATIENT CONSENT STATEMENT

Participants provided verbal consent prior to the completion of screening. Participants eligible for the severe hypertension telehealth intervention provided written informed consent prior to enrolment.

CLINICAL TRIAL REGISTRATION

The study is registered on clinicaltrials.gov (NCT05768763).

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SUPPORTING INFORMATION

Additional information may be found under the Supporting Information tab for this article:

Table S1: Characteristics of hypertension care under standard and intervention conditions.

Table S2: Hypertension intervention delivery, stratified by sex.

Table S3: Characteristics of participants with and without blood pressure measurement at year 1.

Table S4: Community health worker blood pressure measurement and unadjusted prevalence of uncontrolled hypertension at baseline and year 1.

Table S5: Sensitivity analyses and results.

SHORT REPORT

Aligning HIV treatment and hypertension clinic visits and dispensing as a first step towards service delivery integration in South Africa

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Abstract

Introduction: Global and national guidelines recommend the integration of care for HIV and other chronic conditions to improve individual and public health outcomes. South Africa's differentiated service delivery (DSD) models extend beyond HIV care, relying on pickup points that also distribute hypertension (HTN) medications. We assessed the alignment between antiretroviral treatment (ART) and HTN medication collection visits and dispensing intervals as an indicator of integration progress.

Methods: The AMBIT project conducted a SENTINEL survey across 18 public clinics in three South African districts between September 2022 and April 2023, enrolling adult clients ≥ 6 months on ART. We recruited up to 180 clients across each model of care: conventional care-not DSD eligible (conventional-not-eligible); conventional care-DSD eligible but not enrolled (conventional-eligible); facility- (FAC-PuP) and external (EX-PuP) pickup points. Healthcare interaction data were extracted from paper and electronic sources for clients with a 12-month observation period. We analysed both self-reported alignment and actual visit data. We estimated the number and proportion of HTN visits aligned with ART dispensing. Log-binomial regression estimated adjusted risk ratios (ARR) to assess the association with a higher visit burden (> 5 interactions).

Results: Of 724 enrolled, 644 (90%) client records were successfully linked (76% female; median age 42; 15% Conventional-not-eligible; 17% Conventional-eligible; 18% FAC-PuP; 28% EX-PuP). Among these, 85 (13%) with HTN (81 self-reported, 4 from medical records), self-reported 94% and 95% aligned facility visits and medication pickups, respectively. Visit data was retrieved for self-reported HTN diagnoses. Of 477 visits for HIV/HTN comorbid clients, 83% (395) dispensed both ART and HTN medication, and 97% had aligned dispensing durations (Conventional-not-eligible 97%, Conventional-eligible 95%, FAC-PuP 98%, EX-PuP 100%). Comorbid clients had a similar visit burden to ART-only clients (ARR 1.05, 95% CI: 0.80–1.39). FAC-PuP (ARR 0.55, 95% CI: 0.40–0.78) and EX-PuP (ARR 0.75, 95% CI: 0.57–0.98) clients were less likely than Conventional-E clients to have high annual visit burden.

Conclusions: Aligning medication visits and dispensing for HIV and other chronic diseases marks an initial step towards integrated service delivery. Our results demonstrate achievable medication visit alignment without increased visit burden for comorbid clients and those in DSD models, suggesting that HIV-HTN integration is feasible within DSD models, matching client preferences for comprehensive care.

Keywords: differentiated service delivery; HIV co-morbidity; hypertension; interaction burden; service integration; South Africa

Additional information may be found under the Supporting Information tab of this article.

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1 | INTRODUCTION

The long-term success of national HIV treatment programmes in sub-Saharan Africa will depend in part on their ability to

integrate care for the growing burden of non-communicable diseases (NCDs) among people living with HIV (PLHIV) [1, 2]. As this population ages and lives longer due to effective antiretroviral treatment (ART), they become increasingly

susceptible to developing NCDs like hypertension (HTN) and diabetes [3, 4]. This rising comorbidity poses new challenges for health systems and care delivery models originally designed to manage HIV vertically, as a single disease.

In recognition of this shift, global and national guidelines now emphasise the importance of integrating HIV treatment with the management of other chronic diseases [5, 6]. South Africa, with over 5.5 million PLHIV receiving ART, has been at the forefront of this effort [7, 8]. The Centralized Chronic Medicine Distribution and Dispensing (CCMDD) programme operates in eight of the country's nine provinces, using public clinics and private couriers to deliver chronic medications including HIV and HTN. CCMDD supports South Africa's main low-intensity differentiated models of care (DMOCs, also called differentiated service delivery [DSD] models) [9]. Among other goals, these models aim to align the timing of ART and HTN medication delivery to minimise the number of interactions with the healthcare system required for clients with multiple conditions.

Alignment of visits and dispensing represents an important step towards achieving true integrated service delivery for HIV and comorbid conditions. Although simultaneous dispensing of ART and HTN medications is intended through CCMDD, the extent to which care for HIV and common NCDs is aligned in terms of clinic visit schedules and actual medication dispensing intervals remains unclear. This study examined the alignment of care for clients receiving medication for HIV and HTN and investigated factors associated with a high visit burden for clients.

2 | METHODS

2.1 | Study setting, population and data

In South Africa, non-pregnant ART clients with documented viral suppression, ≥ 6 months' experience on treatment and control of co-morbidities were eligible for one of three "repeat prescription strategies" or DSD models during the study period. These included facility-based medication pickup points (Fac-PuP), community-based or external medication pickup points (Ex-PuP), and, less commonly, adherence clubs [10]. ART clients remained in conventional care if they were ineligible for DSD, declined enrolment or were not offered enrolment due to facility or provider preferences or limitations. Dispensing durations were 1–2 months in conventional care and 2–3 months in DSD models.

The multi-component SENTINEL 2.0 study was conducted between September 2022 and April 2023 at 18 public healthcare facilities in three South African districts: King Cetshwayo in KwaZulu-Natal Province, Ehlanzeni in Mpumalanga Province and West Rand in Gauteng Province. The sites represented a mix of ART patient volumes and included both urban and rural locations [11]. All followed South Africa's national guidelines for HIV care and for DSD [12].

At each study site, we first recruited up to 10 ART clients in each of four categories: (1) not eligible for DSD and remaining in conventional care (conventional-not-eligible); (2) eligible for DSD but remaining in conventional care (conventional-eligible); (3) enrolled in Fac-PuP; and (4)

enrolled in Ex-PuP. (We did not find enough clients enrolled in adherence clubs to include this model in the study.) Participants were approached sequentially as they arrived at the study sites, screened for study eligibility and invited to participate. Those who provided written informed consent were enrolled in the study.

We then administered a structured questionnaire that included questions about access to and experience with HIV treatment and comorbidity care during routine visits (Supporting information *Sentinel survey*) [11]. We conducted a manual review of clients' medical records, including paper files, CCMDD prescription sheets and the CCMDD database for chronic disease medications [13], to capture data on clinic visits, off-site medication collection visits, medications dispensed (with HTN medication dispensing not consistently documented), and dispensing intervals and dates. We defined a 12-month observation period for each study participant, starting from the most recent visit captured in our dataset and looking back over the preceding 12 months.

2.2 | Analysis and outcomes

The objective of this analysis was to estimate visit alignment, defined as services received on the same day from the same facility for clients receiving medication for both HIV and HTN, among those who self-reported an HTN diagnosis during the survey, stratified by DSD model. Alignment was determined using the dates the services were received, as our data sources did not include time stamps or specific location information within facilities. Co-morbidity status was classified into three subgroups based on self-reported survey data: (1) ART only (no additional conditions); (2) ART with HTN treatment (with or without other treatments); and (3) ART with other treatment(s) but no HTN treatment.

We assessed visit alignment by first determining the total number of facility visits within the observation period. For clients with a documented HTN diagnosis date, we included all facility visits; for those without a documented HTN diagnosis date, we included facility visits from their first recorded dispensing of HTN medication onwards. We next identified aligned visits and calculated the proportion of aligned visits among total visits. Finally, for the alignment of medication dispensing durations where the number of months was documented for both conditions, we identified visits where the duration dispensed for ART matched the duration of HTN treatment, calculating the proportion of visits with the same dispensing duration among aligned visits.

For each participant, the healthcare interaction burden was defined as the sum of the number of facility-based clinical visits, facility-based medication collection visits and external medication collections during the observation period. We created a binary variable using the sample's median number of 5 interactions per year within the full sample as the cut-off to distinguish between low (≤ 5 visits/year) and high interaction burden (> 5 visits/year). We used a log-binomial regression with binomial errors to investigate factors associated with high healthcare interaction burden and estimate crude and adjusted relative risks. This method used a logarithmic link function and robust Poisson regression and adjusting for variables known to influence healthcare interaction

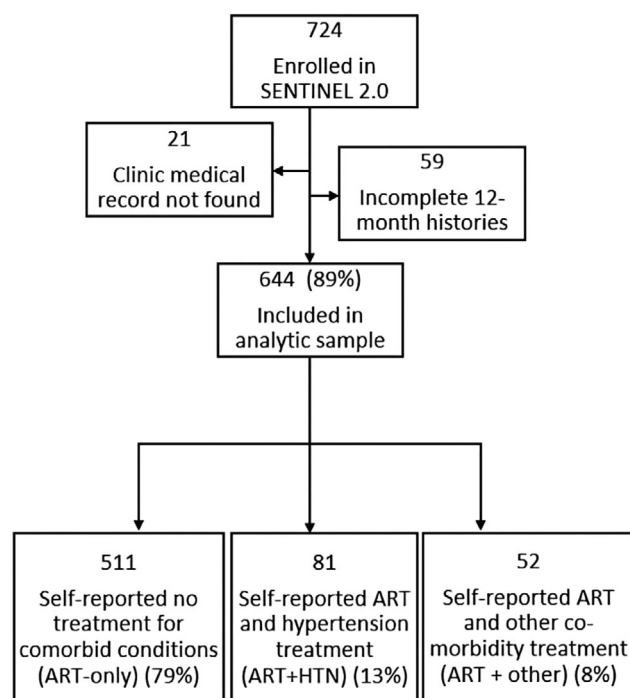


Figure 1. Study population flow diagram: Enrolment and classification of participants in the Sentinel 2.0 survey examining alignment of HIV treatment with HTN treatment. Abbreviations: ART, antiretroviral therapy; HTN, hypertension.

and alter the crude risk ratios by more than 10% (age, sex, duration on ART, marital status and location) [14–16]. Clients who transitioned between care models were excluded from the analysis as they represented a mix of care models over time.

3 | RESULTS

3.1 | Enrolment and classification of enrolment in the study

Enrolment in the SENTINEL 2.0 survey is illustrated in Figure 1. Of the 644 participants in the analytic sample, 132/644 (21%) self-reported having conditions in addition to HIV. HTN was most common, with 81/644 clients (13%) self-reporting HTN treatment. Of these HTN clients, 16/81 also reported receiving treatment for another condition in addition to HIV and HTN; they were included in the ART+HTN subgroup. The remaining 51/132 clients reported other conditions like diabetes without HTN. We also identified 21 clients with some evidence of HTN treatment in medical records but no self-report. Upon review, 4/21 had both a diagnosis date and consistent HTN treatment and were included in the ART+HTN subgroup, bringing the final ART+HTN subgroup sample to 85. The other 17/21 were kept in their respective groups: ART-only or ART+ other due to potential acute or inconsistent medication use. The analytic cohort is described in Table 1.

3.2 | Socio-demographic and clinical characteristics of people living with HIV in the study

Clients receiving ART and HTN treatment were found in all DSD models of care as shown in Table 1. The ART-only subgroup was somewhat younger than the ART+HTN subgroup (median age 40 vs. 51 years). A higher proportion of clients in the ART+HTN subgroup resided in urban areas (58% vs. 48% for ART-only clients). Nearly, all (76/81; 94%) clients receiving both ART and HTN treatment reported that they always combine their HIV visits with HTN care, and 95% (77/81) reported that they always pick up their HTN medication alongside their HIV medications.

3.3 | Alignment of care for clients receiving medication for HIV and HTN

The 85 participants receiving ART+HTN treatment had a total of 477 facility-based medication dispensing visits during the 12-month observation period. Across all model of care categories, the majority (395 visits, 83% overall) of facility visits for clients receiving both ART and HTN medication were aligned (ART and HTN medications were dispensed during a single visit): 86% for conventional-not-eligible, 82% for conventional-eligible, 70% for Fac-PuP, 84% for Ex-PuP and 86% for transitioned. For visits at which medications were not dispensed for all conditions, clients most commonly received only ART (8% of visits for conventional-not-eligible, 13% for conventional-eligible, 20% for Fac-PuP, 10% for Ex-PuP and 5% for transitioned). Very few visits resulted in HTN medication being dispensed alone or in no medications being dispensed. Duration of dispensing (number of months dispensed at a visit) for ART and HTN medications was aligned in 97% (319/329) of client visits with complete dispensing duration documentation across the different models of care. Dispensing alignment was 97% for conventional-not-eligible, 95% for conventional-eligible, transition clients (98%), Fac-PuP clients (98%) and 100% for Ex-PuP.

3.4 | Factors associated with a high visit burden for all clients in the study

The median visit burden (annual number of healthcare interactions per year) for participants ($N = 508$) in our cohort was 5.0. By model of care, participants in the conventional-not-eligible had a median visit burden of 7.0 and a median medication dispensing of 1 month, followed by conventional-eligible with 6.0 interactions per year and a median dispensing of 2 months. Both Fac-PuP and Ex-PuP had a median of 4.0 interactions per year, with median medication dispensing of 2 months.

Figure 2 illustrates associations between client characteristics and the risk of having a high visit burden. Clients in conventional care who were not eligible for DSD had a significantly higher visit burden than did those in conventional care who were eligible for DSD (adjusted relative risk 1.27, 95% CI 1.01–1.60). Both DSD models showed significantly lower visit burdens than did conventional-eligible (Fac-PuP 0.55, 0.40–0.78; Ex-PuP 0.75, 0.57–0.98). There was no significant difference in the risk of high visit burden between ART-only and ART+HTN clients, but ART+ other clients had

Table 1. Demographic, clinical and care integration characteristics of people living with HIV receiving treatment in three South African districts, 2022–2023

Characteristic (n, %)	ART only	ART and HTN treatment	ART and other co-morbidity treatment ^a	Total
N	508	85	51	644
Demographic, social and economic characteristics				
Sex (female)	381 (75%)	69 (81%)	39 (76%)	489 (76%)
Age (years)				
Median (IQR)	40 (34, 47)	51 (42, 60)	47 (38, 52)	42 (35, 49)
18–24	27 (5%)	0 (0%)	0 (0%)	27 (4%)
25–34	149 (29%)	4 (5%)	8 (15%)	161 (25%)
35–49	265 (53%)	39 (46%)	27 (53%)	331 (52%)
50+	67 (13%)	42 (49%)	16 (31%)	125 (19%)
Marital status				
Never married (currently single)	84 (17%)	16 (19%)	14 (27%)	114 (18%)
Never married (currently in a relationship)	299 (59%)	35 (41%)	25 (49%)	359 (56%)
Married	91 (18%)	20 (24%)	10 (20%)	121 (19%)
Divorced/separated/widowed	34 (6%)	14 (16%)	2 (4%)	50 (8%)
Model of care for HIV treatment				
Conventional-not-eligible	64 (13%)	23 (28%)	22 (42%)	109 (17%)
Conventional-eligible	80 (16%)	13 (14%)	4 (8%)	97 (15%)
Fac-PuP	93 (18%)	15 (19%)	7 (14%)	115 (18%)
Ex-PuP	159 (31%)	14 (17%)	7 (14%)	180 (28%)
Transitioned	112 (22%)	18 (22%)	11 (22%)	143 (22%)
Duration on ART at time of survey (years)				
Median (IQR)	6 (3, 10)	7 (4, 11)	8 (3, 11)	7 (3, 10)
6 months–1 year	43 (8%)	1 (1%)	4 (8%)	48 (7%)
2–4	156 (31%)	25 (29%)	12 (24%)	193 (31%)
5–9	189 (37%)	28 (34%)	18 (35%)	235 (36%)
10+	120 (24%)	31 (36%)	17 (33%)	168 (26%)
Time on HTN ^b (with diagnosis date)				
Median (IQR)	–	4 (2,7)	–	
District				
West Rand	164 (32%)	47 (55%)	13 (26%)	224 (35%)
Ehlanzeni	197 (39%)	23 (27%)	20 (39%)	240 (37%)
King Cetshwayo	147 (29%)	15 (18%)	18 (35%)	180 (28%)
Location				
Rural	262 (52%)	33 (42%)	26 (51%)	324 (50%)
Urban	246 (48%)	49 (58%)	26 (49%)	320 (50%)
Self-reported clinical characteristics and alignment of care				
Self-reported co-morbid condition(s) ^c	0	81	51	132
Hypertension	0	81 (100%)	0 (0%)	81 (61%)
Diabetes	0	6 (7%)	11 (23%)	17 (13%)
Asthma	0	3 (2%)	6 (4%)	9 (7%)
TB	0	0 (0%)	7 (14%)	7 (5%)
Mental health	0	2 (2%)	7 (14%)	9 (7%)
Other	0	5 (6%)	23 (45%)	28 (19%)
Are you able to combine your ART visits with your additional diseases? ^d				
Always	n.a.	76 (94%)	44 (86%)	120 (91%)
Very often	n.a.	3 (4%)	0 (0%)	3 (2%)
Sometimes	n.a.	0 (0%)	1 (2%)	1 (1%)
Rarely/never	n.a.	2 (2%)	6 (12%)	8 (6%)

(Continued)

Table 1. (Continued)

Characteristic (n, %)	ART only	ART and HTN treatment	ART and other co-morbidity treatment ^a	Total
Can you pick up your medication alongside your HIV medications?				
Always	n.a.	77 (95%)	43 (85%)	120 (90%)
Very often	n.a.	1 (1%)	0 (0%)	1 (1%)
Sometimes	n.a.	0 (0%)	1 (2%)	1 (1%)
Rarely/never	n.a.	3 (4%)	7 (13%)	11 (8%)

Abbreviations: ART, antiretroviral therapy; DSD, differentiated service delivery; Ex-PuP, external medication pickup points; Fac-PuP, facility-based medication pickup points; HTN, hypertension; IQR, interquartile range; n.a., not applicable; TB, tuberculosis.

^aOther treatment includes chronic conditions, communicable diseases and opportunistic infections.

^b55/85 individuals with diagnosis date.

^cIndividuals can fall into more than one category.

^dCare integration measures (ability to combine visits and pick up medications) were only assessed for participants reporting co-morbid conditions.

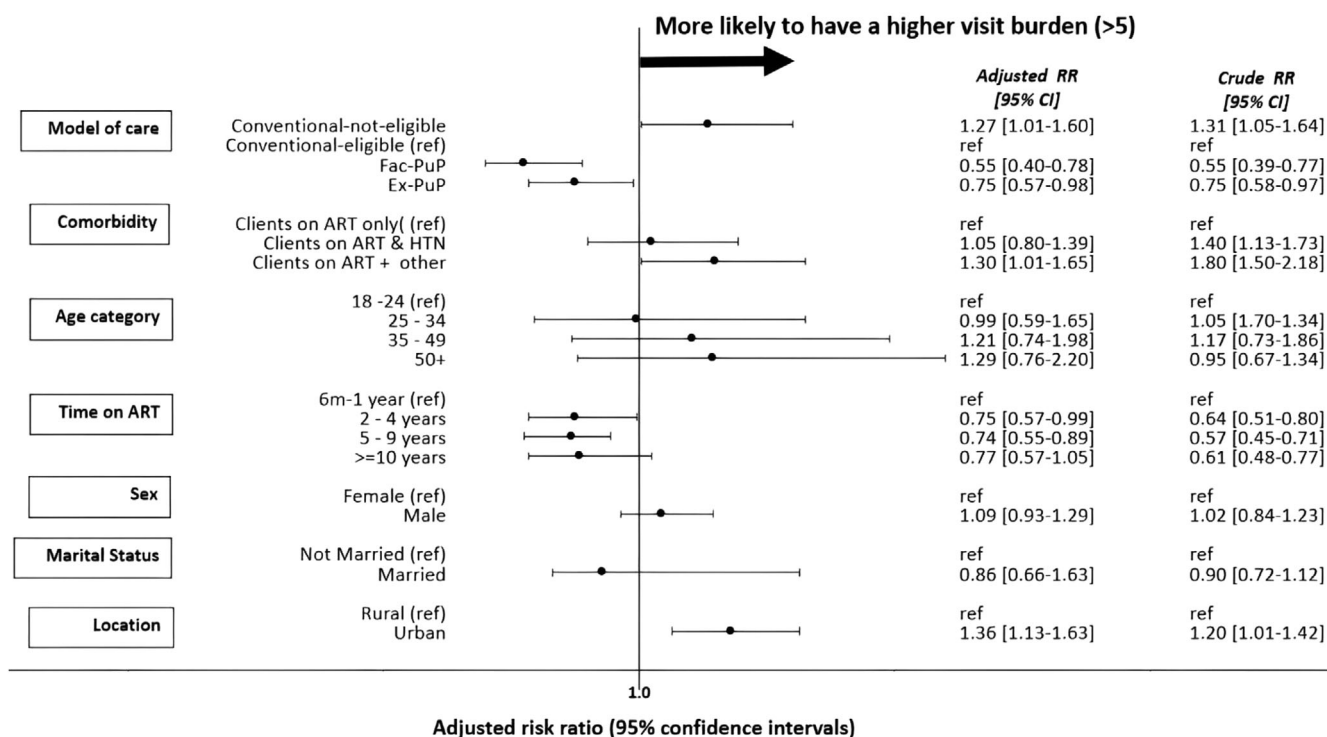


Figure 2. Forest plot presenting the crude and adjusted risk ratios for high interaction burden (> 5 interactions) among differentiated service delivery model and comorbidity status (n = 508), adjusting for age, sex, duration on ART, marital status and location of facility.

*For this analysis, we included 508 clients; we excluded the 136 clients in the Transition category.

Abbreviations: ART, antiretroviral therapy; CI, confidence interval; HTN, hypertension; PuP, pick-up point; RR, risk ratio; Ref, reference.

a significantly higher visit burden (1.30, 1.01–1.65). Clients on ART for 2–4 years (0.75, 0.57–0.99) and 5–9 years (0.74, 0.55–0.99) experienced a lower visit burden compared to those on treatment for 6 months to 1 year.

4 | DISCUSSION

In this study of the alignment of HIV and HTN care in South Africa, we found that a large majority of ART and HTN

medication refill visits and dispensing durations were aligned across all models of care. To our surprise, we observed no significant difference in visit burden between clients receiving only ART and those receiving ART and HTN medication. We had expected that the need to provide care for multiple chronic conditions would increase logistical demands (visits, dispensing events), but the DSD models employed in South Africa appear to have achieved a high degree of visit and dispensing alignment without adding to the overall burden for affected clients or facilities.

The level of ART-NCD visit alignment reported in our study is much higher than the 60% previously reported in an earlier study conducted in the Western Cape Province in 2020 in a population with similar characteristics [17]. Our results may reflect differences among the provinces—Western Cape does not utilise the same dispensing system or models of care as the rest of South Africa—or may indicate progress towards greater alignment in the past 4 years.

The data utilised for this study allowed us to document the alignment of care within a single clinic visit, but it did not indicate the total number of healthcare providers seen during the course of that visit. Even clients with perfect visit and dispensing alignment in our study may have been required to see multiple providers in different parts of the clinic. Concern also remains about the lack of integration of tools and systems recording this information. TIER.Net, South Africa's HIV electronic medical record, captures only HIV and TB-related services making it difficult to track co-morbid clients. Integrating records across different conditions is essential to fully understanding integrated care.

The main limitations of our study were reliance on self-report to identify treatment of co-morbidities and on potentially incomplete medical record data to evaluate alignment. It is likely that some clients receiving treatment for conditions other than HIV did not disclose this in the survey, potentially reducing observed differences between the ART-only and ART+HTN categories. Although we conducted a manual record review, the clinical stationery used did not have structured fields for non-HIV chronic conditions, potentially leading to missing information about NCD care, in particular for HTN dispensing duration. If HTN-related interactions were missed, our study would overestimate the actual level of alignment achieved. Finally, the small sample size for clients with both HIV and HTN and lack of HTN clinical outcome data constrained our ability to evaluate the impact of the alignment observed.

South Africa's journey towards integrated chronic care delivery offers valuable insights for health systems globally. Through the Integrated Chronic Disease Management model [18], the country has implemented practical strategies including facility reorganisation, population screening, standardised treatment protocols and patient empowerment programmes. South Africa successfully merged a previously vertical HIV treatment programme into a broader chronic disease care model that allowed the alignment of visits and dispensing reported above, a step that many other countries have not yet taken.

5 | CONCLUSIONS

This study demonstrates that successfully aligning treatment visits and medication dispensing for clients with multiple chronic conditions may be achievable in both conventional and differentiated care settings and lead to a reduction in the burden of care-seeking for clients with multiple conditions.

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COMPETING INTERESTS

The authors declare that they have no competing interests.

AUTHORS' CONTRIBUTIONS

NOM, AH, IM, KS, SP and SR conceptualised the study. AH and VN oversaw data collection. OM did data analysis and drafted the manuscript with inputs from AH, IM, KS, VN and SR. All authors contributed to reviewing and editing the manuscript for submission.

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DATA AVAILABILITY STATEMENT

Data available on request from the authors.

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SUPPORTING INFORMATION

Additional information may be found under the Supporting Information tab for this article:

Supporting information: Sentinel survey.

RESEARCH ARTICLE

Non-communicable disease (NCD) risk among people living with HIV in KwaZulu-Natal, South Africa: evidence from a randomised trial of community-based differentiated service delivery

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Abstract

Introduction: As differentiated HIV services provided outside of clinics are scaled up, clients may have fewer interactions with ancillary services for non-communicable disease (NCD) prevention and management traditionally offered within facilities. This study was embedded in the DO ART randomised trial (2016–2019), which demonstrated that community-based differentiated service delivery (DSD) improved HIV viral suppression compared with facility-based care. We assessed NCD risk among men and women living with HIV accessing community-based DSD versus facility-based care in KwaZulu-Natal, South Africa.

Methods: First, we described lifestyle and clinical NCD risk among DO ART participants in rural and semi-rural KwaZulu-Natal. Next, we compared clinical NCD risk at 12 months by randomisation arm (community-based DSD vs. facility-based care). Finally, we explored the relationship between 12-month viral suppression and clinical NCD risk, overall and stratified by randomisation arm (i.e. service delivery type).

Results: Among 1010 participants, the median age was 32 years, 245 (24%) smoked, 229 (23%) had hypertension and 502 (50%) were overweight or obese (body mass index [BMI] ≥ 25). Smoking was more common among men than women (43% vs. 6%, $p \leq 0.001$), while overweight/obesity was more common among women than men (65% vs. 34%, $p \leq 0.001$). We found no statistically significant association between service delivery type and clinical NCD risk factors at 1 year. We also found no significant associations between viral suppression at 12 months and blood pressure, haemoglobin A1c or smoking. However, virally suppressed clients had higher mean BMI ($+0.93 \text{ kg/m}^2$, $p = 0.004$) and higher mean cholesterol ($+5.79 \text{ mg/dl}$, $p = 0.001$). These associations were greater in effect size and statistically significant among clients receiving community-based DSD (BMI: $p = 0.003$; cholesterol: $p = 0.001$), but smaller and not significant for facility-based care (BMI: $p = 0.299$; cholesterol: $p = 0.448$).

Conclusions: Relatively younger adults accessing HIV treatment in South Africa had substantial NCD risk, which differed by gender and may increase with age. Among clients receiving community-based DSD, viral suppression was associated with modestly higher BMI and cholesterol levels. Community-based DSD programmes should consider integrating NCD risk screening and management that addresses gender-specific needs to prevent premature mortality among people living with HIV.

Clinical Trial Number: NCT0292999

Keywords: antiretroviral therapy; non-communicable diseases; cardiovascular risk; community health services; differentiated service delivery; integrated care

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1 | INTRODUCTION

Sub-Saharan Africa (SSA) is home to 26 million people living with HIV, nearly 20 million of whom are achieving viral suppression through antiretroviral therapy (ART) [1], but who face a growing burden of non-communicable disease (NCD) risk [2, 3], especially as the population ages [4, 5]. People liv-

ing with HIV have an estimated 2.5-fold higher risk of cardiovascular disease than people without HIV [6]. Moreover, nearly one-third of people living with HIV in SSA are overweight or obese, one-fifth have hypertension and one-fifth have high cholesterol [7].

Differentiated service delivery (DSD)—including both community-based and facility-based models—has emerged

as a promising strategy for HIV control [8, 9], maintaining or improving ART outcomes [10, 11] while alleviating strain on health systems and patients [12, 13]. However, as these services reduce the frequency of client contact with health facilities [14, 15], clients may have fewer interactions with ancillary clinic services for NCDs. This has important implications, as studies from eastern and southern Africa suggest that individuals receiving ART at clinics may experience lower NCD risk than people without HIV—despite the increased cardiometabolic risk associated with HIV acquisition [6, 16] and treatment [17–23]—due to their engagement with services such as nutritional counselling and NCD management [24–26].

In response to this dual burden, integrated DSD programmes that address both HIV and NCD risk are being considered [9, 27]. For example, South Africa's Central Chronic Medicine Dispensing and Distribution (CCMDD) programme—serving over four million patients—enables stable individuals to collect medicines for HIV, hypertension and diabetes at shared community pick-up points [28, 29]. However, in the context of DSD, the burden of NCD risk, how it is affected by community-based service delivery and its implications are not well understood.

In this study, we report NCD risk among adults accessing community-based DSD and facility-based HIV services in South Africa. The first objective was (1) to describe the burden of lifestyle and clinical NCD risk among men and women receiving community- and facility-based ART. Next, we (2) assessed if clients randomised to receive community-based DSD experienced higher clinical NCD risk after 1 year compared with standard facility-based care, and (3) evaluated the relationship between effective ART (defined by viral suppression) and clinical NCD risk at 1 year for both models of care. These objectives aim to inform DSD programmes in SSA about NCD risk, gender-specific strategies for mitigation, and opportunities to integrate NCD prevention and management.

2 | METHODS

This study was embedded within the DO ART randomised trial in South Africa (2016–2019), conducted in 16 communities in the Northern and Midlands regions of KwaZulu-Natal [11]. Clients newly initiating HIV treatment were randomised at the household level to one of three arms: (1) clinic-based ART initiation and follow-up (standard of care); (2) community-based ART initiation and follow-up; or (3) a hybrid model with clinic-based ART initiation and community follow-up. The trial results showed that community-based ART improved viral suppression compared to clinic-based care, and the hybrid model was non-inferior to clinic-based care [11].

Integrated NCD care was not provided in any arm, but NCD risk factors were assessed at baseline and/or exit. Randomisation was independent NCD risk, which did not influence the assignment to study arms. For this analysis, we combined the community and hybrid trial arms — both of which involved follow-up outside the clinic — and refer to them collectively as “community-based DSD,” with the standard-of-care arm referred to as “facility-based care.”

2.1 | Data collection

Data related to NCD risk and HIV clinical outcomes were collected at baseline, study exit (12 months after enrolment) or quarterly visits as follows:

- (i) **Demographics:** Age and gender were recorded at baseline [11].
- (ii) **Self-reported NCD risk factors:** These included smoking status (baseline), weekly exercise (exit), vegetable intake (exit) and history of stroke or heart attack (exit).
- (iii) **Clinically measured NCD risk factors:** Trained study nurses collected several clinical NCD measures. For consistency, only exit values were used for analysis.
 - Blood pressure (systolic and diastolic) was measured in triplicate at quarterly visits;
 - Body mass index [BMI] at baseline and exit;
 - Haemoglobin A1c (exit only);
 - Total cholesterol (exit only);
- (iv) **HIV clinical outcomes:** Viral suppression, the primary outcome of the DO ART trial, has been previously published [11]. In this analysis, 12-month viral suppression was examined as a predictor of NCD risk.

2.2 | Variable definitions

Clinically measured NCD risk factors were categorised using standard guidelines:

- **Blood pressure.** We applied American College of Cardiology/American Heart Association (ACC/AHA) cutoffs using the average of three readings: < 120/80 mmHg (normal), systolic between 120–129 and diastolic < 80 (elevated), systolic between 130–139 or diastolic between 80–89 (Hypertension Stage 1), systolic $\geq$ 140 or diastolic $\geq$ 90 (Hypertension Stage 2) and systolic $\geq$ 180 or diastolic $\geq$ 120 (Hypertensive crisis) [30].
- **BMI.** BMI $\leq$ 18.5 kg/m² (underweight), BMI > 18.5 kg/m² and < 25 kg/m², BMI $\geq$ 25 kg/m² (overweight), BMI $\geq$ 30 kg/m² (obesity).
- **Glycaemic control.** Haemoglobin A1c < 5.7% (normal), $\geq$ 5.7% and < 6.5% (prediabetes), $\geq$ 6.5% (diabetes) [31].
- **Total cholesterol.** < 200 mg/dl (normal), $\geq$ 200 and < 240 (borderline high), and $\geq$ 240 (high) [32].

We also dichotomised clinical NCD risk measures into “elevated risk” and “no elevated risk” (with reference categories shown in Tables 2 and 3). Given that only 12 participants had elevated total cholesterol, dichotomised cholesterol level was not included in our analysis.

2.3 | Analysis

We conducted the following analyses:

1. We described NCD risk (including demographic variables, lifestyle risk factors and clinical risk measures), using chi-squared tests to assess differences by gender.

Table 1. Non-communicable disease risk in the DO ART Study in South Africa, by trial arm and gender (N = 1010)

	Category	Community-based DSD n (%)	Facility-based care n (%)	p-value	Women n (%)	Men n (%)	p-value	Total N (%)
(i) Demographics								
Age	18–39	490 (74%)	252 (72%)	0.302	386 (76%)	356 (70%)	0.101	742 (73%)
	40–59	164 (25%)	91 (26%)		113 (22%)	142 (28%)		255 (25%)
	60+	6 (1%)	7 (2%)		6 (1%)	7 (1%)		13 (1%)
Gender	Median (IQR)	32 (26–40)	32 (27–40)	–	30 (25–38)	34 (29–41)	–	32 (27–40)
	Women	336 (51%)	169 (48%)	0.467	–	–	–	505 (50%)
	Men	324 (49%)	181 (52%)		–	–		505 (50%)
Education	Primary	121 (18%)	79 (23%)	0.099	74 (15%)	126 (25%)	0.001	200 (20%)
	Secondary	502 (76%)	261 (75%)		406 (80%)	357 (71%)		763 (76%)
	Tertiary and above	21 (3%)	7 (2%)		16 (3%)	12 (2%)		28 (3%)
	Missing	16 (2%)	3 (1%)		9 (2%)	10 (2%)		19 (2%)
(ii) Self-reported risk factors								
Smoking status [Baseline]	Not at all	497 (75%)	261 (75%)	0.429	475 (94%)	283 (56%)	< 0.001	758 (75%)
	Former	3 (0%)	4 (1%)		2 (0%)	5 (1%)		7 (1%)
	Current—occasional	42 (6%)	17 (5%)		13 (3%)	46 (9%)		59 (6%)
Days of exercise (per week) [Exit]	Current—frequent	118 (18%)	68 (19%)		15 (3%)	171 (34%)		186 (18%)
	5–7	38 (6%)	14 (4%)	0.534	13 (3%)	39 (8%)	< 0.001	52 (5%)
	3–4	262 (40%)	136 (39%)		185 (37%)	213 (42%)		398 (39%)
Vegetable intake [Exit]	1–2	187 (28%)	113 (32%)		163 (32%)	137 (27%)		300 (30%)
	0	114 (17%)	54 (15%)		101 (20%)	67 (13%)		168 (17%)
	Missing	59 (9%)	33 (9%)		43 (9%)	49 (10%)		92 (9%)
Prior stroke or heart attack [Exit]	Always or usually	122 (18%)	53 (15%)	0.050	103 (20%)	72 (14%)	< 0.001	175 (17%)
	Sometimes	326 (49%)	166 (47%)		266 (53%)	226 (45%)		492 (49%)
	Never or rarely	166 (25%)	114 (33%)		107 (21%)	173 (34%)		280 (28%)
Missing	Missing	46 (7%)	17 (5%)		29 (6%)	34 (7%)		63 (6%)
	No	606 (92%)	328 (94%)	0.466	469 (93%)	465 (92%)	0.643	934 (92%)
	Yes	9 (1%)	5 (1%)		8 (2%)	6 (1%)		14 (1%)
	Missing	45 (7%)	17 (5%)		28 (6%)	34 (7%)		62 (6%)

(Continued)

Table 1. (Continued)

	Category	Community-based DSD n (%)	Facility-based care n (%)	Women n (%)	Men n (%)	p-value	Total N (%)
(iii) Clinically measured risk factors							
Blood pressure [Exit]	Normal	334 (51%)	171 (49%)	263 (52%)	242 (48%)	0.253	505 (50%)
	Elevated	133 (20%)	88 (25%)	99 (20%)	122 (24%)		221 (22%)
	Hypertension Stage 1	136 (21%)	61 (17%)	104 (21%)	93 (18%)		197 (20%)
	Hypertension Stage 2	20 (3%)	12 (3%)	16 (3%)	16 (3%)		32 (3%)
	Missing	37 (6%)	18 (5%)	23 (5%)	32 (6%)		55 (5%)
BMI (kg/m ²) [Exit]	< 18.5	20 (3%)	10 (3%)	4 (1%)	26 (5%)	0.496	30 (3%)
	18.5–24.9	268 (41%)	152 (43%)	149 (30%)	271 (54%)		< 0.001
Haemoglobin A1C (%) [Exit]	25–29.9	219 (33%)	100 (29%)	187 (37%)	132 (26%)	0.013	319 (32%)
	30+	113 (17%)	70 (20%)	142 (28%)	41 (8%)		183 (18%)
	Missing	40 (6%)	18 (5%)	23 (5%)	35 (7%)		58 (6%)
	Normal	403 (61%)	235 (67%)	341 (68%)	297 (59%)		638 (63%)
	Prediabetes	35 (5%)	19 (5%)	20 (4%)	34 (7%)		54 (5%)
	Diabetes	6 (1%)	2 (1%)	2 (0%)	6 (1%)		8 (1%)
	Missing	216 (33%)	94 (27%)	142 (28%)	168 (33%)		310 (31%)
	Normal	584 (88%)	324 (93%)	449 (89%)	459 (91%)		908 (90%)
	Borderline high	9 (1%)	1 (0%)	7 (1%)	3 (1%)		10 (1%)
	High	2 (0%)	0 (0%)	1 (0%)	1 (0%)		2 (0%)
(iv) HIV clinical outcomes Viral suppression ^a [Exit]	Missing	65 (10%)	25 (7%)	48 (10%)	42 (8%)	0.014	90 (9%)
	Yes	448 (68%)	204 (58%)	348 (69%)	304 (60%)		652 (65%)
	No	194 (29%)	137 (39%)	146 (29%)	185 (37%)		331 (33%)
	Missing	18 (3%)	9 (3%)	11 (2%)	16 (3%)		27 (3%)

Notes: P-values are estimated from chi-squared tests comparing the distribution of each categorical variable across trial arm or gender. Each p-value reflects the overall association across all levels of the variable.

Abbreviations: BMI, body mass index; DSD, differentiated service delivery; IQR, interquartile range.

^aViral suppression was the primary outcome for the DO ART Study. In South Africa, community-based DSD was found to significantly increase viral suppression by 1.22 (95% CI: 1.09–1.36) for community-based initiation and community-based follow-up, that is the “community arm” of the trial, and by 1.12 (95% CI: 1.00–1.25) for facility-based initiation and community-based follow-up, that is the “hybrid arm” of the trial [11].

Table 2. Impact of HIV service delivery model on non-communicable disease risk factors: community-based differentiated service delivery versus facility-based care (N = 1010)

NCD risk factors		Sample characteristics			Unadjusted analysis			Adjusted analysis		
	Reference category	Total (n)	Elevated risk (n)	No elevated risk (n)	RR	95% CI	p-value	aRR	95% CI	p-value
A. Binary outcomes										
Above-normal blood pressure	Normal blood pressure	955	450	505	0.93	(0.79, 1.09)	0.368	0.94	(0.81, 1.10)	0.455
Elevated BMI (BMI ≥ 25 kg/m²)	BMI < 25 kg/m²	952	502	450	1.03	(0.91, 1.17)	0.633	1.02	(0.89, 1.15)	0.802
Elevated blood sugar (A1c ≥ 5.7%)	A1c < 5.7%	700	62	638	1.22	(0.74, 2.00)	0.440	1.19	(0.73, 1.96)	0.478
Current smoker [baseline]	Non-former smoker	1010	245	765	0.99	(0.79, 1.24)	0.919	1.02	(0.81, 1.28)	0.887
B. Continuous outcomes										
		Total (n)	Mean	SD	AD	95% CI	p-value	aAD	95% CI	p-value
Systolic blood pressure (mmHg)		955	116.7	10.2	−0.80	(−2.16, 0.56)	0.247	−0.70	(−2.06, 0.66)	0.306
Diastolic blood pressure (mmHg)		955	74.2	8.3	−0.03	(−1.11, 1.05)	0.956	−0.08	(−1.15, 1.00)	0.888
BMI (kg/m²)		952	26.1	5.1	−0.02	(−0.68, 0.64)	0.964	−0.11	(−0.77, 0.55)	0.726
Haemoglobin A1c (%)		700	5.0	0.5	0.04	(−0.04, 0.12)	0.287	0.04	(−0.04, 0.12)	0.278
Total cholesterol (mg/dl)		920	145.6	25.6	3.13	(−0.18, 6.43)	0.064	2.92	(−0.38, 6.22)	0.080

Notes: This table shows the randomised comparison of NCD risk for community-based differentiated service delivery (DSD) compared to facility-based care. RRs (for dichotomised outcomes) and ADs (for continuous outcomes) were estimated using Poisson and linear generalised estimating equations, respectively. Unadjusted models controlled for trial site only (Northern or Midlands KwaZulu-Natal). Adjusted models controlled for trial site, age, smoking, gender and education (except the "current smoker" outcome, which did not include smoking). "Above normal" blood pressure includes elevated blood pressure, Stage 1 Hypertension and Stage 2 Hypertension per ACC/AHA guidelines.

Abbreviations: aAD, adjusted average (mean) difference; AD, unadjusted average difference; aRR, adjusted relative risk; BMI, body mass index; CI, confidence interval; RR, unadjusted relative risk; SD, standard deviation.

Table 3. Associations between HIV viral suppression and non-communicable disease risk factors, stratified by type of HIV service delivery model: community-based differentiated service delivery (DSD) and facility-based care (N = 983)

NCD risk factors A. Binary outcomes	Community-based DSD				Facility-based care				Overall (pooled)			
	n	aRR	95% CI	p-value	n	aRR	95% CI	p-value	N	aRR	95% CI	p-value
Above-normal blood pressure	621	1.17	(0.94, 1.46)	0.158	331	0.93	(0.72, 1.19)	0.542	952	1.05	(0.89, 1.24)	0.535
Elevated BMI (BMI ≥ 25 kg/m ²)	618	1.21	(1.03, 1.42)	0.024	331	1.08	(0.87, 1.34)	0.489	949	1.16	(1.01, 1.33)	0.024
Elevated blood sugar (A1c ≥ 5.7%)	443	1.05	(0.57, 1.95)	0.874	255	0.76	(0.32, 1.78)	0.530	698	0.95	(0.58, 1.56)	0.832
Current smoker [baseline]	642	0.95	(0.72, 1.24)	0.690	341	0.95	(0.67, 1.33)	0.748	983	0.95	(0.75, 1.19)	0.598
B. Continuous outcomes												
Systolic blood pressure (mmHg)	621	0.94	(−0.70, 2.59)	0.261	331	−1.58	(−3.84, 0.67)	0.169	952	−0.12	(−1.47, 1.23)	0.861
Diastolic blood pressure (mmHg)	621	0.20	(−1.13, 1.53)	0.767	331	−0.95	(−2.62, 0.73)	0.268	952	−0.25	(−1.33, 0.84)	0.648
BMI (kg/m ²)	618	1.18	(0.41, 1.95)	0.003	331	0.56	(−0.49, 1.61)	0.299	949	0.93	(0.28, 1.59)	0.004
Haemoglobin A1c (%)	443	−0.08	(−0.18, 0.02)	0.118	255	0.06	(−0.07, 0.20)	0.360	698	−0.02	(−0.10, 0.07)	0.709
Total cholesterol (mg/dl)	593	7.52	(2.93, 12.10)	0.001	324	2.06	(−3.26, 7.39)	0.448	917	5.79	(2.35, 9.23)	0.001

Notes: This table shows the association between HIV viral suppression and NCD risk factors stratified by trial arm, i.e. type of HIV service delivery model. aRRs (for dichotomised outcomes) and aADs (for continuous outcomes) were estimated using Poisson and linear generalised estimating equations, respectively. Adjusted models (all) control for trial site, age, smoking, gender and education (except the “current smoker” outcome, which did not include smoking). The p-value for the interaction term is from a pooled analysis additionally including an interaction term between HIV viral suppression and trial arm. Reference categories for dichotomous outcomes were: normal blood pressure, BMI < 25 kg/m², A1c < 5.7% and non-former smoker. “Above normal” blood pressure includes elevated blood pressure, Stage 1 Hypertension and Stage 2 Hypertension per ACC/AHA guidelines. Twenty-seven participants without viral load data at exit were excluded from this analysis (N = 983).

Abbreviations: aAD, adjusted average (mean) difference; aRR, adjusted relative risk; BMI, body mass index; CI, confidence interval.

2. We compared clinically measured NCD risk factors between participants randomised to receive community-based DSD versus facility-based care.
3. We compared clinically measured NCD risk factors between clients who were virally suppressed and those not virally suppressed at 1 year. To assess whether the relationship between viral suppression and NCD risk varied by HIV service delivery type, we conducted:
 - (i) stratified analyses by type of HIV service delivery model, and
 - (ii) a pooled analysis including an interaction term between viral suppression status and trial arm (i.e. type of HIV service delivery) to test for statistical evidence of effect modification.

We estimated relative risks [RRs] for binary outcomes using Poisson regression and average (mean) differences [ADs] for continuous outcomes using linear regression. To account for household clustering (1% of individuals in the study [10/1010] were from households with more than one enrolled individual), we used generalised estimating equations with an independence working covariance structure. Unadjusted models included trial site (i.e. Northern or Midlands KwaZulu-Natal) as the only covariate, while adjusted models also included age (categorical), gender (binary), smoking status (binary) and education level (categorical). Adjusted results are presented as aRRs and aADs throughout the manuscript.

2.4 | Missing data

Since NCD clinical measures generally had good coverage except for A1c, which was missing from one site due to incorrect test administration, regressions used complete case analysis assuming that NCD data missingness was independent of the outcome, after conditioning on site.

2.5 | Ethics

All participants provided written informed consent prior to enrolment. The DO ART Study was approved by the Human Sciences Research Council Research Ethics Committee in South Africa and the University of Washington Institutional Review Board, Seattle, WA (REC6/13/11/15).

3 | RESULTS

Among 1010 eligible participants in the DO ART Study in South Africa, the median age was 32 years (interquartile range: 27–40) (Table 1). Overall, 245 participants (24%) were current smokers (occasional or frequent), 468 (46%) exercised ≤ 2 days/week, 280 (28%) never or rarely ate vegetables and 14 (1%) reported a history of stroke or heart attack. Clinically, 450 (45%) had above-normal blood pressure including 229 (23%) with Stage 1 or Stage 2 Hypertension, 502 (50%) had BMI ≥ 25 , 62 (6%) had prediabetes or diabetes and 12 (1%) had elevated cholesterol.

Certain clinical NCD risk factors varied significantly by gender (Table 1). Among men, 217 of 505 (43%) were current smokers, compared to 28 of 505 (6%) of women ($p < 0.001$).

For BMI, 173 men (34%) and 329 women (65%) were overweight, including 41 men (8%) and 142 women (28%) classified as obese ($p < 0.001$). Elevated haemoglobin A1c (prediabetes or diabetes) was observed in 40 men (8%) and 22 women (4%) ($p = 0.013$).

Our regression analysis found no significant differences in clinically measured NCD risk factors (blood pressure, BMI, A1c and total cholesterol) between clients randomised to receive community-based DSD versus those receiving facility-based care (Table 2).

At 12 months, virally suppressed clients had higher BMI (aAD = +0.94 kg/m², $p = 0.003$), total cholesterol (aAD = +5.71 mg/dl, $p = 0.001$) and risk of overweight/obesity (aRR = 1.16, $p = 0.024$) compared with clients not virally suppressed (Table 3). These associations were not observed for other NCD risk factors, including blood pressure, haemoglobin A1c and baseline smoking. While the interaction term between viral suppression and trial arm (i.e. type of service delivery) was not statistically significant, the patterns differed by service model. In community-based DSD, virally suppressed persons had significantly higher BMI (aAD = +1.18 kg/m², $p = 0.003$), total cholesterol (aAD = +7.52 mg/dl, $p = 0.001$) and risk of overweight/obesity (aRR = 1.21, $p = 0.024$) compared with clients not suppressed. In contrast, no significant associations were observed among clients in facility-based care; effect sizes were either attenuated (cholesterol, BMI) or reversed (blood pressure).

4 | DISCUSSION

In a largely younger cohort (73% aged 18–39) receiving HIV care in rural/semi-rural South Africa, we observed a substantial burden of clinical NCD risk: 50% had BMI ≥ 25 , 45% had above-normal blood pressure and 24% were current smokers. As this population ages, additional risk factors—such as high cholesterol and diabetes—are also likely to increase [4, 5]. Building on decades of research on gendered patterns of NCD risk [33–35], we found significant gender differences: 43% of men were current smokers compared with just 6% of women, while 65% of women were overweight/obese compared with 34% of men. Despite the cohort's younger age, the prevalence of smoking, high BMI and blood pressure exceeded average levels in SSA [7], and were comparable to rates observed in the general population in KZN and South Africa [36–39].

Building on extensive literature linking HIV, ART and effective ART (viral suppression) to increased cardiovascular risk through pharmacologic and metabolic pathways (including pro-inflammatory effects and treatment-related weight gain and hyperlipidaemia) [18–22], we observed several trends relevant to DSD programmes. First, community-based DSD did not significantly increase NCD risk compared to facility-based care within 12 months, despite the lack of integrated NCD services. Second, viral suppression was modestly associated with higher BMI and cholesterol in this young population, half of whom were already overweight or obese—an association that may strengthen with expanded use of integrase inhibitor-based ART [21, 40, 41]. Finally, although we did not find statistical evidence of effect modification by the service delivery

model, associations between viral suppression and NCD risk were more pronounced in community-based DSD. This pattern aligns with studies suggesting that access to ancillary services in clinics—including nutritional counselling and preventive medications—may help to mitigate ART-related NCD risk [24–26]. These findings highlight the need for community-based DSD models to prioritise NCD risk screening and management to meet or exceed the standard of care offered in clinics.

Differentiated HIV service delivery models tailor care to the needs of specific populations—including men, women, ageing adults and people with elevated NCD risk. Our findings support this approach by highlighting modifiable risk factors that differ by gender and age. For example, community-based models designed to engage men in care [11, 42] could incorporate smoking cessation, given that 43% of men in our study smoked and that integrated counselling reduces mortality [43, 44]. Similarly, as DSD increasingly reaches older populations, integrating NCD screening and management will be essential. These adaptations align with emerging guidance on chronic disease integration within DSD [9, 27].

Community-based platforms offer a strategic opportunity to deliver integrated NCD services. In South Africa, DSD guidance already includes HIV, tuberculosis (TB) and NCD care at both facility and community levels [27, 28]. In our study, conducted before the integration of NCD services into DSD (2016–2019), 21% of clients enrolled in community-based DSD had Stage I hypertension and 3% had Stage II—but none initiated treatment, highlighting a missed opportunity. South Africa's CCMDD programme, which includes both HIV and NCD medications in its formulary, offers one such integrated model. By requiring in-person eligibility reassessments every 6–12 months, programmes like CCMDD may provide opportunities to screen for and manage NCD risk over time. In addition, the treatment landscape for NCDs in HIV care is evolving. The recent REPRIEVE trial demonstrated the cardiovascular benefits of statins for people living with HIV [45, 46], while GLP-1 agonists, widely used for obesity management [47], are also being explored for use among people living with HIV [48]—further strengthening the case for integrated care. However, even inexpensive generic medicines face frequent shortages in low- and middle-income countries [49, 50], and statins and GLP-1 agonists remain prohibitively expensive for widespread use. Scaling up NCD treatment, including within DSD, will require investment in supply chains to realise the full potential of integrated chronic disease care [51, 52].

Our study had the following limitations. First, our NCD data contained missingness including 31% missing A1c; however, our primary inference relied on measures with less missingness (BMI [3%] and cholesterol [7%]). Second, our analysis did not control for medication use, existing health conditions, diet or alcohol use due to data limitations. Third, most NCD risk factors were measured only at endline, which did not allow for comparisons against the baseline values. Fourth, our exploratory analysis of NCD risk and viral suppression was not randomised and we did not capture long-term associations; however, the results remained consistent across several robustness checks. Moreover, despite multiple comparisons, the strong statistical significance for BMI and cholesterol suggests robustness to multiple testing. Finally, self-reported risk

is prone to underreporting [53, 54]; however, our main interpretation relied primarily on clinical measures.

5 | CONCLUSIONS

Our study found substantial NCD risk in a younger population accessing HIV care in South Africa, with clear gender differences and, for community-based DSD, modest associations between viral suppression and both BMI and cholesterol levels. As HIV services expand beyond clinics, integrating or linking to NCD care will be essential to meeting evolving health needs to prevent premature mortality.

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COMPETING INTERESTS

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AUTHORS' CONTRIBUTIONS

MS, AAS and RVB conceptualised the study. MS analysed the data, generated tables and wrote the manuscript. AAS and RVB provided ongoing feedback and critically revised several versions of the manuscript. DAR, AES, TS, JMB and AvH contributed to the study design and interpretation of results. All authors critically reviewed and approved the final manuscript.

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DATA AVAILABILITY STATEMENT

A de-identified patient dataset sufficient to reproduce the study findings is available upon request, following approval of a concept sheet with proposed analyses to be done. Further inquiries can be directed to the DO ART Scientific Committee at rbarnabas@mgh.harvard.edu.

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RESEARCH ARTICLE

Preferences for TB treatment and support delivery models among people living with TB in Eastern Cape, South Africa: a discrete choice experiment

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Abstract

Introduction: South Africa has one of the highest incidence rates of notified tuberculosis (TB) in the world. Achieving TB control requires strengthening treatment and support services. The implementation of differentiated delivery models can be used to improve service quality and enhance retention in care. This study aimed to identify treatment and support delivery preferences among people on TB treatment, specifically examining gender differences, to inform the development of differentiated care models for improving engagement and retention in TB treatment services.

Methods: A binary, unlabelled, fractional factorial design discrete choice experiment (DCE) was used to investigate preferences for TB treatment adherence support and service delivery. Attributes included who provides the support, how and where support is delivered, medication collection location and frequency of clinic visits. The DCE was administered to individuals who were currently on or recently completed TB treatment, and to those at-risk for being lost-to-care. Data from 284 individuals for the DCE were collected from March to August 2022. Mixed effects logistic regression models were used as primary analysis tools. Latent class analysis (LCA) was used to explore heterogeneity in preference structures.

Results: Compared to standard clinic-based treatment collection, participants preferred collecting their treatment from a mobile community-based location ($\beta = 0.231$; 95% CI: 0.08–0.39), clinic-based fast-tracked pick-ups ($\beta = 0.539$; 95% CI: 0.38–0.70) or home delivery ($\beta = 0.563$; 95% CI: 0.37–0.75). Participants also significantly preferred support offered monthly compared to once-off ($\beta = 0.167$; 95% CI: 0.01–0.32). Furthermore, participants preferred face-to-face support over group ($\beta = -0.142$; 95% CI: -0.27 to -0.02) or phone-based ($\beta = -0.222$; 95% CI: -0.36 to -0.09) support models. LCA revealed three classes with statistically similar preference structures; Class 1 (62%) preferred community-based treatment delivery and support services; Class 2 (28%) preferred clinic-based support and treatment delivery services; and Class 3 (10%), preferred self-selected peer navigator or nurse delivered, and group models of support and prioritised the location of medication pick-ups, with a preference for any model other than standard clinic collection.

Conclusions: Though preference structures did not differ by gender, respondents revealed strong preferences for differentiated service delivery models. Future TB treatment and support interventions must include both clinic- and community-based models of care and support to ensure that those living with TB are provided the greatest access to TB treatment and support services.

Keywords: discrete choice experiment; preferences; tuberculosis; adherence; public health; Africa

Additional information may be found under the Supporting Information tab of this article.

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1 | INTRODUCTION

In 2022, an estimated 280,000 individuals were diagnosed with tuberculosis (TB) in South Africa, and ~54,000 people died of the disease [1]; of those who initiated TB treatment,

only 78% successfully completed their treatment [2]. Poor adherence to TB treatment increases the risk of delayed culture conversion resulting in continued transmission, treatment failure, relapse, death and increases the risk of drug resistance [3]. Studies have shown that men are at increased risk for

poor treatment outcomes due to a host of risk factors, including poor treatment adherence [4, 5]. Poor adherence to TB treatment increases morbidity and mortality among all people living with TB, which can lead to catastrophic economic costs [6]. To achieve the End TB Strategy target of halving TB incidence by 2025, and a 95% reduction in TB deaths by 2035, improving treatment adherence and retention in care is critical [7].

Interventions and services that cater for individual health-care user preferences are more likely to be utilised and effective than those services simply designed based on the capacity of the health system and preferences of providers [8–10]. In this study, we used a discrete choice experiment (DCE) to analyse the preference structures of people on TB treatment [11, 12], to guide the development of differentiated care models for TB treatment and support. DCEs are increasingly used by health researchers to understand intervention preferences for the adaptation of existing interventions and service delivery models or for the development of new interventions [13–15]. Few DCEs have been conducted to assess TB treatment service and support preferences. One DCE conducted in Zambia revealed a preference for accessing TB diagnostic services close to home with short wait times [16]. A study in Uganda found a preference for treatment delivered by community health workers (CHWs) rather than a family member, home rather than workplace deliveries and monthly travel vouchers as a means of support rather than SMS reminders or phone calls [17]. We found no studies which sought to ascertain preferences for TB treatment service delivery models that evaluated differences across genders. However, research has shown that social and gender norms influence men's and women's health-seeking behaviours, and their experience and perceptions of health facilities and healthcare providers—potentially requiring tailored health service models, if health outcomes are to be optimised [18–27].

This study examines the preference structures of people on TB treatment for TB treatment and support service delivery models, including an analysis of gendered differences. The study further unpacks preference distinctions between people currently on TB treatment; those defaulting on treatment, and those who had successfully completed treatment. Evidence is expected to inform the development of differentiated care models with the aim of improving engagement and retention in TB treatment services.

2 | METHODS

The DCE design focused on preferences for TB treatment and support delivery (primarily for adherence support, although we recognise that the nature of support people on TB treatment need may go beyond simply adherence). In addition, we analysed divergence in preferences to understand: (1) whether men and women have different priorities in terms of treatment and support delivery models; (2) whether people who successfully completed TB treatment have different preference structures from those who are at risk of being lost-to-care or those currently on treatment; and (3) whether there were unobserved sub-populations within the sample

Table 1. Buffalo City Metropolitan Health District [2, 28–30]

Population	794,324
Tuberculosis (TB) incidence	769/100,000
TB/HIV co-infection rate	45.7%
Men:Women TB prevalence ratio	1.9:1
Drug-sensitive TB treatment success rate	74.1%
TB patient loss-to-follow up	17.2%
TB patient death rate	7.9%

that share similar preference structures [supporting Information](#).

2.1 | Study setting

Participants were recruited from 12 Primary Health Clinics in Buffalo City Metropolitan Health District, Eastern Cape Province, South Africa—a historically under-resourced and high TB burden province (see Table 1).

2.2 | Study design

An initial list of 18 potential attributes (service delivery model characteristics) was developed based on findings from previous research [31, 32] and analysis of qualitative interviews conducted in a prior stage of the larger study [33]—additional results from the larger study are published elsewhere [33–35]. Following engagement with stakeholders, six attributes were included in the design to reduce the possibility of attribute non-attendance [36] in two dimensions—adherence support delivery characteristics (frequency of support, who provides the support, how support is delivered, where support is delivered) and treatment delivery characteristics (medication collection location and frequency of clinic visits). The levels (possible options available for each attribute) for each attribute were determined based on currently available options and on analysis of qualitative data (Table 2).

The DCE used a binary choice, unlabelled, fractional factorial design generated in STATA17 to produce a statistically optimal design of 48 choice sets using the D-efficiency criterion, based on a modified Federov algorithm [37–39]. Participants were each allocated a sub-set of just 12 choice sets each. A blocking variable was used to divide the 48 choice sets into four blocks each with 12 choice sets—participants were randomly allocated to answer the choice sets in just one block [11].

2.3 | Data collection

Data for the DCE were collected from March to August 2022. The fieldworker administered DCE was embedded in a larger quantitative survey which included basic socio-demographic, behavioural measures and health history questionnaire. DCE choice sets were presented on electronic tablets using RED-Cap hosted at the University of KwaZulu-Natal [40]. Before beginning the DCE, fieldworkers read scripted introductions, which included definitions of each attribute and level to ensure consistency in participants' understanding (see File S1). For example, fast-track clinic-based models were

Table 2. Final attributes and levels included in the discrete choice experiment design

Attribute	Levels			
Frequency of support	Once-off ^a	Weekly	Monthly	As needed
Who provides the support	Peer navigator (self-selected) ^a	Peer navigator (assigned)	Nurse	Community health worker (CHW)
How support is delivered	Individual face-to face ^a	Small group	Individual phone	
Where support is delivered	Clinic-based ^a	Home-based	Community site	
Medication collection	Collection at the clinic (standard, longer waiting time) ^a	Collection at the clinic (fast track, shorter waiting time)	Delivery to your house	Pill collection at mobile/community site
Number of clinic visits	Weekly ^a	Once every 2 weeks	Once a month	Once every 2 months

^aLevels used as the reference category for the analysis were selected as the attributes that were closest to “standard of care.”

explained as being based at a clinic but having separate queues, medication pick-up points or patient flow procedures to speed up service delivery.

2.4 | Sampling and eligibility criteria

Given the limited availability of prior estimates for sample size calculations for the DCE, we used a common convention to estimate a minimum sample size (n), where $n \geq 500 \frac{L}{S \cdot J}$, L is the maximum number of levels for any attribute (three), S is the number of choices in each choice set (two) and J is the number of tasks (or choices) presented to each participant (12) [41]. The minimum sample size for the DCE was 63 participants per stratification.

Participants were recruited based on: (1) gender; and (2) treatment group. Participants self-identified as male or female in the survey; however, we have interpreted this data from a gender perspective, given that preferences are more likely to be associated with socially constructed roles and behaviours of men and women, rather than because of differences in biological sex. Treatment groups were defined as follows: (1) those currently on treatment; (2) those at risk of being lost-to-care (defined as having missed ≥ 15 days of a treatment refill visit); and (3) those who successfully completed treatment within 1 month of recruitment. Eligibility criteria: age ≥ 18 years; currently or recently engaged in TB treatment in one of the selected study clinics; able to speak English or isiXhosa; provided informed consent. Exclusion criteria: extra-pulmonary TB without lung involvement; currently in the intensive phase of treatment; and positive smear grading at treatment initiation without a post-intensive phase smear conversion to smear-negative status.

2.5 | Statistical analysis

A mixed effects logistic regression model was used as the primary analysis tool (Model 1), using dummy coding and Halton draws with 1000 replications to estimate the relative utility of each attribute level to understand overall preference structures. Mixed effects logit models allow for an initial assessment of heterogeneity in preferences across attributes by estimating both the mean utility and standard deviation [10]. Secondary analyses aimed to examine preference heterogeneity. First, we used mixed effects logistic regression

models stratified by gender (Model 2) and then by treatment group (Model 3) and directly compared the β -coefficient estimates and 95% confidence intervals to understand divergence in preferences. Second, we used latent class models to further explore preference heterogeneity in the sample [10]. Latent class models assume that there are classes or segments within a sample that have similar preference weights that are systematically different from preferences in other classes that are linked to unobserved or unobservable participant characteristics [10]. These models are useful for understanding heterogeneity and how preferences cluster within sub-groups of participants. We explored the model fit of four-, three- and two-class models. Goodness of fit was evaluated using the Akaike Information Criterion (AIC) and Bayesian Information Criterion (BIC) statistics, the mean predicted probability of class membership, and an examination of the size of the classes produced in each model. Correlations between Class membership and socio-demographic characteristics were tested using Pearson's Chi-squared test.

2.6 | Ethics and integrity

Ethics approval was obtained from the Human Research Ethics Committee of the Faculty of Health Sciences, the University of Cape Town (Ref no.: 673/2019; Medina-Marino, PI), with an institutional reliance agreement by Arizona State University (Daniels, PI). Study approval was provided by the Eastern Cape Provincial Department of Health (Ref no.: EC202010_023). All participants provided written informed consent and were provided a small snack and R50 (~\$3 USD) for their time. Study staff were trained in DCE administration, human subject's protection and good clinical practice.

3 | RESULTS

3.1 | Sample characteristics

We enrolled 284 participants (Median age = 40 years [IQR: 31–47 years]; $n = 115$ individuals currently on treatment; $n = 90$ who had recently completed treatment; and $n = 79$ at-risk of being lost-to-care). Of those, 193 (66.09%) were men, 130 (50%) were living with HIV and 72 (25%) had a previous history of TB disease (Table 3).

Table 3. Participant socio-demographic and clinical characteristics

	Currently on treatment (n = 115)	Recently completed (n = 90)	Stopping behaviour (n = 79)	Total (N = 284)
Gender	76 (66.09%)	59 (65.56%)	58 (73.42%)	193 (67.96%)
Men				
Women	39 (33.91%)	31 (34.44%)	21 (26.58%)	91 (32.04%)
Median age (years), IQR	42 (33–50)	40 (31–48)	35 (27–43)	40 (31–47)
HIV status				
HIV positive	55 (52.88%)	43 (53.09%)	32 (43.24%)	130 (50.19%)
HIV negative	49 (47.12%)	38 (46.91%)	42 (55.76%)	129 (49.81%)
TB history				
Never had TB	87 (41.23%)	70 (77.78%)	54 (69.23%)	211 (74.56%)
TB diagnosis < 2 years ago	7 (6.09%)	8 (8.89%)	11 (14.1%)	26 (9.19%)
TB diagnosis > 2 years ago	21 (18.26%)	12 (13.33%)	13 (16.67%)	46 (16.25%)
Living status				
Live alone	19 (16.52%)	9 (10.00%)	13 (16.67%)	41 (14.49%)
Live with someone	96 (83.48%)	81 (90.00%)	65 (83.33%)	242 (85.51%)
Relationship status				
Single	72 (62.62%)	50 (43.48%)	58 (50.43%)	180 (63.38%)
Married or living together	34 (29.57%)	33 (28.70%)	18 (15.65%)	85 (29.93%)
Separated/divorced/widowed	9 (7.83%)	7 (6.09%)	3 (2.61%)	19 (6.69%)
Distance to clinic				
Less than 1 km	31 (26.96%)	30 (33.33%)	25 (32.05%)	86 (30.39%)
1–2 km	31 (26.96%)	36 (40%)	32 (41.03%)	99 (34.98%)
3–5 km	31 (26.96%)	15 (16.67%)	8 (10.26%)	54 (19.08%)
More than 5 km	22 (19.13%)	9 (10%)	13 (16.67%)	44 (15.55%)
Education				
None	3 (2.61%)	5 (5.56%)	3 (3.85%)	11 (3.89%)
Grade 7 (primary school)	20 (17.39%)	6 (6.67%)	6 (7.69%)	32 (11.31%)
Grade 8–11 (secondary school)	64 (55.65%)	59 (65.56%)	48 (61.54%)	171 (60.42%)
Grade 12 (completed secondary school)	25 (21.74%)	16 (17.78%)	20 (25.64%)	61 (21.55%)
Tertiary	3 (2.61%)	4 (4.44%)	1 (1.28%)	8 (2.83%)
Employment status				
Working for pay	23 (20.00%)	19 (21.11%)	20 (25.64%)	62 (23.4%)
Homemaker/working without pay	4 (3.48%)	2 (2.22%)	1 (1.28%)	7 (2.64%)
Full-time scholar or student	2 (1.74%)	3 (3.33%)	0 (0.00%)	5 (1.89%)
Long-term sick/disabled/retired	11 (9.57%)	7 (7.78%)	3 (3.85%)	21 (7.92%)
Unemployed	66 (57.39%)	55 (61.11%)	49 (62.82%)	170 (64.15%)
Other	9 (7.83%)	4 (4.44%)	5 (6.41%)	18 (6.79%)
Household income				
Under R 2000 (< \$133USD)	87 (75.65%)	62 (68.89%)	51 (65.38%)	200 (70.67%)
R 2000–R 5000 (≥ \$133–\$333USD)	22 (19.13%)	21 (23.33%)	22 (28.21%)	65 (22.97%)
R 5000–R 10,000 (≥ \$333–\$667USD)	4 (3.48%)	5 (5.56%)	5 (6.41%)	14 (4.95%)
More than R 10,000 (> \$667USD)	2 (1.74%)	2 (2.22%)	0 (0%)	4 (1.41%)

Note: Categories that do not sum to 100% are due to missing data. Abbreviations: IQR, interquartile range; TB, tuberculosis.

3.2 | DCE main effects

Compared to once-off support, participants had a significant preference monthly compared to once-off support ($\beta = 0.167$; 95% CI: 0.01–0.32), but no significant preference between support offered weekly or as needed. Similarly, participants revealed a relatively strong and significant preference for indi-

vidual face-to-face support compared to group ($\beta = -0.142$; 95% CI: -0.27 to -0.02) or phone-based ($\beta = -0.222$; 95% CI: -0.36 to -0.09) models of support. Participants did not reveal any significant preferences for who provides the support, or where the support is delivered (Figure 1).

Preferences for treatment delivery attributes were stronger than those for support delivery. Compared to standard clinic

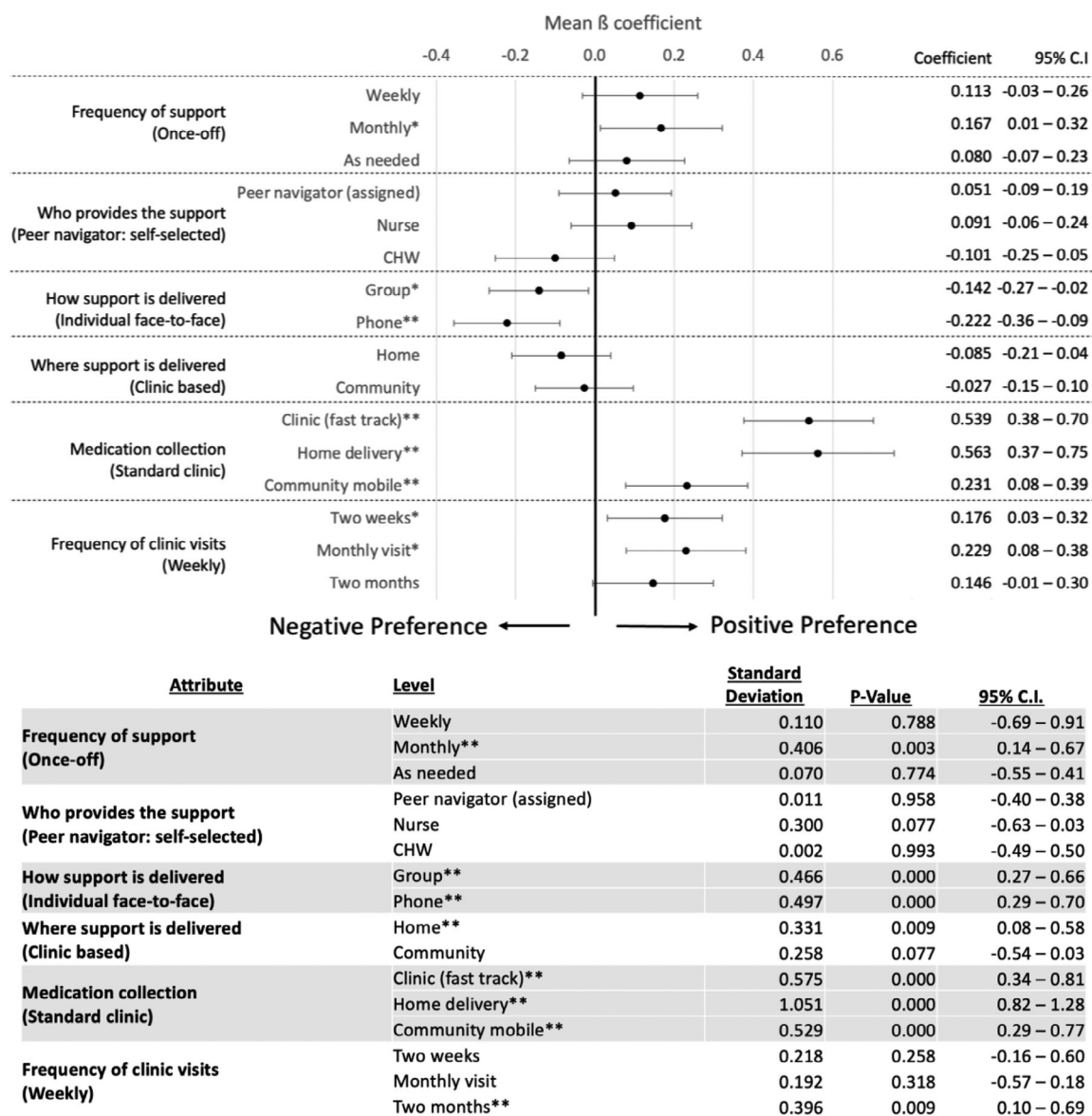


Figure 1. Mixed effects logistic regression main effects. **Top Figure:** Mean β -coefficients quantify the relative utility estimates, represented as point estimates. Error bars represent 95% confidence intervals. Numeric Mean β -coefficient estimates and 95% confidence intervals are shown on the right of the figure. **Bottom Table:** Standard deviation estimates for each of the mean β -coefficients along with 95% confidence intervals and p -values. *Notes significant findings (p -value < 0.05); **Notes highly significant findings (p -value < 0.01); Abbreviations: CHW, community health worker; CI, confidence intervals.

collection, participants had a slight preference for treatment pick-ups from a mobile community-based location ($\beta = 0.231$; 95% CI: 0.08–0.39), and strong preferences for a fast-track clinic-based model ($\beta = 0.539$; 95% CI: 0.38–0.70) and home delivery model ($\beta = 0.563$; 95% CI: 0.37–0.75) for treatment collection. Participants also had a strong preference for monthly compared to weekly clinic visits ($\beta = 0.229$; 95% CI: 0.08–0.38) and for visits every 2 weeks compared to weekly visits ($\beta = 0.176$; 95% CI: 0.03–0.32).

Standard deviation estimates reveal significant divergence in preferences regarding where treatment (clinic fast-track p -value < 0.001; home delivery p -value < 0.001; community

mobile p -value < 0.001) and support (home p -value < 0.001) are delivered, how adherence support is delivered (group support p -value < 0.001; phone-based support p -value < 0.001) and how frequently treatment (2 months p -value = 0.009) and support (monthly p -value = 0.003) are delivered. This finding of preference heterogeneity within the sample is explored more in the stratified analysis by gender and treatment group, as well as in the latent class analysis (LCA). The standard deviation estimates also suggest relatively consistent preferences for who provides the support, for frequency of support and for frequency of clinic visits (i.e. insignificant p -values across most of the levels in these attributes).

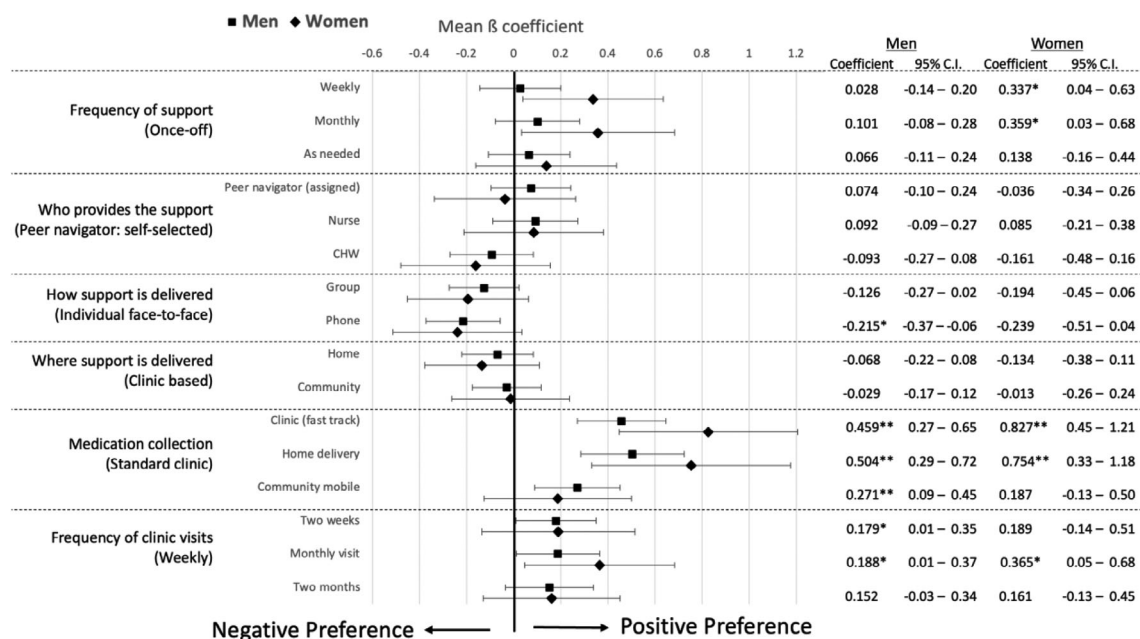


Figure 2. Mixed effects logistic regression stratified by gender. Mean β -coefficients quantify the relative utility estimates, represented as point estimates. Error bars represent 95% confidence intervals. Numeric Mean β -coefficient estimates and 95% confidence intervals are shown on the right of the figure. *Notes significant findings (p -value < 0.05); **Notes highly significant findings (p -value < 0.01). Abbreviation: CI, confidence intervals.

3.3 | Secondary analyses

3.3.1 | Preference structures by gender

We found little divergence in preferences across gender (Figure 2). However, although the 95% confidence intervals are wide and overlapping, we note that while men seemed indifferent between alternatives for frequency of support, women had a significant preference for weekly ($\beta = 0.337$; 95% CI: 0.04–0.63) or monthly support ($\beta = 0.359$; 95% CI: 0.03–0.68) compared to once-off support. Women also had a stronger preference than men for in-clinic fast-tracking ($\beta = 0.827$; 95% CI: 0.45–1.21) and home delivery models of treatment collection ($\beta = 0.754$; 95% CI: 0.33–1.18) compared to standard clinic-based treatment collection. In addition, men's preference for face-to-face support compared to phone-based models of support was significant ($\beta = -0.215$; 95% CI: -0.37 to -0.06).

3.3.2 | Preference structures by treatment group

Preferences did not diverge substantially between treatment groups (Figure 3). However, some findings are worth noting. *Frequency of support.* Participants currently on treatment had a significant preference for monthly support ($\beta = 0.318$; 95% CI 0.07–0.57), while participants in the other two groups' preferences regarding frequency of support were not significant.

Who provides the support. There was no provider that participants significantly preferred to a self-assigned peer navigator. Among participants at-risk for loss-to-care, there is a statistically meaningful preference for a nurse compared to a CHW (95% CIs do not overlap β -coefficient estimates).

How support is delivered. First, participants at-risk for being loss-to-care had a significant preference for individual face-to-face support compared to group-based models of support ($\beta = -0.343$; 95% CI: -0.67 to -0.02); this was not significant for participants in the other two groups. Second, participants currently on treatment expressed a significant preference for individual face-to-face support compared to phone-based support ($\beta = -0.225$; 95% CI: -0.47 to -0.04); this was not significant in the other two groups.

Medication collection. First, participants currently on treatment ($\beta = -0.543$; 95% CI: 0.29–0.79) and those who recently completed treatment ($\beta = -0.903$; 95% CI: 0.57–1.23) had a stronger preference for clinic-based fast-track medication collection compared to standard clinic collection; this was not significant for participants at-risk for being loss-to-care. Second, participants who had recently completed treatment had a significant preference for community mobile medication collection compared to standard clinic collection ($\beta = -0.41$; 95% CI: 0.15–0.68); this was not significant for participants in other groups. Third, all participant groups had a significant preference for home delivery of treatment compared to standard clinic collection of their medication.

Frequency of clinic visits. Participants currently on treatment showed a significant preference for less frequent clinic visits ($\beta = -0.225$; 95% CI: -0.47 to -0.04); this was not significant for participants in other groups.

3.3.3 | Latent class analysis

Three latent class models were explored (with two, three and four classes, respectively). The mean predicted probability of all three models was high, and the AIC and BIC measures for

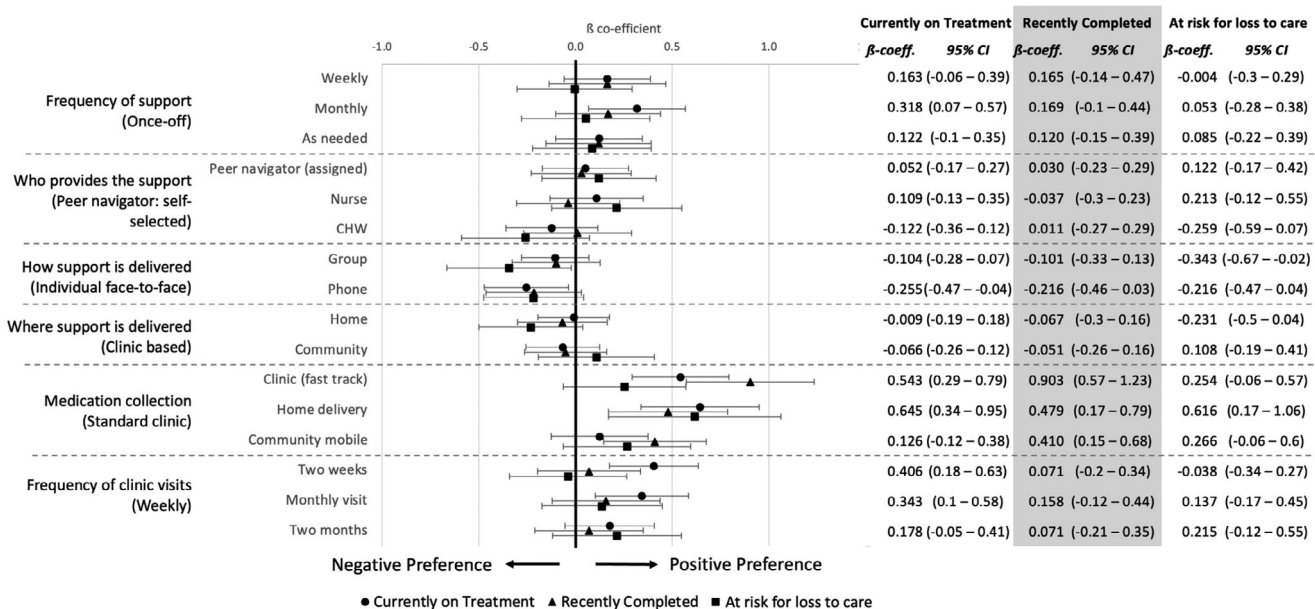


Figure 3. Mixed effects logistic regression stratified by treatment group. Mean β -coefficients quantify the relative utility estimates, represented as point estimates. Error bars represent 95% confidence intervals. Numeric Mean β -coefficient estimates, and 95% confidence intervals are shown on the right of the figure. Abbreviations: CHW, community health worker; CI, confidence intervals.

Table 4. Latent class model fit statistics

	Number of observations	Log-likelihood	Akaike Information Criterion	Bayesian Information Criterion	Mean probability of class membership
Two-class model	6816	-2242.8521	4551.7038	4672.12	0.9744865
Three-class model	6816	-2213.3963	4526.7921	4709.2408	0.8750903
Four-class model	6816	-2193.74	4521.48	4765.9613	0.8727274

model fit did not suggest an objectively better fit of any of the three models. The three-class model fit the data best based on the log-likelihood and BIC criterion and had a high mean probability of class membership (see Table 4).

The two- and four-class models produced very small class sizes for all but one of the classes. We thus present results from the three-class model (Table 5). Results from the two- and four-class models are presented in Supporting information File S2. We found no significant correlations between socio-demographic characteristics and class membership.

Class 1 contained 176 (61.97%) participants, characterised by a preference for home-based compared to clinic-based support, and for home or community mobile delivery of treatment compared to standard clinic medication collection. Participants in this class also preferred clinic-based fast-tracking of medication collection compared to standard clinic-based medication collection. Participants in Class 1 had a significant preference for monthly compared to weekly clinic visits, and monthly support or support provided as needed compared to once-off support. Participants in Class 1 preferred not to have support delivered by CHWs compared to a self-selected peer navigator, and preferred not to have support delivered using group models, compared to individual face-to-face support.

Class 2 contained 80 (28.17%) participants, characterised by a preference for clinic-based support compared to support delivered at home or in the community, and for medication delivered to their home or picked up in the community compared to standard clinic-based medication collection. These participants had a significant preference for clinic-based fast-tracking of medication collection compared to standard clinic-based medication collection. Participants in Class 2 had a significant preference for individual face-to-face support compared to support delivered by phone.

Class 3 contained 28 (9.86%) participants, characterised by a preference for home delivery of medication, community mobile medication collection and a fast-track clinic-based model for medication collection compared to the standard clinic-based model. There was also a significant preference for once-off support compared to monthly, weekly or as-needed support. Class 3 participants also preferred: (1) a self-selected versus an assigned peer navigator to deliver support to them; (2) group models of support compared to individual face-to-face support; and (3) not to have support delivered by phone compared to individual face-to-face support. Finally, there was a preference in this class for clinic visits every 2 weeks compared to clinic visits every week.

Table 5. Latent class analysis results for a three-class model

Attribute (reference category)	Level	Class 1 (n = 176)	Class 2 (n = 80)	Class 3 (n = 28)
		Coeff. (SE)	Coeff. (SE)	Coeff. (SE)
Frequency of support (Once-off)	Weekly	0.106 (0.09)	0.127 (0.18)	−2.503 (1.07) ^b
	Monthly	0.267 (0.11) ^b	−0.01 (0.20)	−4.292 (2.01) ^b
	As needed	0.210 (0.09) ^b	−0.17 (0.17)	−2.375 (1.30) ^a
Who provides the support (Peer navigator: self-selected)	Peer navigator	0.023 (0.09)	0.088 (0.17)	−2.405 (1.15) ^b
	Nurse	−0.027 (0.09)	0.250 (0.17)	1.507 (1.00)
	CHW	−0.173 (0.10) ^a	0.073 (0.19)	−1.034 (1.02)
How support is delivered (Individual face-to-face)	Group	−0.205 (0.08) ^b	0.024 (0.14)	2.442 (1.05) ^b
	Phone	−0.07 (0.08)	−0.375 (0.15) ^c	−2.93 (1.41) ^b
Where support is delivered (Clinic-based)	Home	0.194 (0.09) ^b	−0.696 (0.21) ^c	−1.125 (1.05)
	Community	0.089 (0.08)	−0.327 (0.18) ^a	−1.049 (0.84)
Medication collection (Standard clinic)	Clinic (fast-track)	0.348 (0.1) ^a	0.296 (0.17) ^a	9.899 (3.84) ^c
	Home delivery	0.627 (0.13) ^a	−0.701 (0.21) ^c	14.092 (4.84) ^c
	Community mobile	0.327 (0.11) ^a	−0.425 (0.18) ^b	7.665 (2.74) ^c
Frequency of clinic visits (Weekly)	Two weeks	0.071 (0.09)	0.226 (0.16)	4.171 (1.77) ^b
	Monthly visit	0.265 (0.09) ^a	−0.056 (0.19)	−0.080 (0.83)
	Two months	0.117 (0.10)	0.043 (0.20)	0.672 (0.56)

Abbreviations: CHW, community health worker; SE, standard error.

^{a-c} Significance at 10% (a), 5% (b) and 1% (c) levels.

4 | DISCUSSION

This is one of the first studies using a DCE to identify the preferences of people on TB treatment for service delivery models of TB treatment and support interventions in South Africa. Study participants prioritised treatment service delivery model characteristics above adherence support model characteristics. Participants preferred less frequent clinic visits, and fast-track medication pick-up, community-based or home delivery of treatment were favoured over standard clinic medication pick-up, a finding consistent with global guidance for designing differentiated models of care [42]. Fast-track clinic-based models for providing differentiated treatment services have been applied in different ways for HIV treatment, but share the same broad characteristic of creating separate queues, medication pick-up points or patient flow procedures at a health facility to speed up service delivery for stable patients [43]. However, these models have not yet been systematically developed or tested for stable TB patients. There was no clear preference for who (i.e. peer navigator, nurse or CHW) provided treatment support, and participants expressed preference for individual, face-to-face support rather than group- or phone-based support.

Our findings suggest that preferences for TB treatment service delivery in South Africa may not vary substantially across gender. However, preferences are likely to have distinct gendered motivations, and previous research suggests that beyond service delivery model characteristics, the content and focus of the support may need to be responsive to men's and women's specific needs. For example, masculinity conventions and social structures can affect how men interpret the severity of their illness, influencing their healthcare

behaviour [19]. Further, pervasive social expectations, including viewing men's primary role as family provider, can restrict their optimal treatment adherence and retention in care [34, 44]. For women, the perceived stigma associated with TB illness and treatment will need to be addressed to ensure care is sought [45–48].

The analysis of preference structures by treatment group suggests that preference structures were mostly consistent across groups, with a few notable exceptions. Participants at-risk for being lost-to-care had a stronger preference for individual face-to-face support over group- or phone-based models, and for support delivered by a peer navigator (either self-selected or assigned) rather than a CHW. In addition to these service delivery model considerations, efforts to reduce stigma and strengthen social support networks, mental resources and health services for people on TB treatment are likely to be equally important in subsequent intervention design [4, 34, 35].

The LCA revealed two dominant groupings of participants with similar preference structures—those who prefer community-based services (Class 1) and those who prefer clinic-based services (Class 2). A small percentage (Class 3—10%) preferred any treatment delivery option, other than standard clinic collection and community-based support. Furthermore, home-based support provided by peer navigators or nurses was preferred to support provided by CHWs. Such preferences align with studies reporting that community-based models of care could help reduce the burden on health facilities and improve the convenience of medication pick-up [49]. Our findings differed from those found in a DCE conducted in Uganda where people living with multi-drug resistant TB support to be provided by a CHW [17].

Our findings show that community-based services are not preferred by all participants and that some participants prefer clinic-based services, both in terms of medication collection and support. In particular, fast-track medication collection was preferred, highlighting the importance of improving and streamlining processes for TB treatment and support at the clinic level.

The treatment of TB does not occur within a vacuum, with substantial evidence on the linkages between HIV and TB, and a higher likelihood of mortality among people living with co-infections [50]. A consolidation of findings across studies examining preferences for differentiated models of care for both HIV and TB may be useful for the design of TB interventions and integrated services. HIV treatment studies have found a preference for less frequent visits and shorter wait times [51–53], individual adherence support [52] and fast-track health facility-based models over home-delivery or community-based models [51, 53]. Several HIV studies have also shown little difference in preference structures across gender [51, 52, 54].

Our study has several limitations. First, the limited geographic scope of the study limits its generalisability to other contexts. The small sample size in each treatment group may have prevented us from identifying all statistical differences in preferences. However, based on our results, the magnitude of these differences is likely to remain small, even if statistical significance could be improved. Further, differences in preferences may not be driven solely or primarily by gender or treatment outcomes. Although we conducted a substantial exploration of the correlation between the latent classes that emerged and socio-demographic characteristics of interest (including treatment group and gender), we found no significant correlations. This may be related to the small sample, or to complex interactions between participant characteristics (both observed and unobserved) that drive preferences. We leave for future research the task of linking participant characteristics to latent class groupings.

Third, participants were not eligible for inclusion if they were still engaged in the intensive phase of treatment meaning we could not capture preferences of people on TB treatment in this early phase, or those lost from care before the continuation phase of treatment. The data are also cross-sectional so we are unable to capture how preferences change over time.

Finally, our DCE focused on the characteristics of service delivery models for TB treatment support rather than the characteristics of the types or content of the support—a design decision based on the research question. Further investigation is needed to understand how participants value and prioritise different types of support content.

5 | CONCLUSIONS

One-size-fits-all interventions for TB treatment service delivery and adherence support will not work for all people on TB treatment in South Africa. Both clinic-based and community-based models of care and support require strengthening. Improving differentiated models for medication collection and tailoring the frequency of clinic visits to individual preferences

is key for improving treatment outcomes. In recognition of the high prevalence of TB-HIV co-morbidity, the evidence generated from this study provides valuable insights into the design and delivery of differentiated and integrated TB-HIV services [55]. While this will require significant investment, the long-term returns will be high in terms of better health, quality of life and economic productivity in a setting where HIV and TB prevalence remain high.

AUTHORS' AFFILIATIONS

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COMPETING INTERESTS

The authors declare no conflicts of interest.

AUTHORS' CONTRIBUTIONS

MS, GG, AM-M and JD conceptualised and designed the study. MS, GG, AM-M, JD and KF developed the DCE instrument and KF and EL oversaw data collection, extraction and validation. MS and EL conducted the formal analysis and all authors provided critical input for the interpretation of findings and contextualisation of results. MS, GG and JD produced the first draft, and all authors contributed critical input for finalizing the manuscript. All authors have read and approved the final manuscript.

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DATA AVAILABILITY STATEMENT

The data used for the analysis presented in this manuscript will be made available by the study PI on request.

ETHICS APPROVAL STATEMENT

Ethics approval was obtained from the Human Research Ethics Committee of the Faculty of Health Sciences, the University of Cape Town (Ref no.: 673/2019; Medina-Marino, PI), with an institutional reliance agreement by Arizona State University (Daniels, PI). Study approval was provided by the Eastern Cape Provincial Department of Health (Ref no.: EC202010_023).

PATIENT CONSENT STATEMENT

All participants provided written informed consent. Participants were provided a small snack and R50 (~\$3 USD) for their time. Study staff were trained in DCE administration, human subject's protection and good clinical practice.

MATERIAL FROM OTHER SOURCES

No material from other sources was used in this manuscript.

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SUPPORTING INFORMATION

Additional information may be found under the Supporting Information tab for this article:

Supporting file 1: Introduction to DCE Questions.

Supporting file 2: 2-class and 4-class solutions for the latent class analysis.

RESEARCH ARTICLE

Introducing differentiated service delivery models for tuberculosis treatment: a pilot project to inform national policy in Uganda

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Abstract

Introduction: Differentiated service delivery (DSD) models aim to tailor health services delivery to clients' preferences and clinical characteristics while reducing the burden on health systems. In Uganda, DSD models developed for HIV care were adapted to the tuberculosis (TB) services context to mitigate disruptions from the COVID-19 pandemic and inform national efforts to improve TB care.

Methods: Beginning in April 2021, four facility-based and five community-based DSD models were implemented in 28 TB clinics in Kampala and Soroti Regions. All clients in the intensive (months 1–2) and continuation (months 3–6) phases of treatment were eligible. Client preference and clinician concurrence determined model choice. All models allowed TB medication dispensing intervals ranging from biweekly to multi-month dispensing (MMD; ≥ 2 months). Data abstracted in December 2022 from TB registers and DSD enrolment tracking tools at 21 of 28 implementing facilities were used to evaluate the intervention. The TB treatment success rate (i.e. proportion cured or who completed treatment, vs. those who died, failed, were lost-to-follow-up or had no recorded outcome) in the DSD cohort was compared to facilities' 2018–2019 results using Fischer's exact test.

Results: Most facilities offered one (Kampala) or two (Soroti) facility-based models and one community-based model. Among 1864 TB clients enrolled between April 2021 and March 2022, 1822 (97.7%) used ≥ 1 DSD models; 210/1822 (11.5%) ever switched models. Overall, 70.5% (1284/1822) of clients enrolled in ≥ 1 facility-based model and 40.5% (737/1822) in ≥ 1 community-based model. The use of community-based models increased during the continuation phase. Facility-Based Individual Management and Home Delivery were the most-used models. In the intensive phase, the longest medication dispensation interval was biweekly for 50.0% of patients, monthly for 41.3% and MMD for 8.8%. During the continuation phase, the longest interval was biweekly for 0.6%, monthly for 71.7% and MMD for 27.6%. Overall, 1582/1864 (84.9%) clients were successfully treated, compared to 858/1177 (72.9%) in 2018–2019 ($p < 0.001$). Seven (0.4%) patients failed treatment, 32 (1.7%) were lost to follow-up, 101 (5.4%) died and 142 (7.6%) were not evaluated.

Conclusions: TB DSD models were successfully implemented. TB treatment outcomes under DSD compared favourably to historical outcomes. Investigating factors affecting MMD use and model choice could further inform programme design.

Keywords: community health services; delivery of healthcare; differentiated care; retention in care; tuberculosis; Uganda

Additional information may be found under the Supporting Information tab of this article.

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1 | INTRODUCTION

Differentiated service delivery (DSD) refers to person-centred outpatient clinical care that reflects the preferences and expectations of various groups of clients while reducing unnecessary burdens on health systems [1]. DSD models can consider the clinical (e.g. virally suppressed or not if living with HIV) or behavioural (e.g. adherent to treatment or not) characteristics of the patient, specific populations (e.g. adults, children) and context (e.g. urban, rural). They tailor service delivery along several dimensions: the services offered, timing or frequency of service delivery, delivery location and staff cadre offering the service [2]. This allows for the creation of delivery approaches that improve access to and uptake of services, reduce patient costs [3] and enhance the overall quality of care for targeted populations.

Since 2017, DSD models have become an integral part of HIV care programmes in many countries, including Uganda [4–8], evolving continually to meet the changing needs of people living with HIV (PLHIV). Evidence exists that DSD models have optimised HIV prevention and treatment services, including antiretroviral therapy (ART), while also streamlining care in contexts of limited human resources and infrastructure [5]. In addition, DSD models appear to have improved treatment outcomes for PLHIV, particularly retention in care and viral suppression [9, 10]. In contrast, DSD use in tuberculosis (TB) care has been limited primarily to the provision of TB preventive treatment among PLHIV [2, 11–14].

In Uganda, the TB DSD pilot project was developed to mitigate disruptions to healthcare service delivery by the COVID-19 pandemic, as containment measures, including movement restrictions and staff reassignments, affected the provision of care. In line with international guidelines, standard care for drug-susceptible TB patients in Uganda [15] requires frequent health facility visits. Treatment includes a 2-month intensive phase of isoniazid, rifampicin, pyrazinamide and ethambutol, followed by a 4-month continuation phase of isoniazid and rifampicin. During month 1, patients collect medications in 2-week increments. In months 2–6, drug dispensing occurs monthly. Patients collect their medications from the facility's pharmacy after being seen by the TB nurse for clinical monitoring. At months 2, 5 and 6, the visit to the facility also includes the collection of a specimen for sputum smear testing, a negative month-6 smear serving to confirm cure. Directly observed therapy (DOT) is provided in facility by a health worker (primarily to hospitalised patients) or in community by a trained community worker or a family member for treatment adherence.

At the pandemic outset, there were concerns that the negative impacts of COVID-19 on global TB programmes would reverse gains made over the past decade to reduce TB morbidity and mortality [16]. Ensuring the continuity of TB services by adopting innovative approaches for screening, diagnosis, prevention and treatment [17] was critical. In collaboration with the Uganda Ministry of Health (MOH), notably the National TB and Leprosy Program (NTLP), and with funding from the U.S. Centers for Disease Control and Prevention (CDC), the Infectious Diseases Institute (IDI) (Kampala) and The AIDS Support Organization (TASO) (Soroti) implemented a pilot project aimed at differentiating TB service

delivery, innovated around the approaches successfully used for HIV care. For TB treatment, the project focused on lessening the burden of biweekly or monthly facility-based medication dispensation. Lessons from this pilot were to inform MOH efforts to develop national guidelines on TB DSD models.

2 | METHODS

2.1 | Implementation approach

The project's long-term goal was to test innovative strategies to improve the quality of TB services using a patient-centred approach. Its short-term purpose was to ensure the continuity of TB services during the COVID-19 pandemic. The project was implemented in 28 health facilities managing rifampicin-sensitive TB patients across 16 districts in two localities, Kampala and Soroti, supported by partners implementing CDC-funded comprehensive HIV/TB projects. Selected sites were high-volume facilities not implementing any form of TB services differentiation; in Kampala, the project also targeted sites that performed sub-optimally on > 1 NTLP indicators in 2019 (Table S1) to learn lessons applicable to settings where patients stand to gain most from improvements in service delivery.

Project rollout occurred in March–November 2021 in Kampala and in April–August 2021 in Soroti. TB DSD models proposed for implementation matched the facility- and community-based models developed for HIV care in Uganda [5] (Table 1), and sites' initial offering largely reflected the models already operating for PLHIVs. Facility-Based Individual Management (FBIM) was the model closest to standard TB care. All TB patients managed at each site were eligible for enrolment into DSD, regardless of age, HIV status, clinical condition or phase of TB treatment, with model options contingent on whether a patient was categorised as stable or unstable. "Unstable" patients included those in the intensive phase, lacking reliable contact information, who had missed ≥ 2 weeks of treatment or virally unsuppressed (> 1000 copies/ml) if living with HIV. All models allowed medication dispensation intervals ranging from biweekly to multi-month dispensing (MMD; 2 months in Kampala, 2–4 months in Soroti). Suitable DSD models for a patient were proposed by clinicians based on the patient's clinical characteristics. When multiple models were suitable, enrolment considered patient preference. Model switches, at patient's request or upon clinician's recommendation, were possible during and between treatment phases. To help staff track DSD enrolment, project-specific electronic and paper-based tools were introduced for data elements not available in the routine health information system.

Importantly, in addition to introducing DSD models for TB treatment, IDI and TASO comprehensively reorganised many aspects of TB diagnosis and care service delivery through a client-centred lens. For example, rosters of TB patients were assigned to community-based volunteers supported by mentors to provide ongoing treatment literacy and monitor adherence and side effects. The use of appointment registers and pre-appointment reminders was strengthened, with same-day follow-up for patients failing to appear. Community activities

Table 1. Description of differentiated service delivery (DSD) models for tuberculosis (TB) treatment considered for implementation and eligibility in 21 health facilities, Kampala and Soroti regions, Uganda, 2021–2022

Model	Description	Eligible clients	When	Where	Who	What
FACILITY						
Facility-Based Individual Management (FBIM)	A more intensive model for patients needing in-person review at their drug pick-ups	S, U	Intensive and continuation phase	TB clinic and pharmacy in health facility	TB nurse Pharmacist Cough monitor Community-based volunteer	Clinical review TB drug refills Adherence support Psychosocial support Laboratory tests
Fast-Track Drug Refill (FTDR)	Client picks up TB drugs from pharmacy on scheduled appointment date without first seeing clinician	S	Continuation phase	Pharmacy in health facility	Pharmacist/dispenser	TB drug refills without seeing the clinician alternating with scheduled clinician reviews every 1–2 months
Refill Alignment with Comorbidities (RAC)	Client receives TB drugs along with medication for another chronic condition (e.g. HIV); appointment dates are harmonised	S	Continuation phase	Pharmacy in health facility	Pharmacist/dispenser	TB drug refills
Facility-Based Group (FBG)	Patient attending specialty clinics (e.g. comorbidities, high viral load) is attended to in that clinic	S, U	Intensive and continuation phase	HIV clinic or any other specialty clinic in health facility	Health worker Peers	Adherence support Psychosocial support
COMMUNITY						
Home Delivery (HD)	Cough monitors on motorcycles deliver TB drugs to patients' home; health workers may ride along to check on unstable patients	S, U	Intensive and continuation phase	Patient home	Motorcycle driver Cough monitor Health worker	TB drug refills Clinical monitoring Adherence support Psychosocial support Sputum collection
Community Drug Distribution Points (CDDP)	TB drugs delivered to location convenient to 5+ patients in given area	S	Continuation phase	Any community location	Health worker Peers Pharmacist	TB drug refills Clinical evaluation by health worker if integrated into HIV outreach programme
Community Pharmacy Refills (CPR)	Patient picks up TB drugs at community retail pharmacy	S	Continuation phase	Retail pharmacy in community	Retail pharmacist	TB drug refills

(Continued)

Table 1. (Continued)

Model	Description	Eligible clients	When	Where	Who	What
Community Refill Groups (CRG)	TB drugs resupply distributed through community-based support groups	S, U		Any community location		TB drug refills
Community Client-Led Distribution (CCLD)	Delivery of medication at the community level to a community TB group by one of the group members on a rotational basis	S	Continuation phase	Any community location	Peers/expert client	TB drug refills

Abbreviations: S, stable (patient in continuation phase, with valid contact information/address, virally suppressed if living with HIV, with no treatment interruption ≥ 2 weeks); U, unstable (patient in intensive phase, with unreliable contact information, virally unsuppressed if living with HIV, with treatment interruptions ≥ 2 weeks, sputum smear positive at month 2 or month 5).

were integrated: for example home deliveries integrated sputum sample collection for treatment follow-up.

2.2 | Evaluation

To describe the implementation of DSD models and relate changes in TB service delivery with TB treatment outcomes (defined according to World Health Organization criteria [18] and national guidelines [15]), data were abstracted from TB unit registers and DSD enrolment tracking tools at 21 of the 28 pilot facilities. All TB patients registered in the 21 pilot facilities between the facility's implementation start date (March–November 2021) and March 2022 were included in the implementation cohort, and their deidentified individual-level data was abstracted retrospectively. As a measure of TB care quality under DSD, we assessed whether bacteriologically confirmed pulmonary (PBC) TB patients received follow-up sputum smears at months 2, 5 and 6 to monitor progress towards cure, as less frequent encounters or community-based care might hamper timely sputum collection. To assess the relative performance of DSD compared to traditional service delivery in ensuring treatment success (i.e. cured or completed treatment), a historical cohort of patients registered for TB treatment at the same facilities during the corresponding months of 2018–2019 (i.e. March–November 2018, depending on the facility, until March 2019) was selected. Patients registered in 2020, when the health system was experiencing the greatest pandemic-related upheavals, were purposively excluded. For the historical comparison cohort, only aggregate (monthly) data were collected from facilities' TB registers. TB treatment outcomes were abstracted as assigned by facility clinicians.

Data abstraction was performed by research assistants trained on the DSD models, evaluation protocol, field procedures and data sources. The data abstraction censor date was 23 December 2022. Data abstraction tools were piloted at two non-intervention sites before being finalised and

standard operating procedures generated. Abstracted data were entered into an online database with built-in completeness and accuracy logic checks, hosted on a secure Kobo server.

Models with similar design but different labels across localities (e.g. "home delivery with on-call support" and "community-supported refills") were combined for analysis. Data analysis was performed using Stata software (version 16.1, Stata Corp LLC, College Station, TX, USA). Descriptive statistics including proportions (for categorical variables) and means with standard deviations or medians with interquartile ranges (IQR) (for continuous variables) were computed. Group differences in treatment success rates (between the DSD cohort and the historical cohort as well as for subgroups within the DSD cohort) were tested using chi-square statistics for categorical variables. All tests were two-tailed; statistical significance was set at $p \leq 0.05$.

The evaluation was reviewed and approved by Makerere University School of Public Health's Research and Ethics Committee (SPH-2022-254), and the Uganda National Council for Science and Technology (HS3122ES). CDC reviewed the protocol and deemed it not research (CGH-UGDA-12/14/21-3d907). The evaluation was conducted consistent with applicable federal law and CDC policy 45 C.F.R. part 46.102(l)(2), 21 C.F.R. part 56; 42 U.S.C. §241(d); 5 U.S.C. §552a; 44 U.S.C. §3501 et seq.

3 | RESULTS

3.1 | Characteristics of patients in implementation cohort

The DSD implementation cohort (Table 2) comprised 1864 TB patients (1026 in Kampala, 838 in Soroti) who initiated treatment at 21 of 28 pilot facilities between the intervention start date (March–November 2021) and 30 March 2022. Fifty-six percent (1044/1864) were males. Median age was 38

Table 2. Characteristics of patients receiving treatment for drug-sensitive tuberculosis (TB) in differentiated service delivery (DSD) implementation cohort in 21 health facilities, Kampala and Soroti regions, Uganda, 2021–2022

Characteristic	Kampala region N = 1026 n (%)	Soroti region N = 838 n (%)	Total N = 1864 n (%)
Sex			
Male	608 (59.3%)	436 (52.0)	1044 (56.0)
Female	418 (40.7)	402 (48.0)	820 (44.0)
Age (years)			
< 15	86 (8.4)	95 (11.4)	181 (9.7)
15–24	119 (11.6)	68 (8.1)	187 (10.0)
25–34	284 (27.7)	112 (13.4)	396 (21.3)
35–44	263 (25.7)	158 (18.9)	421 (22.6)
45–54	156 (15.2)	147 (17.6)	303 (16.3)
55–64	74 (7.2)	98 (11.7)	172 (9.2)
≥ 65	43 (4.2)	158 (18.9)	201 (10.8)
Missing ^a	1	2	3
TB type			
PBC	476 (46.6)	506 (60.4)	982 (52.8)
PCD	511 (50.0)	288 (34.4)	799 (42.9)
EPTB	35 (3.4)	44 (5.2)	79 (4.3)
Missing ^a	4	0	4
Type of TB case			
New	951 (93.5)	757 (91.0)	1708 (92.4)
Relapse	45 (4.4)	60 (7.2)	105 (5.7)
Treatment after failure	3 (0.3)	7 (0.8)	10 (0.5)
Treatment after loss to follow-up	18 (1.8)	8 (1.0)	26 (1.4)
Missing ^a	9	6	15
HIV status			
Negative	502 (48.9)	513 (61.2)	1015 (54.5)
Known positive	327 (31.9)	258 (30.8)	585 (31.4)
New positive	182 (17.7)	48 (5.7)	230 (12.3)
Unknown	15 (1.5)	19 (2.3)	34 (1.8)

Abbreviations: EPTB, extrapulmonary TB; PBC, pulmonary TB, bacteriologically confirmed; PCD, pulmonary TB, clinically diagnosed.

^aMissing values are excluded from percentage calculations.

years (IQR: 27–51); 190 (10.2%) patients were ≤ 15 years of age. HIV status was known for 1830 patients (98.2%); 815 (44.5%) were PLHIV. Overall, 1708 (91.6%) were new TB cases; 1781 (95.5%) had pulmonary TB, including 982 (55.1%) with bacteriologic confirmation. Information about DSD enrolment was available for 1822 patients (97.7%). Availability of DSD modality information did not vary significantly by locality, age, sex or HIV status.

3.2 | Model rollout

Table 3 summarises model use across the two localities. Of nine DSD models considered for implementation during the project planning phase, eight were used across the two localities: five (two facility-based, three community-based) in Kampala and six (four facility-based, two community-based)

in Soroti. Most Kampala facilities offered one facility-based and one community-based model, while most Soroti facilities offered two facility-based and one community-based model.

3.3 | Facility versus community-based models

Overall, 1284/1822 patients (70.5%) enrolled in at least one facility-based model and 738/1822 (40.5%) in at least one community-based model; 1084/1822 (59.5%) patients used only facility-based models and 538/1822 (29.5%) used only community-based models. Two hundred patients (11.0%) used at least one facility-based and one community-based model over the course of treatment. FBIM and Home Delivery were the facility-based and community-based models, respectively, that enrolled the most patients (Table 3).

Table 3. Tuberculosis (TB) differentiated service delivery (DSD) model offering and enrolment in 21 health facilities, Kampala and Soroti regions, Uganda, 2021–2022^a

	KAMPALA		SOROTI		Total patients ever enrolled in model
	Facilities implementing in region	Patients ever enrolled in model in region	Facilities implementing in region	Patients ever enrolled in model in region	
FACILITY					
FBIM	12	799 (77.9%)	9	207 (24.7%)	1006 (54.0%)
FTDR	2	30 (2.9%)	8	248 (29.6%)	278 (14.9%)
RAC	0	0	1	8 (1.0%)	8 (0.4%)
FBG	0	0	2	5 (0.6%)	5 (0.3%)
HD	12	346 (33.7%)	9	352 (42.0%)	698 (37.4%)
COMMUNITY					
CDDP	2	32 (3.1%)	0	0	32 (1.7%)
CPR	1	1 (0.1%)	0	0	1 (< 0.1%)
CRG	0	0	3	24 (2.9%)	24 (1.3%)
CCLD	0	0	0	0	0

Abbreviations: CCLD, community client-led distribution; CDDP, community drug-distribution point; CPR, community pharmacy refill; CRG, community refill group; FBG, facility-based group; FBIM, facility-based individual management; FTDR, fast-track drug delivery; HD, home delivery; RAC, refill alignment with comorbidities.

^aPatients could enrol in more than one model over the course of TB treatment.

3.4 | Model switches

Only 210/1822 patients (11.5%) were recorded as having enrolled in ≥ 2 DSD models over the course of TB treatment. Model switching was more frequent in Kampala (198/1026, 19.3%) than in Soroti (12/838, 1.4%) ($p < 0.001$).

3.5 | Intensive versus continuation phase

Information about model enrolment disaggregated by TB treatment phase was available for a subset of 1698 patients (93.2%). Enrolment in facility-based models was stable across treatment phases (approximately 70.0%); use of community-based models increased from 33.5% (569/1698) during the intensive phase to 44.0% (668/1519) during the continuation phase ($p < 0.001$, data not reflected in tables).

3.6 | Medication dispensation

Information about drug dispensation schedules was available for 1838 patients (98.6%) during the intensive phase and 1671 patients (89.6%) during the continuation phase. In the intensive phase, a patient's longest dispensation interval was biweekly for 50.0% of patients, monthly for 41.3% and MMD for 8.8%. In the continuation phase, the longest interval was biweekly for 0.6%, monthly for 71.7% and MMD for 27.6%. Overall, 483/1864 patients (26.3%) ever received MMD during TB treatment. The likelihood of ever receiving MMD was comparable whether patients enrolled only in facility-based models (26.8%), only in community-based models (25.7%) or in both model types (24.5%).

Non-digital community DOT was the most commonly used treatment observation method among the DSD cohort (1620, 86.9%). Only 35 patients received facility-based DOT. Thirty-

nine patients, 36 from one Kampala facility, received digital community DOT.

3.7 | Follow-up smears

Among patients recorded as having PBC TB, 536 (54.6%) had a month-6 sputum smear documented in the TB register; 432/982 (44.0%) had follow-up smears at all three time points. The proportions for month 6 and all three time points were 59.2% (282/476) and 55.2% (263/476) in Kampala and 50.2% (254/506) and 33.4% (169/506) in Soroti, respectively. Among PBC TB patients enrolled in at least one community-based DSD model, 55.9% (214/383) had a month-6 smear, compared to 52.9% (376/669) among those enrolled in at least one facility-based model ($p = 0.92$). Finally, 66.4% of PBC TB patients on MMD during the continuation phase had a month-6 smear, compared to 56.5% of patients who got more frequent resupplies ($p < 0.01$).

3.8 | TB treatment outcomes

Overall, 1582/1864 patients (84.9%) in the DSD cohort were successfully treated (cured or completed treatment), compared to 858/1177 patients (72.9%, $p < 0.01$) at the same facilities in 2018–2019 (Tables 4 and S2). The proportion of TB patients with undocumented outcome/not evaluated was lower in the DSD cohort than in the historical cohort. In the DSD cohort, the probability of treatment success was higher in Kampala than in Soroti, and in women compared to men, but differences in treatment success rates by HIV status and TB patient type were not statistically significant (Table 5).

Table 4. Tuberculosis (TB) treatment outcomes for individual models and for overall differentiated service delivery (DSD) and comparison cohorts in 21 health facilities, Kampala and Soroti regions, Uganda, 2021–2022^a

TB treatment outcome	Facility-based models				Community-based models				Overall DSD cohort	Historical comparison cohort
	FBIM	FTDR	RAC	FBG	HD	CDDP	CPR	CRG		
	N = 1006 ^b	N = 278 ^b	N = 8 ^b	N = 5 ^b	N = 698 ^b	N = 32 ^b	N = 1 ^b	N = 24 ^b	N = 1864	N = 1177
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Cured/completed	843 (83.8)	242 (87.1)	5 (62.5)	5 (100)	629 (90.1)	31 (96.9)	1 (100)	21 (87.5)	1582 (84.9) ^c	858 (72.9) ^c
Lost to follow-up	15 (1.5)	7 (2.5)	0	0	7 (1.0)	0	0	3 (12.5)	32 (1.7)	100 (8.5)
Failed	4 (0.4)	2 (0.7)	0	0	1 (0.1)	0	0	0	7 (0.4)	9 (0.8)
Died	70 (7.0)	10 (3.6)	1 (12.5)	0	21 (3.0)	1 (3.1)	0	0	101 (5.4)	82 (7.0)
No recorded outcome ^d	74 (7.4)	17 (6.1)	2 (25.0)	0	40 (5.7)	0	0	0	142 (7.6)	128 (10.9)

Abbreviations: CDDP, community drug-distribution point; CPR, community pharmacy refill; CRG, community pharmacy refill; FBG, community pharmacy refill; FBIM, facility-based individual management; FTDR, fast-track drug delivery; HD, home delivery; RAC, refill alignment with comorbidities.

^aPatients in DSD cohort could enrol in more than one DSD model over the course of TB treatment.

^bDSD cohort patients ever enrolled in the model during either intensive or continuation phase of TB treatment.

^cThe *p*-value for the chi-square test of significance comparing the treatment success rates (proportion of patients recorded as cured or having completed treatment) was < 0.0001.

^dOutcome field in TB register left blank or patient marked as not evaluated.

Table 5. Tuberculosis (TB) treatment outcomes in the differentiated service delivery (DSD) cohort in 21 health facilities, Kampala and Soroti regions, Uganda, 2021–2022, by region, sex, HIV status and type of TB case

	Unsuccessful outcome n (%)	Successful outcome n (%)	Relative risk of experiencing a successful outcome			
			Risk ratio	95% CI	X ²	p value
By region						
Soroti (n = 838)	136 (16.6)	699 (83.4)	Reference			
LTFU	22 (2.6)					
Failed	4 (0.5)					
Died	53 (6.3)					
Not recorded ^a	60 (7.2)					
Kampala (n = 1026)	126 (14.0)	883 (86.0)	1.04	1.00–1.09	5.41	0.0200
LTFU	10 (1.0)					
Failed	3 (0.3)					
Died	48 (4.7)					
Not recorded ^a	82 (8.0)					
By sex						
Male (n = 1044)	178 (17.0)	866 (83.0)	Reference			
LTFU	15 (1.4)					
Failed	5 (0.5)					
Died	65 (6.2)					
Not recorded ^a	93 (8.9)					
Female (n = 820)	104 (12.7)	716 (87.3)	1.05	1.01–1.09	6.82	0.0090
LTFU	17 (2.1)					
Failed	2 (0.2)					
Died	36(4.4)					
Not recorded ^a	49 (6.0)					
By HIV status						
HIV negative (n = 1015)	138 (13.6)	877 (86.4)	Reference			
LTFU	19 (1.9)					
Failed	4 (0.4)					
Died	47 (4.6)					
Not recorded ^a	68 (6.7)					
HIV positive (n = 815)	130 (16.0)	685 (84.0)	0.97	0.94–1.01	2.01	0.1567
LTFU	11 (1.3)					
Failed	2 (0.2)					
Died	51 (6.3)					
Not recorded ^a	66 (8.1)					
By TB patient type						
Retreatment (n = 141)	29 (10.6)	112 (79.4)	Reference			
LTFU	3 (2.1)					
Failed	2 (1.4)					
Died	11 (7.8)					
Not recorded ^a	13 (9.2)					
New (n = 1708)	252 (14.8)	1456 (85.2)	1.07	0.98–1.17	3.42	0.0646
LTFU	29 (1.7)					
Failed	5 (0.3)					
Died	90 (5.3)					
Not recorded ^a	128 (7.5)					

Abbreviations: CI, confidence interval; LTFU, lost to follow-up.

^aOutcome field in TB register left blank or patient marked as “not evaluated.”

4 | DISCUSSION

This evaluation documents the successful piloting of TB DSD models in Uganda in the context of the COVID-19 epidemic. The national-level TB treatment success rate increased from 78.3% in 2018–2019 to 88.9% in 2021 [19]. Results at pilot sites show a similar trend, even with flexibilisation of medication pick-up schedules and location, including in Kampala sites selected for their suboptimal pre-intervention performance on a range of TB indicators. Improvements in the treatment success rate appear to be due primarily to improved tracking of patients throughout treatment, as measured in the decreased proportion of patients lost-to-follow-up, not evaluated or with no recorded outcome in the DSD cohort. Examples of interventions that improved retention and tracking included strengthening the role of community-based volunteers, conducting cohort reviews and developing individual follow-up plans for each client. These methods were integrated into routine practice at pilot sites and expanded to other facilities. Their implementation beyond the evaluation phase demonstrates their feasibility. However, resource availability remains a critical factor for long-term adoption.

The Uganda approach to DSD for TB care is inclusive: it does not limit eligibility to patients deemed “stable” (clinically or socially) and modulates the intensity of follow-up to match patients’ needs and preferences. FBIM, the model that is closest to standard-of-care for TB treatment and was the most-used facility-based model during the pilot, still allows flexibility through MMD to decrease the frequency of clinic attendance. In addition, FBIM varies from standard of care, because participation in FBIM is chosen by, rather than imposed upon, TB patients. Home Delivery, the most-used community-based model, is particularly well-suited for sicker patients who struggle to attend health facilities for drug pick-ups and clinical monitoring. Uganda’s approach frames DSD as a person-centred approach tailored to each person’s needs, not as a reward for those showing good adherence or clinical improvement.

The pilot facilities provide TB services to drug-susceptible TB patients only. Therefore, the evaluation could not ascertain how DSD could serve patients with drug-resistant TB, who, facing even greater adherence challenges, stand to benefit considerably from differentiated care. All-oral short-course regimens for drug-resistant TB, now available in Uganda, create opportunities for differentiation mirroring those offered to patients with drug-susceptible TB. However, resource-related factors (e.g. drug availability) need to be considered.

While the project intended to offer the same broad range of DSD options available for HIV care, evaluation data show that TB patients’ DSD enrolment was highly concentrated in a few models. Counterintuitively, more community-based models were used in Kampala (mostly urban/peri-urban, with working/mobile population) and more facility-based models in Soroti (more rural, less densely populated). It is unclear whether this reflected patients’ preferences or the difficulty of delivering community care in rural settings. Evidence of the latter may be seen in the plurality of Soroti patients opting for community-based models, while patients in Kampala more frequently opted for facility-based models. This suggests that the geographic context of service delivery might

affect both patient preferences and health facilities’ ability to offer certain DSD options. In addition, the pilot showed that community-based group models previously shown to work well for patients on ART [4, 6–7] did not translate easily to the context of TB service provision. Because there are far fewer TB patients in a given locality at a given time and TB treatment is relatively short, Community Drug Distribution Points were more difficult to set up for TB than for ART. Similarly, the Community Pharmacy Refills network for antiretrovirals distribution, which uses local retail pharmacies as medication pick-up points, struggled to onboard new pharmacies in areas where HIV-negative TB patients reside. In addition, site staff reported during project monitoring visits that some clients expressed fears of stigma and loss of privacy in association with community models. This is a reminder for planners and policymakers that a broad range of factors impact programme design and that “one coat will not fit all” across diseases. Investigating these factors may be informative prior to expanding DSD to other settings in Uganda and beyond to strike the right balances between patient needs and preferences and feasibility. Some barriers might disappear over time, as networks of community distribution points, be they retail pharmacies or patient support groups, mature and become established beyond the shorter-term perspective of this pilot intervention. Greater patient enrolment in a broader range of models will in turn generate more granular data to evaluate the relative performance of individual models.

The evaluation found that few patients switched models over time. This could indicate that the models offered by the facilities, coupled with the MMD option, met patients’ needs and preferences. It could also reflect the fact that individual sites offered a limited range of model options, although all sites offered at least two (one facility-based, one community-based). Yet, another explanation might be the relatively short span of TB treatment (6 months), compared to lifelong ART, which affords less time (and less need) to plan for transitions to different models [20]. TB patients’ relative stability may assuage concerns about the need for substantial health staff effort to track patients’ changes of modality over time.

Overall, approximately a quarter of patients in the DSD cohort benefited from MMD at some point during TB treatment. This relatively low estimate may reflect health workers’ lack of awareness or initial reluctance to vary from standard practice. It could also correlate with site-level tensions on TB drug stocks that may have constrained dispensing to ensure that all patients were served. In this evaluation, we were unable to disaggregate the analysis by length of MMD interval (2 months vs. longer). As evidence becomes available about longer dispensing intervals (e.g. 4 months during the continuation phase), especially among patients on ART, combined with the introduction of shorter treatment regimens, there may be opportunities to further decrease the burden of treatment on TB patients.

Across all DSD models, evaluation findings highlight the need to reinforce to TB patients and to health staff the importance of performing follow-up smear evaluations at intervals set by national TB guidelines and recording their results, so the paramount goal of successful treatment is not jeopardised. Strategies could involve strengthening community sputum sample collection, aligning sputum collection with clinic

visits, and issuing reminders to both staff and patients. Importantly for DSD, patients in less intensive modalities, particularly those receiving MMD or enrolled in community models, were no less likely to undergo follow-up sputum smear testing than patients receiving facility-based care or more frequent drug distribution.

This evaluation had several limitations. First, the design did not include a set of control sites. Therefore, we cannot dismiss the possibility that, although statistically significant, improved treatment success rates in the DSD cohort reflected a national or locality-wide improvement in TB outcomes attributable to other MoH- or donor-backed efforts. Second, it is difficult to isolate the effect of DSD from that of other concurrent modifications to TB case management (e.g. the use of appointment registers and pre-appointment reminders), as both TASO and IDI comprehensively reorganised their approaches through a patient-centred lens. Some of these interventions, including the provision of intensive education and psychosocial support to patients, unmeasured in our evaluation, may well be essential to the success of DSD. Third, included sites represent a variety of care settings, but their small number might limit generalisability. Additionally, the use of aggregate data for the historical cohort hampers our ability to assess whether the two cohorts' composition (e.g. age, HIV status) was similar. Moreover, as in any evaluation relying on retrospectively abstracted programmatic data, we could not ascertain whether the absence of information (e.g. about follow-up smears) reflected the non-provision of a service or failure to record it appropriately. Similarly, the "true" status of patients with no TB treatment outcome or categorised as lost-to-follow-up was not ascertained. Furthermore, without detailed information about individual patients' clinical status, we could not control for disease severity when assessing the relationship between model participation and treatment outcomes. Finally, the scope of the evaluation did not include an assessment of the DSD approach's sustainability or scale-up cost implications, nor of its impact on participating sites' patient management practices beyond the intervention phase.

5 | CONCLUSIONS

Uganda's pilot of DSD for TB treatment to mitigate the impact of the COVID-19 pandemic while improving the quality of TB care built on experience gained in HIV care. Treatment outcomes under DSD models compare favourably with pre-pandemic results in the same facilities. Although not without limitations, this evaluation adds to the evidence base about the differentiation of services by national TB programmes to improve quality, efficiency, impact and potentially patient satisfaction. As models mature and more data become available to evaluate effectiveness, investigating patient and staff perspectives, and costs, efficiency and sustainability, will also be needed.

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COMPETING INTERESTS

The authors have no competing interests to declare.

AUTHORS' CONTRIBUTIONS

Funding acquisition: BM, DL, JK and JNK. *Principal investigators:* MNM and ST. *Conceptualization of project:* AB, BM, CK, DL, EB, EQ, HL, IA, ID, JK, JNK, MM, MS, PA, PN, RB, SA, SD and ST. *Project methodology/protocol development:* AB, BM, CK, DL, EB, EQ, HL, IA, ID, JK, JNK, MM, MS, OF-D, PA, PN, RB, SA, SD and ST. *Data collection/abstraction:* JBK, JN, MNM and SA. *Data analysis:* BN, JBK, JN and OF-D. *Manuscript drafting and finalisation:* OF-D. *Manuscript review and editing:* BM, BN, DL, JBK, JK, JNK, MM and MNA. *Project administration:* BN, IA, PA, PN and ST. *Project supervision:* AB, CK, DL, EQ, HL, IA, JK, JNK, MNM, MS, PA, PN, RB, SA and ST. All authors read and approved the final manuscript.

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DISCLAIMER

The findings and conclusions are those of the authors and do not necessarily represent the official position of the funding agencies.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

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SUPPORTING INFORMATION

Additional information may be found under the Supporting Information tab for this article:

Table S1: Selection criteria for health care facilities included in the differentiated service delivery (DSD) pilot project in Kampala and Soroti regions, Uganda, 2021-2022.

Table S2: Tuberculosis (TB) treatment outcomes by category of differentiated service delivery (DSD) model in 21 health facilities, Kampala and Soroti regions, Uganda, 2021-2022.

RESEARCH ARTICLE

Data-informed Stepped Care (DiSC) to improve adolescent and young adult HIV care outcomes in Kenya: a cluster randomized trial

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Abstract

Introduction: Systematic use of data-driven tools to allocate care services based on needs, including differentiated care for stable individuals and intensive care for those with higher risk, may improve retention and viral suppression in adolescents and young adults living with HIV (AYLHIV).

Methods: This cluster randomised trial in western Kenya tested a data-informed stepped care intervention that assigned AYLHIV to four intensities of care according to need. AYLHIV at 12 intervention facilities underwent step assignment at each visit; those at lowest risk were offered differentiated models of service delivery (DSD), and those with risk factors more intensive services. AYLHIV at control sites received standard care. AYLHIV were followed for 12 months. Clinical and viral load data were abstracted from medical records. The primary outcome was the proportion of missed visits (defined as > 30 days late for scheduled visit). Secondary outcomes included loss to follow-up, viral non-suppression and assignment to DSD (multi-month refills or pharmacy fast-track visits). Mixed effects regression was clustered by individual and facility and adjusted for outcomes during the pre-enrolment period and baseline variables that differed by arm.

Results: Between April and July 2022, 1911 AYLHIV ages 10–24 were enrolled (control: 1016, intervention: 895, 1708.8 person-years). Median age was 17, and 1512 (79.5%) were in school. Characteristics were balanced by arm, except for a higher proportion coming to the clinic alone in control arm (68.5% vs. 61.1%, $p = 0.04$). At intervention facilities, using the DiSC tool, 574 (64.6%) AYLHIV were assigned to DSD, 122 (13.7%) to standard care, 100 (11.3%) to mental health and retention counselling, and 92 (10.4%) to intensive case management. Missed visits were 8.5% in intervention versus 8.3% in control (adjusted risk ratio [aRR]: 1.04, 95% CI: 0.89–1.20); viral non-suppression (7.7% vs. 9.7%, aRR 0.79 95% CI: 0.54–1.16) and antiretroviral therapy adherence (92.8% vs. 94.6%, aRR 0.98 95% CI: 0.94–1.02) were similar between arms. AYLHIV in the intervention arm received more fast-track visits (aRR 1.21, 95% CI: 1.01–1.46). Intervention facilities experienced fewer scheduled appointments compared to control (aRR: 0.95, 95% CI: 0.91–0.98, $p = 0.004$).

Conclusions: Overall, missed visits and non-suppression were infrequent (< 10%) and did not decrease with the DiSC intervention. The DiSC intervention resulted in increased assignment to differentiated services without increasing missed visits or viral non-suppression.

Keywords: adolescents and young adults; ART adherence; differentiated service delivery; retention; stepped care; viral suppression

Additional information may be found under the Supporting Information tab of this article.

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1 | INTRODUCTION

There are an estimated 3.7 million adolescents and young people (ages 10–24) living with HIV worldwide, of whom

82% live in sub-Saharan Africa [1]. Globally, adolescents and young adults living with HIV (AYLHIV) experience disproportionately poor care outcomes—including viral non-suppression and lower retention in care—compared to other age groups

[2, 3]. In Kenya, 56% of 15- to 24-year olds living with HIV are virally suppressed, compared to 71% of those ages 25–49 [4].

The World Health Organization (WHO) recommends differentiated models of service delivery (DSD) for HIV treatment as a client-centred approach of simplifying and adapting HIV services across the care cascade to meet population needs and reduce the burden on the health system [5, 6]. DSD models may be group-focused (managed by healthcare workers [HCWs] or clients) or individual-focused (based at facilities or not) and may include multi-month refills, pharmacy fast-track visits and/or community-based antiretroviral therapy (ART) delivery [7]. However, due to concerns over poor care outcomes, some countries have classified adolescents as “unstable” or otherwise ineligible for DSD [8, 9].

The adolescent and young adulthood life stages are a transitional time of increasing independence in seeking care and management of health [7, 8]. Those enrolled in school, particularly boarding schools which are common in Kenya and result in youth being away from home for most of the year, face additional challenges in navigating treatment schedules that may not align with school breaks [9]. Despite being not widely available to AYLHIV, differentiated approaches may better meet the needs of this population and free up HCW time to provide more intensive care to youth needing additional support.

Two different evidence-based interventions may offer a data-driven approach to safely tailor AYLHIV care to population needs: clinical prediction tools and stepped care services. Clinical prediction tools use cohort or programme data to classify individuals into high- and low-risk categories, thereby identifying those in need of intervention prior to the occurrence of poor outcomes [10–13]. Stepped care involves a process in which HCWs assign clients to different intervention steps according to their level of need [14]. The model has been used in mental healthcare to align client services with effective and appropriate interventions, starting with low-intensity treatments and systematically progressing to higher levels of care based on client monitoring [15–17]. Thus, a prediction tool for loss to follow-up could enable HCWs to identify youth at risk for missed visits and be used to assign youth into appropriate steps of service delivery—including less frequent or differentiated services, according to need.

This study aims to evaluate a data-driven, stepped care intervention assigning AYLHIV in Kenya to more- or less-intensive service steps.

2 | METHODS

2.1 | Study design

This was an unblinded 2-arm cluster randomised clinical trial of a multicomponent stepped care intervention conducted at 24 HIV care and treatment facilities located in western Kenya. The trial protocol was previously published [18] and registered at clinicaltrials.gov (NCT05007717). The cluster design was used because the intervention was adopted at the health facility level and not the individual client level. Clusters were defined as health facilities that provide HIV care and treat-

ment to AYLHIV. Intervention facilities implemented the clinical prediction tool plus stepped care model, while control sites continued their current usual care.

2.2 | Population and setting

Eligible clinics were located in Kisumu, HomaBay or Migori County, Kenya; had at least 100 AYLHIV enrolled in care, a functional electronic medical record (EMR) system and interest in participating. Adolescent and young adult clients were recruited from study sites; eligible participants were age 10–24 years old, enrolled in HIV care and aware of their HIV diagnosis.

2.3 | Randomization

Participating clinics were randomised in a 1:1 ratio using computer-generated random numbers to either intervention or control, using restricted randomization to balance county and facility size between arms. The timing of randomization was prior to the study start. Randomization was done at the University of Washington by a biostatistician not involved in study procedures. A list of clinics with their allocation arms was sent to the study team. The intervention was administered at the clinic level; it was not possible to blind participating clinics or study team members.

2.4 | Intervention

The Data-informed Stepped Care (DiSC) tool was a 10-item clinical risk assessment tool (Supporting information) that assigned a score based on risk for loss to follow-up at each clinic visit. Based on risk score, AYLHIV were assigned to different levels of care, or “steps” (Table 1). Services ranged from a relative position of increased AYLHIV autonomy to more intensive service provision for those at the highest risk. Low-risk AYLHIV were assigned to Step 1 if they were on ART for 12 months, had no opportunistic infection in the last 6 months and were virally suppressed at the last measure. Participants were eligible for Step 2 (standard of care) based on ineligibility for Step 1, duration enrolled in care < 6 months, client preference, or pregnant or breastfeeding status. Step 3 was assigned to those reporting depression as evaluated by standardised Patient Health Questionnaire-2 (PHQ-2) screening or having missed more than one clinic visit in the last 6 months. Step 4 clients were those with current unsuppressed viral loads (VLs). Services assigned to each step included: Step 1: differentiated services (fast-track pharmacy visits and longer visit intervals); Step 2: job tools for standard of care, support groups, standard visit intervals; Step 3: motivational interviewing and/or psychosocial counselling; and Step 4: adherence counselling, case management, transportation support and/or home visits. Psychosocial counselling sessions were brief, flexible, delivered by routine HIV care providers or adherence counsellors over five sessions, and adapted from problem-solving and cognitive-based therapy interventions [19, 20].

The intervention was integrated into routine care, with facility HCWs employed by the participating sites conducting the loss to follow-up (LTFU) risk assessment, step assignment and delivering services. Control sites continued with

Table 1. Overview of step eligibility and services

Step	Eligibility	Services offered
1	On antiretroviral therapy × 12 months [AND] No opportunistic infections (OIs) in last 6 months [AND] Viral suppression at last measure	Differentiated services • Longer visit intervals (when)^a • Pharmacy fast-track (where/who)
2	Does not meet criteria for Step 1 [OR] Client preference for standard care [OR] Pregnant/breastfeeding	Standard care • Job tools: OI, pregnancy, newly enrolled • Support groups (what) • Standard visit intervals (when)
3	Depression (Patient Health Questionnaire-2 [PHQ-2] ≥ 3) [OR] Missed one or more visits in last 6 months	Individual counselling • Motivational interviewing (what) • Psychosocial counselling (what)
4	Unsuppressed viral load (VL)	Intensive support services • Adherence counselling (what) • Case management (what) • Transportation support (what) • Home visits (what)

^awhen/where/who/what refers to relevant differentiated models of service delivery (DSD) building blocks.

standard-of-care approaches for adolescent clinic visits (usually 1–3 monthly visits) regardless of healthcare needs, providing additional support as needed.

2.5 | Data collection

Medical record data from all AYLHIV with at least one clinic record within the 12-month period prior to the first data abstraction date were included. EMR data abstraction was conducted at the facility or at the office of the technical partner that supports the EMR system, at baseline and every 4 months throughout the study. Routine programmatic HIV VL testing data (done 6 months after ART initiation, then annually) were abstracted from the national laboratory database of the National AIDS & STI Control Programme and/or the EMR, if available. Questionnaires were conducted to collect data on client anthropometric measures, socio-demographics, healthcare use, sexual behaviour, depression (using Patient Health Questionnaire 9 [PHQ-9]) [21], anxiety (using General Anxiety Disorder-7 [GAD-7]) [22], drug use (using WHO Alcohol, Smoking and Substance Involvement Screening Test for Young people [ASSIST-Y]) [23], social support (using Multidimensional Scale of Perceived Social Support [MSPSS] 12-item scale) [24], resilience (using Connor-Davidson Resilience Scale-2 [CDRS-2]) [25], adherence self-efficacy (using Adherence Self-Efficacy Scale [ASES]) [26], social stigma (using Youth HIV Brief Stigma Scale [YHBSS]) [27], HIV disclosure, HIV testing history, CD4 count and clinical history. Transfer-out status and treatment discontinuations were actively reviewed. Surveys were administered at enrolment and every 6 months thereafter, either in-person or over the phone by a trained study staff.

2.6 | Study outcomes

The primary trial outcome was missed visits, defined as a participant being > 30 days late for a scheduled visit. Secondary outcomes included loss to follow-up, defined as a participant not seen within 30 days of a scheduled visit and not returning to care within the 12-month study interval; viral non-suppression, defined as HIV VL > 1000 copies/ml; receipt of differentiated services (defined either as multi-month refills with long inter-visit intervals or “fast-track” pharmacy visits for expedited ART pick-up without a full clinical evaluation); and ART adherence (defined as the proportion of days with ART coverage between the most recent ART refill and the next scheduled refill date (> 80% indicating good adherence).

2.7 | Statistical analyses

The trial sample size was calculated for 80% power to detect a 14–17% increase in retention, assuming alpha = 5% and a coefficient of variation of 0.1–0.15. Missed visits were compared between study arms using mixed effects Poisson regression, clustered by individual and facility. Time to loss to follow-up was compared between arms using survival curves and Cox proportional hazards regression, with censoring of deaths or transfers. Viral non-suppression, receipt of DSD and ART adherence were each compared between study arms using mixed effects Poisson regression clustered by individual and facility. Proportions of participants ever missed a visit, ever received DSD or always good adherence were each compared between study arms using mixed effects Poisson regression clustered by facility. All analyses were intent-to-treat, using robust standard errors, adjusted for baseline level of corresponding outcomes during a 6-month pre-enrolment

period and variables that differed by arm at study enrolment. All analyses were conducted using RStudio Version 1.2.5042 (RStudio, Inc).

2.8 | Ethical considerations

Ethical approval was obtained from the University of Washington (STUDY00011096), Maseno University Ethical Review Committee (MUERC/00917/20) and the Kenya National Commission for Science, Technology and Innovation (NACOSTI 444824). Study staff obtained written consent/assent before assessing participant eligibility. If AYLHIV ages < 18 were brought to the clinic by a caregiver, the caregiver provided written informed consent and the AYLHIV assented to participate. AYLHIV ages < 18 who met the definition of emancipated minor (pregnant/has child, married/partnered, financially or otherwise independent of parents) or mature minor (age 15, living apart from parents and managing own finances) under Kenyan law were able to provide written consent as adults. A waiver of parental permission was obtained for AYLHIV ages 15–17 years who did not meet emancipated or mature minor criteria and whose caregivers were not present. Enrolment for all AYLHIV ages < 15 years of age required caregiver consent. Severe adverse events were monitored and reported to the trial Data Safety Monitoring Board and study monitors in real time.

3 | RESULTS

Between 19 April 2022 and 19 July 2022, 1974 AYLHIV were screened for eligibility at 24 study facilities. Of those screened, 1967 AYLHIV (99.6%) were found to be eligible for the study and 1911 (97.2%) were enrolled, with 895 AYLHIV enrolled from the 12 intervention facilities randomised to receive DiSC stepped care, and 1016 AYLHIV enrolled from the 12 control facilities randomised to receive standard of care (Figure 1). The number of participants enrolled per facility was between 51 and 113. Enrolled AYLHIV were followed until 19 September 2023 and contributed 1708.8 person-years of follow-up. Five AYLHIV died during study follow-up (three in the intervention arm and two in the control arm). Among the intervention arm, 888 AYLHIV actually received their allocated intervention (99.2%).

3.1 | Baseline participant characteristics

Median age was 17 years (interquartile range [IQR] 14–19) and 1102 (57.9%) were girls and young women (Table 2). Most AYLHIV were currently in school (79.5%) and most reported having at least one parent alive (83.4%). The majority (98.2%) of AYLHIV had disclosed their HIV status to other people. Few AYLHIV reported mental health issues, with 8.3% having at least mild depression (PHQ-9 score ≥ 5), 3.7% at least mild anxiety (GAD-7 score ≥ 5), and 7.7% reporting any use of alcohol or drugs. Almost all AYLHIV reported high social support (95.6%, MSPSS score > 3) and high adherence self-efficacy (98.6%, ASES score ≥ 5), and 48.1% were part of a peer support group. Usage of the DSD model at baseline was reported by 35.1% of AYLHIV, and 57.9% reported having an unmet service need. Regarding ART use, 38.3% were

on a dolutegravir-based regimen, 21.7% were on an efavirenz-based regimen, 28.1% were on a nevirapine-based regimen and 8.1% were on lopinavir/ritonavir-based regimen. Characteristics were balanced by randomization arm, with the exception of a higher proportion of AYLHIV self-reporting always coming to the clinic by themselves in control versus intervention arms.

Among AYLHIV in the intervention arm, at baseline, 574 (64.6%) were assigned to Step 1 as stably viral suppressed; 122 (13.7%) were assigned to Step 2 as requiring standard care or declining other steps; 100 (11.3%) were assigned to Step 3 needing mental health or retention support; and 92 (10.4%) were assigned to Step 4 with unsuppressed VL.

3.2 | Clinical outcomes

3.2.1 | Missed visits

A total of 1906 (99.7%) AYLHIV had at least one clinic appointment scheduled during study follow-up, with 10,032 scheduled visits included in analyses. AYLHIV had a median of five scheduled visits (IQR 4–6). During follow-up to 12 months, 91.6% of visits were attended within 30 days of scheduled dates. The proportion of missed visits was 8.3% in the control arm and 8.5% in the intervention arm. There was no significant difference in missed visits between arms (adjusted risk ratio [aRR]: 1.04 [0.89–1.20], $p = 0.594$). Overall, 36.8% of AYLHIV ever missed a visit (> 30 days from scheduled date), and the proportions were similar between AYLHIV enrolled from intervention facilities and AYLHIV enrolled from control facilities (Table 3).

3.2.2 | Loss to follow-up

Incidence of LTFU was 7.84/100 person-years (py), with no difference between control (8.00/100py) and intervention (7.67/100py, adjusted hazard ratio [aHR]: 1.00 [0.71–1.41], $p = 0.991$) (Table 3 and Figure 2).

3.2.3 | Viral non-suppression

Overall, 1767 AYLHIV had ≥ 1 VL testing result available, for a total of 3523 VL results included in analyses. AYLHIV had a median of 2 VL results (IQR 1–2). The overall proportion of VL results that were non-suppressed was 8.8%, and 12.4% of AYLHIV were ever virally unsuppressed (Table 3). There were no differences in the frequency of non-suppression over time between the intervention and control arm (aRR: 0.79 [0.54–1.16], $p = 0.237$). Sensitivity analyses stratified by age (10–19 and 20–24) yielded similar results.

3.2.4 | DSD

Among 1906 AYLHIV with clinical visit data available, a total of 11,033 visits were included in the analysis of long inter-visit intervals (next visit scheduled for ≥ 3 months due to multi-month dispensing). The proportion of scheduled visits with long inter-visit interval was 37.3% and similar between arms (aRR: 1.04 [0.97–1.12], $p = 0.276$) (Table 3). For the analysis of visits with “fast-track” care model, 10.9% of the total 9549 visits with data on care models were observed.

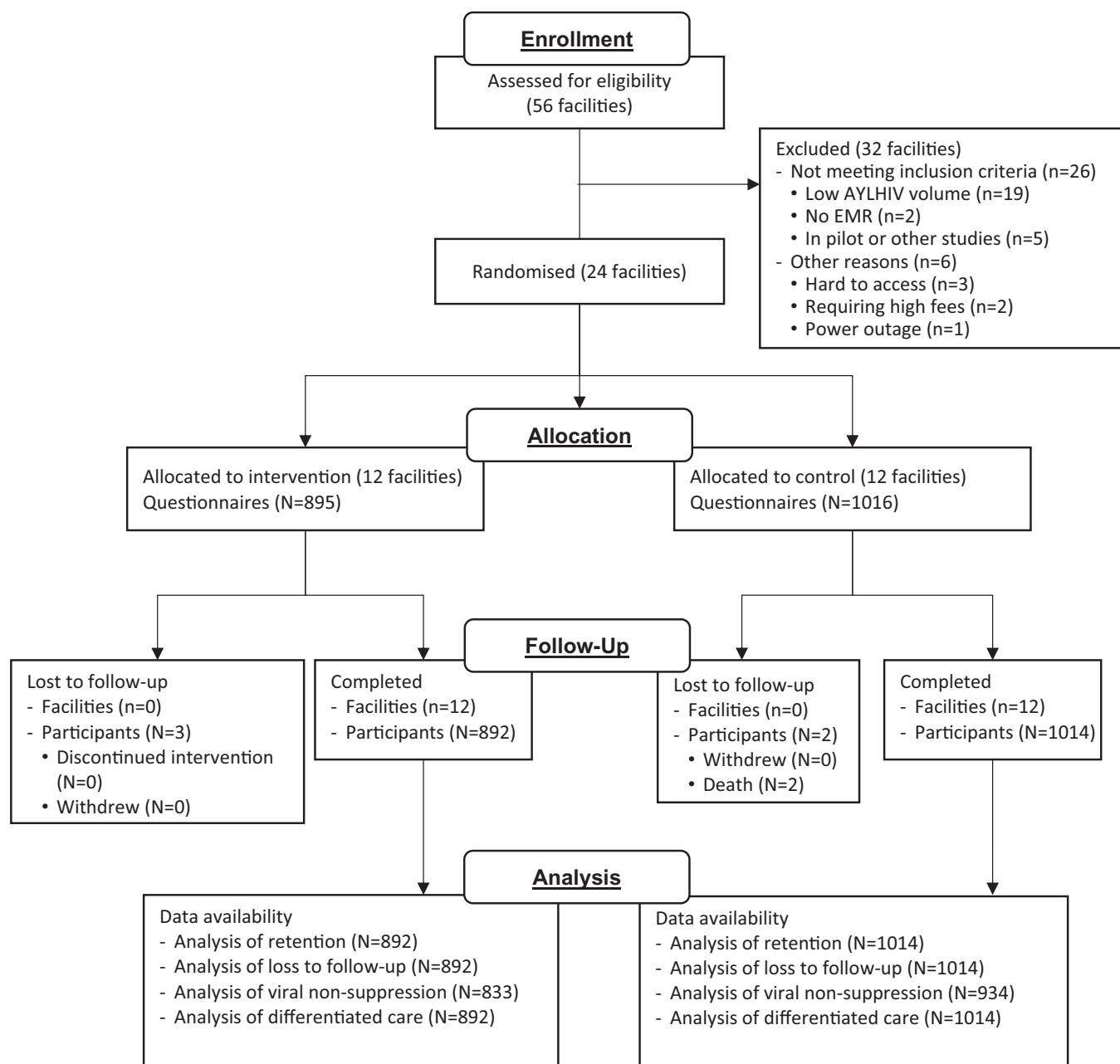


Figure 1. Consort diagram. Abbreviation: AYHLHIV, young adults living with HIV.

AYHLHIV in the intervention arm had a higher proportion of receiving “fast-track” models than AYHLHIV in the control arm (aRR: 1.21 [1.01–1.46], $p = 0.037$).

3.2.5 | Adherence

Among all clinic visits, 8551 visits (93.7%) were attended soon enough after the preceding visit that > 80% of days in the interval were covered by ART doses dispensed at the preceding visit. There were no significant differences between intervention and control arm (aRR: 0.98 [0.94–1.02], $p = 0.386$). Most (77.7%) of AYHLHIV always had > 80% pill coverage dur-

ing study follow-up (Table 3). Results were similar in sensitivity analysis using 95% as the cutoff (data not shown).

3.2.6 | Clinic burden

At baseline, control sites averaged 34 AYHLHIV visits per clinic per month, and intervention sites averaged 33 visits per clinic per month. Adjusting for 6 months pre-enrolment at baseline, facilities implementing the DiSC tool experienced a 6% decrease in the number of visits compared to facilities in the control arm (prevalence ratio [PR]: 0.94 [0.91–0.97], $p < 0.001$).

Table 2. Participant baseline characteristics

Characteristic	Control (n = 1016) n (%) or median (IQR) ^a	Intervention (n = 888) [^] n (%) or median (IQR)	Overall (N = 1904) n (%) or median (IQR)
Age (years)	17.0 (15.0, 19.0)	16.0 (14.0, 19.0)	17.0 (14.0, 19.0)
Gender			
Boys/young men	443 (43.6%)	353 (39.8%)	796 (41.9%)
Girls/young women	570 (56.2%)	532 (60.0%)	1102 (57.9%)
Currently in school	806 (79.6%)	706 (79.5%)	1512 (79.5%)
At least one parent alive	854 (84.1%)	734 (82.8%)	1588 (83.4%)
At least one parent died	570 (56.1%)	504 (56.8%)	1074 (56.4%)
Depression ^b			
None/minimal (0–4)	906 (91.3%)	789 (92.1%)	1695 (91.7%)
At least mild (5+)	86 (8.7%)	68 (7.9%)	154 (8.3%)
Anxiety ^c			
None/minimal (0–4)	967 (96.9%)	830 (95.5%)	1797 (96.3%)
At least mild (5+)	31 (3.1%)	39 (4.5%)	70 (3.7%)
Any alcohol or drug use in life ^d	79 (7.8%)	68 (7.7%)	147 (7.7%)
Social support ^e	924 (96.6%)	777 (94.5%)	1701 (95.6%)
Resilience ^f	930 (93.2%)	799 (92.1%)	1729 (92.7%)
Adherence self-efficacy ^g	979 (98.9%)	856 (98.3%)	1835 (98.6%)
Stigma ^h	351 (37.1%)	266 (33.0%)	617 (35.2%)
Part of a peer support group	499 (49.7%)	404 (46.2%)	903 (48.1%)
Violence in the last 6 months	54 (5.3%)	62 (7.0%)	116 (6.1%)
Transport to clinic ≥ 1 hour	479 (47.9%)	351 (40.4%)	830 (44.5%)
Wait time in clinic ≥ 1 hour	97 (9.6%)	59 (6.7%)	156 (8.2%)
Use at least one differentiated service delivery (DSD) model ⁱ	334 (33.0%)	331 (37.4%)	665 (35.1%)
Report service needed but not received	580 (57.1%)	523 (58.9%)	1103 (57.9%)
Able to come for appointments without help from caregiver	794 (84.3%)	687 (79.3%)	1481 (81.9%)
Able to take medication without reminders from caregiver	892 (94.9%)	778 (90.4%)	1670 (92.7%)
Always coming to this clinic by yourself ^{***}	694 (68.6%)	541 (61.1%)	1235 (65.1%)
Other person in charge of healthcare decision	759 (75.0%)	684 (77.4%)	1443 (76.1%)
Know HIV status of last partner	258 (75.2%)	178 (73.3%)	436 (74.4%)
Disclosed to anyone	995 (97.9%)	874 (98.4%)	1869 (98.2%)
Antiretroviral therapy regimen			
Dolutegravir (DTG)-based ^j	348 (35.4%)	362 (41.7%)	710 (38.3%)
Efavirenz (EFV)-based ^k	222 (22.6%)	179 (20.6%)	401 (21.7%)
Lopinavir/ritonavir (LPV/r)-based ^l	89 (9.1%)	61 (7.0%)	150 (8.1%)
Nevirapine (NVP)-based ^m	281 (28.6%)	240 (27.6%)	521 (28.1%)
Other	43 (4.4%)	27 (3.1%)	70 (3.8%)

^aInterquartile range.

^bEvaluated using Patient Health Questionnaire-9 (PHQ-9) with a score of 0–4 indicating none/minimal depression, 5–9 mild depression, 10–14 moderate depression, ≥ 15 severe depression.

^cEvaluated using General Anxiety Disorder-7 (GAD-7) with a score of 0–4 indicating none/minimal anxiety, 5–9 mild anxiety, 10–14 moderate anxiety, ≥ 15 severe anxiety.

^dUsing WHO Alcohol, Smoking and Substance Involvement Screening Test for Young people (ASSIST-Y).

^eEvaluated using Multidimensional Scale of Perceived Social Support (MSPSS) 12-item scale with a score > 3 indicating high social support.

^fEvaluated using Connor-Davidson Resilience Scale-2 (CDRS-2) with a score ≥ 3 indicating high resilience.

^gEvaluated using Adherence Self-Efficacy Scale (ASES) with a score ≥ 5 indicating high adherence.

^hEvaluated using Youth HIV Stigma Scale (YHBSS) with a score ≥ 3 indicating high stigma experience.

ⁱDifferentiated service delivery.

^jDolutegravir.

^kEfavirenz.

^lLopinavir/ritonavir.

^mNevirapine.

[^]Seven participants in the intervention arm missed the baseline survey.

^{***}Significance by arm estimated by generalised linear mixed model (GLM regression clustered by facility; *p*-value < 0.05.

Table 3. Effects of DiSC intervention on study outcomes

Primary outcome				
	Overall (N = 1906)	Control (n = 1014)	Intervention (n = 892)	Intervention versus control
Missed visits				
Number of scheduled visits	10,032	5248	4784	–
Proportion of missed visits/scheduled visits	839 (8.4%)	433 (8.3%)	406 (8.5%)	aRR ^a 1.04 (0.89–1.20); p = 0.631
Proportion of AYLHIV ever missed a visit	701 (36.8%)	360 (35.5%)	341 (38.2%)	aRR ^a 1.08 (0.92–1.25); p = 0.340
Secondary outcomes				
LTFU				
Proportion of AYLHIV lost to follow-up	7.0%	7.2%	6.8%	aPR ^b 1.00 (0.71–1.40); p = 0.987
Incidence rate/100py	7.84	8.00	7.67	aHR ^b 1.00 (0.71–1.41); p = 0.991
	Overall (N = 1767)	Control (n = 934)	Intervention (n = 833)	Intervention versus control
Viral non-suppression				
Number of VL assays	3523	1899	1624	–
Proportion of non-suppression results of all VL assays	309 (8.8%)	184 (9.7%)	125 (7.7%)	aRR ^c 0.79 (0.54–1.16); p = 0.237
Proportion of AYLHIV ever virally unsuppressed	219 (12.4%)	123 (13.2%)	96 (11.5%)	aRR ^c 0.80 (0.52–1.25); p = 0.329
	Overall (N = 1904)	Control (n = 1013)	Intervention (n = 891)	Intervention versus control
ART adherence (pill coverage > 80%)				
Number of inter-visit intervals with pill data recorded	9123	4741	4382	–
Proportion of inter-visit intervals with good adherence	8551 (93.7%)	4486 (94.6%)	4065 (92.8%)	aRR ^d 0.98 (0.94–1.02); p = 0.386
Proportion of AYLHIV always with good adherence	1479 (77.7%)	810 (80.0%)	669 (75.1%)	aRR ^d 0.94 (0.85–1.05); p = 0.299
Differentiated service delivery				
	Overall (N = 1906)	Control (n = 1014)	Intervention (n = 892)	Intervention versus control
Long-interval visits				
Number of scheduled visits	11,033	5760	5273	–
Proportion of long-duration interval among all scheduled visits	4119 (37.3%)	2180 (37.8%)	1939 (36.8%)	aRR ^e 1.04 (0.97–1.12); p = 0.276
Proportion of AYLHIV ever given long-duration schedules	1621 (85.0%)	838 (82.6%)	783 (87.8%)	aRR ^e 1.10 (0.90–1.35); p = 0.353
Fast-track visits				
Number of visits with non-missing care model	9549	4963	4586	–
Proportion of fast-track visits of all visits	1037 (10.9%)	520 (10.5%)	517 (11.3%)	aRR ^f 1.21 (1.01–1.46); p = 0.037

(Continued)

Table 3. (Continued)

	<i>Differentiated service delivery</i>			
	Overall (N = 1906)	Control (n = 1014)	Intervention (n = 892)	Intervention versus control
Proportion of AYLHIV ever having fast-track visits	611 (32.1%)	264 (26.0%)	347 (38.9%)	aRR ^f 1.61 (0.68–3.83); p = 0.278

Abbreviations: (a)HR, (adjusted) hazard ratio; (a)PR, (adjusted) prevalence risk; (a)RR, (adjusted) relative risk; ART, antiretroviral therapy; AYLHIV, adolescents and young adults living with HIV; DiSC, Data-informed Stepped Care; LTFU, loss to follow-up; py, person-years; VL, viral loads.

^aAdjusted for attending clinic alone and ever having missed visits at baseline.

^bAdjusted for attending clinic alone; no adjustment for baseline LTFU.

^cAdjusted for attending clinic alone and ever being virally unsuppressed at baseline.

^dAdjusted for attending clinic alone and always having > 80% pill coverage at baseline.

^eAdjusted for attending clinic alone and ever being given a long duration interval visit at baseline.

^fAdjusted for attending clinic alone and ever being given fast-track visits at baseline.

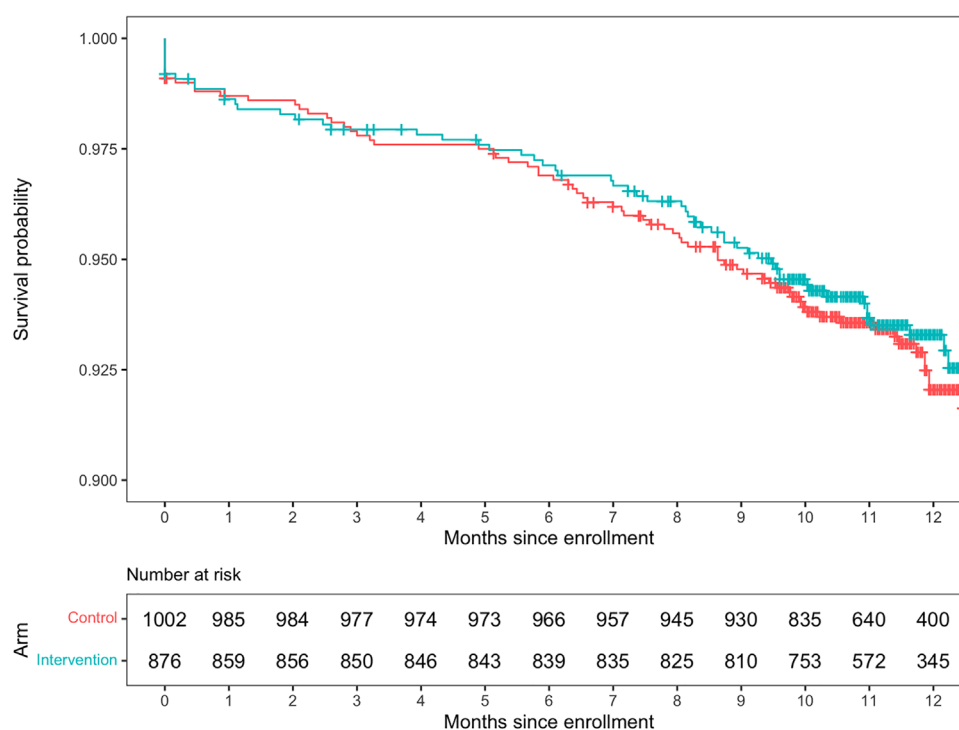


Figure 2. Time to loss to follow-up.

4 | DISCUSSION

In this cluster randomised trial, we found that a data-driven stepped care intervention did not improve AYLHIV viral suppression or retention in HIV care. However, it was encouraging that the use of the DiSC risk assessment tool was successful in assigning significantly more AYLHIV to differentiated fast-track services than standard care, while maintaining high retention in care and viral suppression, and decreasing workforce burden.

Other studies in the region have documented the maintenance of positive HIV care outcomes and reduced costs associated with the adoption of DSD [28–32]. One study of DSD rollout in Uganda reported 98% retention and 91% viral sup-

pression, with costs similar to standard of care [28]. It is hypothesised that these client-centred models result in the reallocation of staff time and improved health system efficiency. This hypothesis is supported by our finding of significant decreases in the volume of clinic visits per site, suggesting the potential for freeing up clinic time to focus on individuals with more intensive needs while minimising workforce burden.

We found that fast-track services increased in the intervention arm, while inter-visit intervals were similar between arms. Fast-track visits, where expedited pharmacy dispensing is done rather than a comprehensive evaluation, are useful to improve clinic flow and decrease wait and visit time [29], and have been shown to improve on-time ART pick-up [30]. In our

study, it is possible that clinicians in the intervention arm may have felt more comfortable allocating ALYHIV to fast track after using the systematic DiSC stepping tool. Because of COVID-19 and changing guidelines, inter-visit intervals were longer in both arms than anticipated in the trial design phase, which may have contributed to the lack of difference between arms. In addition, our age range included a sizeable number of ALYHIV aged 20–24 who were already eligible for longer inter-visit intervals, making the intervention less impactful in this group.

While some elements of DSD, specifically visit intervals aligned with school schedules, have been implemented in this setting, some providers also may feel reluctance to not see ALYHIV as frequently as monthly, with concerns over loss to follow-up and poor adherence, and fear that they will not come back if away for too long. Interestingly, in Sierra Leone, monthly refill requirements were associated with a higher frequency of viral failure (67%) compared to longer refill durations of 2–3 months (33%) [31]. A study in South Africa of even longer refill durations found similarly high (> 90%) retention and suppression rates among those attending community-based refills at 6 and 12 months [32]. These findings suggest that longer refill durations may be beneficial in maintaining viral suppression, particularly among young people attending boarding schools.

In this clinical trial, we did not find that the intervention improved retention (the primary outcome of the trial) or viral suppression. This may be due to generally high retention (> 90% of scheduled visits were attended) and viral suppression (> 90% of VLs assessed were suppressed) in the cohort, making it difficult to discern a small difference between trial arms despite the large sample size. However, more than a third of ALYHIV ever missed a visit and 12% of ALYHIV were unsuppressed at some point during follow-up, suggesting continued need for programmatic improvements. Our intervention may not have had sufficient time to exert improvement in retention or viral suppression for some ALYHIV who were stepped later in the study period. Alternatively, our intervention services (mental health counselling and adherence counselling) may not have differed substantially from existing similar services in control clinics or may not have addressed residual structural issues that challenge retention and adherence. Long-acting (LA) ART may address some of these issues, but implementation may take time and it is likely that some ALYHIV will still face challenges consistently accessing LA-ART. Our study contributes to a body of research that suggests longer duration between visits does not negatively affect treatment outcomes.

Our study has strengths and limitations. Strengths of the study include that it was a large cluster randomised trial that combined implementation science strategies to optimise the intervention, and that it was a pragmatic intervention delivered by clinic personnel within the context of routine care. There was likely some cross-over of elements of the intervention, as care components—with the exception of systematic mental health counselling—existed at control sites, though not using the DiSC tool for systematic assignments based on risk. The COVID-19 pandemic similarly forced longer visit intervals across both sites, which could explain why differences found were primarily in the fast-track pharmacy approach. Clinical

outcomes within both arms were high, suggesting potential a Hawthorne effect, or improved care and support based on the knowledge that this was being observed, at control sites [33]. Expanding consent to include young people ages 15–17 seeking care independently may have improved the representativeness of the age group; however, it may also have contributed to the selection of a more stable care-seeking population overall.

5 | CONCLUSIONS

We found relatively high rates of retention and viral suppression in this cohort of ALYHIV which were not improved by use of the DiSC intervention in Kenya. The DiSC tool effectively identified ALYHIV doing well in care who were shifted to differentiated services, while also identifying those in need of more intensive counselling and intervention. The use of the DiSC tool improved the implementation of differentiated services among ALYHIV without compromising retention or viral suppression. Future trials in other settings, including community-based approaches, or with additional key populations will inform further implementation and health policy.

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COMPETING INTERESTS

BAR is a member of the Data and Safety Monitoring Board for Gilead Sciences clinical trials of pre-exposure prophylaxis. The remaining authors have no additional conflicts of interest to declare.

AUTHORS' CONTRIBUTIONS

PK, GJ-S, KA, BAR, SKS and KB-S were responsible for conceptualisation and methodology. JB, JKl, JD, JKa, DO and SH contributed to study implementation and data collection. WJ and BAR contributed to data analysis. PK wrote the original draft of the paper. All authors contributed to the article and approved the submitted version.

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DATA AVAILABILITY STATEMENT

The data that support the findings of this study will be openly available in the NICHD Data and Specimen Hub (DASH) in 2025. Until available in the DASH repository, the data that support the findings of this study are available from the corresponding author upon reasonable request.

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SUPPORTING INFORMATION

Additional information may be found under the Supporting Information tab for this article:

File S1: DiSC stepped care placement tool.

Supplementary Table: Participant baseline characteristics by Step.

RESEARCH ARTICLE

Cost-effectiveness analysis of a community-based model for delivery of antiretroviral therapy to people with clinically stable HIV in Cambodia

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Abstract

Introduction: In Cambodia, of all people living with HIV, 89% knew their status, 89% were receiving antiretroviral therapy (ART) and 87% had their viral load suppressed in 2023. In 2017, the national HIV programme introduced the multi-month dispensing (MMD) model to reduce visits to ART clinics, thereby reducing the burden on people living with HIV and health facilities. A quasi-experimental study introduced the community ART delivery (CAD) model, where community action workers (CAWs) delivered pre-packaged antiretrovirals to their peers in the community. This study examined the cost-effectiveness of the CAD compared to the MMD model.

Methods: This study was conducted between 2021 and 2023 and involved 2040 stable people living with HIV in the CAD arm and 2049 in the MMD arm. Baseline and endline surveys included self-reported ART adherence, quality of life, and medical and non-medical expenses. Intention-to-treat analyses (ITTs) were conducted based on participants' original treatment assignment, with multiple imputations performed for participants lost to follow-up at the endline. Incremental cost-effectiveness ratios (ICERs) on ART adherence and quality of life were generated using health system and societal perspectives. Cost-effectiveness thresholds (CETs) were one-time gross domestic product (GDP) per capita and opportunity cost.

Results: Both arms observed a decline in ART adherence and good physical health, with a decline in CAD less than in the MMD (p -value < 0.001). Similarly, a reduced proportion of participants reported good mental health across both arms; however, the difference was statistically insignificant. The ICERs for good physical health at the health system and societal levels were below the one-time GDP per capita (Incremental Net Benefit = 77.49–83.03) but exceeded the opportunity cost CET. The ICERs for ART adherence at the health system and societal levels were above both CETs.

Conclusions: The results showed that the CAD model was cost-effective in reducing the decline in the physical health of people living with HIV during the COVID-19 pandemic in Cambodia when a less stringent threshold was used. Further investigations are required to ascertain the cost-effectiveness of the CAD model by factoring in the productivity gains within the health system.

Clinical Trial Number: NCT04766710

Keywords: people living with HIV; differentiated service delivery; multi-month dispensing; community anti-retroviral delivery; community intervention; Cambodia

Additional information may be found under the Supporting Information tab of this article.

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1 | INTRODUCTION

In 2023, 89% of people living with HIV in Cambodia knew their HIV status, 89% were receiving antiretroviral therapy (ART) and 87% had achieved viral load suppression [1, 2]. People living with HIV continue to face structural barriers

such as internalised and experienced stigma that contribute to their fear of disclosing their HIV status and poorer mental and physical health [3]. Non-disclosure of HIV status can impact their social support [4] and, altogether, affect their adherence to ART and retention in care [5–8]. Lifelong treatment for HIV is another challenge in terms of time and

resources [9]. HIV treatment in Cambodia is provided free of charge to people living with HIV. Since 2019, they have also been included in the Identification of Poor Households (IDPoor) mechanism, a national programme to support impoverished households. People living with HIV who are registered in the IDPoor receive an Equity Card, which entitles them to monthly stipends and free healthcare services under the Health Equity Fund (HEF) at public health facilities [10, 11]. However, transportation subsidies are no longer available under the revised HEF package [12]. Although transport is provided by some non-governmental organizations (NGOs), the support is limited and does not cover all people living with HIV.

On the supply side, the Cambodian government grapples with an overstretched health workforce, particularly in rural areas [13, 14]. To reduce the burden on health facilities and people living with HIV, the World Health Organization (WHO) recommends ART differentiated service delivery (DSD) models [15]. DSD includes approaches such as multi-month dispensing (MMD), a model introduced by the National Center for HIV/AIDS, Dermatology and STD (NCHADS) in 2017. Under the MMD model, stable people living with HIV receive antiretrovirals (ARVs) for a 3–6 month supply from ART clinics [16]. Another DSD model, the community ART delivery (CAD), was implemented and evaluated in Cambodia by the Khmer HIV/AIDS NGO Alliance (KHANA) from 2021 to 2023 [17]. The CAD model involved people living with HIV who served as community action workers (CAWs) in collecting pre-packaged ARVs from ART clinics and distributing them to people living with HIV in their community action groups (CAGs) at monthly group sessions.

Additionally, CAWs provided medical support by monitoring vital signs and ART adherence and conducting health education and counselling with their members. Apart from medical support and ART delivery, the core of the CAD model is psychosocial support among people living with HIV through peer-to-peer interactions during the group sessions. The effectiveness of MMD and CAD models on people living with HIV and healthcare providers in the ART clinics was evaluated through the quasi-experimental study [17]. This paper focuses on the cost-effectiveness analysis of the CAD model by comparing it with the MMD model.

2 | METHODS

2.1 | Study design

The quasi-experimental study involved 2040 people living with HIV in the CAD arm (intervention) and 2049 in the MMD arm (control). Before enrolment, people living with HIV were confirmed by clinicians to be clinically stable, based on the following eligibility criteria: (1) aged 15 years or older; (2) had been receiving first-line ART for at least 1 year; (3) did not report ART-related adverse reactions or drug interactions requiring regular monitoring; (4) were free from tuberculosis (either presumptive or confirmed) and other opportunistic infections; (5) were not taking any prophylactic treatment; (6) had good understanding of lifelong treatment and medication adherence; and (7) achieved at least two consecutive unde-

tectable viral loads or CD4 counts above 200 cells/mm³. Pregnant or breastfeeding women were excluded from the study.

In the MMD arm, participants were recruited from 10 ART clinics in Phnom Penh, Kampong Cham, Pailin, Preah Sihanouk, Siem Reap and Prey Veng. Participants received 3–6 months of ARVs at each visit. In the CAD arm, participants were recruited from 10 other ART clinics in Phnom Penh, Kampong Thom, Kampot, Koh Kong and Takeo. Eighty-two CAWs collected ARVs from the ART clinics and distributed them to their CAG members at monthly community meetings. All MMD and CAD arm participants visited the ART clinics for ad-hoc consultation and required routine clinical review every 6 months. At the start of the study, CAWs received training from ART clinicians, pharmacists, counsellors and NCHADS programme staff on ART delivery, referral system and medication adherence to enable them to lead the community sessions. This study adhered to the Consolidated Health Economic Evaluation Reporting Standards (CHEERS) [18] (Supporting information).

2.2 | Variables and measurements

Questionnaire surveys were planned for baseline (0 months), midline (12th month) and endline (24th month). However, the surveys were conducted only at two time points: baseline in October 2021 (0 months) and endline in May 2023 (19th month). The midline survey was not possible due to operational and budget challenges during the COVID-19 pandemic. Trained data collectors administered the surveys, which captured participants' socio-demographic characteristics and self-reported HIV treatment history and comorbidities. Outcomes of interest for the cost-effectiveness analysis were self-reported ART adherence and quality of life.

Self-reported adherence has been recommended as a valid and reliable tool for research [19, 20]. The survey included five primary questions on ART adherence adapted from the Morisky Medication Adherence Scale [21, 22], widely used in HIV populations [23–25]. The questionnaire asked whether participants had missed any ARVs in the past 2 months, whether they found it difficult to remember taking ARVs, whether they sometimes stopped taking ARVs when they felt better, whether they had missed any doses in the past 4 days and whether they stopped taking ARVs when they felt worse. Two secondary items asked participants about the last time they missed taking ARVs and why they sometimes found it difficult to adhere to their ARV regimen. Participants were considered adherent if they answered “no” to all five primary questions.

Quality of life was measured using the Short-Form-12 (SF-12) survey validated for use in people living with HIV [26, 27]. SF-12 comprises 12 items representing eight health domains—physical function, social function, role limitations due to physical health, role limitations due to emotional problems, mental health, vitality, bodily pain and general health [28]. Responses to SF-12 generated the Physical Component Score (PCS) and Mental Component Score (MCS). PCS higher than 50 indicates good physical health, and MCS higher than 42 indicates good mental health.

On costing, participants were asked to report on the medical (e.g. consultation) and non-medical costs (e.g. transport)

incurred by them and their caregivers when they travelled to the ART clinics. Separate questionnaire surveys were administered to the CAWs at the endline and the healthcare providers at the baseline and endline. In addition to questions on socio-demographics, the survey for the CAWs included non-medical costs incurred in their travel to the ART clinics and meetings with their CAG members. For the healthcare providers, the survey included questions on their roles, tasks, work characteristics and the time spent at the ART clinics.

2.3 | Data analyses

A health economic analysis plan was developed to guide the evaluation. Analyses were performed in R (version 4.4.3) using the intention-to-treat (ITT) principle based on participants' original treatment assignment. The time horizon was the intervention period, as outcomes were expected to occur during the study. Continuous variables were analysed for descriptive statistics using the two-sample Student's *t*-test or Mann-Whitney U test when the normality assumption was not upheld. Pearson's Chi-square or Fisher's exact test was used for categorical variables if the cell count was smaller than five.

To account for the loss-to-follow-up (LTFU), multiple imputations were first performed using the fully conditional specification implemented by the MICE (multivariate imputation by chained equations) package under the assumption of *missing at random* [29, 30]. This approach was informed by observed associations between outcome variables, socio-demographic characteristics and LTFU (Supporting information Table S1). Socio-demographic characteristics and imputed variables, including outcomes and costs, were used as predictor variables to impute missing outcomes and costs of LTFU participants at the endline. The number of facility visits during the intervention period was imputed separately using socio-demographic characteristics as predictors. The socio-demographic characteristics of LTFU participants were assumed to remain unchanged from the baseline based on the rationale that they were likely stable over the 18-month study period.

Within MICE, predictive mean matching was used for continuous variables, logistic regression for binary variables, proportional odds regression for ordinal variables and multinomial logistic regression for multi-level categorical variables. Ten imputed datasets were generated using chained equations with 50 iterations for each multiple imputation. Convergence diagnostics was done to assess imputation stability.

Multivariable logistic regression was then used to assess the intervention effect on ART adherence and quality of life, adjusting for significantly different baseline covariates ($p < 0.10$) and those known to influence these outcomes [31–40]. Nested models were compared to the full model using likelihood ratio tests, and model fit was assessed using Akaike Information Criterion and Bayesian Information Criterion. The final model selection prioritised parsimony and explanatory value. Final models were fitted in each imputed dataset and pooled using Rubin's rules [30]. Imputation uncertainty was assessed using the fraction of missing information (FMI) and variance components. FMI and the proportion of total variance due to between-imputation variation were considered acceptable if they were below 0.25 [41].

Based on the final models, the average treatment effect for ART adherence and quality of life was estimated across imputed datasets using a difference-in-differences (DiD) approach [42, 43]. The final regression model was applied to each imputed dataset to predict the average outcomes of ART adherence and quality of life at baseline and endline for each study arm. The predicted probabilities were then pooled across imputations using Rubin's rules to account for within- and between-imputation variance, incorporating uncertainty introduced by missing data. The DiD estimate was calculated as the difference in outcome change between endline and baseline between the intervention and control arms.

Health system and societal costs between October 2021 and April 2023 were estimated using a micro-costing approach. Health system costs included salaries, training expenses and operational costs. Societal costs encompassed out-of-pocket expenditures (OOPEs) and productivity losses for people living with HIV, their caregivers and CAWs (Supporting information Table S2). All costs were adjusted for inflation using the Cambodia Consumer Price Index (CPI) to April 2024 [44] and converted to the United States Dollars (USD) at an exchange rate of 1 Riel = 0.00024 USD.

OOPE and productivity costs for people living with HIV were estimated using inverse probability weighting (IPW) to adjust for imbalances in baseline socio-demographic characteristics between the intervention and control arms [45]. IPW was implemented by fitting a propensity score model using logistic regression, with treatment assignment as the outcome and socio-demographic covariates as predictors. Predicted probabilities were bounded between 0.01 and 0.95, and stabilised IPW weights were then calculated and truncated at the 99th percentile to reduce the influence of extreme values. These weights were applied to the observed costs to derive weighted cost estimates. Weighted mean and total OOPE and productivity costs were computed within each treatment group and pooled across the imputed datasets using Rubin's rules to account for imputation-related variance.

All cost items at both the health system and societal levels were aggregated to estimate the mean cost per participant for each study arm at each level. Incremental cost-effectiveness ratios (ICERs) were then calculated by dividing the difference in mean costs per participant by the difference in the DiD of predicted outcome probabilities between the CAD and MMD models. ICERs were reported as cost per participant with good physical health and per ART-adherent participant. The primary perspective was the health system, reflecting policymakers' priorities, while the secondary perspective incorporated societal costs to capture broader economic implications. Two cost-effectiveness thresholds (CETs) were applied: (1) one-time Cambodia's gross domestic product (GDP) per capita in 2022 (USD 1799) and (2) a more stringent threshold of USD 304, based on opportunity cost estimates by Ochalek et al., both adjusted to April 2024 using Cambodia's CPI [46, 47].

2.4 | Ethics

The National Ethics Committee for Health Research, Ministry of Health, Cambodia, approved this study (Reference:

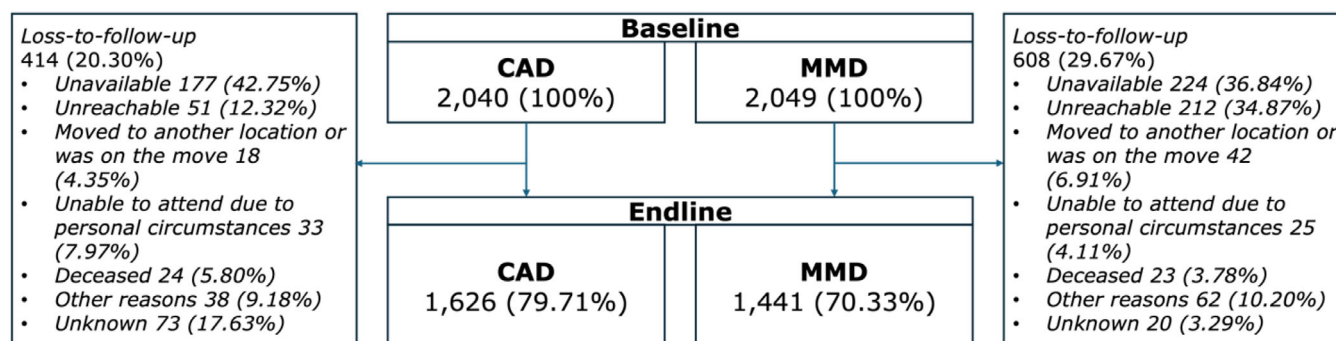


Figure 1. Number of participants in the MMD (control) and CAD (intervention) arms and reasons for loss-to-follow-up. Abbreviations: CAD, community antiretroviral delivery; MMD, multi-month dispensing. Number (%) of total sample size or total loss-to-follow-up.

258/NECHR). All participants provided written informed consent before data collection started.

3 | RESULTS

Among the 4089 participants, 1626 out of 2040 from the CAD arm (79.71%) and 1441 out of 2049 from the MMD arm (70.33%) remained at the endline (Figure 1).

3.1 | Socio-demographic characteristics

A higher proportion of participants in the MMD arm (77.11%) than in the CAD arm (61.42%) received HIV care in urban areas. Additionally, participants in the MMD arm were over four times more likely than those in the CAD arm (5.42% vs. 1.27%) to identify themselves as lesbian, gay, bisexual, transgender, queer, intersex, asexual or to prefer not to disclose their sexual orientation. Most participants were married, had a primary school education and were farmers or fishermen, self-employed, or unemployed. Nearly twice as many participants in the MMD arm (19.42%) as in the CAD arm (10.74%) were diagnosed with HIV within the past 5 years. However, in both arms, the majority had been living with HIV and receiving ART for 11–20 years. The primary mode of transportation to ART clinics was motorised vehicles, including Tuk Tuks (trishaws), motorcycles or cars. Almost half of the participants in both arms reported spending less than 30 minutes travelling to ART clinics. Most remaining participants reported travel times of less than 2 hours. The median household income significantly differed between MMD and CAD arm participants. Furthermore, a significantly higher proportion of participants in the CAD arm (24.90%) reported having at least one comorbidity than those in the MMD arm (17.18%) (Table 1).

3.2 | Intervention effects

ART adherence declined in both arms at endline (Table 2), with a less pronounced decline in the CAD arm compared to the MMD arm (AOR: 1.59, p -value < 0.001) (Table 3). The estimated probability of ART adherence was 5 percentage points higher in the CAD arm than in the MMD arm (Table 4). Similarly, the proportion of participants reporting good physical health decreased in both arms (Table 2), with a

greater decline in the MMD arm (AOR:1.64, p -value < 0.001) (Table 3). The estimated probability of good physical health was 11 percentage points higher in the CAD arm than in the MMD arm (Table 4). A lower proportion of participants in both arms reported good mental health at endline (Table 2), with no significant difference between arms (AOR: 1.21, p -value = 0.10) (Table 3).

3.3 | Cost-effectiveness

Most participants did not incur any medical expenses at baseline and endline. However, expenses as high as 400,000 Riel (USD 96) were reported for other medical costs, including service fees, charges for extended ARV supplies, additional medications, laboratory tests and informal fees requested by doctors for “noodles and coffee” (Table 5). Transport and food were the primary contributors of OOPE in both arms (Table 5). On average, participants in the MMD arm made 5.25 trips to the ART clinics over the study period, slightly higher than the 4.72 times in the CAD arm (p -value < 0.001). The trip reduction among CAD participants translated into time and cost savings, contributing to lower OOPE and productivity gains (Table 6). The ICERs for achieving good physical health per participant were \$1094.55 at the health system and \$1044.18 at the societal levels. These ICERs fell below the CET of one-time Cambodia’s GDP per capita (incremental net benefit = 77.49–83.03) but exceeded the opportunity cost CET. In contrast, all other ICERs, including the ICER per ART-adherent participant at the health system (\$2408) and societal levels (\$2297.2), exceeded both CETs (Table 7).

4 | DISCUSSION

The analyses demonstrated the cost-effectiveness of the CAD model in mitigating the decline in good physical health at both health system and societal levels when evaluated against the CET of one-time Cambodia’s GDP per capita. However, the CAD model was not cost-effective when assessed using the more stringent opportunity cost CET. Notably, there was a decline in good physical and mental health and ART adherence across both arms. As the study coincided with the third phase of the COVID-19 pandemic in Cambodia, the decline in ART adherence and quality of life could be due to the

Table 1. Socio-demographic characteristics of participants in the MMD (control) and CAD (intervention) arms

	MMD (n = 2049)	CAD (n = 2040)	p-value
ART clinic setting			
Urban	1580 (77.11)	1253 (61.42)	< 0.001
Rural	469 (22.89)	787 (38.58)	
Age groups			
Young adults (15–24)	107 (5.22)	134 (6.57)	0.003
Adults (25–49)	1164 (56.81)	1046 (51.27)	
Older adults (50–64)	708 (34.55)	791 (38.77)	
Elderly (65+)	70 (3.42)	69 (3.38)	
Gender groups			
Male at birth	794 (38.75)	781 (38.28)	< 0.001
Female at birth	1144 (55.83)	1233 (60.44)	
LGBTQIA+	111 (5.42)	26 (1.27)	
Marital status			
Single	863 (42.12)	811 (39.75)	0.13
Married	1186 (57.88)	1229 (60.25)	
Formal education			
No formal education (0 years)	343 (16.74)	380 (18.63)	< 0.001
Primary school (1–6 years)	934 (45.58)	1040 (50.98)	
Secondary school (7–9 years)	443 (21.62)	404 (19.80)	
Tertiary (10–12 years)	235 (11.47)	151 (7.40)	
University (> 12 years)	94 (4.59)	65 (3.19)	
Employment			
Unemployed	356 (17.37)	411 (20.15)	< 0.001
Farmer/fisherman	501 (24.45)	571 (27.99)	
Motor/taxi driver	59 (2.88)	65 (3.19)	
Self-employed business	428 (20.89)	338 (16.57)	
Government staff/uniformed officer	102 (4.98)	69 (3.38)	
Private employee/NGO staff	180 (8.78)	148 (7.25)	
Construction/factory worker	291 (14.20)	325 (15.93)	
Others	132 (6.44)	113 (5.54)	
Family size			
Living alone	45 (2.20)	54 (2.65)	0.01
Small family (2–4 members)	1421 (69.35)	1495 (73.28)	
Medium family (5–7 members)	515 (25.13)	442 (21.67)	
Large family (> 8 members)	68 (3.32)	49 (2.40)	
Family with or without children			
No children under 15	869 (42.41)	848 (41.57)	0.23
One child under 15	641 (31.28)	680 (33.33)	
Two children under 15	383 (18.69)	342 (16.76)	
> Three children under 15	156 (7.61)	170 (8.33)	
Duration living with HIV			
Newly diagnosed (1–5 years)	398 (19.42)	219 (10.74)	< 0.001
Medium duration (6–10 years)	392 (19.13)	325 (15.93)	
Long duration (11–15 years)	527 (25.72)	655 (32.11)	
Very long duration (16–20 years)	551 (26.89)	645 (31.62)	
Extensive duration (> 21 years)	181 (8.83)	196 (9.61)	

(Continued)

Table 1. (Continued)

	MMD (n = 2049)	CAD (n = 2040)	p-value
Duration receiving ART therapy			
Newly on ART (0–5 years)	445 (21.72)	277 (13.58)	< 0.001
Medium duration (6–10 years)	445 (21.72)	407 (19.95)	
Long duration (11–15 years)	625 (30.50)	724 (35.49)	
Very long duration (16–20 years)	469 (22.89)	556 (27.25)	
Extensive duration (> 21 years)	65 (3.17)	76 (3.73)	
Mode of transportation to ART clinic			
On foot/bicycle	71 (3.47)	82 (4.02)	< 0.001
Tuk tuk/motorcycle/car	1900 (92.73)	1946 (95.39)	
Boat/ship/others	78 (3.81)	12 (0.59)	
Travel time to ART clinic			
Short travel (< 0.5 hours)	855 (41.73)	944 (46.27)	0.005
Medium travel (> 0.5–2 hours)	985 (48.07)	918 (45.00)	
Long travel (> 2–8 hours)	198 (9.66)	160 (7.84)	
Very long travel (> 8 hours)	11 (0.54)	18 (0.88)	
Other variables			
Waiting time at ART clinic (Median [IQR], hour)	1.5 (1)	2 (2)	< 0.001
Household monthly income (Median [IQR], USD)	216 (240)	192 (237.6)	< 0.001
Has at least one co-morbidity ^a	352 (17.18)	508 (24.90)	< 0.001

Note: Values in the table are numbers (%) unless indicated.

Abbreviations: ART, antiretroviral therapy; CAD, community antiretroviral delivery; IQR, interquartile range; LGBTQIA+, lesbian, gay, bisexual, transgender, queer, intersex, asexual or preferred not to reveal their orientation; MMD, multi-month dispensing; NGO, non-governmental organization; SD, standard deviation; USD, United States Dollar.

^aCo-morbidity includes diabetes mellitus, high cholesterol and hypertension.

direct and indirect impacts of the pandemic [48]. During the pandemic, essential health services and ARV supplies were disrupted, and the health workforce, already overstretched before the pandemic, struggled with an even heavier workload due to additional COVID-19-related responsibilities [49–54]. These disruptions impacted access to ART, and fear of visiting health facilities, financial hardships and caregiving duties also affected the use of HIV services [52]. Although not definitive due to conflicting study results, reviews have indicated that people living with HIV have a higher likelihood of experiencing severe COVID-19 [55], increased mortality [55, 56] and higher rates of hospitalisation from COVID-19 [57]. These factors could affect ART adherence and the quality of life of people living with HIV, potentially explaining the deteriorated outcomes observed in this study.

Social distancing and COVID-19 restrictions necessitated several adaptations in this study. For instance, community workers in the MMD sites have been reported to deliver ARVs to people living with HIV to support continued treatment. In the CAD arm, on some occasions, CAGs had to meet in smaller groups, or CAWs had to deliver ARVs to their members' houses rather than meet as a group. These adaptations might have affected the peer-to-peer support envisaged for the CAD model. Though necessary during the pandemic, these deviations from the protocol potentially account for the small difference in the number of visits to the ART clinics made by

participants in the MMD and CAD arms. This suggests that the cost-effectiveness of the CAD model might have been underestimated, as the differences in the OOEPE and productivity losses for participants between the two models might have been more significant if not for these protocol deviations.

Altogether, despite the protocol deviations, the CAD model has shown mitigating effects on the drop in ART adherence and quality of life of people living with HIV during the COVID-19 pandemic. These findings support earlier studies that showed that the CAD model had delivered comparable or better outcomes than facility-based services in ART adherence, viral load suppression, retention in care and HIV-related mortality [58, 59]. Although the effectiveness of DSD, such as MMD and CAD models, has been studied in Asia and Africa [60–64], there is a lack of cost-effectiveness studies on DSD models. Most literature focuses on cost analysis [65–67]. This cost-effectiveness study contributes to the literature on the economic evaluation of DSD and, more broadly, on the economic evaluation of HIV, which has seen an increase in publications but is concentrated in developed countries [68].

Another interesting finding is the consultation fee, informal service fees, charges for more extended ARV supplies and other payments requested by doctors reported in this study, reinforcing previous reports of unofficial charges for HIV

Table 2. ART adherence and quality of life of participants at baseline and endline in the MMD (control) and CAD (intervention) arms

	Baseline			Endline		
	MMD	CAD	<i>p</i> -value	MMD	CAD	<i>p</i> -value
	(<i>n</i> = 2049) <i>n</i> (%)	(<i>n</i> = 2040) <i>n</i> (%)		(<i>n</i> = 2049) <i>n</i> (%)	(<i>n</i> = 2040) <i>n</i> (%)	
ART adherence						
ART adherent	1840 (89.80)	1766 (86.60)	0.002	1635 (79.78)	1680 (82.34)	0.04
Non-ART adherent	209 (10.20)	274 (13.43)		414 (20.22)	360 (17.66)	
Quality of life – physical health						
Good physical health (PCS ≥ 50)	1431 (69.84)	1128 (55.29)	< 0.001	1020 (49.78)	947 (46.41)	0.03
Poor physical health (PCS < 50)	618 (30.16)	912 (44.71)		1029 (50.23)	1093 (53.59)	
Quality of life – mental health						
Good mental health (MCS ≥ 42)	1706 (83.26)	1557 (76.32)	< 0.001	1605 (78.33)	1520 (74.53)	0.004
Poor mental health (MCS < 42)	343 (16.74)	483 (23.68)		444 (21.67)	520 (25.47)	

Abbreviations: ART, antiretroviral therapy; CAD, community antiretroviral delivery; MCS, Mental Component Score; MMD, multi-month dispensing; PCS, Physical Component Score.

Table 3. Intervention effect on ART adherence and quality of life

	Crude		Adjusted model	
	OR (95% CI)	<i>p</i> -value	AOR (95% CI)	<i>p</i> -value
ART adherent	1.61 (1.24, 2.10)	< 0.001	1.59 (1.22, 2.08) ^a	< 0.001
Good physical health	1.64 (1.36, 1.97)	< 0.001	1.64 (1.35, 1.99) ^b	< 0.001
Good mental health	1.25 (1.00, 1.56)	0.05	1.21 (0.97, 1.52) ^c	0.10

Abbreviations: AOR, adjusted odds ratio; ART, antiretroviral therapy; CI, confidence interval; OR, odds ratio.

^aCovariates included for adjustment: ART site setting, age, employment and duration of receiving anti-retroviral treatment.

^bCovariates included for adjustment: Gender, age, formal education, employment, travel time, monthly household income and presence of comorbidity.

^cCovariates included for adjustment: ART site setting, gender, formal education, employment, size of family, travel time, monthly household income, duration receiving anti-retroviral treatment and presence of comorbidity.

services [69]. In addition, transport costs, similar to other studies in Indonesia and Vietnam, made up the bulk of OOPe for HIV treatment [70, 71]. Considering that cost is a barrier to care, especially for people living with HIV who often face socio-economic hardships and are more likely to be from the lower socio-economic strata [72], future studies should explore the effect of these OOPes on retention in the HIV care continuum in low- and middle-income country settings.

This study has several limitations. First, the absence of midline data limited the verification of outcome trends, which may not accurately reflect the true intervention effect and could instead indicate regression towards the mean. Additionally, the assumption of parallel trends required for the DiD method could not be validated due to the use of data from

only two time points. Second, the time participants spent with the CAWs in the CAD model was not quantified. Therefore, the productivity gains from reduced time at the ART clinics might be overestimated, inflating the CAD model's cost-effectiveness. Third, adherence to routine viral load tests was challenging during the pandemic. Consequently, self-reported adherence was used, which is subject to recall bias and social desirability bias, potentially resulting in over-reporting. Furthermore, the Morisky Medication Adherence Scale, though widely used in HIV populations, has not been validated specifically for people living with HIV, and its reliability as a measure of adherence for HIV populations remains uncertain.

Fourth, the LTFU participants were imputed under their assigned study arms consistent with the ITT principle.

Table 4. Difference-in-difference of predicted probabilities of participants adhering to ART and having good physical health between the MMD (control) and CAD (intervention) arms, accounting for baseline differences

	MMD (n = 2049)			CAD (n = 2040)			DiD (B–A)
	Baseline Mean (95% CI)	Endline Mean (95% CI)	Diff (A)	Baseline Mean (95% CI)	Endline Mean (95% CI)	Diff (B)	
ART adherent	0.91 (0.89, 0.92)	0.81 (0.78, 0.84)	–0.10	0.87 (0.84, 0.89)	0.82 (0.79, 0.85)	–0.05	0.05
Good physical health	0.65 (0.62, 0.68)	0.43 (0.40, 0.47)	–0.22	0.51 (0.47, 0.54)	0.42 (0.38, 0.45)	–0.09	0.11

Abbreviations: ART, antiretroviral therapy; CAD, community antiretroviral delivery; CI, confidence interval; DiD, difference in difference; MMD, multi-month dispensing.

Table 5. Medical and non-medical costs incurred by people living with HIV and their caregivers on their last trip to the ART clinic in the MMD (control) and CAD (intervention) arms (in Riel, unadjusted)

	Baseline		p-value	Endline		p-value
	MMD	CAD		MMD	CAD	
	(n = 2049)	(n = 2040)		(n = 1441)	(n = 1626)	
	Median (range)	Median (range)		Median (range)	Median (range)	
Medical cost						
Consultation fee	0 (60,000)	0 (0)	0.05	0 (100,000)	0 (100,000)	0.29
Diagnostic fee	0 (40,000)	0 (40,000)	0.42	0 (10,000)	0 (20,000)	0.33
Medicine fee	0 (60,000)	0 (5000)	< 0.001	0 (300,000)	0 (5000)	0.11
Other medical cost	0 (40,000)	0 (400,000)	0.05	0 (15,000)	0 (10,000)	0.98
Total direct cost	0 (80,000)	0 (400,000)	< 0.001	0 (400,000) ^a	0 (100,000) ^b	0.47
Non-medical cost						
Transport cost	8000 (1,400,000)	6000 (230,000)	< 0.001	10,000 (400,000)	10,000 (2,000,000)	< 0.001
Food cost	5000 (80,000)	5000 (80,000)	0.47	5000 (230,000)	5000 (200,000)	0.28
Lodging cost	0 (60,000)	0 (90,000)	0.99	0 (40,000)	0 (28,000)	0.17
Other non-medical cost	0 (40,000)	0 (80,000)	< 0.001	0 (60,000)	0 (50,000)	0.77
Total indirect cost	14,500 (1,410,000)	12,450 (247,000)	< 0.001	15,000 (605,000) ^c	15,000 (2,200,000) ^d	< 0.001
Total OOPE	15,000 (1,410,000)	12,900 (402,000)	< 0.001	15,000 (800,000) ^e	15,000 (2,200,000) ^f	< 0.001

Abbreviations: CAD, community antiretroviral delivery; LTFU, loss to follow-up; MMD, multi-month dispensing; OOPE, out-of-pocket expenditure.

^aThe median (range) total direct cost for all participants in MMD, including imputed costs of those LTFU at the endline, is 0 (400,000).

^bThe median (range) total direct cost for all participants in CAD, including imputed costs of those LTFU at the endline, is 0 (100,000).

^cThe median (range) total indirect cost for all participants in MMD, including imputed costs of those LTFU at the endline, is 15,000 (1,090,600).

^dThe median (range) total indirect cost for all participants in CAD, including imputed costs of those LTFU at the endline, is 15,000 (2,200,000).

^eThe median (range) total OOPE for all participants in MMD, including imputed costs of those LTFU at the endline, is 15,200 (1,166,000).

^fThe median (range) total OOPE for all participants in CAD, including imputed costs of those LTFU at the endline, is 15,000 (2,200,000).

Table 6. Total cost incurred at the health system and societal levels in the MMD (control) and CAD (intervention) arms (in USD and adjusted for inflation)

	MMD (n = 2049)	CAD (n = 2040)
Health system cost		
CAW salary	—	235,260
Training	4733.30	6007.37
Meetings with CAWs and communication cost for ART clinics to communicate with CAWs		9055.03
Total health system cost (primary perspective)	4733.30	250,322.40
Mean cost/person living with HIV	2.31	122.71
Societal cost		
OOPE (people living with HIV and their caregivers) ^a	58,764.57	51,008.84
OOPE (CAW)	0	135,891.18
Productivity cost (people living with HIV)	21,910.09	18,007.79
Productivity cost (CAW)	0	85,991.17
Subtotal cost	80,674.66	290,898.98
Total health system and societal cost (secondary perspective)	85,407.96	319,339.03 ^b
Mean cost/person living with HIV (secondary perspective)	41.68	156.54

Abbreviations: CAD, community antiretroviral delivery; CAW, community action worker; MMD, multi-month dispensing; OOPE, out-of-pocket expenditure.

^aAt the baseline, a total of 144 (93 in the CAD [intervention] and 51 in the MMD [control]), and at the endline, a total of 176 (91 in the CAD [intervention] and 85 in the MMD [control]) brought a caregiver for their last visit to the ART facility. Expenses incurred by their caregiver are included in the OOPE cost reported in this table.

^bTotal health system and societal costs exclude OOPE and productivity losses incurred by CAWs, as their salary, transport and communication costs were covered by the health system.

Table 7. Incremental cost-effectiveness ratios of the difference in cost and outcomes in ART adherence and quality of life between the MMD (control) and CAD (intervention) arms

	Incremental cost	Incremental effect	ICER	CET (1): One-time GDP per capita (USD1799) INB	CET (2): Opportunity cost (USD304) INB
ART adherence					
Health system	120.40	0.05	2408	−30.45	−105.2
Societal	114.86	0.05	2297.2	−24.91	−99.66
Good physical health					
Health system	120.40	0.11	1094.55	77.49	−86.96
Societal	114.86	0.11	1044.18	83.03	−81.42

Abbreviations: ART, antiretroviral therapy; CET, cost-effectiveness threshold; ICER, incremental cost-effectiveness ratio; INB, incremental net benefit.

However, some LTFU participants may have died during the study period. As a result, imputing outcomes for deceased participants could either underestimate or overestimate the estimated intervention effect, depending on the distribution of unobserved mortality among LTFU across study arms. Lastly, while improvements in healthcare provider productivity were of interest, the data lacked the granularity to quantify productivity gains in the health system from the CAD model. Field visit feedback revealed that healthcare workers at CAD sites redirected the time saved to people living with HIV who

required more attention. Further investigation is needed to validate the cost-effectiveness of the CAD model, considering productivity gains and improvements in quality of care within the health system.

5 | CONCLUSIONS

The CAD model helped mitigate the decline in ART adherence and quality of life of stable people living with HIV during the

COVID-19 pandemic and was cost-effective in reducing the drop in physical health when evaluated against a less stringent threshold. However, further studies are needed to validate the cost-effectiveness of the CAD model.

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COMPETING INTERESTS

The authors declare that they have no competing interests.

AUTHORS' CONTRIBUTIONS

LYEY contributed to the study design, developed the data analysis plan, conducted the data analyses and wrote the draft. PC contributed to the study design, led the data collection and provided input on the draft. ZT, MN-H and MZ supported the data analyses and provided feedback on the draft. SS, BN and VO contributed to the study design and offered strategic advice on the study's implementation, ensuring alignment with the national strategic plan for HIV/AIDS and prioritising the needs of beneficiaries in the study's implementation. ST and KP contributed to the study design. KP supported the data analyses and the draft. SY led the overall study, encompassing study design, implementation, data collection, analyses and finalising the draft. All authors have read and approved the final manuscript.

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DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

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SUPPORTING INFORMATION

Additional information may be found under the Supporting Information tab for this article:

Supporting information: CHEERS 2022 Checklist.

Table S1: Univariate regression analysis of loss to follow-up with outcomes and sociodemographic characteristics at baseline.

Table S2: Computation of cost items at the health system and societal levels.

RESEARCH ARTICLE

Exploring healthcare experiences of transgender people in the Jabula Uzibone study, South Africa: a longitudinal implementation science study

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Abstract

Introduction: The World Health Organization promotes a transgender-differentiated service delivery (TG-DSD) model to overcome barriers to HIV service engagement among transgender people (TGP). For TGP, an essential element of DSD includes gender-affirming care which is non-stigmatising, free from discrimination and celebrates their gender identity. The *Jabula Uzibone* Study, launched in November 2023, assesses the cost and effectiveness of TG-DSD on HIV outcomes. In this paper, we describe the baseline characteristics of TGP in our study and explore whether there are differences in healthcare experiences among those seeking care at TG-DSD clinics versus standard service delivery (SSD) clinics at baseline.

Methods: This observational, mixed-method, prospective implementation study compares models of care at four TG-DSD and four SSD facilities using standardised observation checklists, in-depth and key informant interviews. For this paper, we asked participants about healthcare experiences and experiences of stigma through a structured, interviewer-administered quantitative survey. We assessed the sections of the quantitative survey which ask about self-reported experiences of stigma.

Results: The study enrolled 422 TGP with HIV (217 TG-DSD and 205 SSD) and 248 TGP without HIV (128 TG-DSD and 120 SSD); 15% (102/670) gender non-conforming, 15% (91/670) TG men and 70% (477/670) TG women. Participants' median age was 29 years, interquartile range: 24–35 years. SSD participants at baseline were 46% more likely to experience stigma compared to their TG-DSD counterparts (aOR = 1.46, 95% CI: 1.06, 2.01). SSD participants were more likely to encounter a healthcare provider who is unwilling to provide care for them (aOR = 1.55, 95% CI: 1.09, 2.21) and to report that healthcare workers are unable to provide the same quality care to TGP as they do other people (aOR = 1.46, 95% CI: 1.00, 1.91) compared to their TG-DSD counterparts.

Conclusions: TGP from TG-DSD facilities were less likely to report experiences of facility-based enacted stigma at baseline, compared to the TGP from SSD facilities. Our study highlights the importance of provider training in tailored transgender healthcare to provide gender-affirming healthcare services. Results from the *Jabula Uzibone* study will provide further evidence of the effectiveness of TG-DSD models in sub-Saharan Africa, and the role of stigma and discrimination in HIV outcomes among TGP.

Keywords: differentiated service delivery; gender-affirming care; healthcare access; South Africa; stigma; transgender healthcare

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1 | INTRODUCTION

Despite growing global recognition of the unique challenges faced by transgender people (TGP) within health systems, they continue to experience systemic discrimination, a lack of culturally competent care and provider bias. Consequently, TGP experience significant health disparities, including a disproportionately higher prevalence of HIV [1–3]. Contributing factors include healthcare avoidance, fear of discrimination and previous negative healthcare experiences within

healthcare settings [4–6]. HIV prevalence among transgender women is estimated at 63% in Johannesburg, and approximately 50% in Cape Town and Buffalo City; data for Nelson Mandela Bay were unavailable at the time of writing [7].

In South Africa, recent data from 1423 TGP revealed persistent systemic discrimination in public health facilities. Only 7% of respondents felt safe and comfortable accessing care at public health facilities, and 10% reported being denied care in 2022 due to their gender identity or sexual orientation [8]. Despite constitutional guarantees of the right to

health, TGP in South Africa continue to encounter health-care denial and provider unwillingness to provide care [3, 9]. A systematic review exploring access and utilisation among African transgender communities reported that discriminatory practices among healthcare providers led to shame, fear and anxiety [2]. These experiences contribute to mistrust in the health system and delays in seeking timely medical care, further exacerbating health disparities [10].

To address such inequities, the World Health Organization and the International AIDS Society have endorsed differentiated service delivery (DSD) models which aim to improve access and engagement in care among marginalised populations [11, 12]. For transgender individuals, DSD models are designed to remove barriers such as provider biases, discrimination and a lack of affirming services [13]. Central to transgender-specific DSD (TG-DSD) is the provision of gender-affirming healthcare, which includes the use of chosen names and pronouns, access to psychosocial support, provision of gender-affirming hormone therapy (GAHT) and the creation of inclusive, discrimination-free clinical environments [14]. Evidence indicates that TGP who access gender-affirming healthcare demonstrate improved quality of life, higher engagement in care, better adherence to HIV treatment, improved psychological wellbeing and reduced disparities compared to those without access to such services [15–18].

While GAHT can be administered safely within a primary healthcare setting, it is seldom offered in public health facilities in sub-Saharan African countries [19]. Accessing GAHT typically requires regular clinic visits and monitoring, which may foster routine health-seeking behaviour and improve overall outcomes. In South Africa, TG-DSD services are primarily delivered through donor-funded programmes, which are geographically limited. As a result, many TGP must rely on public healthcare facilities where stigma and discrimination from facility staff persists [8, 16]. Wits RHI delivers TG-DSD models in four South African health districts (Buffalo City, City of Cape Town, Johannesburg and Nelson Mandela Bay) through funding from the United States Agency for International Development (USAID).

Despite well-documented barriers to healthcare access for TGP, there remains a paucity of research directly comparing service delivery models. The *Jabula Uzibone* study (Zulu term meaning Be Happy and See Yourself) aims to evaluate the effectiveness and cost of TG-DSD in delivering HIV prevention and care compared to standard service delivery (SSD) clinics, that is public health facilities. The overall study hypothesises that healthcare experiences differ substantially between DSD and SSD settings, driven by the affirming environments at TG-DSD clinics. This paper describes the baseline characteristics of enrolled participants and presents a cross-sectional analysis of baseline healthcare experiences in DSD versus standard service delivery (SSD) clinics.

2 | METHODS

The *Jabula Uzibone* study is an observational multi-site mixed methods prospective implementation science study assessing the implementation of TG-DSD models and SSD models at

the facility level using standardised observation checklists at all eight facilities (four DSD and four SSD). Participants will complete a quarterly survey to assess changes over time in experiences of gender affirmation as well as experiences of stigma. For TGP on antiretroviral therapy (ART), we will measure their HIV RNA levels at baseline and at 12 months. For TGP on pre-exposure prophylaxis (PrEP), we will measure tenofovir levels at baseline and at 12 months. The objective of this paper is to assess the baseline characteristics of participants in this study, focusing on the differences between self-reported healthcare experiences among the TG-DSD and SSD participants.

2.1 | Study setting

We conducted the study in the four South African health districts where Wits RHI clinics are located. Buffalo City and Nelson Mandela Bay clinics are co-located within the department of health facilities in a park home, which serves as a separate clinic from the facility in which they are located. The City of Cape Town and Johannesburg operate stand-alone clinics. These four clinics, operating since 2019, were the first USAID-funded transgender clinics in South Africa [16]. Staff provide services to over 5000 TGP in 1 year, more than 1000 are on ART, close to 1000 are on PrEP and more than 600 are on GAHT. Peer educators, who mostly identify as transgender or queer, drive the community outreach model. All sites offer free gender-affirming care, which includes GAHT, and other primary healthcare services. The SSD facilities, operated by the Department of Health in South Africa, provide standard primary healthcare, including HIV prevention and treatment service, but exclude GAHT.

2.2 | Participant eligibility, recruitment, enrolment and data collection

2.2.1 | Eligibility

Eligibility criteria included: being ≥ 18 years old, having a gender identity that differs from sex assigned at birth, receiving healthcare in one of the TG-DSD clinics or in an SSD clinic within the four districts. Participants who tested HIV negative may or may not be on oral PrEP, and participants who tested HIV positive were required to have been prescribed ART.

2.2.2 | Recruitment

We used stratified purposive sampling to ensure the enrolment of participants. Peer educators, who all identified as transgender or queer, recruited participants from their social networks, via social media posts, WhatsApp groups, and word of mouth in the community and facilities within the study districts using flyers and palm cards. Power statistics and sample size for the overall study were based on the primary outcome of viral suppression. There are no documented viral suppression results for TGP, nevertheless, we used 47% as reported by Fearon et al. [20]. Our unpublished study among TGP in South Africa showed that those who were on GAHT were 2.73 times more likely to be virally suppressed compared to TGP who did not have access to GAHT, suggesting an effect size $\sim 20\%$. An effect size as low as 15% is considered clin-

ically significant. We considered our sample size based on these data and an estimated loss to follow-up of ~10%, to provide adequate statistical power. Once in the study, participants could switch their model of care dependent on service convenience, as it would have been unethical to restrict participants from choosing their preferred model of service delivery.

2.2.3 | Enrolment

Peer educators pre-screened participants who met the eligibility criteria and conducted a rapid HIV test to confirm self-reported HIV status. Study staff conducted the informed consent process in private areas, ensuring that the potential participants understood all the study requirements, including the potential risks of study participation. Once the participants consented to participate, they signed the informed consent form, and the study staff offered them a copy to take home. Enrolment commenced in November 2023 and the final participant was enrolled in September 2024.

2.2.4 | Data collection

Data collection took place either in the Wits RHI TGD-DSD clinics or in the community (in a private gazebo, a dedicated consulting room at an SSD facility or in a mobile clinic). Study staff administered a 1-hour long electronic quantitative survey for participants. Socio-demographic information including age, education, gender and gender identity was collected. We operationalised gender based on participant self-report as gender non-conforming, transgender man and transgender woman.

We assessed the sections of the quantitative survey which asks about self-reported experiences of stigma for the objective of this paper. Enacted stigma can be described as outright discrimination, violence or derision of people's experience because of an actual or perceived transgender identity [21, 22]. Stigma was assessed using the brief health facility stigma index developed by Nyblade et al. [23]. The index includes four items with Yes/No response options (e.g. Has the following happened to you or others when getting healthcare—"Healthcare workers unwilling to care for a transgender person or gender non-conforming client?"). A response of "yes" was coded as 1 and a "no" was a 0. Then, scores were summed for each participant to arrive at a final score. Higher scores indicate greater facility-based stigma. Responses of "don't know," or "prefer not to answer" were treated as missing for the final analysis. For the four questions, the range of this type of response was from 1.94% to 4.93%.

We also assessed healthcare experiences by asking participants about their experiences when they accessed healthcare in the past 3 months (e.g. "Did a healthcare provider refuse to give you care?"), with possible responses of "yes," "no," "don't know" and "prefer not to answer." Participants who responded, "don't know," or "prefer not to answer" were excluded from the final analysis (range: 0.15–1.02%). We also read out statements to participants as if it were a statement they made and asked them to rate each one with "never," "rarely," "sometimes," "often," "always," "don't know," "does not apply" and "prefer not to answer." The statement included

items such as "I delay seeking medical care because of my gender identity or expression." Participants who responded, "don't know," "does not apply" or "prefer not to answer" were excluded from the final analysis (0.3–8.8%).

2.3 | Data analysis

We used STATA 18.0 [24] to conduct statistical analysis for the baseline results. Categorical variables, such as healthcare experiences, were described with proportions, and continuous variables, such as age, were presented as medians with standard deviations and interquartile ranges. We performed chi-square tests for associations between categorical variables. We used Pearson's correlations for bivariate analyses of continuous variables. Variables significant at p -value < 0.2 on univariate analysis were included in the multivariable analyses to compare differences in various experiences based on participants accessing care at a TG-DSD or SSD site.

2.4 | Ethical considerations

The *Jabula Uzibone* study was approved by the University of Witwatersrand Human Research Ethics Committee (Protocol Number: M220420) and the Duke University Health System Institutional Review Board (Protocol Number:00113320). Participants signed the informed consent form before any study procedures were conducted. Participants were reimbursed with ZAR300 (USD16) for each study visit.

3 | RESULTS

3.1 | Characteristics of enrolled participants

The study enrolled 670 transgender participants across the four sites (Table 1). The majority, 71% (477/670), were transgender women, 15% (102/670) were gender non-conforming and 14% (91/670) were transgender men. The median age of the participants was 29 years, with an interquartile range of 24–35 years, and the majority, 64% (429/670), completed high school. Most of the participants were from Johannesburg, 41% (275/670) across both models. Of the 248 participants without HIV, 56% (138/248) reported to have taken oral PrEP to prevent HIV, and 73% (101/139) had taken oral PrEP in the last 30 days. Forty percent of participants (263/654) reported they wanted to be on hormone therapy, but they did not have access to it. Participant's gender, age, PrEP and GAHT use were significantly associated ($p < 0.01$) with the service delivery model.

3.2 | Facility-based enacted stigma

Half (50%, 331/666) of the participants reported that they had experienced at least one of the four manifestations of facility-based stigma (Table 2). Stigma experiences included healthcare workers unwilling to provide healthcare to TGP because of their gender identity (31%, 200/654); experiencing poorer quality of healthcare being provided to TGP compared to other people (38%, 248/657); having heard healthcare workers talk badly about a transgender person (38%, 243/647); and having a healthcare worker unnecessarily disclose a client's gender identity (32%, 206/637).

Table 1. Characteristics of *Jabula Uzibone* participants

	Overall N (%)	Transgender-differentiated service delivery n (%)	Standard service delivery n (%)	p-value
Gender				
Gender non-conforming	102 (15.22)	48 (47.1)	54 (52.9)	0.005
Transgender man	91 (13.58)	34 (37.4)	57 (62.6)	
Transgender woman	477 (71.19)	263 (55.1)	214 (44.9)	
Age				
Median, interquartile range		28 (24–34)	30 (25–36)	0.051
18–24	196 (29.25)	114 (58.2)	82 (41.8)	
25–29	174 (25.97)	95 (54.6)	79 (45.4)	
30–34	141 (21.04)	67 (47.5)	74 (52.5)	
35–39	82 (12.24)	37 (45.1)	45 (54.9)	
40+	77 (11.49)	32 (41.6)	45 (58.4)	
Education				
Primary	9 (1.34)	3 (33.3)	6 (66.7)	0.1
Grade 8–10	94 (14.03)	48 (51.1)	46 (48.9)	
Grade 11–12	429 (64.03)	211 (49.2)	218 (50.8)	
Higher education	138 (20.60)	83 (60.1)	55 (39.9)	
District service delivery model				
Buffalo City Municipality TG-DSD	48 (7.16)	48 (100)		< 0.001
Buffalo City Municipality SSD	42 (6.27)		42 (100)	
City of Cape Town TG-DSD	102 (15.22)	102 (100)		
City of Cape Town SSD	101 (15.07)		101 (100)	
Johannesburg TG-DSD	140 (20.90)	140 (100)		
Johannesburg SSD	134 (20)		134 (100)	
Nelson Mandela Bay TG-DSD	55 (8.21)	55 (100)		
Nelson Mandela Bay SSD	48 (7.16)		48 (100)	
HIV status				
HIV negative	248 (37.01)	128 (51.6)	120 (48.4)	0.96
HIV positive	422 (62.99)	217 (51.4)	205 (48.6)	
Ever started oral PrEP				
No	110 (44.35)	36 (33.96)	74 (69.81)	< 0.001
Yes	138 (55.65)	93 (70.45)	45 (34.09)	
Taken oral PrEP in past 30 days				
No	38 (27.34)	20 (52.6)	18 (47.4)	0.028
Yes	101 (72.66)	73 (72.3)	28 (27.7)	
Currently on hormone therapy				
No, and I do not want to be on hormones	184 (28.13)	71 (38.6)	113 (61.4)	< 0.001
Yes	207 (31.65)	150 (72.5)	57 (27.5)	
No, but I want to be taking hormones	263 (40.21)	115 (43.7)	148 (56.3)	

Abbreviations: PrEP, pre-exposure prophylaxis; SSD, standard service delivery; TG-DSD, transgender-specific differentiated service delivery.

3.3 | Healthcare experiences

More than a quarter (29%, 191/667) of the participants reported that they had ever avoided seeking medical care they needed because of fear of being mistreated as a transgender person (Table 3), 19% (129/667) had done so in the past 12 months. Seventy-three percent (73%) of DSD and SSD participants had seen a healthcare provider in the past 3 months and reported several bad experiences, including, being disrespected (10%, 47/483), healthcare provider refusing to

provide care (5%, 25/487) and being harassed at a healthcare facility while receiving care (8%, 37/485). Additionally, a third (32%, 180/558) of the participants reported at least one negative experience during a healthcare visit.

3.4 | Health survey

Forty-six percent of participants reported having ever delayed seeking medical care because of their gender identity or expression (Table 4). More than a quarter (27%, 176/663)

Table 2. Facility-based enacted stigma reported by *Jabula Uzibone* participants

	Overall N (%)	Transgender- differentiated service delivery n (%)	Standard service delivery n (%)	p-value
Healthcare workers unwilling to care				
Yes	200 (30.58)	90 (45)	110 (55)	0.027
Healthcare workers providing poorer quality of care				
Yes	248 (37.75)	115 (46.4)	133 (53.6)	0.043
Healthcare workers talking badly				
Yes	243 (37.56)	119 (49)	124 (51)	0.268
Healthcare workers disclosing a client's gender identity				
Yes	206 (32.34)	94 (45.6)	112 (54.4)	0.031

Table 3. Healthcare experiences among *Jabula Uzibone* participants

	Overall N (%)	Transgender- differentiated service delivery n (%)	Standard service delivery n (%)	p-value
Ever avoided healthcare because of previous bad experiences				
No	476 (71.36)	252 (52.9)	224 (47.1)	0.496
Yes, in the past 12 months	129 (19.34)	59 (45.7)	70 (54.3)	
Yes, more than 12 months ago	62 (9.30)	32 (51.6)	30 (48.4)	
Seen a healthcare provider in the last 3 months				
Yes	488 (72.94)	266 (54.5)	222 (45.5)	0.02
Healthcare experiences				
Treated with respect				
Yes	436 (90.27)	242 (55.5)	194 (44.5)	0.094
Healthcare provider refused to give you care				
Yes	25 (5.13)	16 (64)	9 (36)	0.344
Harassed in a healthcare setting				
Yes	37 (7.63)	20 (54.1)	17 (45.9)	0.412
Touched inappropriately by someone during a healthcare visit				
Yes	21 (4.30)	11 (52.4)	10 (47.6)	0.841

of the participants reported that they are never comfortable seeking healthcare in their own communities and (20%, 134/655) reported that being transgender changed the way healthcare providers interacted with them. Twenty-three per cent (21%, 141/665) of participants reported they are always afraid of being harassed when they seek medical care, and (15%, 97/667) reported that they always accept mistreatment due to their gender identity or expression to get medical care ((Table 5)).

3.5 | Examining differences in healthcare between differentiated service delivery model and SSD model

3.5.1 | Facility-based enacted stigma

We examined facility-based enacted stigma as an overall score and each of the forms of facility-based enacted stigma (i.e. healthcare workers: 1. unwilling to provide healthcare to a transgender person; 2. providing poorer quality of healthcare

to a transgender person; 3. talking badly about a transgender person; 4. disclosing a client's transgender identity with colleagues without consent when not medically necessary). Participants who accessed healthcare services at the SSD facilities were 1.46 times (aOR = 1.46, 95% CI [1.06, 2.01]) more likely to experience facility-enacted stigma compared to their TG-DSD counterparts. Additionally, when each of the forms of facility-enacted stigma were examined for differences between service delivery models adjusting for age, education and receiving hormone therapy, SSD participants were more likely to have a healthcare provider who is unwilling to provide care for them (aOR = 1.55, 95% CI [1.09, 2.21]) and to report poorer quality care from healthcare workers (aOR = 1.46, 95% CI [1.00, 1.91]) compared to TG-DSD participants. Additionally, SSD participants were 1.45 times more likely to have a healthcare worker disclose their gender identity without consent when not medically necessary (aOR = 1.45, 95% CI [1.02, 2.05]) compared to TG-DSD participants.

Table 4. Health survey results from *Jabula Uzibone* participants

	Overall N (%)	Transgender- differentiated service delivery n (%)	Standard service delivery n (%)	p-value
Health survey results				
Delay seeking medical care				
Never	361 (54.20)	199 (55.1)	162 (44.9)	0.312
Rarely	90 (13.51)	41 (45.6)	49 (54.4)	
Sometimes	134 (20.12)	68 (50.7)	66 (49.3)	
Often	44 (6.61)	17 (38.6)	27 (61.4)	
Always	37 (5.56)	18 (48.6)	19 (51.4)	
Healthcare providers provide same quality of care to transgender people as they do to other peoplea				
Never	147 (22.51)	87 (59.2)	60 (40.8)	0.033
Rarely	75 (11.49)	41 (54.7)	34 (45.3)	
Sometimes	170 (26.03)	94 (55.3)	76 (44.7)	
Often	95 (14.55)	45 (47.4)	50 (52.6)	
Always	166 (25.42)	69 (41.6)	97 (58.4)	
Comfortable seeking healthcare in own communitya				
Never	176 (26.55)	117 (66.5)	59 (33.5)	< 0.001
Rarely	59 (8.90)	35 (59.3)	24 (40.7)	
Sometimes	111 (16.74)	55 (49.5)	56 (50.5)	
Often	74 (11.16)	34 (45.9)	40 (54.1)	
Always	243 (36.65)	99 (40.7)	144 (59.3)	
Being transgender changes the way healthcare provider interacts with me				
Never	170 (25.95)	88 (51.8)	82 (48.2)	0.811
Rarely	52 (7.94)	23 (44.2)	29 (55.8)	
Sometimes	208 (31.76)	112 (53.8)	96 (46.2)	
Often	91 (13.89)	47 (51.6)	44 (48.4)	
Always	134 (20.46)	66 (49.3)	68 (50.7)	
Experience with health providers has been positive				
Never	18 (2.69)	10 (55.6)	8 (44.4)	0.079
Rarely	37 (5.53)	14 (37.8)	23 (62.2)	
Sometimes	125 (18.68)	54 (43.2)	71 (56.8)	
Often	104 (15.55)	61 (58.7)	43 (41.3)	
Always	385 (57.55)	205 (53.2)	180 (46.8)	
Experience with mental health providers has been positive				
Never	21 (3.44)	8 (38.1)	13 (61.9)	0.201
Rarely	30 (4.91)	11 (36.7)	19 (63.3)	
Sometimes	87 (14.24)	42 (48.3)	45 (51.7)	
Often	85 (13.91)	42 (49.4)	43 (50.6)	
Always	388 (63.50)	217 (55.9)	171 (44.1)	
Afraid of experiencing physical violence/abuse when seeking medical care				
Never	296 (44.51)	158 (53.4)	138 (46.6)	0.708
Rarely	83 (12.48)	46 (55.4)	37 (44.6)	
Sometimes	121 (18.20)	60 (49.6)	61 (50.4)	
Often	24 (3.61)	13 (54.2)	11 (45.8)	
Always	141 (21.20)	65 (46.1)	76 (53.9)	
Afraid of experiencing harassment when seeking medical care				
Never	273 (41.05)	150 (54.9)	123 (45.1)	0.431
Rarely	83 (12.48)	44 (53)	39 (47)	
Sometimes	132 (19.85)	66 (50)	66 (50)	
Often	26 (3.91)	10 (38.5)	16 (61.5)	
Always	151 (22.71)	73 (48.3)	78 (51.7)	

(Continued)

Table 4. (Continued)

	Overall N (%)	Transgender- differentiated service delivery n (%)	Standard service delivery n (%)	p-value
I have to educate healthcare providers about my healthcare needs				
Never	163 (24.40)	95 (58.3)	68 (41.7)	0.538
Rarely	68 (10.18)	33 (48.5)	35 (51.5)	
Sometimes	163 (24.40)	82 (50.3)	81 (49.7)	
Often	73 (10.93)	36 (49.3)	37 (50.7)	
Always	201 (30.09)	98 (48.8)	103 (51.2)	
I accept mistreatment due to my gender identity				
Never	381 (57.12)	205 (53.8)	176 (46.2)	0.074
Rarely	52 (7.80)	17 (32.7)	35 (67.3)	
Sometimes	98 (14.69)	56 (57.1)	42 (42.9)	
Often	39 (5.85)	17 (43.6)	22 (56.4)	
Always	97 (14.54)	49 (50.5)	48 (49.5)	

^aNumber of responses excluded those who answered neutrally.

Table 5. Multivariable logistic regression analysis to investigate differences in healthcare experiences among TG-DSD and SSD participants

	Unadjusted odds ratios (95% confidence interval)	p-value	Adjusted odds ratios (95% confidence interval) ^a	p-value
Healthcare workers unwilling to provide healthcare to a transgender person	1.45 (1.04–2.04)	0.03	1.55 (1.09–2.21)	0.01
Healthcare workers providing poorer quality of healthcare to a transgender person	1.39 (1.01–1.90)	0.04	1.46 (1.00–1.91)	0.03
Healthcare workers talking badly about a transgender person	1.20 (0.87–1.65)	0.27	1.25 (0.89–1.75)	0.19
Healthcare workers disclosing a client's transgender or gender non-conforming identity with colleagues without consent when not medically necessary	1.44 (1.03–2.01)	0.03	1.45 (1.02–2.05)	0.04
Enacted stigma	1.38 (1.01–1.87)	0.04	1.46 (1.06–2.01)	0.02

Abbreviations: SSD, standard service delivery; TG-DSD, transgender-specific differentiated service delivery.

^aThe multivariable model adjusted for HIV status, age and education.

4 | DISCUSSION

Our findings on facility-based enacted stigma reveal that TGP continue to face a myriad of negative experiences when they access healthcare, and those who access SSD facilities are more likely to experience stigma. These results echo a systematic review which concluded that TGP in Africa continue to experience healthcare stigma [2]. Gender-affirming care in these facilities could reduce stigma and potentially lead to improved overall health, psychological wellbeing and self-fulfilment as reported in other reviews [2, 18].

Participants who accessed SSD facilities were more likely to experience healthcare worker unwillingness to provide care, report poorer quality of care compared to their cisgender counterparts and unnecessary disclosure of their gender identity. This is consistent with some studies where TGP reported

unwillingness from healthcare workers to provide care, being denied medication and having their gender identity disclosed without their consent [4, 25, 26]. King et al. noted that transgender participants in their Ugandan study reported receiving inferior healthcare compared to cisgender people [27]. Several studies have documented healthcare stigma and healthcare worker attitudes as a key barrier to healthcare access and utilisation for TGP [28–30], consistent with our findings.

When asked about their health experience in the last 3 months, a third of the participants reported at least one of the following: avoiding healthcare, being disrespected, refused care, harassed or touched inappropriately at the healthcare facility. Previous research has documented healthcare avoidance by TGP and is consistent with our study findings [5, 6, 31]. Negative experiences such as the ones reported by our participants and lack of adequate gender-affirming care could

drive TGP to avoid healthcare or forego seeking appropriate medical care even when they are in poor health, further exacerbating health inequalities.

Analysis of healthcare experiences by HIV status suggested that differences in healthcare experiences were primarily driven by the model of service delivery rather than the HIV status itself. Specifically, TGP living with HIV from SSD sites were more likely to report healthcare worker unwillingness to provide care and breaches of confidentiality on their gender identity. However, these disparities were not significantly different from those reported by TGP living without HIV from the SSD sites, suggesting that HIV status alone did not drive these negative experiences.

Our study findings reflect the scarcity of GAHT, which TGP often prioritise over other healthcare needs [32], with 31% of participants reporting they had access to GAHT. This is consistent with a review from nine countries which reported that only 31% of participants had access to hormone therapy [2]. In a South African study, 49% of participants expressed the desire to affirm their gender with hormone therapy but only 11% had access to such therapy [33]. Limited access to GAHT among the *Jabula Uzibone* study participants may be because of such therapy only being available at tertiary healthcare institutions in South Africa or financial constraints if TGP resort to private healthcare. Although our study findings did not explore this, studies have documented that TGP often resort to unsupervised and illicit hormone use in the absence of accessible, affordable and affirming care [4, 9].

At least a fifth of our participants reported that healthcare workers do not provide the same quality of care to them as they do cisgender people, and that being transgender changes the way healthcare professionals interact with them. This finding could be a lack of clinical competence among health workers to provide appropriate care for TGP as has been found in several studies [34, 35]. Incorporating specialised curricula for healthcare providers such as sensitisation training which is tailored to the transgender and gender-diverse communities is an essential intervention to improve trans-specific knowledge among healthcare providers [2, 36].

We found that 14% of participants had avoided healthcare in the last year, and more than 20% of them were afraid of experiencing violence or being harassed at healthcare facilities. Mbede et al. [37] reported fear of seeking medical care as the most frequent consequence of healthcare-related stigma among TGP. In other studies, transgender participants reported discrimination and shaming as drivers of their fear and anxiety when accessing healthcare [26, 38]. The repercussions of discriminatory behaviour amplify health disparities and can threaten the success of health programmes such as HIV prevention and treatment [39, 40].

Our study has limitations. As an observational study, we could not randomise study sites or participants; and doing so may have been seen as unethical due to the well-documented benefits of gender-affirming care for TGP. However, enrolling participants from existing TG-DSD demonstration sites and comparing them with participants who receive care at SSD sites provided a key opportunity to assess TG-DSD models in real-world settings. The data presented in this cross-sectional paper is self-reported and may be skewed by recall or social desirability bias, or reluctance to divulge sensitive individ-

ual experiences to interviewers. To minimise this, the study recruited and trained data collectors to maximise participant comfort, safety and confidentiality.

TGP who seek care at TG-DSD clinics may have different healthcare-seeking behaviours, experiences and expectations compared to those who access SSD clinics. As such, they may have been more likely to report positive healthcare experiences compared to their SSD counterparts. In our regression analysis, we controlled for different potential confounders such as HIV status, age and education, to mitigate this bias. Our study could also be limited by selection bias. First, differences in healthcare experiences between TG-DSD and SSD participants may reflect underlying differences in population characteristics rather than the direct effects of the model of care. Second, the findings may not be fully generalisable to all TGP in South Africa, particularly those who do not access care through either model. To mitigate this selection bias, we endeavoured to enrol a diverse range of participants within each stratum.

5 | CONCLUSIONS

Our study contributes to the growing literature on healthcare experiences among TGP and fills an important gap in knowledge about healthcare among TGP in South Africa. Our results highlight the critical need for gender-affirming healthcare in South African health facilities. We have shown that TGP continue to face pervasive stigma, discrimination and negative health experiences when they seek medical care. We noted several significant differences in health experiences between participants who sought care at TG-DSD versus SSD facilities, with the latter reporting more negative health experiences in some instances. Our findings support the call for clinically and culturally competent healthcare providers in South Africa. Providing gender-affirming care, including hormone therapy, is imperative, especially at a primary care level where accessibility is easier compared to tertiary or quaternary hospitals, which may require long and/or expensive commutes for TGP.

The National Department of Health in South Africa has developed the Key Populations Health Implementation Plan which seeks to address the health needs of key populations, including TGP [41]. In the health plan, gender-affirming healthcare for TGP is highlighted as a cornerstone to improving their healthcare. The full rollout of this plan could capacitate healthcare workers with the necessary skills, resources and knowledge to provide gender-affirming care, thereby reducing incidents of facility-based stigma among TGP. Further research to understand the readiness of the South African health system to provide gender-affirming care is indicated.

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COMPETING INTERESTS

The authors declare that they have no competing interests.

AUTHORS' CONTRIBUTIONS

TP, RB and AP: Conceptualisation. RB and PN: Data curation. IM and TP: Methodology. RB: Writing—original draft. All authors: Writing—review and editing.

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DISCLAIMER

The content is solely the responsibility of the authors and does not necessarily represent the official views of the United States National Institutes of Health.

DATA AVAILABILITY STATEMENT

The datasets generated during the current study will be available from the senior author upon reasonable request 1 year after the completion of data collection.

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RESEARCH ARTICLE

Preferences for models of sexual health service delivery among gay, bisexual and other men who have sex with men in Australia: a discrete choice experiment

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Abstract

Introduction: Gay, bisexual and other men who have sex with men are disproportionately affected by HIV and other sexually transmitted infections (STIs). This study explores preferences for different models of sexual health services among gay, bisexual and other men who have sex with men in Australia, using discrete choice experiments (DCEs).

Methods: A cross-sectional online survey was conducted from November 2022 to February 2023, targeting three groups: (1) gay, bisexual and other men who have sex with men living with HIV; (2) pre-exposure prophylaxis (PrEP) users; and (3) non-PrEP users. Participants were recruited through paid advertisements, sexual health clinics and community networks. The survey included demographic questions, sexual behaviour inquiries and three tailored DCEs to quantify preferences for service delivery attributes such as cost, type of clinic, appointment type, appointment frequency, extra services and where samples are taken for HIV/STI testing. We used latent class analyses to identify subgroups of people with similar preferences.

Results: We recruited 1422 participants. The median age was 41 (interquartile range [IQR]: 32–54) for gay, bisexual and other men who have sex with men living with HIV ($N = 396$), 35 (IQR: 29–45) for PrEP users ($N = 436$) and 33 (IQR: 26–44) for non-PrEP users ($N = 590$). In our latent class analyses, gay, bisexual and other men who have sex with men living with HIV preferred sexual health services to be delivered via sexual health clinics (46.2%), general practitioners (GP) with expertise in lesbian, gay, bisexual, trans, queer and others (LGBTQ+) health (33.0%) or were happy to go anywhere and to pay (20.7%). PrEP users preferred either PrEP-only clinics or GP with expertise in LGBTQ+ health (75.2%) and GP with expertise in LGBTQ+ health only (24.8%). Non-PrEP users preferred GP with expertise in LGBTQ+ health (44.7%) or any free service (22.8%); some did not want to test (22.2%) or were unsure of their preferences (10.2%).

Conclusions: To align service models with client needs, investment in specialist sexual health clinics and LGBTQ+ competent GPs is important, though this may depend on local resources and infrastructure. Future research should focus on addressing financial barriers, evaluating telehealth and digital health interventions, and understanding testing reluctance among non-PrEP users.

Keywords: general practice; HIV; LGBTQ; people living with HIV; sexually transmitted infections; testing

Additional information may be found under the Supporting Information tab of this article.

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1 | INTRODUCTION

Globally, gay, bisexual and other men who have sex with men (GBM) are disproportionately affected by HIV, accounting for a majority of new HIV diagnoses in high-income countries despite making up a small percentage of the population [1]. In Australia, gay, bisexual and other men who have sex with men represent over 60% of cases of people living

with HIV, highlighting the urgent need for tailored prevention and care services [2]. Evidence shows that tailored services may improve engagement in care and reduce HIV transmission [3, 4]. Thus, innovations in HIV care and prevention clinical services with a focus on differentiated service delivery in relation to individual needs and preferences could further contribute to reductions in the HIV burden of disease [5, 6]. Similarly, access to sexual health services is a powerful

determinant of outcomes for sexually transmitted infections (STIs) [7].

To understand preferences for sexual health services among gay, bisexual and other men who have sex with men, there are three key groups: those living with HIV, pre-exposure prophylaxis (PrEP) users and non-PrEP users. Each group has distinct healthcare needs and service utilisation patterns. Gay, bisexual and other men who have sex with men living with HIV require regular HIV care, including viral load monitoring, antiretroviral therapy adherence support and routine STI screenings [8]. PrEP users engage with healthcare primarily for ongoing PrEP prescriptions, quarterly HIV/STI screenings and monitoring for medication side effects. Non-PrEP users are recommended to have at least annual HIV/STI screening or more frequent testing if they have multiple partners [9]. These distinct healthcare needs underscore the importance of differentiated and tailored service delivery models.

Sexual health services are traditionally delivered through specialised sexual health clinics that are predominantly located in major cities. Alternatively, any general practitioner can also offer sexual health services. While general practitioners (GPs) are widely accessible, the fear of stigma and homophobia may prevent individuals from seeking care [10, 11]. Individuals can access limited sexual health services (e.g. HIV/STI screening) through online services or community-based organisations [12]. During the coronavirus disease 19 (COVID-19) pandemic, sexual health services adapted by expanding telehealth and digital services to enhance accessibility [13–16]. While these non-face-to-face models were necessary during restrictions, it remains unclear whether they align with the long-term preferences of GBM, who may now favour a return to in-person care for STI testing and provider interaction. Thus, it is timely to examine such preferences given the ways in which the COVID-19 pandemic necessitated the rapid implementation of novel models of care [16].

2 | METHODS

2.1 | Study design and participants

Discrete choice experiments (DCEs) can quantify preferences between choices with multiple components [17]. By systematically assessing preferences for different aspects of service delivery, like appointment type, frequency and location of sample collection, DCEs can provide insights into client-centred service delivery models. The DCE was used to assess trade-offs rather than absolute preferences. For example, while few people would “prefer” to pay \$150 versus receiving a service for free, the analysis helps quantify price sensitivity, that is how changes in cost impact service utilisation.

We conducted a cross-sectional online survey of attitudes to sexual healthcare delivery using Qualtrics (Provo, UT, USA) from November 2022 to February 2023. Participants were eligible if they: were living in Australia; self-identified as gay, bisexual and other men who have sex with men (inclusive of transgender men); were at least 18 years of age; and had a clinical appointment, including telehealth, for HIV management or sexual health screening in Australia since March 2020. The survey took approximately 10 minutes to com-

plete and participants were offered the chance to opt-in for a prize draw for one of ten \$200 vouchers after submitting the survey. The survey was promoted using paid advertising on Grindr (a gay dating app), by direct contact to patients of sexual health clinics in New South Wales and Victoria, and unpaid promotions through networks of people living with HIV and gay, bisexual and other men who have sex with men. Before starting the survey, participants provided consent by confirming the statement “I agree to participate and have read the Participant Information Statement, begin survey.”

2.2 | Measures

All participants provided demographic information (age, education, occupation, income, country of birth, sexuality). They were also asked about their relationship status, sexual behaviour (number of sexual partners, condom use, group sex). Participants were asked about their HIV status and PrEP use, and were organised into three different groups based on their responses: gay, bisexual and other men who have sex with men living with HIV, PrEP users and non-PrEP users. Based on which group participants belonged, they were asked questions about their experience of and attitudes to sexual healthcare delivery and preferences for the future. Participants were asked where they usually went for HIV care/sexual healthcare/PrEP and were asked a series of questions about their attitudes to different elements of healthcare delivery as well as about their satisfaction with different modalities of consultation (face-to-face, telephone, video call) on a scale of 1 (very unsatisfied) to 5 (very satisfied).

2.3 | Discrete choice experiment

The survey included three DCEs to quantify preferences for service delivery: one for gay, bisexual and other men who have sex with men living with HIV, one for PrEP users and one for non-PrEP users. A literature review was performed to identify potential attributes related to accessing HIV care and prevention and sexual health services for gay, bisexual and other men who have sex with men. We conducted a structured consultation of the potential attributes with a group of experts including researchers, clinicians and community representatives who ranked the attributes according to their importance and were given the opportunity to suggest additional attributes and amendments. The final list of attributes and levels is presented in Table S1. The survey was pilot-tested with five in-house staff identifying as gay men to assess usability, clarity and completion time, leading to only minor wording refinements in the choice set introductions without major modifications. Each participant was presented with six choice sets (Figure 1). Within each choice set respondents were asked to choose their preferred option from two options and if they did not like either options, they can choose to opt-out. Gay, bisexual and other men who have sex with men living with HIV were asked “Thinking about your routine clinical appointments for HIV care in the future, which option do you prefer?” PrEP users were asked “Thinking about your routine clinical appointments for PrEP in the future, which option do you prefer?”. Non-PrEP users were asked “Thinking about your

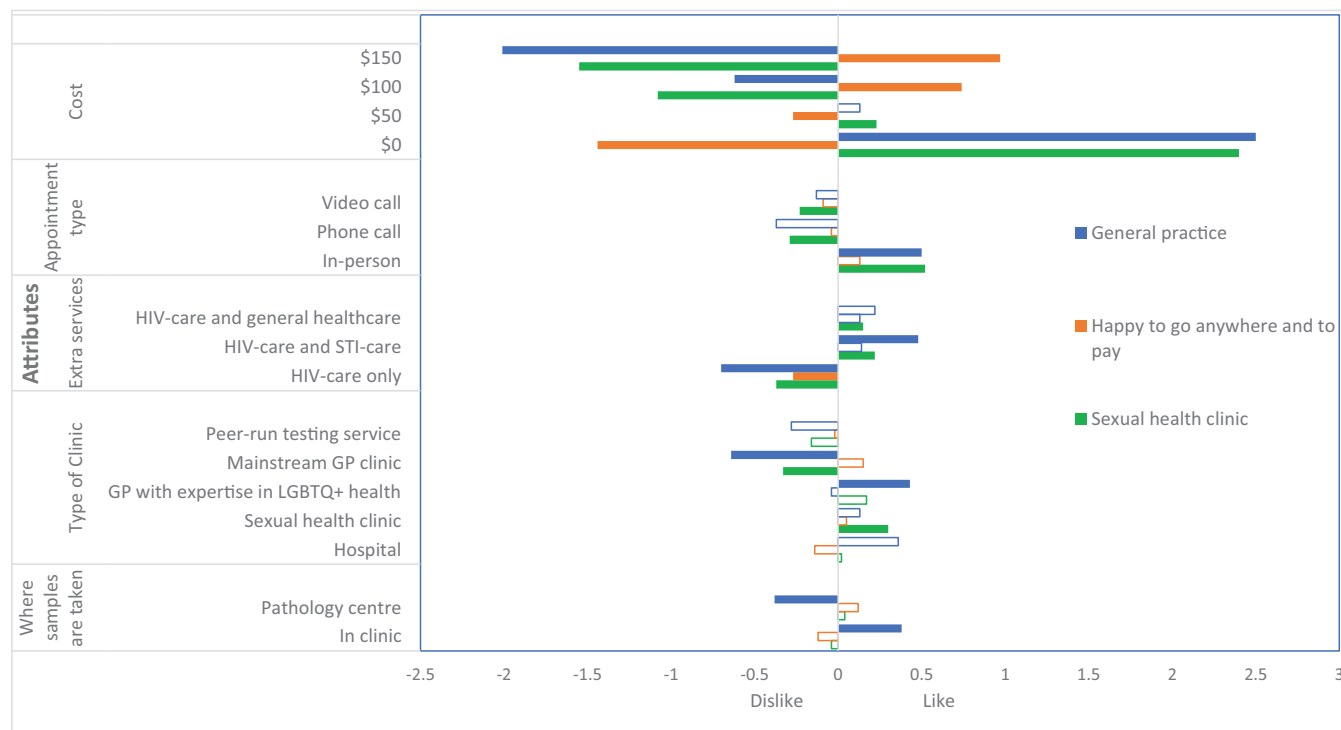


Figure 1. Latent class analysis of preferences of sexual health service delivery from gay, bisexual and other men who have sex with men living with HIV. Notes: Colour-filled bars = level is statistically significant (p -value < 0.05). No-filled bars = level is not statistically significant (p -value ≥ 0.05). Currency is in Australian dollars (1 AUD = 0.64 USD). GBM, gay, bisexual and other men who have sex with men; GP, general practitioner; LGBTQ+, lesbian, gay, bisexual, trans, queer and others; PrEP, pre-exposure prophylaxis; STI, sexually transmitted infection.

routine clinical appointments for asymptomatic sexual health check-ups in the future, which option do you prefer?"

2.4 | Statistical analysis

We used descriptive statistics to summarise socio-demographic characteristics. We analysed the choice data using latent class conditional logit regression models to explore similarities (or "classes") in preference behaviour. The number of classes was determined based on the Akaike Information Criteria and interpretability. We hypothesised *a priori* that the following characteristics may influence preferences: education level, country of birth, work status, number of sexual partners, age and consistency of condom use. Statistical significance was defined as p -value < 0.05 . We calculated the relative importance of each attribute using the coefficient range of an attribute divided by the sum of ranges from all attributes [18]. The relative importance indicates how much weight an attribute has in the decision to use the HIV/sexual health service. We used NLOGIT (version 6, Econometric Software Inc, USA) for the model estimations.

2.5 | Ethics approval

Ethical approval was obtained from the University of New South Wales (UNSW) Sydney Human Research Ethics Committee (HC210939). We present our study according to the STROBE statement.

3 | RESULTS

Of the 1657 participants who consented to participate and met eligibility requirements, 1422 participants (85.8%) completed at least one DCE choice set and were included in this analysis. Most participants (72.6%) were recruited through paid advertising (Grindr), while the remaining participants were recruited through publicly funded sexual health services (19.3%) and unpaid promotions (8.1%). Unpaid promotions included anything that was not a paid ad, for example the clinics sending out emails/messages.

3.1 | Study population characteristics

Table 1 summarises the characteristics of the participants. The median age for gay, bisexual and other men who have sex with men living with HIV was 41 (interquartile range [IQR]: 32–54), PrEP users was 35 (IQR: 29–45) and non-PrEP users was 33 (IQR: 26–44). The median number of years living with HIV was 8 (IQR: 4–17). Most identified as gay (people with HIV = 83.6%; PrEP users = 80.5%; people without HIV and not on PrEP = 57.1%). The majority usually attended a sexual health clinic (gay, bisexual and other men who have sex with men living with HIV = 73.5%; PrEP users = 58.3%) or a general practitioner (non-PrEP users = 57.1%). The majority were born in Australia (gay, bisexual and other men who have sex with men living with HIV = 54.0%; PrEP users = 50.2%; and non-PrEP users = 51.7%); while a substantial proportion

Table 1. Study participant socio-demographic characteristics and sexual behaviours, comparing gay, bisexual and other men who have sex with men living with HIV, PrEP users and non-PrEP users

Characteristic	GBM living with HIV <i>n</i> = 396 <i>n</i> (%) ^a	PrEP users (<i>n</i> = 436) <i>n</i> (%) ^a	Non-PrEP users (<i>n</i> = 590) <i>n</i> (%) ^a
Usual services attended^b			
General Practice clinic	88 (22.2)	219 (50.2)	337 (57.1)
Sexual health clinic	291 (73.5)	254 (58.3)	230 (39.0)
Hospital	50 (12.6)	16 (3.7)	49 (8.3)
Other	6 (1.5)	25 (5.7)	29 (4.9)
Missing data ^c	26	23	61
Country of birth			
Australia	214 (54.0)	219 (50.2)	305 (51.7)
Overseas	130 (32.8)	138 (31.7)	146 (24.7)
Missing data	52 (13.1)	79 (18.1)	139 (23.6)
Gay postcode categories^d			
> 10% gay	26 (6.6)	54 (12.4)	28 (4.7)
5–9.9% gay	82 (20.7)	64 (14.7)	57 (9.7)
< 5%	231 (58.3)	240 (55.0)	371 (62.9)
Missing data	57 (14.4)	78 (17.9)	134 (22.7)
Highest education level			
Up to year 10	30 (7.6)	23 (5.3)	67 (11.4)
Up to year 12	54 (13.6)	51 (11.7)	88 (14.9)
Tertiary diploma or trade certificate	106 (26.8)	76 (17.4)	127 (21.5)
University degree	167 (42.2)	216 (49.5)	187 (31.7)
Missing data	39 (9.8)	70 (16.1)	121 (20.5)
Current occupation			
Employed full time	215 (54.3)	245 (56.2)	224 (38.0)
Employed part-time	41 (10.4)	41 (9.4)	89 (15.1)
Pension/social security	34 (8.6)	14 (3.2)	38 (6.4)
Student	15 (3.8)	38 (8.7)	38 (6.4)
Unemployed	24 (6.1)	13 (3.0)	54 (9.2)
Missing data	67 (16.9)	85 (19.5)	147 (24.9)
Annual personal income			
< \$20,000	68 (17.2)	48 (11.0)	132 (22.4)
\$20,000–\$49,999	93 (23.5)	65 (14.9)	122 (20.7)
\$50,000–\$99,999	133 (33.6)	155 (35.6)	150 (25.4)
≥ \$100,000	62 (15.7)	97 (22.2)	66 (11.2)
Missing data	40 (10.1)	71 (16.3)	120 (20.3)
Number of male sexual partners in the last 6 months			
None	53 (13.4)	12 (2.8)	58 (9.8)
1	71 (17.9)	14 (3.2)	54 (9.2)
2–10	158 (39.9)	193 (44.3)	271 (45.9)
> 10	65 (16.4)	135 (31.0)	54 (9.2)
Missing data	49 (12.4)	82 (18.8)	153 (25.9)
Condom use with casual partners			
Never	114 (28.8)	125 (28.7)	101 (17.1)
Occasionally	79 (19.9)	148 (33.9)	114 (19.3)
Often	38 (9.6)	44 (10.1)	66 (11.2)
Always	38 (9.6)	16 (3.7)	94 (15.9)

(Continued)

Table 1. (Continued)

Characteristic	GBM living with HIV <i>n</i> = 396 <i>n</i> (%) ^a	PrEP users (<i>n</i> = 436) <i>n</i> (%) ^a	Non-PrEP users (<i>n</i> = 590) <i>n</i> (%) ^a
No sex in the past 6 months	47 (11.9)	8 (1.8)	51 (8.6)
No casual partners	31 (7.8)	6 (1.4)	19 (3.2)
Missing data	41(10.4)	74 (17.0)	127 (21.5)

Abbreviations: GBM, gay, bisexual and other men who have sex with men; PrEP, pre-exposure prophylaxis for HIV.

^aPercentages use total population as the denominator. Thus, the percentage of missing data can be calculated if needed.

^bParticipants can choose more than one option for this question.

^cMissing data here are respondents who did not respond to at least one of these options.

^dPostcodes of residence were categorised based on the estimated resident gay male population [19].

Table 2. Satisfaction^a with current HIV and sexual healthcare, comparing gay, bisexual and other men who have sex with men living with HIV, PrEP users and non-PrEP users

Characteristic	GBM living with HIV <i>n</i> (%) ^b	PrEP users <i>n</i> (%) ^b	Non-PrEP users <i>n</i> (%) ^b
Modality			
Face-to-face	318 (88.1)	322 (92.5)	363 (89.2)
Telephone	235 (74.8)	202 (86.0)	238 (82.9)
Video call	127 (63.8)	108 (82.4)	148 (77.1)
STI test from the following services			
Public sexual health clinic	306 (94.2)	277 (93.0)	316 (90.5)
General practice clinic with expertise in LGBTQ+ health	234 (99.2)	223 (95.3)	266 (89.3)
Mainstream general practice clinic	174 (79.1)	196 (77.8)	274 (82.3)
Peer-run community-based testing	141 (84.9)	135 (90.0)	202 (88.6)
Pathology collection centre	171 (82.2)	189 (87.9)	241 (88.9)
Own home	101 (77.1)	86 (83.5)	162 (86.6)

Abbreviations: GBM, gay, bisexual and other men who have sex with men; LGBTQ+, lesbian, gay, bisexual, trans, queer and others; PrEP, pre-exposure prophylaxis; STI, sexually transmitted infection.

^aSatisfaction was assessed using a 5-point Likert scale. We collapsed the categories of “very satisfied” and “satisfied” as the outcome of this table.

^bDenominator removes those with no experience in this mode.

were born overseas (those living with HIV: 32.8%, PrEP users: 31.7%, non-PrEP users: 24.7%).

3.2 | Satisfaction with sexual health services

Table 2 summarises participants' satisfaction with modalities of receiving sexual healthcare. In general, individuals were more satisfied with face-to-face interactions (range: 88.1–92.5%) than telephone (range: 74.8–86%) or video calls (range: 63.8–82.4%). Chi-square tests comparing face-to-face consultations with telephone or video calls across the three groups showed statistically significant differences for each of the comparisons (*p*-values < 0.05). Regarding STI testing, individuals were more satisfied with public sexual health clinics (range: 90.5–94.2%) and general practice clinics with expertise in lesbian, gay, bisexual, trans, queer and others (LGBTQ+) health (range: 89.3–99.2%), and had the lowest satisfaction with mainstream general practice clinics (range: 79.1–82.3%).

3.3 | Preferences of gay, bisexual and other men who have sex with men living with HIV

Figure 1 (and Table S2) demonstrates three latent classes: “Sexual Health Clinic,” “General Practice” and “Happy to go anywhere and to pay.” For those in the “Sexual Health Clinic” class (46.2%), they preferred attending a sexual health clinic that is low-cost (up to \$50) or free, in-person, and includes HIV, STI and general healthcare. For those in the “General Practice” class (33.0%), they preferred their GP to have expertise in LGBTQ+ health and for services to be free, in-person, including HIV and STI care, and for staff in clinic to take the samples for STI testing (rather than going to a pathology centre). For those in the “Happy to go anywhere and to pay” class (20.7%), they were willing to pay up to \$150 and disliked receiving only HIV care. Participants in this group were more likely to be aged < 25 years old, report inconsistent condom use and be born in Australia. Figure S1

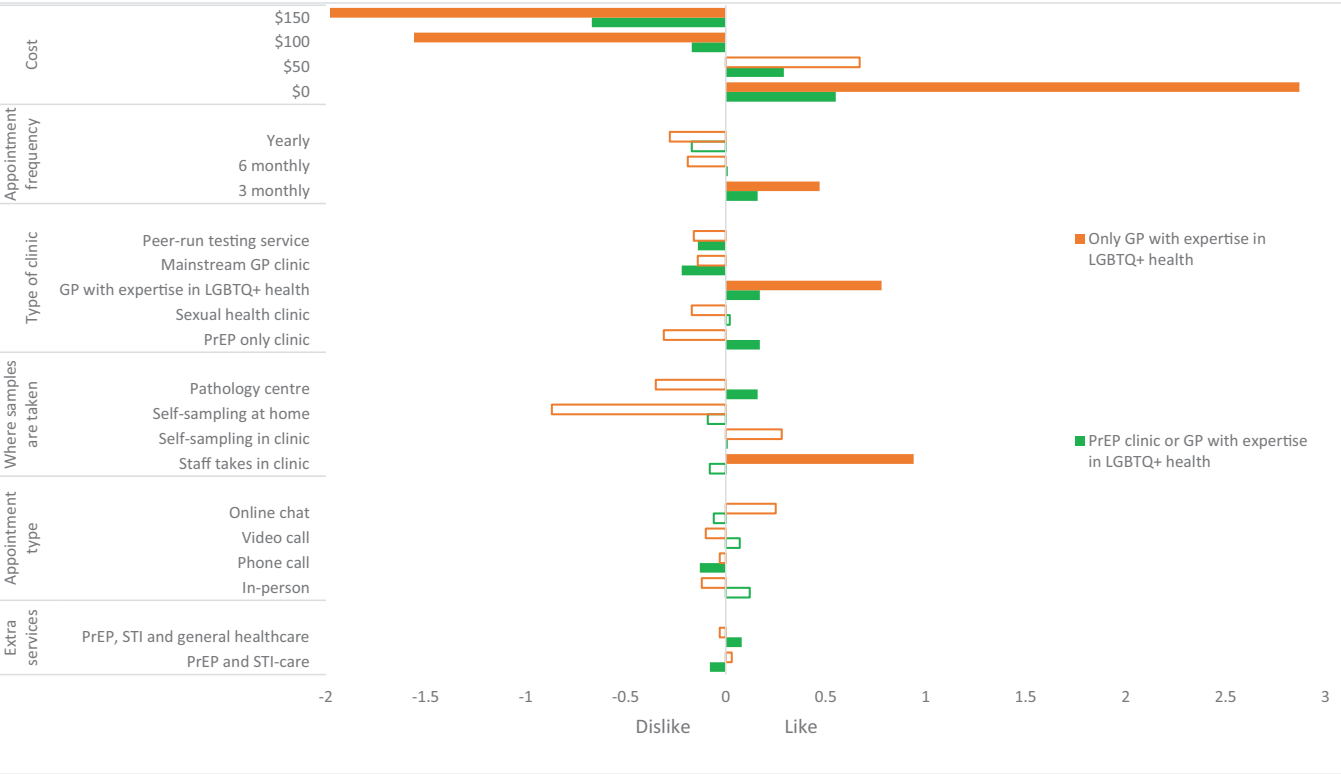


Figure 2. Latent class analysis of preferences of sexual health service delivery from PrEP users. Notes: Colour-filled bars = level is statistically significant (p -value < 0.05). No filled bars = level is not statistically significant (p -value ≥ 0.05). Currency is in Australian dollars (1 AUD = 0.64 USD). GP, general practitioner; LGBTQ+, lesbian, gay, bisexual, trans, queer and others; PrEP, pre-exposure prophylaxis; STI, sexually transmitted infection.

demonstrates that cost considerations had the highest relative importance: “Sexual Health Clinic” class (67%), “Happy to go anywhere and to pay” class (68%) and “General Practice” class (54%).

3.4 | Preferences of PrEP users

Figure 2 (and Table S3) demonstrates two latent classes: “PrEP clinic or GP with expertise in LGBTQ+ health” and “Only GP with expertise in LGBTQ+ health.” For those in the “PrEP clinic or GP with expertise in LGBTQ+ health” class (75.2%), they preferred services to be low-cost (up to \$50) or free, 3-monthly, provide samples for STI testing at a pathology centre and disliked phone-based consultations. For those in the “Only GP with expertise in LGBTQ+ health” class (24.8%), they were more price-sensitive than those in the first class (i.e. had 5.2 times greater preference for a free service), preferred 3-monthly visits and preferred for staff in clinic to take the samples for STI testing. Figure S2 demonstrates that cost considerations had the highest relative importance: “PrEP clinic or GP with expertise in LGBTQ+ health” class (47%) and “Only GP with expertise in LGBTQ+ health” class (54%).

3.5 | Preferences of non-PrEP users

Figure 3 (and Table S4) demonstrates four latent classes: “Just make it free,” “General Practice,” “Don’t want to test” and

“Unsure about preferences.” For those in the “Just make it free” class (22.8%), they preferred free sexual health services, no matter what form this took. For those in the “General practice” class (44.7%), they preferred their GP to have expertise in LGBTQ+ health, were willing to pay \$50 for the service (i.e. had 1.8 times greater preference to pay \$50 than for a free service), wanted to attend clinics in-person, preferred 3-monthly visits and preferred for visits to include both HIV and STI testing/management. For those in the “Don’t want to test” class (22.2%), they were more likely to choose opt-out (i.e. not attend any service) and preferred free services. For those in the “Unsure about preferences” class (10.2%), there was a preference for self-sampling in the clinic and provision of both HIV and STI testing/management, but other attributes had wide standard errors. Figure S3 demonstrates that cost considerations had the highest relative importance: “Just make it free” class (64%), “General practice” class (23%) and “Don’t want to test” class (67%). For the “unsure about preferences” class, the highest relative importance was for appointment type (43%).

4 | DISCUSSION

This study provides valuable insights into the preferences for sexual health service delivery among gay, bisexual and other men who have sex with men in Australia, revealing

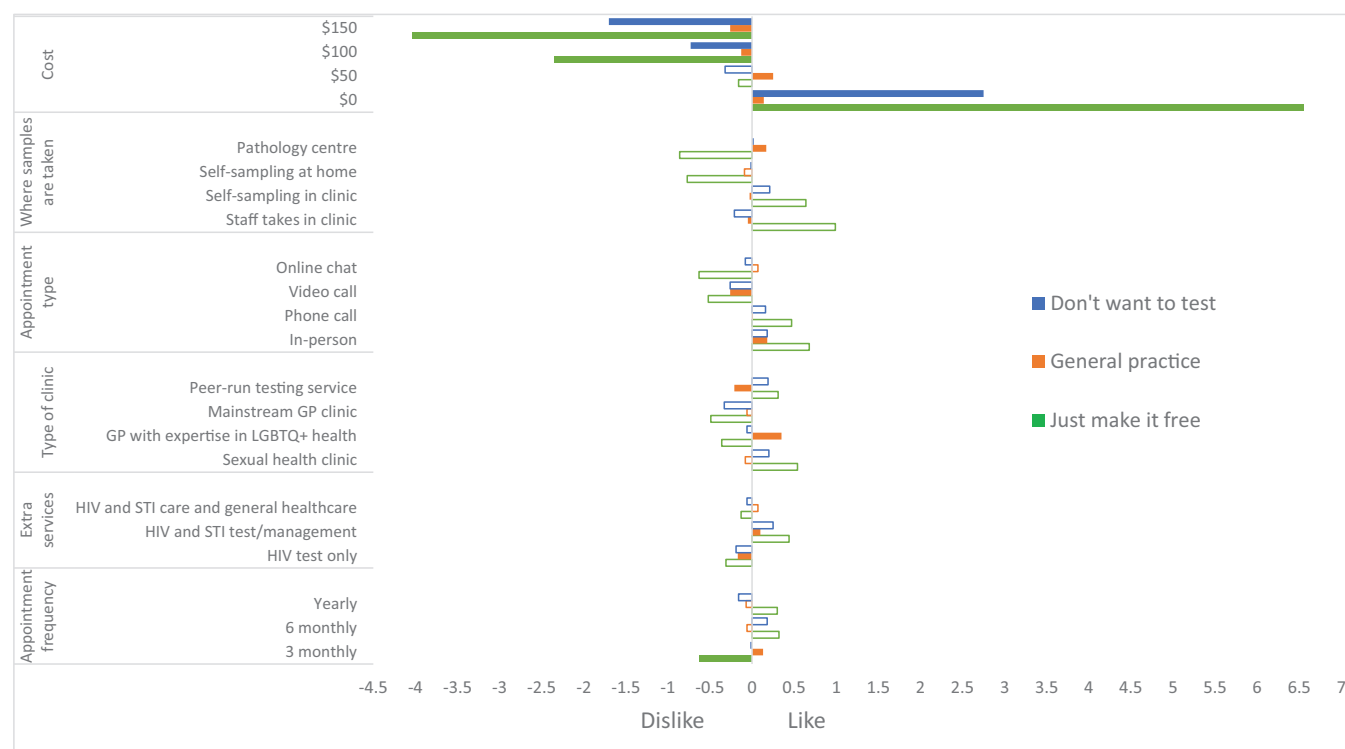


Figure 3. Latent class analyses of preferences for sexual health service delivery from non-PrEP users. Notes: Colour-filled bars = level is statistically significant (p -value < 0.05). No-filled bars = level is not statistically significant (p -value ≥ 0.05). Currency is in Australian dollars (1 AUD = 0.64 USD). Data from class 4 is not shown, given the wide range of statistically insignificant coefficients (for details, see Table S4). GP, general practitioner; LGBTQ+, lesbian, gay, bisexual, trans, queer and others; PrEP, pre-exposure prophylaxis; STI, sexually transmitted infection.

the distinct needs of individuals based on their HIV status and use of PrEP. Among gay, bisexual and other men who have sex with men living with HIV, the most preferred service models included sexual health clinics (46.2%), followed by GPs with LGBTQ+ expertise (33.0%), while a smaller group (20.7%) expressed flexibility to access services anywhere, even with out-of-pocket costs. PrEP users showed a strong preference for either PrEP-only clinics or LGBTQ+ competent GPs (75.2%), with 24.8% preferring LGBTQ+ competent GPs exclusively. For non-PrEP users, preferences were more varied: 44.7% favoured LGBTQ+ competent GPs, 22.8% prioritised free services, while 22.2% were reluctant to test, and 10.2% were unsure about their preferences. Our findings add to the literature by underscoring the necessity for health service models to align with client expectations, emphasising accessibility, affordability and provider expertise in LGBTQ+ health. While these preference data provide valuable insights into service acceptability and engagement, they should be considered alongside other critical factors, including clinical effectiveness, feasibility, cost and healthcare system constraints.

Our findings highlight the diverse therapeutic itineraries undertaken by gay, bisexual and other men who have sex with men in Australia when seeking sexual health services. The concept of therapeutic itineraries—which refers to the dynamic and individualised pathways individuals navigate through healthcare systems—offers a useful lens to understand how different service models align with client needs

and expectations. The latent class analysis in our study underscores that service preferences are shaped not only by accessibility and affordability but also by perceptions of provider expertise, stigma and prior healthcare experiences. While sexual health clinics remain a preferred option, particularly for gay, bisexual and other men who have sex with men living with HIV, our results also indicate a strong preference for GPs with LGBTQ+ expertise, reflecting the importance of trust, continuity of care and holistic health management. There were also notable socio-demographic differences between the three study populations, which may have influenced their healthcare preferences. For example, those living with HIV tended to be older, had higher proportions of full-time employment and were more likely to attend sexual health clinics, while PrEP users were generally younger, more educated and more likely to use LGBTQ+ competent GPs. In contrast, non-PrEP users showed more variation in income, education and care-seeking patterns, with a substantial proportion unsure of their preferences or reluctant to test. These differences highlight the importance of considering socio-demographic context when interpreting service delivery preferences, as structural and social factors likely shape healthcare access and engagement. These findings resonate with broader discussions in healthcare service research that emphasise differentiated service delivery models as key to improving health outcomes and engagement in care. Future research should further explore how structural and psychosocial factors influence the therapeutic itineraries of diverse subgroups within the community,

particularly those who remain hesitant or disengaged from routine sexual health screening.

Cost emerged as a critical factor influencing the choice of sexual health services, which aligns with global evidence on the importance of minimising out-of-pocket expenses to increase the uptake of sexual health services [20]. In Australia, HIV treatment is subsidised under the Pharmaceutical Benefits Scheme for anyone living in Australia, regardless of their visa status. However, out-of-pocket costs may still apply for consultations depending on whether a person accesses care through general practice or sexual health clinics. HIV and STI screening is free at publicly funded sexual health clinics but may incur fees in general practice or private clinics. These cost variations could partly explain differences in service preferences across the three groups. For instance, people living with HIV, who require ongoing specialist HIV care and routine monitoring, were more likely to prioritise access to specialised sexual health clinics, which typically provide free or low-cost services. PrEP users, who need regular 3-monthly HIV/STI testing, showed a strong preference for low-cost PrEP-only clinics or LGBTQ+ competent GPs, as cost and accessibility directly impact their adherence. In contrast, non-PrEP users had a wider range of preferences, with some prioritising free services, while others were less engaged in regular testing, possibly due to financial barriers or lower perceived risk. Overall, there is strong evidence that providing free or low-cost services for the public control of infectious diseases provides significant returns on investment [21]. Testing and managing infectious diseases earlier reduces morbidity and prevents ongoing transmission, particularly reaching those who are disproportionately affected, who are often marginalised populations with lower socio-economic status. For example, the estimated lifetime cost of managing a single case of HIV in Australia is approximately \$282,000, underscoring the potential economic return of investing in prevention and equitable service delivery [22]. In designing sexual health services, we must consider the influence of out-of-pocket costs impacting the accessibility of these services, particularly for those who would benefit most, who are often socio-economically disadvantaged [6].

Preferences for service delivery location varied significantly across subgroups. While many participants favoured specialised sexual health clinics, a notable proportion of gay, bisexual and other men who have sex with men indicated a preference for accessing care through GPs with expertise in LGBTQ+ health. LGBTQ+ competent GPs are more likely to provide inclusive and affirming care, including gender-appropriate language, non-judgemental communication and familiarity with LGBTQ+ health concerns. Stigma in mainstream healthcare settings remains a barrier, with some reporting discomfort in disclosing their sexual history, HIV status or PrEP use due to fear of judgement or discrimination [23, 24]. This preference underscores the pivotal role that GPs can play in expanding access to sexual health services, especially in areas where specialised clinics may not be available. We acknowledge that the availability and accessibility of services are strongly influenced by geographical location, and even some urban centres may experience limited access to

sexual health clinics. Mapping service availability across different regions remains complex, and this issue is currently being addressed through ongoing workforce planning initiatives led by the College of Physicians to improve equitable service distribution. This further reinforces the importance of equipping a broader range of GPs with LGBTQ+ health expertise to address geographic disparities in care. Most Australians see a GP at least once a year (82% in 2023) [25]. However, current limitations in GP training on HIV and sexual health-care present challenges that need to be addressed through targeted educational interventions [26] and support models [27] to ensure high-quality care. Our study also sheds light on the evolving preferences shaped by the COVID-19 pandemic, which accelerated the adoption of telehealth and digital health services. While some participants expressed satisfaction with telehealth, face-to-face consultations remained the preferred mode of service delivery. While telehealth can enhance access to care, its role should be assessed in the context of client needs, clinical effectiveness and service feasibility.

Our study's strengths include a large and diverse sample and the use of DCEs to quantitatively assess preferences, providing robust insights into service delivery attributes that matter most to gay, bisexual and other men who have sex with men. However, limitations should be considered when interpreting these findings. First, our recruitment was primarily from Grindr and publicly funded sexual health services so we may not have adequately captured preferences from participants who are less likely to use these apps and services. The reliance on Grindr-based recruitment (72.6%) may overrepresent tech-savvy, sexually active men while underrepresenting those less digitally connected. Future research should explore alternate recruitment strategies, such as community-based sampling or non-digital outreach, to capture a more diverse representation. Second, we used self-reported data which may be prone to social desirability and recall bias, inherent in self-reported surveys. To mitigate this, the surveys were voluntary and anonymous, recall time frames were relatively short and we pilot-tested the survey to ensure questions were framed appropriately. Future research should explore the reasons behind specific service preferences through qualitative methods, which would further enhance our understanding of the drivers of service uptake. Third, our study is conducted in the socio-economic context of Australia and may not be generalisable to other countries. Similarly, preferences of populations (e.g. heterosexual populations) not included in our study populations may differ. Thus, conducting health preference research in other countries and sub-populations would be valuable in identifying their preferences for sexual health service delivery. Fourth, our study was only available in English, and although almost half were born outside of Australia, we have not captured preferences from those not fluent in English. Future studies could target non-English speakers living in Australia. Finally, we did not collect data on participants' current accessibility to services (e.g. rural vs. urban), which limits our ability to assess how service accessibility may influence preferences. Future research should explore how geographic access shapes service utilisation and preferences.

5 | CONCLUSIONS

Overall, this research highlights the need for tailored sexual health service models that address financial barriers and leverage GPs' potential to provide inclusive and competent care for gay, bisexual and other men who have sex with men. Addressing these preferences will be crucial in ensuring equitable access to HIV and sexual health services, ultimately contributing to better health outcomes in the community.

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COMPETING INTERESTS

JJO and BRB have received honoraria and travel support from Gilead, unrelated to this project. All other authors declare no conflicts of interests.

AUTHORS' CONTRIBUTIONS

BRB and JJO conceived and designed the study. DF and JJO contributed to the data collection. JJO analysed the data and drafted the manuscript. All authors contributed to the interpretation of the data, provided critical revisions to the manuscript and approved the final version of the manuscript.

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DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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SUPPORTING INFORMATION

Additional information may be found under the Supporting Information tab for this article:

Table S1: Final attributes and levels in the DCE.

Table S2: Latent class analysis of preferences for sexual health services for people living with HIV.

Table S3: Latent class analysis of preferences of PrEP users.

Table S4: Latent class analysis of preferences of people without HIV and not using PrEP.

Figure S1: Relative importance of preferences for people living with HIV.

Figure S2: Relative importance of preferences for PrEP users.

Figure S3: Relative importance of preferences of GBM without HIV and not using PrEP.

RESEARCH ARTICLE

Improving PrEP access for adolescent girls and young women: a descriptive analysis of community-based PrEP delivery in the DREAMS programme in Zambia

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Abstract

Introduction: Despite being at high risk of HIV acquisition, access to pre-exposure prophylaxis (PrEP) among adolescent girls and young women (AGYW) is low in Zambia because PrEP is traditionally delivered in clinical settings. We describe the effects of community centres supported by the Determined, Resilient, Empowered, AIDS-free, Mentored, and Safe (DREAMS) initiative on PrEP outcomes in Zambia and examine factors associated with PrEP continuation.

Methods: We collected individual-level PrEP data for AGYW aged 15–24 years at risk of HIV acquisition and enrolled in DREAMS in seven districts of Zambia between August 2022 and August 2024. We used Pearson's Chi-squared test to examine differences in beneficiary characteristics between clients with a PrEP initiation visit and ≥ 2 PrEP visits (i.e. an initiation plus ≥ 1 return visit), and mixed effects Poisson regression modelling to estimate the association between DREAMS enrolment criteria and PrEP continuation (defined as ≥ 1 PrEP visit within 180 days of initiation). We also estimated the marginal probability of PrEP continuation by number of DREAMS enrolment criteria and used Kaplan-Meier methods to estimate the time to the first PrEP return visit by client age band.

Results: Between 11 August 2022 and 23 August 2024, 15,502 AGYW aged 15–24 years were screened for PrEP eligibility, of whom 15,072 (97.2%) initiated PrEP per national guidelines. Of those initiating PrEP, 9807 (65.1%) had sufficient follow-up time to allow for observation of a PrEP return visit. The proportion of AGYW who had ≥ 1 PrEP return visit within 180 days of initiation was 59.0% ($n/N = 5706/9675$). Across age bands, the percent probability of having a PrEP return visit within 180 days of initiation was highest among clients who reported ≥ 4 DREAMS enrolment criteria at 91.7% (95% CI: 70.7, 112.7%) for clients aged 15–19 years and 83.6% (95% CI: 61.1, 106.2%) for clients aged 20–24 years. Overall, 41.5% of clients had a first PrEP return visit between 21 and 42 days of PrEP initiation.

Conclusions: The high number and proportion of AGYW initiated on PrEP suggests that decentralising PrEP services to DREAMS community centres has the potential to improve PrEP access among AGYW. Increasing HIV risk perception among AGYW may improve PrEP continuation.

Keywords: adolescent girls and young women; community centre; HIV prevention; pre-exposure prophylaxis; adherence; Zambia

Additional information may be found under the Supporting Information tab of this article.

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1 | INTRODUCTION

While Zambia has made steady progress towards achieving the UNAIDS 95-95-95 goals (89:98:96), an estimated 28,000 new HIV acquisitions still occur annually [1]. Despite accounting for only 20% of Zambia's population, adolescents and young people (AYP) aged 15–24 years account for 40% of

all new HIV acquisitions annually, with new HIV acquisitions among females being six times higher than their male counterparts [2]. Multiple factors predispose AYP to HIV acquisition risk, including low comprehensive HIV knowledge, multiple sexual partnerships and age-mixing sexual relationships, low condom use, sexual intercourse under the influence of alcohol [3], as well as early sexual debut, transactional sex and

intimate partner violence (IPV) [3–5]. Other barriers include poor attitude of healthcare providers which affects access to quality and youth-friendly sexual and reproductive health services [2, 6].

In response to the increasing incidence of HIV among adolescent girls and young women (AGYW), in 2014, the United States President's Emergency Plan for AIDS Relief (PEPFAR) and partners launched the Determined, Resilient, Empowered, AIDS-free, Mentored and Safe (DREAMS) initiative to comprehensively address HIV vulnerability among AGYW in communities with the highest HIV prevalence across 10 countries in sub-Saharan Africa, including Zambia [7, 8]. The DREAMS initiative delivers multi-layered and linked social asset, biomedical and structural interventions, all aimed at reducing the risk of HIV acquisition among AGYW [7, 9–11].

In 2016, Zambia adopted pre-exposure prophylaxis (PrEP)—oral once-daily tenofovir disoproxil fumarate plus emtricitabine—as part of combination HIV prevention in line with World Health Organization (WHO) guidance [12–14], and started providing PrEP services in health facilities in 2018. By the end of 2022, 131,493 individuals had initiated PrEP, up from 419 in 2019, with DREAMS contributing 78% of AGYW PrEP initiations [15]. In Zambia, PrEP eligibility is based on the following criteria: not living with HIV but at perceived risk of HIV acquisition arising from vaginal/anal intercourse without condoms; sexually active with a partner known to be living with HIV or at substantial risk of HIV acquisition; sexually active with a partner living with HIV who is not on effective treatment; history of sexually transmitted infection (STI); history of post-exposure prophylaxis use; and sharing injection material or equipment [14].

Despite the availability of PrEP free of cost in government health facilities in Zambia, PrEP access remains limited, in part due to PrEP availability being largely restricted to antiretroviral viral therapy (ART) service delivery points. More so, PrEP continuation has been a lingering challenge, with continuation reported as low as 25% at 6 months in the general population in 2019 [16], and as low as 47% among key populations (KPs) in 2023 [17].

Differentiated service delivery (DSD) models offer promising avenues for tailoring HIV prevention to the unique needs and preferences of AGYW and for improving PrEP continuation in this priority population. DSD is an individual-centred approach that moves away from a one-size-fits-all model for providing services to one that is tailored to the unique needs of intended beneficiaries [18]. The DREAMS initiative offers differentiated HIV prevention services characterised by the provision of PrEP in DREAMS centres—non-clinical, community-based health promotion centres that provide a range of multi-layered social asset building, HIV prevention, psychosocial and economic empowerment services. PrEP is provided during 3-monthly visits to the DREAMS centres with peer-led support for PrEP continuation. DREAMS initiative models in different countries have been associated with increased PrEP access [19–21]. In Zimbabwe, a non-randomised “plausibility” evaluation found AGYW in DREAMS sites were more likely to report ever and ongoing PrEP use, consistent condom use, fewer sexual partners and less IPV [20]. In Zambia, utilisation of DREAMS centres resulted in

77% of AGYW at substantial risk of HIV initiating PrEP, with 68% of them receiving at least one refill, although both PrEP initiation and continuation differed by age group and location [21].

In this paper, we report PrEP uptake and continuation among AGYW receiving a community-based DREAMS DSD model in seven districts of Zambia through the USAID/PEPFAR-funded Controlling the HIV Epidemic for Key and Underserved Populations (CHEKUP) I programme. We also examine behavioural, socio-demographic and programmatic factors associated with PrEP continuation to inform future differentiated PrEP service delivery in Zambia and the region.

2 | METHODS

2.1 | USAID CHEKUP I DREAMS programme components

In 2021, the Centre for Infectious Disease Research in Zambia (CIDRZ) started implementing CHEKUP I in partnership with the Young Women Christian Association (YWCA), Copper Rose Zambia, Pact Incorporated, and Tackle Africa. The goal of CHEKUP I is to prevent new HIV acquisition among key and priority populations at risk of HIV, including AGYW. Nested within CHEKUP I was the DREAMS initiative, implemented in 37 communities (i.e. 37 DREAMS centres) in seven districts of Zambia—Livingstone, Lusaka, Ndola, Kitwe, Luanshya, Mufulira and Chingola. These districts were selected by PEPFAR/USAID Zambia because they are all urban districts, lie along the main transport corridor, and were located in provinces with comparatively high HIV prevalence [1].

The DREAMS initiative offered multiple differentiated interventions to AGYW aged 10–24 years to mitigate the risk of HIV acquisition (Figure 1). We adapted the 13-session behavioural change Stepping Stones programme as the primary and compulsory package for all AGYW to help promote sexual health, improve psychological wellbeing and prevent HIV acquisition [22]. The Stepping Stones programme has been widely adapted and recommended for use in different settings to address harmful gender norms, gender inequality and harmful interpersonal power dynamics [4]. Depending on their age group, risk profile and interest, the AGYW also received additional (secondary) services such as HIV testing, vocational skills training, digital literacy and educational support (Figure 1). Eligible HIV-negative AGYW were screened by DREAMS centre nurses for initiation on PrEP. Once initiated on PrEP, DREAMS centre nurses periodically contacted AGYW by phone and occasionally conducted home visits to remind them of upcoming PrEP appointments. Other services provided to AGYW regardless of HIV status were educational support (payment of school fees and uniforms); payment of fees for vocational skills training; digital skills training as a bridge to self or formal employment; linkage to employment opportunities; financial literacy and formation of savings groups; post-sexual and gender-based violence care and mental health screening and counselling.

Eligibility for enrolment in DREAMS was based on the vulnerability and risk profile of the AGYW. DREAMS enrolment

Category	Service	10-14 Years	15-19 Years	20-24 Years
Primary	Safe Spaces (+ basic financial literacy)	X	X	X
Secondary	Condoms	X	X	X
	Contraceptive method mix	X	X	X
	Post-violence care	X	X	X
	HIV testing	X	X	X
	Mental health	X	X	X
	Pre-exposure prophylaxis		X	X
	Parenting and caregiver program	X	X	
	Education support	X	X	X
	Financial literacy		X	X
	Savings groups		X	X
	Vocational skills training		X	X
	Bridge to employment		X	X
	Digital literacy	X	X	X
	iSchool	X		
Contextual	Gender-based violence prevention in communities	Community-based interventions offered in schools and other community settings.		
	HIV and violence prevention in schools			

Figure 1. DREAMS Zambia package of core services by age group (reference: USAID CHEKUP I Implementation Plan). Abbreviations: CHEKUP, controlling the HIV epidemic for key and underserved populations; DREAMS, determined resilient, empowered, AIDS-free, mentored and safe.

criteria for 10- to 14-year-old adolescents were based on any of the following: ever being pregnant, currently pregnant or has a child; being a victim of emotional or physical violence or abuse or neglect; alcohol or drug use; out of school; being an orphan; and engages in sexual activity. For 15- to 19-year-old AGYW, DREAMS enrolment was based on any of the following criteria: had multiple sexual partners in the past year; ever been pregnant, currently pregnant or has a child; ever been diagnosed with an STI; no or irregular condom use; transactional sex including staying in a relationship for material or financial support; experience of sexual violence (lifetime); engaged in alcohol or drug abuse; out of school; and orphanhood. DREAMS enrolment criteria for 20- to 24-year-olds were the same as 15- to 19-year-olds but did not include school status, orphanhood, or current or former pregnancy as criteria.

2.2 | Innovation: from health facilities to community-based DREAMS centres—differentiated PrEP service delivery

In August 2022, instead of referring DREAMS beneficiaries to government health facilities for PrEP services, CHEKUP I began to provide PrEP services to AGYW on-site in community-based DREAMS centres. The CHEKUP I model of PrEP service delivery followed WHO calls to improve PrEP acceptability, accessibility and continuation [23], and the Zambian Ministry of Health (MOH) DSD models [2, 24]. The CHEKUP I DREAMS programme differentiated approach to PrEP delivery incorporated the following DSD building blocks (Table 1): (1) *When*—monthly after initiation followed by 3 monthly PrEP visits; (2) *Where*—community-based DREAMS centres to ensure decentralised and expanded access; (3) *Who*—trained young nurses who work full-time in the DREAMS centres and were supported by peers to facilitate provision of respectful, non-stigmatising PrEP services; and (4) *What*—PrEP initiation and refills for at-risk,

Table 1. CHEKUP I PrEP differentiated service delivery building blocks for PrEP continuation

WHEN	Three-monthly
WHERE	Community-based Determined Resilient Empowered AIDS-free, Mentored Safe centres
WHO	Trained young nurses
	Adolescent girls and young women peers
WHAT	Pre-exposure prophylaxis refills
	HIV testing
	Comprehensive economic strengthening package
	Multi-layered psychosocial support services

Abbreviations: CHEKUP, controlling the HIV epidemic for key and underserved populations; PrEP, pre-exposure prophylaxis.

HIV-negative AGYW, HIV status monitoring, comprehensive economic strengthening package and other multi-layered psychosocial support services (Figure 1). Each DREAMS centre was linked to a government health facility, which served as a bridge for HIV treatment and a source of HIV test kits and PrEP medication.

2.3 | Data collection and outcomes

Data on PrEP initiation and continuation were collected from programmatic data sources and reported according to PEP-FAR indicators for monitoring, evaluation and reporting [25]. The indicators included variables for HIV testing and HIV test results and described each step of the PrEP cascade. These variables captured the number of AGYW enrolled in DREAMS, and the number and proportion of AGYW who: tested HIV negative; were screened for PrEP; found eligible for PrEP; newly initiated PrEP; and returned for PrEP follow-up or re-initiation. Data to report against these indicators were collected at individual-level using a bespoke

DHIS2-compatible data entry system created by CIDRZ and using a unique identifier code that allowed longitudinal client follow-up across DREAMS centres along the prevention-to-care continuum and prevented record duplication. Potential recipients of PrEP services completed a screening form developed in partnership with USAID and PEPFAR, including nine DREAMS enrolment criteria (effectively risk factors) for AGYW aged 15–19 years and six items for AGYW aged 20–24 years (File S1). These DREAMS enrolment criteria formed the basis for the risk analysis presented herein. For this paper, we described PrEP initiation and PrEP continuation, with PrEP initiation defined as documented first-time PrEP collection at a community-based DREAMS centre and PrEP continuation defined as documented evidence of ≥ 1 PrEP refill within 180 days of PrEP initiation. Individuals for which age and/or PrEP dispensation dates were not available in the routine record were excluded from the analysis.

2.4 | Statistical analysis

We analysed de-identified line-listed PrEP data for AGYW aged 15–24 years enrolled in DREAMS between 11 August 2022 and 23 August 2024. We defined the date of introduction of our programme innovation as 1 August 2022 when CHEKUP I started providing PrEP services on site within the DREAMS centres. We described beneficiary characteristics and DREAMS enrolment criteria using descriptive statistics. We used Pearson's Chi-squared test to examine differences in beneficiary characteristics between clients with only a PrEP initiation visit and those with ≥ 2 PrEP visits (i.e. an initiation plus ≥ 1 return visit). We used mixed effects Poisson regression modelling to estimate the association between DREAMS enrolment criteria and PrEP continuation, as well as the association between components of the Zambia DREAMS programme and PrEP continuation adjusting for age, marital status and family planning services accessed (per directed acyclic graph, Figure S1) allowing for random effects at the district level. Using Poisson regression models, we developed marginal probability plots of PrEP continuation by number of DREAM enrolment criteria. Finally, we used Kaplan-Meier methods to estimate the time to the first PrEP return visit by client age band. All analyses were performed using Stata (StataCorp LLC, College Station, TX, USA, release 18).

2.5 | Ethical considerations

The paper used de-identified data routinely available through the CHEKUP I programme. Ethical approval for this study was granted by the ERES Converge IRB (#2023-Oct-009) and the National Health Research Authority of the Ministry of Health (NHRA0003/19/10/23), without requiring patient consent given the use of de-identified, routinely collected data.

3 | RESULTS

3.1 | DREAMS enrolment and PrEP eligibility

Between 11 August 2022 and 23 August 2024, we screened 15,502 AGYW for PrEP eligibility based on their HIV risk profile ascertained during DREAMS programme screening and

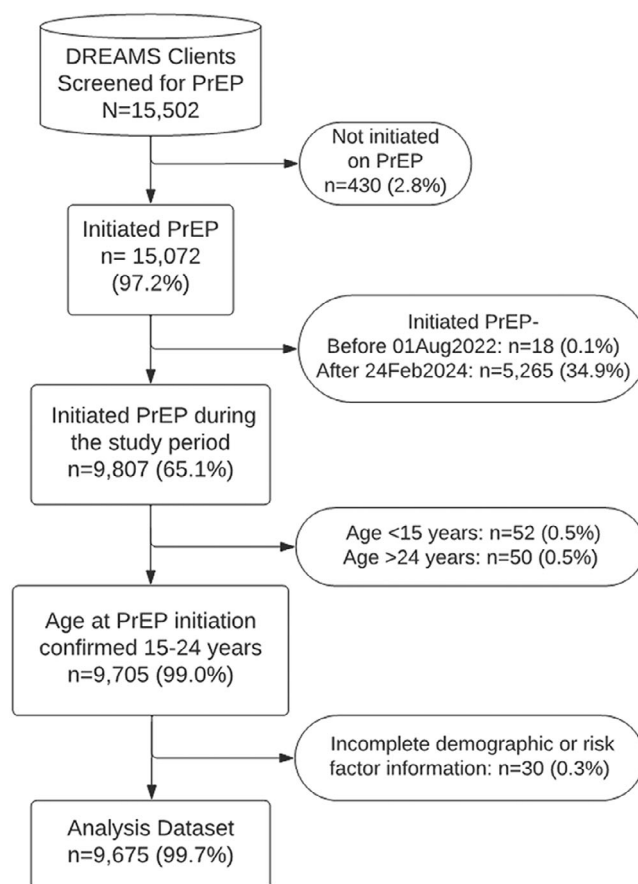


Figure 2. Flow chart of Determined Resilient, Empowered, AIDS-free, Mentored and Safe (DREAMS) adolescent girls and young women (AGYW) beneficiaries of differentiated pre-exposure prophylaxis (PrEP) services.

enrolment. Out of these, 15,072 (97.2%) were initiated on PrEP per MOH PrEP guidelines, and 430 (2.8%) were not initiated on PrEP (Figure 2). Of those initiated on PrEP, 9807 (65.1%) had sufficient follow-up time to allow for observation of a PrEP return visit within 180 days of initiation. We excluded 5265 (34.9%) AGYW who initiated PrEP after 23 February 2024 and did not contribute sufficient follow-up time and 18 (0.1%) who had initiated PrEP before the introduction of our intervention. Of those initiated on PrEP, 9705 (99.0%) were confirmed 15–24 years of age at PrEP initiation, and 9675 (99.7%) had complete data for primary analyses.

3.2 | Baseline characteristics of DREAMS clients who initiated PrEP

Of the 9675 AGYW with complete data analysed, the median age was 21 years (interquartile range: 20–23), with 5.7% under the age of 18 at initiation (Table 2). The majority (83.2%) of PrEP initiators were between 20 and 24 years old; 81.7% were single; and half of AGYW were initiated on PrEP in 2024, showing an upward trend of PrEP initiations following the introduction of our PrEP DSD model. Almost one-third (32.0%) of AGYW initiated on PrEP were from Lusaka

Table 2. DREAMS beneficiary characteristics by PrEP continuation status, August 2022–August 2024 (N = 9675)

Category	Factor	Level	No return visit/refill within 180 days of initiation n (%) n = 3969	≥ 1 PrEP return visit/refill within 180 days of initiation n (%) n = 5706	Total N (%) N = 9675
Demographic characteristics	Enrolment age	Median (IQR)	21 (20–23)	21 (20–23)	21 (20–23)
	Enrolment age (categorically)	15–19 years	775 (19.5)	846 (14.8)	1621 (16.8)
		20–24 years	3194 (80.5)	4860 (85.2)	8054 (83.2)
	Marital status	Married	675 (17.0)	1063 (18.6)	1738 (18.0)
		Single	3277 (82.6)	4625 (81.1)	7902 (81.7)
		Separated/divorced	16 (0.4)	16 (0.3)	32 (0.3)
		Widowed	1 (0.0)	2 (0.0)	3 (0.0)
Other service details	Accessed family planning services	No	2539 (64.0)	3380 (59.2)	5919 (61.2)
		Yes	1430 (36.0)	2326 (40.8)	3756 (38.8)
	DREAMS district	Chingola District	534 (13.5)	431 (7.6)	965 (10.0)
		Kitwe District	640 (16.1)	835 (14.6)	1475 (15.2)
		Livingstone District	346 (8.7)	679 (11.9)	1025 (10.6)
		Luanshya District	151 (3.8)	459 (8.0)	610 (6.3)
		Lusaka District	1479 (37.3)	1615 (28.3)	3094 (32.0)
		Mufulira District	231 (5.8)	542 (9.5)	773 (8.0)
		Ndola District	588 (14.8)	1145 (20.1)	1733 (17.9)
Wrap-around services	Received financial literacy module	No	3354 (84.5)	4708 (82.5)	8062 (83.3)
		Yes	615 (15.5)	998 (17.5)	1613 (16.7)
	Received saving literacy module	No	3643 (91.8)	5357 (93.9)	9000 (93.0)
		Yes	303 (7.6)	323 (5.7)	626 (6.5)
		Missing	23 (0.6)	26 (0.5)	49 (0.5)
	Received digital literacy module	No	3807 (95.9)	5450 (95.5)	9257 (95.7)
		Yes	162 (4.1)	256 (4.5)	418 (4.3)
DREAMS enrolment responses/risk factors	Multiple sexual partners in the past 12 months (screen)	No	3197 (82.0)	4734 (81.9)	7931 (82.0)
		Yes	701 (18.0)	1043 (18.1)	1744 (18.0)
	Current or past pregnancy or has child (screen)	No	737 (18.9)	805 (13.9)	1542 (15.9)
		Yes	28 (0.7)	45 (0.8)	73 (0.8)
		Missing	3133 (80.4)	4927 (85.3)	8060 (83.3)
	Ever diagnosed with STI (screen)	No	3784 (97.1)	5570 (96.4)	9354 (96.7)
		Yes	114 (2.9)	207 (3.6)	321 (3.3)
	No or irregular condom use (screen)	No	1183 (30.3)	1693 (29.3)	2876 (29.7)
		Yes	2715 (69.7)	4084 (70.7)	6799 (70.3)
	Receive material or financial support for sex (screen)	No	3472 (89.1)	5077 (87.9)	8549 (88.4)
		Yes	426 (10.9)	700 (12.1)	1126 (11.6)
	Experience of sexual violence (screen)	No	3696 (94.8)	5400 (93.5)	9096 (94.0)
		Yes	202 (5.2)	377 (6.5)	579 (6.0)
	Alcohol or drug abuse (screen)	No	3007 (77.1)	4232 (73.3)	7239 (74.8)
		Yes	891 (22.9)	1545 (26.7)	2436 (25.2)
	Out of school (screen)	No	747 (19.2)	804 (13.9)	1551 (16.0)
		Yes	17 (0.4)	47 (0.8)	64 (0.7)
		Missing	3134 (80.4)	4926 (85.3)	8060 (83.3)
	Orphanhood (screen)	No	648 (16.6)	752 (13.0)	1400 (14.5)
		Yes	117 (3.0)	100 (1.7)	217 (2.2)
		Missing	3133 (80.4)	4925 (85.3)	8058 (83.3)

(Continued)

Table 2. (Continued)

Category	Factor	Level	No return visit/refill within 180 days of initiation n (%) n = 3969	≥ 1 PrEP return visit/refill within 180 days of initiation n (%) n = 5706	Total N (%) N = 9675
	Count of DREAMS enrolment/risk factors	1	2736 (69.5)	3685 (65.1)	6421 (66.4)
		2	1072 (27.2)	1676 (29.6)	2748 (28.4)
		3	119 (3.0)	257 (4.5)	376 (3.8)
		4	7 (0.2)	36 (0.6)	43 (0.4)
		5	2 (0.1)	6 (0.1)	8 (0.1)
		6	0 (0.0)	2 (0.0)	2 (0.0)
		Unknown	30 (0.8)	43 (0.8)	73 (0.1)

Abbreviations: DREAMS, Determined Resilient, Empowered, AIDS-free, Mentored and Safe; IQR, interquartile range; PrEP, pre-exposure prophylaxis; STI, sexually transmitted infection.

district, which, as the country's capital and largest urban centre in Zambia, was expected, followed by Ndola district, at 17.9%, the third largest city in Zambia (Table 2).

3.3 | Risk profile of AGYW initiated on PrEP

Around 18% of PrEP initiators reported multiple sexual partnerships in the past 12 months; two-thirds (70.3%) reported no or irregular condom use; one-quarter (25.2%) reported unhealthy alcohol or drug use; slightly over 11.6% reported engaging in transactional sex; and 6.0% reported lifetime experience of sexual violence (Table 2).

3.4 | PrEP continuation and associated factors

The proportion of AGYW who had ≥ 1 return visit for a PrEP refill within 180 days of initiation was 59.0% (n/N = 5706/9675). After adjusting for age, marital status and family planning service access, clients 20–24 years old were 1.23 (95% CI: 1.07, 1.42) times as likely to return for a PrEP refill during the specified time frame than beneficiaries 15–19 years old. Notably, DREAMS programme “wrap-around” services such as economic strengthening were not statistically significantly associated with return PrEP visit. Though not statistically significant, receipt of saving literacy training was associated with a lower likelihood (aPR: 0.74, 95% CI: 0.23, 1.91) of a return PrEP visit (Table 3).

DREAMS clients who reported being out of school were 1.35 (95% CI: 1.20, 1.52) times as likely to have a return PrEP visit compared to those who reported being in school (Table 4). Though not statistically significant, clients self-identifying as being an orphan were less likely (PR: 0.81, 95% CI: 0.66, 1.00) to have a return PrEP visit compared to counterparts who did not self-identify as such (Table 4).

Across age bands, the percent probability of having a PrEP return visit within 180 days of initiation was highest among clients who reported ≥ 4 DREAMS enrolment criteria/risk fac-

tors at 91.7% (95% CI: 70.7, 112.7%) for clients aged 15–19 years and 83.6% (95% CI: 61.1, 106.2%) for clients aged 20–24 years (Figure 3). Probability of return PrEP visit varied significantly by the number of DREAMS enrolment/risk factors among clients in the 15–19 years age band. Specifically, the percent probability of a PrEP return visit among individuals with ≥ 4 DREAM enrolment criteria/risk factors was 91.7% (95% CI: 70.7, 112.7%), higher than among clients with one risk factor (52.7%, 95% CI: 41.2, 64.1%) (Figure 3). Thus, the lower the number of DREAM enrolment criteria/risk factors reported, the lower the marginal probability of a PrEP follow-up visit, among clients aged 15–19 years.

Older AGYW had an overall higher proportion of return for the first return PrEP visit within the first 180 days after PrEP initiation compared to AGYW in the younger age band (Figure 4). Overall, 41.5% of the clients had a first return PrEP visit between 21 and 42 days after PrEP initiation. A total of 13.7% of clients had a first return PrEP visit between 42 and 180 days after initiation.

4 | DISCUSSION

In this report, we describe DREAMS centres as a community-based model for differentiated PrEP service delivery among AGYW in Zambia. We note the high numbers of AGYW initiating and continuing PrEP in CHEKUP I DREAMS programme, with PrEP initiation reaching nearly 10,000 AGYW in 37 communities in seven districts of Zambia. Differentiated PrEP delivery relied upon DSD building blocks involving full-time young nurses supported by AGYW peers who provided HIV testing and PrEP refills to clients at DREAMS centres located in the community. We observed higher PrEP continuation among AGYW who reported a higher number of DREAMS enrolment criteria, which are risk factors for HIV acquisition, and might suggest alignment of PrEP use with self-perceptions of HIV risk.

Table 3. Regression for at least one return PrEP visit within 180 days of initiation (N = 9675)

Factor	Level	Unadjusted			Adjusted		
		PR	95% CI	p-value	aPR	95% CI	p-value
Age	15–19 years	1.00 (ref)	–	–	1.00 (ref)	–	–
	20–24 years	1.23	(1.08, 1.41)	0.003	1.23	(1.07, 1.42)	0.005
Marital status	Married	1.00 (ref)	–	–	1.00 (ref)	–	–
	Single	0.97	(0.94, 1.01)	0.109	1.00	(0.96, 1.05)	0.948
	Separated/divorced	0.85	(0.63, 1.15)	0.303	0.86	(0.63, 1.18)	0.358
	Widowed	0.99	(0.46, 2.14)	0.986	0.97	(0.46, 2.05)	0.941
Accessed family planning services	No	1.00 (ref)	–	–	1.00 (ref)	–	–
	Yes	1.05	(0.97, 1.13)	0.215	1.03	(0.96, 1.12)	0.399
Received financial literacy module	No	1.00 (ref)	–	–	1.00 (ref)	–	–
	Yes	1.03	(0.95, 1.12)	0.476	1.02	(0.92, 1.12)	0.645
Received saving literacy module	No	1.00 (ref)	–	–	1.00 (ref)	–	–
	Yes	0.77	(0.33, 1.77)	0.535	0.74	(0.23, 1.91)	0.499
Received digital literacy module	No	1.00 (ref)	–	–	1.00 (ref)	–	–
	Yes	0.92	(0.66, 1.28)	0.617	0.92	(0.66, 1.28)	0.628

Note: Adjustment set—age, marital status, family planning access and district of DREAMS community centre (as random effect).

Abbreviations: aPR, adjusted prevalence ratio; CI, confidence interval; DREAMS, Determined Resilient, Empowered, AIDS-free, Mentored and Safe; PR, prevalence ratio; STI, sexually transmitted infection.

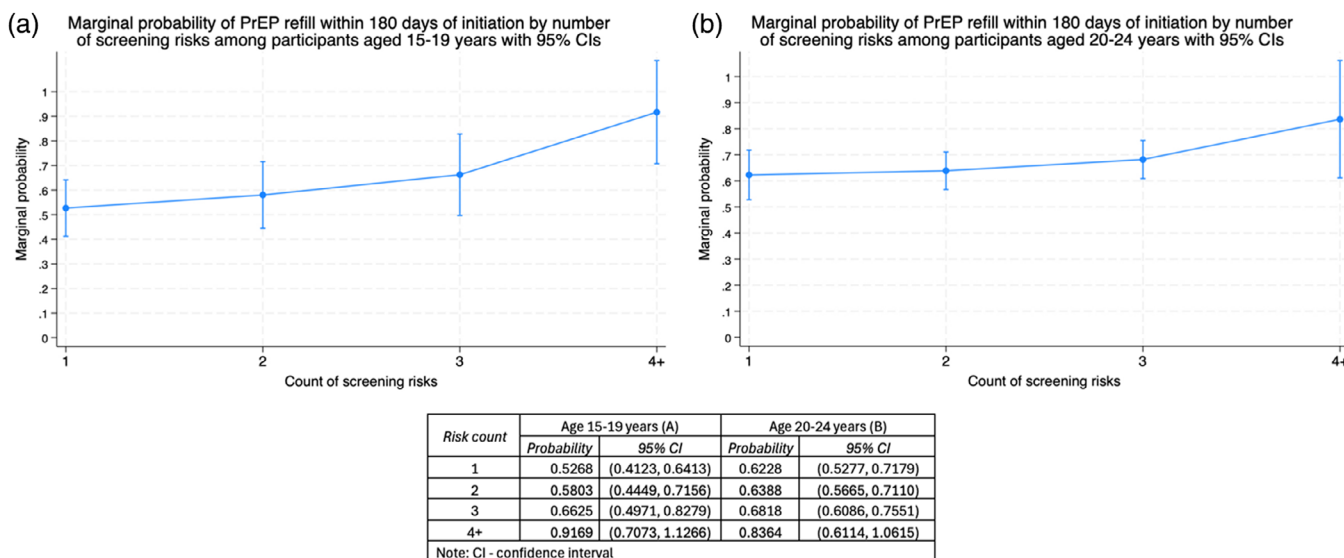


Figure 3. (a) Marginal probability of pre-exposure prophylaxis (PrEP) continuation by risk factor among clients aged 15–19 years. **(b)** Marginal probability of PrEP continuation by risk factor among clients aged 20–24 years (Table S1). Point probability estimates and associated 95% confidence intervals by age category.

The high number of AGYW initiating PrEP in our DREAMS programme corroborates evidence from similar DSD programmes in Zambia [15, 17, 21] and the region [26–30]. In Zambia, by the end of 2022, 78% of all AGYW on PrEP had received PrEP through a DREAMS centre [15]. The high PrEP initiation rate observed in our programme suggests a large unmet need for PrEP among AGYW, and the willingness of AGYW to adopt this service when it is made easily accessible

and differentiated to their unique needs and preferences as opposed to lower PrEP uptake when PrEP offerings are limited to traditional health facilities providing ART services [15]. Our finding of community-based DREAMS centres supporting the uptake of differentiated PrEP services for AGYW aligns with results from a similar community-based intervention in Zambia in which the number of KP accessing PrEP markedly increased following the introduction of venue-based PrEP

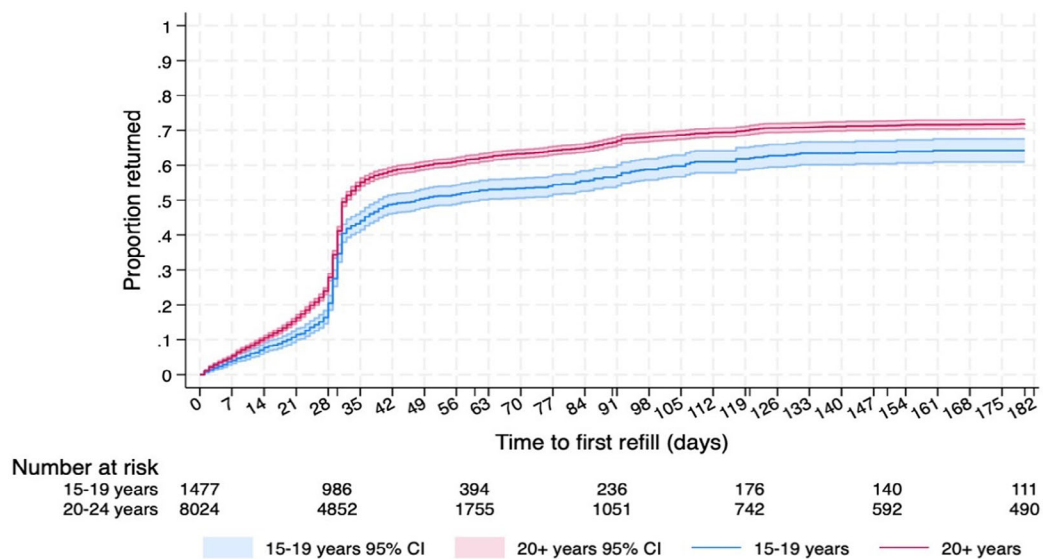


Figure 4. Kaplan-Meier estimates for time to first pre-exposure prophylaxis (PrEP) return visit with accompanying 95% confidence intervals (CI) by age band.

Table 4. Regression results for PrEP continuation (defined as follow-up within 180 days of next appointment) by screening factor for DREAMS enrolment (N = 9675)

<i>Factor</i>	<i>Level</i>	<i>PR</i>	<i>95% CI</i>	<i>p-value</i>
Multiple sex partners last 12 months	No	1.00 (ref)	–	–
	Yes	1.02	(0.93, 1.11)	0.680
Ever pregnant ^a	No	1.00 (ref)	–	–
	Yes	1.16	(0.82, 1.63)	0.394
STI diagnosis	No	1.00 (ref)	–	–
	Yes	1.03	(0.92, 1.16)	0.739
Inconsistent/no condom use	No	1.00 (ref)	–	–
	Yes	1.02	(0.97, 1.08)	0.098
Transactional sex	No	1.00 (ref)	–	–
	Yes	1.02	(0.93, 1.12)	0.919
Experienced sexual violence	No	1.00 (ref)	–	–
	Yes	1.06	(1.00, 1.14)	0.058
Alcohol and/or drug abuse	No	1.00 (ref)	–	–
	Yes	1.05	(0.99, 1.13)	0.182
Out of school ^a	No	1.00 (ref)	–	–
	Yes	1.35	(1.20, 1.52)	< 0.001
Orphanhood ^a	No	1.00 (ref)	–	–
	Yes	0.81	(0.66, 1.00)	0.051

Abbreviations: CI, confidence interval; PrEP, pre-exposure prophylaxis; PR, prevalence ratio; STI, sexually transmitted infection.

^aOnly asked of population aged 15–19 years (N = 1617).

services [17]. Taken together, these findings underscore the utility of differentiated approaches for expanding access to community-based PrEP services in Zambia.

Notwithstanding the high PrEP uptake at the first visit in our DREAMS programme, PrEP continuation decreased over time. We conjecture that this decrease in PrEP continuation could have been due to not all AGYW remaining at risk and needing PrEP. Our analysis found that the availability of other DREAMS support services such as social asset building and economic strengthening interventions were not significantly associated with the likelihood of a return PrEP visit. Instead, PrEP continuation varied by cumulative self-reported HIV acquisition risk and social vulnerability. Across all age bands (15–19 and 20–24 years), AGYW who reported multiple risk DREAMS enrolment criteria/risk factors were more likely to continue PrEP compared to those who reported fewer such risk factors. Similarly, older AGYW (20–24 years) had an overall higher proportion of return for the PrEP in the first 180 days after PrEP initiation compared to younger AGYW (15–19 years).

The relatively low number of AGYW continuing on PrEP fits with other evidence from Zambia [21] and other African regions [30, 31]. Factors as varied as medication attributes and pill burden [31], stigma and discrimination [32, 33], and concerns about people conflating PrEP with ART [34] negatively affecting PrEP continuation. Therefore, improving PrEP continuation requires recognising the heterogeneity among AGYW in terms of their socio-demographics, HIV risk perceptions, experiences and tailoring service delivery to their unique circumstances. The introduction of new injectable PrEP agents, such as cabotegravir [35] and lenacapavir [36], may offer a more acceptable, anonymous and longer-acting formulation to assuage stigma, concerns about pill burden and challenges of disclosure.

Our study was not without limitations. First, due to periodic PrEP stock-outs, the programme had to ration the provision of PrEP services. This could have undermined beneficiary interest to return for PrEP and/or could have created concerns about long-term PrEP availability, either of which could have influenced PrEP initiation and continuation. Second, we conceptualised DREAMS enrolment criteria to be equally additive risk factors in our regression analysis, with limited empiric evidence to support this assumption, although this type of risk appraisal is operationally useful in DREAMS programme settings where simple risk screening tools are used to help providers decide on programme eligibility. Third, while a screening and enrolment tool was administered to characterise AGYW's risk profiles, the social desirability not to be viewed as sexually active could have resulted in the under-reporting of the enrolment criteria we examined in the study. Fourth, this is a descriptive study that did not include a comparator group. Therefore, the effect of our differentiated, DREAMS-based PrEP model compared to standard health facility-based PrEP services could not be ascertained. Despite these limitations, our report adds to the body of knowledge on the utility of community-based DSD models to promote equity of access to HIV prevention services.

As countries scale-up PrEP, further research is needed to assess the effectiveness of various differentiated PrEP delivery models to inform HIV prevention programming and policy. Questions remain about the implementation strategies needed to increase the likelihood of PrEP continuation, such as the optimal frequency, cadence and delivery modality (e.g. home delivery, mobile, DREAMS centre, etc.) for providing PrEP, the impact of support groups and peer navigation on PrEP adherence and continuation, and the effects of "wrap-around" services on PrEP outcomes. These questions must be answered to optimally differentiate PrEP services to reduce stubbornly high HIV incidence among AGYW.

5 | CONCLUSIONS

We have described community DREAMS centres as a differentiated model to improve access to PrEP services for AGYW in Zambia. We observed relatively high rates of PrEP initiation, but a need to improve PrEP continuation. Our analysis has also shown an association between DREAMS enrolment criteria at baseline and PrEP continuation, suggesting that the degree of HIV risk and/or risk perception may be aligned with PrEP use among AGYW in our programme. As countries scale-up PrEP, differentiating prevention services will be crucial to improving access for populations that remain marginalised and underserved.

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COMPETING INTERESTS

None of the authors have any competing interests.

AUTHORS' CONTRIBUTIONS

MM led the CHEKUP I DREAMS programme management, conceptualised and led the writing of the manuscript. All authors contributed to PrEP service delivery as part of the implementing team. MM led the writing and coordination with support from MEH. WJM and KC were responsible for data extraction cleaning. JMP led the data analysis with support from WJM and KC. All authors reviewed and contributed to the writing.

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DISCLAIMER

The findings and conclusions of this paper are those of the authors and do not necessarily represent the official position of the funding agency.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

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SUPPORTING INFORMATION

Additional information may be found under the Supporting Information tab for this article:

Table S1: Marginal probability estimates and 95% confidence intervals.

Figure S1: Directed acyclic graph (DAG) for relationship between wrap-around services and pre-exposure prophylaxis refill/persistence.

RESEARCH ARTICLE

High acceptability, feasibility and sustainability of a direct-to-pharmacy differentiated PrEP delivery model in public health HIV clinics in Kenya: perspectives of PrEP clients and healthcare providers

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Abstract

Introduction: High client opportunity costs and a burdened healthcare system limit oral pre-exposure prophylaxis (PrEP) delivery in Kenyan public HIV clinics. We conducted a qualitative study among PrEP clients and providers to understand the acceptability, feasibility and willingness to implement a client-centred, differentiated direct-to-pharmacy (DTP) PrEP refill visits intervention aimed at improving the efficiency of PrEP implementation in real-world clinics.

Methods: From March 2021 to March 2022, we conducted in-depth interviews with clients and healthcare providers participating in an individual facility pharmacy-based PrEP delivery model for PrEP refills among clients in the continuation phase at two public HIV clinics in central Kenya. The core components of the DTP model included directed-to-PrEP pharmacy refill visits conducted by facility pharmacy staff and client HIV self-testing (HIVST) while waiting for services at the pharmacy. We used semi-structured interview guides informed by the Consolidated Framework for Implementation Research (CFIR). We analysed data using thematic content analysis and organised findings by CFIR constructs.

Results: We interviewed 20 PrEP clients and 20 healthcare providers. PrEP clients included 15 females and had a median age of 39 years (interquartile range [IQR]: 33–48). Providers included 13 females, had a median age of 32 years (IQR: 30–41), and included 10 HIV counsellors, 5 pharmacy and 3 clinical providers. Both providers and clients reported high satisfaction with DTP PrEP refill visits derived from improved clinic flow and quality of service. Among clients, shorter waiting times and less movement between multiple clinic rooms reduced delays, improved privacy and reduced stigma associated with visiting HIV clinics. Furthermore, shorter waiting times and infrequent clinic visits reduced loss of working hours and income among clients, motivating PrEP continuation. Providers reported improved clinic flow, reduced work burden among non-pharmacy providers, improved knowledge and ease of implementing DTP refill visits. However, providers expressed concerns about the potential loss of roles among HIV counsellors and the shifting of workload burden to pharmacy providers.

Conclusions: Differentiated DTP refill visits with HIVST were highly acceptable and feasible among PrEP clients and providers. Context-specific modifications and scale-up of the intervention could improve the efficiency of PrEP delivery within public HIV clinics in Kenya and similar settings.

Keywords: direct-to-pharmacy; public HIV clinics; implementation science; Kenya; differentiated service delivery; pre-exposure prophylaxis

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1 | INTRODUCTION

Oral HIV pre-exposure-prophylaxis (PrEP) is a highly effective and safe HIV prevention strategy among populations at substantial risk of HIV acquisition [1, 2]. PrEP uptake, adherence and continuation have been sub-optimal among populations that could benefit from PrEP in high HIV-burden, resource-

limited regions [3–5]. In eastern and southern African countries, inadequate staffing and infrastructure, long waiting times and frequent refill visits are major health system barriers that hinder efficient PrEP delivery and access in public HIV clinics [6, 7]. These barriers exacerbate already burdened healthcare systems and increase clients' opportunity costs [8, 9]. Eliminating clinic-based barriers can reduce opportunity

costs and HIV-clinic-associated stigma, contributing to higher PrEP uptake and continuation, particularly among sub-populations that show high initial interest in PrEP but experience challenges in adherence and continuation [10, 11].

Studies in sub-Saharan Africa (SSA) have revealed distinct patterns of PrEP uptake and continuation among priority sub-populations such as adolescent girls and young women (AGYW), heterosexual men and women, and individuals in HIV-serodifferent partnerships [12, 13]. Early PrEP discontinuation has been reported among individuals with significant ongoing HIV risk, including AGYW and people with partners of unknown HIV status or multiple sexual partners [11, 12, 14]. Gender differences in health-seeking behaviours, low HIV and PrEP knowledge, and low HIV risk perceptions among young people have been linked to early discontinuation [14–16]. Providing options through differentiated service delivery (DSD) approaches could cater to differences in individual needs and preferences [5, 17]. Differentiated service strategies simplify care for clients, are tailored to individual needs and preferences, and maximise health system impacts, efficiency and cost-effectiveness [18]. The World Health Organization (WHO) recommends DSD to eliminate PrEP access barriers and to enhance its uptake, continuation and effective use [18]. Differentiated care interventions can improve the acceptability and effectiveness of PrEP services, and support PrEP scale-up and implementation [18, 19].

Adapting the “where,” “who,” “when” and “what” components of DSD through service decentralisation, task-sharing, multi-month dispensing, and separated clinical consultation and refill-only visits, has optimised HIV care and treatment programmes, yielding improved clients’ adherence, retention and viral suppression outcomes [20–23]. Similar differentiated interventions have been applied within PrEP delivery in Kenya and other SSA countries, demonstrating high levels of acceptability and feasibility [24–28]. Few interventions have focused on improving service efficiency and quality in public health HIV clinics, despite these being among the largest PrEP delivery locations in SSA [29, 30]. Our study sought to demonstrate the feasibility, acceptability and sustainability of direct-to-pharmacy (DTP) PrEP refill visits with HIV self-testing (HIVST), an individual facility-based differentiated PrEP care model, within public health HIV clinics in central Kenya.

2 | METHODS

2.1 | Study design and approach

The Efficiency Study (ClinicalTrials.gov: NCT04424524) was a prospective pilot implementation evaluation of a client-centred, differentiated care intervention aimed at improving the efficiency of PrEP delivery in Kenyan public HIV clinics. The study’s overall objective was to demonstrate the feasibility and acceptability of DTP PrEP follow-up visits among PrEP clients in the continuation phase, with the key expected outcomes including greater efficiency, reduced workload, diminished client burden, and improved service and client outcomes. The study design and approach have been previously described [31]. Four HIV clinics participated in this pilot study, two implementing a differentiated pharmacy-based follow-up PrEP care pathway (DTP), and two a standard PrEP client

flow without any change (control). The clinics were purposively selected from 12 facilities that implemented PrEP in the Partners Scale-Up Project [32], based on willingness to implement DTP, high clinic volume and space availability.

In the intervention arm, clients accessed 3-monthly DTP PrEP refill visits. At the initiation visit, clients were informed they would receive PrEP services directly at the pharmacy at their next follow-up visit. At follow-up, a PrEP clients’ navigator retrieved client files and directed clients to the pharmacy, where a pharmacy provider conducted a rapid risk assessment (for ongoing HIV risk, adherence and side effects), and PrEP dispensing. Clients conducted HIVST at a private place at the pharmacy while waiting for PrEP refills and had the opportunity to access clinical review from a clinician on request or if they had an indication. Under the standard client flow, clients accessed 3-monthly PrEP refills with clinical review and follow-up HIV testing as per Kenya’s HIV prevention and treatment guidelines [33]. Clients had numerous stopovers for services, including HIV risk assessment and testing by an HIV counsellor, clinical review and PrEP prescription by a clinician, and PrEP dispensing by a pharmacy provider.

Overall, 746 PrEP clients (380 DTP; 366 control) were enrolled in the study and followed up for 6 months. The primary quantitative findings of this study have been previously described [31]. This paper presents the results of an in-depth qualitative assessment conducted among a sub-set of PrEP clients and healthcare providers in the intervention arm, who had experience with the DTP model, to understand their experiences and perceptions about the intervention.

2.2 | Study population and setting

We conducted this study in two healthcare facilities: Facility A (Level 4) and Facility B (Level 5) in central Kenya, with county population-level HIV prevalence rates of up to 2.7% [34]. We enrolled PrEP clients and providers to participate in in-depth interviews. Eligible clients and providers were aged ≥ 18 years and were able and willing to provide written consent. Additionally, clients were not living with HIV, based on negative HIV tests per Kenya’s HIV guidelines and were currently or previously accessing PrEP at the intervention clinics. Clients were purposively sampled by sex, while providers were sampled by cadres (HIV counsellors, pharmacy providers, clinicians, nurses) and experience in implementing DTP refill visits in the intervention clinics. Eligible clients were informed about the study by clinic staff, and the contact information of those willing to participate was shared with the researchers for interview scheduling. Providers were recruited by the researchers during in-person facility visits. Our sample size was guided by the principle of theme saturation, where we stopped interviews once no new information emerged [35].

2.3 | Data collection

We conducted in-depth interviews between March 2021 and March 2022 to obtain an in-depth understanding of participants’ experiences and perceptions about the DTP intervention [36]. All interviews were conducted in-person by three Bachelors-level female social scientists in private rooms

Table 1. Participant demographic characteristics

	PrEP clients (N = 20)			PrEP providers (N = 20)		
	All	Facility A (n = 10)	Facility B (n = 10)	All	Facility A (n = 10)	Facility B (n = 10)
Sex						
Female	15 (75%)	7 (70%)	8 (80%)	13 (65%)	7 (70%)	6 (60%)
Male	5 (25%)	3 (30%)	2 (20%)	7 (35%)	3 (30%)	4 (40%)
Age						
Mean (SD)	39 (10)	43 (7)	35 (10)	37 (12)	34 (8)	39 (15)
Median [IQR]	39 [33–48]	43 [38–50]	34 [27–39]	32 [30–41]	32 [29–40]	34 [30–40]
Relationship type						
HIV-serodifferent	17 (85%)	10 (100%)	7 (70%)	–	–	–
Unknown partner status	3 (15%)	0 (0%)	3 (30%)	–	–	–
Current position						
Clinic manager (Nurse)	–	–	–	1 (5%)	0 (0%)	1 (10%)
Clinical officer	–	–	–	1 (5%)	1 (10%)	0 (0%)
Nurse	–	–	–	1 (5%)	0 (0%)	1 (10%)
Health records and information officer	–	–	–	1 (5%)	1 (10.0%)	0 (0%)
HIV counsellor	–	–	–	10 (50%)	6 (60%)	4 (40%)
Pharmacy provider	–	–	–	5 (25%)	1 (10%)	4 (40%)
Social worker	–	–	–	1 (5%)	1 (10.0%)	0 (0%)
Participation in PrEP delivery (months)						
Mean (SD)	–	–	–	32 (19)	36.8 (16.2)	26 (20)
Median [IQR]	–	–	–	42 [12–48]	48 [27–48]	24 [7–48]
Duration of PrEP use (months)						
Mean (SD)	18 (23)	17 (17)	20 (29)	–	–	–
Median [IQR]	6 [5–26]	7 [5–31]	6 [4–23]	–	–	–

Abbreviations: IQR, inter-quartile range; PrEP, pre-exposure prophylaxis; SD, standard deviation.

at the HIV clinics in the participants' preferred language (English or Kiswahili), each lasting approximately 1 hour. We used separate semi-structured interview guides for clients and providers informed by the Consolidated Framework for Implementation Research (CFIR). We used CFIR during data collection and analysis to identify the relevant contextual barriers and facilitators that influenced the implementation of DTP refill visits to guide the design of tailored implementation strategies [37]. Relevant CFIR constructs were applied to explore the outcomes of the DTP refill visits, including their acceptability, feasibility and sustainability within our setting.

2.4 | Data management and analysis

Interviews were audio-recorded, transcribed and translated into English. After each interview, the interviewers summarised key points in a debriefing report. Interview data was analysed inductively and deductively using thematic content analysis [38]. All analyses were performed on de-identified data using Dedoose Version 9.2.007 (Sociocultural Research Consultants LLC, Los Angeles, CA, 2021) [39]. First, EO reviewed all the transcripts, generated key themes and developed separate codebooks for clients and providers based on the CFIR framework and the interview guides. Authors EO, VO and NW selected a subset (15%; $n = 3$) of the client and provider interviews and double-coded them for consistency.

The authors reviewed the codes and resolved discrepancies over weekly meetings until an agreement was reached. EO and VO independently coded the remaining transcripts and grouped the emerging themes from the interviews. Once coding was complete, the authors summarised key themes and compared findings from clients and providers.

2.5 | Ethical statement

The University of Washington Human Subjects Ethical Committee and the Scientific and Ethics Review Unit of the Kenya Medical Research Institute approved this study. All participants provided individual written informed consent before study participation.

3 | RESULTS

3.1 | Participant characteristics

We interviewed 20 PrEP clients and 20 healthcare providers. Among clients, 75% were female ($n = 15$), the median age was 39 years (IQR: 33–48) and PrEP use experience was 6 months (IQR: 5–26). Of the providers, 65% ($n = 13$) were female, the median age was 32 years (IQR: 30–41) and PrEP delivery experience was 42 months (IQR: 12–48), as outlined in Table 1.

Table 2. Perceived determinants and outcomes of DTP PrEP refill visits by CFIR constructs

CFIR domain/ construct	DTP PrEP refill visits determinants and outcomes	Beneficiary/ affected
Innovation		
Relative advantage	Waiting time: Reduced waiting time and improved time efficiency.	Clients Providers
	Client flow: Reduced queuing and movement between clinic rooms, smooth clinic flow, reduced congestion.	Clients Providers Health system
	Workload: General reduced burden among clinic staff; concerns of potential workload shift to pharmacy providers.	Providers
Adaptability	Clinic modifications: Pre-scheduled PrEP refill visit dates and differentiated PrEP delivery spaces.	Clients
Complexity	Low complexity: Ease of implementing PrEP refills.	Providers
Outer setting		
Local attitudes	Service quality and satisfaction: Improved service quality, satisfaction, convenience and comfort.	Clients Providers
	Privacy and HIV stigma: Improved privacy and reduced risk of exposure to HIV-clinic-associated stigma.	Clients
Inner setting		
Work infrastructure	Staffing organisation: Adequate clinic staffing overall, but shortage of pharmacy and HIV counselling providers.	Providers Health system
Physical/information technology infrastructure	Clinic infrastructure: Adequate overall but inadequate rooms and electronic medical records (EMR) systems.	Providers Health system
Recipient-centredness	Differentiated refill visits: Prioritising and fast-tracking PrEP refill clients, client navigation.	Clients
Deliverer-centredness	Task-sharing: Improved teamwork and flexibility in PrEP service delivery.	Providers
Learning-centredness	Knowledge and skills: Increased empowerment and knowledge in HIV prevention and PrEP delivery skills.	Clients Providers Health system
Compatibility	Ease of adoption: Few changes to routine operations, addressed service challenges and staff shortage.	Health system Providers
Relative priority and mission alignment	PrEP prioritisation: Facilitated prioritisation of PrEP services and achievement of HIV prevention targets.	Health system
Access to knowledge and information	Provider training: Adequate PrEP delivery training facilitated intervention implementation and ownership.	Providers
Individuals		
Clients' needs	Opportunity costs: Reduced time and costs of travel to clinics, less disruption of clients' schedules and less worry over missing important activities.	Clients
Capability	Self-efficacy: Increased skills and confidence in implementing DTP refill visits and PrEP delivery.	Providers
Motivation	Future willingness: General confidence and willingness to participate in DTP refill visits.	Clients Providers

Abbreviations: CFIR, Consolidated Framework for Implementation Research; DTP, direct-to-pharmacy; PrEP, pre-exposure prophylaxis.

Clients and providers reported that DTP PrEP refill visits resulted in improved service efficiency, quality and satisfaction attributed to reduced waiting times, less movement between clinic rooms and infrequent clinic visits. Table 2 summarises the key determinants and outcomes of DTP refill visits related to their acceptability, feasibility and sustainment.

3.2 | Innovation domain

3.2.1 | Innovation relative advantage

Improved waiting time. PrEP clients and providers preferred DTP refill visits due to short waiting times and few delays in HIV clinics. Short waiting times were attributed to clients seeing few (2–3) providers, less movement between clinic rooms,

ease and convenience of HIVST, and prioritisation of PrEP clients during refill visits. The short waiting times motivated clients to continue PrEP:

"[DTP] has really given me the morale [motivation] of taking the drugs because you spend less time in the hospital. Also, you are dispensed drugs for three months, not like before when it used to be for one month only." (Female Client, Age 33, Facility A).

Short waiting times were less preferred among older clients, particularly males (≥ 45 years) in HIV-serodifferent relationships who reported prioritising their health over waiting time and perceived that seeing few providers resulted in inadequate counselling and clinical assessments. HIV counsellors and triage nurses shared concerns about possible missed opportunities for clinical assessments, adherence counselling and psychosocial support for HIV-serodifferent couples.

Improved client flow. Providers perceived DTP refill visits to improve client flow, attributed to less queuing and movement of clients within HIV clinics and fewer PrEP delivery steps. This resulted in faster service delivery, reduced clinic congestion and freed up providers to perform other roles:

"[DTP] has improved the workflow; you can see more patients, we have more time for other things, you are spending less time on one client...Before, [clients] used to go to the clinician, the social worker...So, they are free to attend to other more needy clients." (Male Pharmacist, Facility B).

Reduced workload burden. DTP refill visits were perceived to be less burdensome among non-pharmacy providers due to the fewer service delivery steps and less interaction with PrEP clients compared to standard client flow. Clients' use of HIVST also reduced workload from provider-conducted HIV testing:

"[Workload] has changed significantly because you can imagine all the people who normally come to the HIV clinic for PrEP coming to the HIV counsellor for HIV testing. Now...we give them self-test and they go and test themselves"... (Male HIV Counsellor, Facility A).

Providers across all cadres reported concerns of increased pharmacy burden, attributed to pharmacy staff shortage, and added PrEP documentation and counselling roles. However, pharmacy providers reported high to moderate workload, relative to daily changes in clinic volume:

"[Workload] is not something that we can't handle; it's just adequate, it's not overburdening, it's okay. I cannot say that the workload is too much." (Female Pharmacist, Facility B).

3.2.2 | Innovation adaptability

Clinics reported modifications to accommodate DTP refill visits, including pre-scheduling PrEP clients' refill visits, to manage the number of PrEP clients visiting the clinics per day.

This ensured a manageable provider workload and facilitated clinic flow planning. Changes were also made to service delivery areas to ease clinic flow and enhance the privacy and comfort of PrEP clients:

"[PrEP clients] are served by the same pharmacist but from a different setting because HIV clients sit outside, they queue outside the pharmacy...but PrEP clients go inside the pharmacy, there is a hall there for them to sit on." (Female Clinic Manager, Facility B).

3.2.3 | Innovation complexity

Performing DTP refill visits was perceived as easy and uncomplicated, "smooth," "straightforward" and "easy to learn," attributed to the few steps and procedures involved, use of HIVST, reduced workload and improved provider PrEP delivery skills:

"[DTP] is easy because you are empowered, you understand all the process. So, when the client comes, you are able to serve them as it should be and refer them where it's appropriate." (Female HIV Counsellor, Facility B).

3.3 | Outer setting domain

3.3.1 | Community attitudes

Improved service quality and satisfaction. PrEP clients reported high service quality and satisfaction with DTP refill visits, attributed to good interaction with providers, receiving adequate counselling, and comfort and convenience of short waiting times, fewer queues and seeing few providers, which motivated PrEP continuation:

"I always feel comfortable. I feel so happy in my heart because I see that [providers] are so concerned with me...I told my husband that we always have an easy time here. We are always done in one minute, and we leave." (Female Client, Age 40, Facility B).

Providers and clients also perceived improvement in service quality and satisfaction related to reduced clients' complaints about lengthy clinic waiting times:

"There was a time we [clients] were so many...and everyone was complaining about going to work. Now in your mind, you are just like, "...I will come back when there are no [fewer] people"...But now...there are a few people." (Female Client, Age 33, Facility A).

Service dissatisfaction among clients was related to concerns about inadequate counselling due to the short time spent with providers, particularly among older male clients (≥ 45 years). However, younger female clients (≤ 40 years) reported that they could request counselling if they had a problem. Two clients reported experiencing long queues at the pharmacy. This concern was shared by HIV counselling and pharmacy providers, who worried about longer waiting times at the pharmacy during high-volume clinic days, which potentially affected service quality:

"At times, the patients are so many that you get overwhelmed; so it affects [DTP] because when you are tired, the type of services you offer to patients in the morning is not the same as what you will do in the afternoon"... (Female Pharmaceutical Technologist, Facility A).

Improved privacy and reduced HIV-clinic-associated stigma. DTP refill visits were perceived to improve clients' privacy and reduce the stigma associated with receiving care at HIV clinics. Among younger male and female clients (≤ 40 years), spending less time at the clinics reduced the risk of being seen by familiar people and seeing few providers reduced the embarrassment of sharing personal issues with multiple providers. Use of HIVST and client navigation also expedited clients' access to services, reducing privacy and stigma concerns:

"One thing I love [about DTP] is privacy; if I test myself and go directly to the pharmacy, they will give me my drugs, and I will put them in my bag, then I leave. So, before other people think or see me there, I have already gone." (Male Client, Age 40, Facility A).

3.4 | Inner setting domain

3.4.1 | Staffing organisation

Clinics reported the availability of adequate staffing for implementing DTP refill visits. Providers performed different roles during PrEP initiation or refill visits, including training and assisting clients to perform HIVST and providing PrEP and HIV prevention counselling (HIV/adherence counsellors), PrEP prescribing and dispensing (clinicians/pharmacists) and client scheduling (health records and information officers [HRIOs]). However, occasions of shortages were reported among HIV counselling and pharmacy providers:

"In [facility A], we only have one pharmacist...who is dispensing [medication]. So, the workload is too much bearing in mind in [facility A], we have more than eighty patients getting into the clinic every day." (Female Pharmaceutical Technologist, Facility A).

3.4.2 | Physical and information technology infrastructure

Clinics reported adequate infrastructure and resources for PrEP delivery during DTP refill visits. However, there were inadequate private spaces for HIVST and pharmacy procedures, which providers addressed by utilising alternative clinic rooms. Shortages of commodities, including HIVST kits, during the COVID-19 pandemic were also reported. Electronic medical records (EMR) systems facilitated the documentation of clients' records. However, in one clinic, PrEP clients' records were not integrated into the EMR, and the manual records were inconvenient for providers:

"There hasn't been an integration of PrEP and the EMR. That is, I think, the only challenge we still have...coming to retrieve the files and moving with the files to every delivery

point. But if it can be integrated with the EMR, I think it will be easier." (Female Clinician, Facility A).

3.4.3 | Client-centredness

Providers prioritised and fast-tracked PrEP clients during DTP refill visits to ensure they did not queue at the waiting bay:

"[DTP] is good because once I have tested myself, the pharmacist...stops providing services to other patients, and you're given [your] drugs first. You then leave and go because he has to continue attending to others." (Female Client, Age 24, Facility B).

Strategies to reduce delays and movement between clinic rooms included providing separate locations in the pharmacy for PrEP clients to pick refills, retrieving clients' files before visits, having clients' navigators escorting clients to clinic rooms and providers moving files to providers in other rooms:

"Sometimes, it is us [HIV counsellors] to take that file to the clinician...because of prescription. So, you can take the file, then the clinician prescribes in the absence of the client, then you take it to the pharmacy." (Female HIV Counsellor, Facility A).

3.4.4 | Provider-centredness

Providers reported improved teamwork and flexibility in PrEP delivery since most HIV clinic providers were trained in delivering PrEP. Other providers helped with PrEP delivery tasks when the assigned providers had a high workload. In one clinic, clinical providers assisted pharmacy providers in PrEP dispensing or filling clinical encounter forms during high-volume clinic days:

"When it comes to a clinic day...we have more than ten [PrEP] clients, with clients living with HIV being very few. So, to try and decongest the pharmacy, the clinician fills the clinical encounter form, then the client will just land to the pharmacy to get the drugs only." (Female HRIO, Facility A).

3.4.5 | Client learning-centredness

DTP refill visits empowered clients through active involvement in their HIV prevention actions, particularly through performing HIVST, and from the adherence counselling provided:

"First, the provider guided me on how I would do it [HIVST]; the second time, they asked me to do it on my own. I felt it was good. You know, at times, you may be exposed...Like I said, condom-burst before three months are over; you can go to the chemist and buy the self-testing kit and do the test by yourself at home." (Female Client, Age 37, Facility A).

3.4.6 | Compatibility with the clinic environment

DTP refill visits were perceived to be easy to adopt and implement as they easily fit in and did not require much

change to existing clinic operations and infrastructure. DTP refill visits also addressed previously experienced service delivery challenges in both clinics, particularly poor clinic flow, time inefficiencies for clients and providers, and HIV clinic staff shortages:

"[DTP] fits well; it doesn't affect how we carry out other services...our daily routine, and it fits well...We only spend extra minutes with the client of which the client saves those minutes by not going to see other healthcare providers, so it really doesn't affect our daily routine." (Male Pharmacist, Facility B).

3.4.7 | Relative priority and mission alignment

DTP refill visits facilitated the prioritisation of PrEP services within HIV clinics and contributed to the achievement of facility HIV prevention targets. Providers felt PrEP delivery was an important part of their duties and that DTP refill visits complemented their roles. However, HIV counsellors were concerned about the loss of previous roles that involved more interaction with PrEP clients:

"There were some issues with some HIV counsellors who thought they were not doing their work since they were not serving the PrEP clients the way they were supposed to...So, we were like, 'Why are we not doing the work we ought to have been doing?' ... [But] we came to understand that it was all for the benefit of our clients." (Female HIV Counsellor, Facility A).

3.4.8 | Access to knowledge and information

Providers acquired knowledge through training provided on DTP refill visits and PrEP delivery before and during the implementation of DTP refill visits, which enhanced their competence. Continuous on-the-job training and supportive supervision by project staff enhanced providers' skills and confidence and facilitated ownership of the intervention. This influenced providers' willingness to implement DTP refill visits and was perceived as key for sustainability:

"I don't think there is any worry since we have been given refreshers, a lot of information, we have been well oriented, so even if they exit, we understand there is the DTP model, and other providers understand as well, so in case they are called, the client will be attended to even if [client's navigator] is not there." (Female HIV Counsellor, Facility B).

3.5 | Individuals domain

3.5.1 | Clients' needs

Reduced opportunity costs. DTP refill visits were perceived to reduce clients' opportunity costs, including foregoing important activities, long travel distances, high travel costs and getting permission from work to attend clinic visits. This resulted in less disruption of clients' schedules and reduced concerns about missing work and income among clients. There were fewer concerns of opportunity costs among older male and female clients (≥ 45 years). Younger male and female clients

(≤ 40 years) reported reduced risk of losing jobs during DTP refill visits, or exposure to social harm among younger females (≤ 30 years) – due to fewer delays at the clinics, which motivated PrEP continuation:

"Because the time I spend here at the clinic is little, when the scheduled day for the refill reaches, I feel I have the motivation for coming to pick the drugs because I know I will not waste time. I know I will come then go to my other work." (Female Client, Age 40, Facility A).

3.5.2 | Provider capacity

Providers were comfortable implementing DTP refill visits, attributed to adequate training, continuous learning opportunities, and ease of learning and implementation. However, PrEP knowledge gaps initially affected confidence among pharmacy providers who were concerned about their readiness to deliver DTP refill visits. Providers later accepted DTP refill visits after knowledge gaps were addressed through training and after observing its benefits to clients:

"I think the pharmacy was where the problem was...It was said that there was a lot of workload, and they [pharmacy providers] might not be able to fill out the forms. They felt it should be done elsewhere; they should only be left to dispense the drugs." (Female HIV Counselling Team Lead, Facility A).

3.5.3 | Client and provider motivation

Clients and providers expressed confidence and future willingness to participate in DTP refill visits. Providers were motivated to continue the intervention since they recognised that the changes to client flow were effective, worked well in their clinics, and benefited both clients and providers. Providers believed that DTP refill visits would improve future PrEP uptake and retention:

"We believe the [PrEP] uptake will be a bit higher because most of the clients were defaulting because they were coming here, they line up, they go through the process over again, and again they come here. Now that it is direct-to-pharmacy, I think the uptake will be a bit higher." (Male HIV Counsellor, Facility A).

4 | DISCUSSION

In this project implemented in an existing PrEP programme, DTP PrEP refill visits with HIVST were highly acceptable as a differentiated PrEP delivery model for PrEP clients and providers. The high enthusiasm was attributed to perceived higher service efficiency, quality, and satisfaction related to shorter waiting times and improved client flow. These findings are consistent with the quantitative results of this study population, which showed a high acceptability and satisfaction with DTP refill visits among PrEP clients [31]. In our quantitative data, more than a three-fold reduction in waiting time and higher PrEP continuations and adherence were reported over the 6-month follow-up period in the two intervention clinics

compared to the control clinics. Our qualitative findings provide insights to explain the high acceptability of DTP refill visits.

Among clients, high acceptability was attributed to good service quality and satisfaction related to comfort and convenience of short waiting times, improved privacy, reduced stigma and opportunity costs, which increased the motivation for PrEP continuation. Among providers, improved client flow, reduced burden and improved capacity were key facilitators. These findings concur with previous studies that have highlighted strong preference among clients and providers for DSD interventions that provide convenience and reduce clients' opportunity costs, HIV-clinic-associated stigma, provider workload and clinic congestion [40–43]. DSD interventions within HIV treatment have reported similar outcomes of improved service quality and reduced clients' opportunity costs, which are major barriers to HIV service access in SSA [44, 45]. The WHO-endorsed DSD HIV care approaches focus on improving the quality of care through health system efficiency and client-centredness [46]. Studies in Eswatini, South Africa and Malawi have reported high satisfaction among HIV care clients and providers related to efficiency, convenience and timesaving benefits of DSD models compared to conventional care [47–49].

A high enthusiasm for implementing DTP PrEP refill visits among providers was attributed to reduced workload among non-pharmacy cadres, ease of implementation, task-sharing and compatibility with routine clinic operations. Our findings are consistent with other studies showing the potential of task-sharing strategies to enhance PrEP delivery with minimal additional resources [50]. We previously showed that the "one-stop-shop" PrEP delivery model that involved redesigning workflow and task-shifting resulted in reduced waiting time, improved privacy for PrEP clients and reduced provider workload within public clinics in western Kenya [29]. Differentiated PrEP delivery strategies within Kenyan public HIV clinics, including longer refills, fast-tracking clients and task-shifting, have addressed concerns of long waiting times and HIV clinic stigma, with positive impacts on PrEP uptake and continuation [30, 51]. Pharmacy provider-led PrEP delivery has been shown to be acceptable in community pharmacy-based PrEP delivery models in Kenya, South Africa and the United States [52]. In Kenya and Malawi, HIV care clients have reported a preference for individual facility-based DSD models delivered by pharmacy providers, indicating a potential acceptability of individual facility-based pharmacy PrEP delivery [53, 54].

The main concerns of DTP refill visits included potential missed opportunities for counselling and clinical assessments among clients and increased workload among pharmacy providers. The changes in client flow were perceived to result in fewer opportunities for counselling, particularly among clients in HIV-serodifferent relationships, who may need regular counselling [55]. Clients were given an opportunity to request to see a clinician or HIV counsellor if they needed support. However, older male clients may have found it challenging to approach providers compared to younger female clients. Hence, regular reinforcement of the message regarding the availability of counselling may be beneficial for older clients. Counselling is an essential component of PrEP care, and studies have reported concerns of perceived

reduced quality of services when clients feel they have less time with clinicians [42, 51]. Proactive screening and innovative counselling strategies may be necessary for clients who need additional support during PrEP refill visits [42, 56]. Client-centred counselling strategies, focused on improving knowledge, motivation and self-efficacy, have been shown to result in increased PrEP effective use among vulnerable populations such as AGYW in South Africa and Black women in the United States [57–59].

Increased pharmacy provider burden and other feasibility concerns were addressed through clinic-level modifications, with clinicians assisting pharmacy providers in PrEP dispensing. Facility-based DSD HIV care interventions have been effective in addressing staffing challenges in public HIV clinics, yielding potential cost-saving benefits through task-shifting and sharing strategies [60–63]. An increased workload burden has been reported among some provider cadres implementing task-shifted DSD HIV care interventions [29, 64]. In Burkina Faso and Eswatini, varying workload concerns were reported, attributed to the additional administrative tasks of filling clinical forms [47, 64]. This is consistent with our findings where workload burden was related to additional documentation roles and staffing shortage. However, the perceived benefits to clients outweighed workload concerns [29]. Continuous monitoring and adaptations to address workload concerns may be critical. In our setting, the task-sharing modification—although unintended, continuous provider training, and the observed benefits to clients and providers, contributed to the acceptability of the DTP model, indicating a high likelihood for its sustainability.

We found a high willingness among clients and providers to continue participating in DTP PrEP refill visits. The DTP model also aligned with multi-level factors critical for the sustainability of healthcare innovations. These included observable client outcomes; adaptability, low complexity and burden; client and provider satisfaction and belief in the intervention; alignment with clinic priorities and culture; staff training, ownership and capacity to implement the intervention [65–67]. However, future implementation and scalability of the DTP model may largely depend on resource availability since shortages of commodities such as HIVST kits and PrEP supplies experienced during the COVID-19 pandemic, and inadequate pharmacy staffing, EMR systems and space, may affect sustained implementation. Continuous provider training and supervision, community engagement, facility leadership support, integration in PrEP service guidelines, and continuous monitoring and evaluation will also be crucial for sustainability [68, 69].

Our study had strengths and limitations. First, our study population was largely comprised of individuals in HIV-serodifferent relationships; hence, the perspectives presented could have been different from those of other populations. Second, we focused on the experiences of clients and providers during the implementation of DTP refill visits, which limited the comparison of acceptability before and after implementation. Third, participants' selection was based on willingness to consent for study participation and experience with DTP, which may have restricted a balanced representation of clients' sex and provider cadres. We also interviewed a small sample of PrEP clients and providers within two

public HIV clinics, limiting the generalisability of our findings. Our study had the strength of exploring in-depth perspectives of PrEP providers and users, providing an adequate representation of real-world experiences with DTP refill visits.

5 | CONCLUSIONS

In this study aimed at improving the efficiency of PrEP delivery in a real-world setting within public HIV clinics, DTP refill visits demonstrated high acceptability, feasibility and sustainability among PrEP clients and providers. DTP PrEP refill visits achieved the key outcome of improved service efficiency, yielding positive impacts for clients, providers and health systems. Context-specific adaptations and scale-up of the intervention could improve the efficiency of PrEP delivery within public HIV clinics in Kenya and similar settings. Future studies could target other priority sub-populations of PrEP users and offer tailored, differentiated care strategies, including alternative PrEP delivery locations, provider training models and task-sharing among different provider cadres.

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COMPETING INTERESTS

The authors declare no competing interests.

AUTHORS' CONTRIBUTIONS

Study conceptualisation and funding acquisition: KM. Qualitative study design: KM and KN. Data collection: EO, VO and NW. Project administration: KM, KN, LE, WW, CK and NM. Data analysis: EO, VO and NW. Writing—original draft: EO. All authors reviewed and edited the manuscript and approved the final version.

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DATA AVAILABILITY STATEMENT

De-identified transcripts will be available upon author request and under appropriate data-sharing agreements to those who provide a methodologically sound proposal by contacting the International Clinical Research Center at the University of Washington (Email: icrc@uw.edu).

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RESEARCH ARTICLE

Scale of differentiated service delivery implementation in HIV care facilities in low- and middle-income countries: a global facility survey

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Abstract

Introduction: In 2016, the World Health Organization recommended differentiated service delivery (DSD) as a client-centred approach to simplify HIV care in frequency and intensity, thus reducing the clinic visit burden on individuals and HIV programmes. We describe the scale of DSD implementation among HIV facilities in low- and middle-income countries (LMICs) in Latin America, Africa and the Asia-Pacific before the COVID-19 pandemic.

Methods: We analysed facility-level survey data from HIV care facilities participating in the International epidemiology Databases to Evaluate AIDS consortium in 2019. We used descriptive statistics to summarise the availability of DSD, multi-month dispensing (MMD) and DSD for HIV treatment models. We explored factors associated with DSD implementation using multivariable models.

Results: We included 175 facilities in the Asia-Pacific ($n = 30$), Latin America ($n = 8$), Central Africa ($n = 21$), East Africa ($n = 74$), Southern Africa ($n = 28$) and West Africa ($n = 14$). Overall, 133 facilities (76%) reported implementing DSD. Of these, 91% offered DSD for HIV treatment, 61% for HIV testing and 59% for antiretroviral therapy (ART) initiation. The most common duration of ART refills for clinically stable clients was 3MMD, (70%), followed by monthly (14%) and 6MMD (10%). Facility-based individual models were the most frequently available DSD for the HIV treatment model (82%), followed by client-managed group models (60%). Out-of-facility individual models were available at 48% of facilities. Facility-based individual models were particularly common among facilities in East (92%) and Southern Africa (96%). Facilities in medium and high HIV prevalence countries, and those with 3MMD, were more likely to implement DSD.

Conclusions: In 2019, DSD was available in most HIV care facilities globally but was not evenly implemented across regions and HIV services. Most offered facility-based DSD for HIV treatment models and 3MMD for clinically stable clients. Efforts to expand DSD for HIV testing and ART initiation and to offer longer MMD can improve long-term retention in care of people living with HIV in LMICs, while further alleviating the operational burden on healthcare services. These findings from the pre-COVID-19 era underline the need for strengthening DSD in HIV care, which remains at the centre of current efforts towards client-centred care.

Keywords: antiretroviral therapy; differentiated service delivery; HIV; key and vulnerable populations; low- and middle-income countries; patient-centred care

Additional information may be found under the Supporting Information tab of this article.

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1 | INTRODUCTION

Recommended by the World Health Organization (WHO) since 2016 [1], differentiated service delivery (DSD) is a healthcare approach that aims to provide greater flexibility and capacity to better manage an increasingly large and diverse population of people living with HIV (PWH) [1]. In contrast to a “one size fits all” approach [2], DSD is a client-centred approach that strives to simplify and adjust HIV services across the cascade of HIV care based on the preferences and needs of individuals seeking care [3–5]. DSD can be applied across the entire HIV care cascade by offering targeted interventions such as pre-exposure prophylaxis, simplifying treatment initiation with differentiated follow-up schedules, improving retention by offering multi-month dispensing (MMD) and flexible clinical consultation systems, and facilitating re-engagement in care through decentralised service delivery points, task shifting and peer-led support [3, 6]. DSD for HIV treatment can be defined within one of the following models: group models managed by healthcare workers, group models managed by clients, individual models based at facilities and individual models not based at facilities [6]. Each model aims to address the various clients’ concerns. Facility-based models with MMD and fast-track services may minimise the risk of sharing an individual’s HIV status to others besides healthcare workers and minimise waiting times [7, 8]. In contrast, community-based models may reduce travel costs and waiting times for PWH and have the additional benefit of lowering staff workload and congestion at health facilities [9, 10].

Coinciding with the DSD recommendations in 2016, the WHO began advocating for less frequent clinical consultations and extended MMD for clinically stable clients who attained viral suppression. Extended MMD contributes to reducing the time and financial burden of care for clients [11, 12] and to reducing clinic congestion. It also allows the reallocation of resources to other specialised services targeted towards populations with distinct needs [11, 13], including clients with advanced disease [1, 5, 14]. The implementation of national policies on DSD can be influenced by different factors such as the capacity and funding of HIV programmes, the availability and training of healthcare workers and the decentralisation of services to the community. These factors collectively can impact the effectiveness of DSD policy implementation in various settings [9].

While previous studies have explored the regional implementation of DSD in HIV care [12, 15–20], little is known about the global rollout of DSD in resource-constrained settings, which carry most of the HIV burden. In this study, we described the implementation of DSD before the effects of COVID-19 in a large sample of HIV treatment and care facilities in low- and middle-income countries (LMICs) across Latin America, Africa and Asia-Pacific. We summarised the availability of DSD for HIV treatment models and explored factors associated with the probability of implementing DSD. Additionally, we examined the frequency of MMD and the availability of dedicated HIV clinics for different population groups. Our analysis provides a global overview of DSD implementation in the pre-COVID-19 era.

2 | METHODS

2.1 | Study design

We conducted a cross-sectional study within the International epidemiology Databases to Evaluate AIDS (IeDEA) consortium. IeDEA is an international research collaboration that collects data from HIV care and treatment programmes in 44 countries in seven geographic regions: the Asia-Pacific; the Caribbean, Central and South America (Latin America); Central, East, Southern and West Africa; and North America [21]. As described elsewhere [22], IeDEA comprises a heterogeneous combination of HIV care and treatment facilities at academic and community-based hospitals and health centres, including facilities that provide specialised HIV care and serve a large number of clients, as well as numerous facilities in Southern Africa that are part of large HIV treatment programmes.

We used data from a site-level survey that was conducted from September 2020 to March 2021 on a global sample of 238 HIV treatment and care facilities that participated in the IeDEA consortium in 2019. The survey explored standard practices and services in facilities prior to the COVID-19 pandemic (Supporting information Text S2). It used standardised online questionnaires that were available in English and French [22, 23]. All facilities that were contributing data to IeDEA in 2020 were eligible for the survey. In IeDEA’s Southern Africa region, where large HIV programmes contribute data for numerous facilities, approximately 15% of participating facilities were included based on a combined convenience and stratified random sample of all facilities in the region [22]. The convenience sample included facilities that had responded to prior IeDEA-wide surveys to allow for longitudinal analyses of HIV care and service attributes across time, whereas the stratified random sample was drawn from facilities that are part of large programmatic cohorts, with the number of urban versus rural sites reflecting each cohort’s distribution of facilities.

The survey included questions to assess the type and availability of differentiated services (HIV testing, antiretroviral therapy [ART] initiation and HIV treatment); the characteristics of clients eligible for DSD for HIV treatment (e.g. returning clients, clients stable on ART, clients with virologic failure); and the type of DSD for HIV treatment models available at the facility (e.g. patient-managed groups, healthcare worker managed groups, facility-based individual models, out-of-facility-based individual models). The survey questionnaire was distributed via paper forms and via a REDCap survey – a web-based software platform for secure data capture in research studies [24, 25]. For facilities that completed the survey using the paper forms, responses were entered into the REDCap electronic database by local or regional data managers.

2.2 | Eligibility criteria

We included survey results from facilities located in LMICs, as defined by the World Bank in 2019 [26]. We excluded facilities that did not complete the survey, meaning no information was provided by these facilities.

2.3 | Definitions

We obtained national HIV prevalence from the UNAIDS 2019 estimates for adults aged 15–49 [27] for all countries except Mozambique and China, where data was unavailable. For Mozambique, we obtained HIV prevalence estimates from the CDC Country Profile [28], and for China from the Global Burden of Diseases (GBD) study [29]. We categorised HIV prevalence as low (< 1%), medium (1–4.9%) or high ($\geq$ 5%). We categorised facilities based on the level of care provided, and facility type was defined as either health centre; district hospital; regional, provincial or university hospital; or unknown. We defined the residence of the population served by facilities as predominantly urban, mixed urban/rural or predominantly rural. This definition was based on facilities' own assessment of how they would describe the residence of the population served. We categorised age groups served at the facility as children (0–9 years of age), adolescents (10–24 years of age) and adults ($\geq$ 20 years of age). Provision of DSD and type of DSD provided including HIV testing, ART initiation and HIV treatment were categorised as binary variables (yes/no). Standard frequency of refills/MMD was defined as monthly, every 3 months, every 6 months or other. We categorised DSD for HIV treatment models as: client-managed groups (e.g. community ART refill group, community patient-led ART delivery, community adherence group, peer support group), healthcare worker-managed groups (e.g. ART adherence clubs, patient adherence club, youth club, teen club), facility-based individual models (e.g. fast track, quick pick-up, pharmacy refill without clinical consultation) and out-of-facility individual models (e.g. mobile outreach, fixed community ART distribution points, community pharmacy, home delivery). We defined key population groups as gay men and other men who have sex with men, female sex workers, transgender individuals, people who inject drugs and incarcerated people or in other closed settings such as in detention centres or institutional care facilities.

2.4 | Statistical methods

We used descriptive statistics to summarise the characteristics of facilities, stratified by region. We ran univariable models with the implementation of DSD (no/yes) as the dependent variable and each of the following factors as the independent variable: country income designation, HIV prevalence, facility type, residence of the population served and age group of clients served (children [yes/no], adolescents [yes/no] and adults [yes/no]). We assumed binomial distribution of the error and used a logit link function. We considered the country where the facilities were located ($n = 35$) as a random factor to account for the non-independence of facilities within the same country. We built a multivariable generalised linear mixed-effect model with the implementation of DSD (no/yes) as the dependent variable, all factors listed above as independent variables and country as the random factor. For this multivariable model, we computed marginal odds ratios that allow a comparison of the association between a given explanatory factor and the implementation of DSD across different studies and data sets [30].

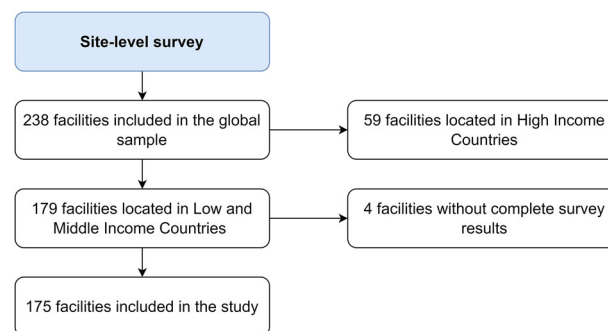


Figure 1. Flow diagram of included HIV care facilities.

All statistical analyses were performed using RStudio version 4.2.2 [31], and the geographical representation was done using ArcGIS version 10.8.2 using the boundaries provided by ESRI [32]. The graphical representation of the analysis was performed using the packages ggplot2 [33] and gridExtra [34].

2.5 | Ethics

The site-level survey was designated as a non-human subjects operational/quality improvement project by the Vanderbilt University Medical Center (VUMC) Institutional Review Board (#200013) [22].

3 | RESULTS

Of the 179 facilities in LMICs, four (2.2%) did not complete the survey (Figure 1). Thus, we included 175 facilities in the study from six leDEA regions: Asia-Pacific ($n = 30$), Latin America ($n = 8$), Central Africa ($n = 21$), East Africa ($n = 74$), Southern Africa ($n = 28$) and West Africa ($n = 14$) (Figure 2 and Table S1). Out of the 175 facilities, 48% (84/175) were in lower-middle-income countries, 30% (52/175) in low-income countries and 22% (39/175) in upper-middle-income countries (Table 1). Almost half of the facilities (83/175, 47%) were in countries with medium HIV prevalence, 33% (57/175) in countries with high HIV prevalence and 20% (35/175) in countries with low HIV prevalence.

3.1 | Facility characteristics

Half of the facilities (88/175, 50%) were health centres; 37% (64/175) regional, provincial or university hospitals; and 9% (15/175) district hospitals (Table 1). Overall, 84/175 (48%) facilities served populations living in mixed urban/rural areas, 49/175 (28%) predominantly urban and 42/175 (24%) predominantly rural, with variations across regions. Most facilities (157/175, 90%) provided HIV services to children, 94% (165/175) to adolescents and 87% (152/175) to adults. Overall, 77% (134/175) provided HIV services to all age groups.

3.2 | DSD for HIV care

Three-quarters of facilities (133/175, 76%) reported providing DSD for HIV care in general, with the Asia-Pacific (8/30,

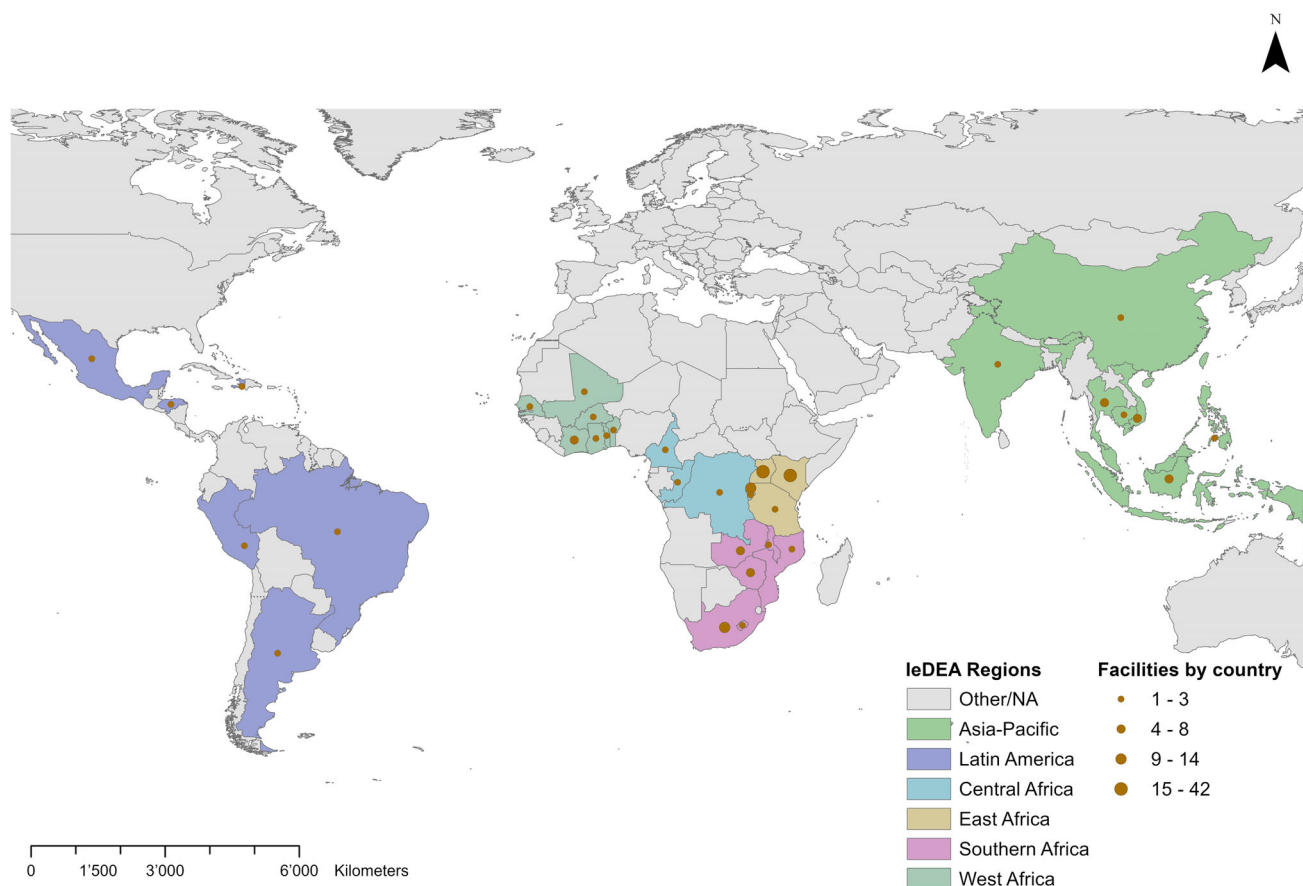


Figure 2. Surveyed HIV care facilities, by country and by the International epidemiology Databases to Evaluate AIDS region ($n = 175$).

27%) and Latin America (3/8, 37%) regions having the lowest proportion, and East Africa having the highest proportion of facilities offering DSD (69/74, 93%) (Table 2). While 91% of facilities (121/133) reported providing DSD for HIV treatment, only 61% (81/133) provided DSD for HIV testing and 59% (79/133) provided DSD for ART initiation. Almost half of the facilities (64/133, 48%) reported providing DSD for all three services. None of the three facilities in Latin America reported providing DSD for HIV treatment.

3.3 | MMD and ART refill frequency

The most common frequency of ART refills for clinically stable clients across all regions was 3 months (122/175, 70%), followed by monthly (24/175, 14%), and every 6 months (17/175, 10%) (Table 2). The Central African (18/21, 86%) and Eastern African (65/74, 88%) regions reported higher proportions of 3MMD, while monthly refills were highest for the Asia-Pacific (10/30, 33%) and Latin American (3/8, 37%) regions.

3.4 | Factors associated with DSD availability

In multivariable models, facilities located in countries with a medium HIV prevalence were twice as likely (aOR 2.87; 95% CI 1.14–7.22) and those with a high HIV prevalence were

10 times as likely (aOR 10.20; 95% CI 1.96–52.94) to have implemented DSD than those with a low HIV prevalence. Similarly, facilities offering 3MMD were twice as likely (aOR 2.85; 95% CI 1.19–6.85) to implement DSD than those on a monthly schedule (Figure 3).

3.5 | DSD for HIV treatment models

DSD for HIV treatment was used for clinically stable clients on ART in almost all facilities (110/121, 91%), for clients presenting or returning to care when clinically well (80/121, 66%) and for clients on ART with virological failure in more than half of them (69/121, 57%) (Table 2).

Of the 119/121 facilities providing information on DSD for HIV treatment models, 98/119 (82%) reported offering facility-based individual models, 71/119 (60%) patient-managed group models, 63/119 (53%) healthcare worker-managed group models and 57/119 (48%) out-of-facility individual models (Figure 4). These models were not mutually exclusive, and facilities could implement one or more models concurrently. Facility-based individual models were particularly common among facilities in East (60/65, 92%) and Southern Africa (22/23, 96%). Almost half of the facilities (47/119, 40%) reported the introduction of at least one of the four DSD for HIV treatment models in 2018 (Supporting information Table S2 and Figure S1).

Table 1. Characteristics of included health facilities by the International epidemiology Databases to Evaluate AIDS region

Characteristic	Subgroups	Overall N = 175 (100%)	Asia-Pacific n = 30 (17.1%)	Latin America n = 8 (4.6%)	Central Africa n = 21 (12%)	East Africa n = 74 (42.3%)	Southern Africa n = 28 (16%)	West Africa n = 14 (8%)
Country income designation ^a								
	Low income	52 (30.0)	0 (0.0)	1 (12.5)	16 (76.2)	29 (39.2)	3 (10.7)	3 (21.4)
	Lower-middle income	84 (48.0)	11 (36.7)	1 (12.5)	5 (23.8)	45 (60.8)	11 (39.3)	11 (78.6)
	Upper-middle income	39 (22.0)	19 (63.3)	6 (75)	0 (0.0)	0 (0.0)	14 (50.0)	0 (0.0)
HIV prevalence ^a								
	Low (< 1%)	35 (20.0)	22 (73.3)	7 (87.5)	1 (4.8)	0 (0.0)	0 (0.0)	5 (35.7)
	Medium (1–4.9%)	83 (47.0)	8 (26.7)	1 (12.5)	20 (95.2)	45 (60.8)	0 (0.0)	9 (64.3)
	High (≥ 5%)	57 (33.0)	0 (0.0)	0 (0.0)	0 (0.0)	29 (39.2)	28 (100.0)	0 (0.0)
Facility type								
	Health centre	88 (50.2)	4 (13.3)	0 (0.0)	12 (57.1)	54 (73.0)	15 (53.6)	3 (21.4)
	District hospital	15 (8.6)	0 (0.0)	0 (0.0)	0 (0.0)	12 (16.2)	1 (3.6)	2 (14.3)
	Regional, provincial or university hospital	64 (36.6)	26 (86.7)	8 (100.0)	9 (42.9)	7 (9.5)	5 (17.8)	9 (64.3)
Residence of the population served at the facilities								
	Unknown	8 (4.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.3)	7 (25.0)	0 (0.0)
	Predominantly urban	49 (28.0)	10 (33.3)	8 (100.0)	7 (33.3)	1 (1.4)	16 (57.1)	7 (50.0)
	Predominantly rural	42 (24.0)	0 (0.0)	0 (0.0)	2 (9.5)	37 (50.0)	3 (10.7)	0 (0.0)
	Mixed urban/rural	84 (48.0)	20 (66.7)	0 (0.0)	12 (57.1)	36 (48.6)	9 (32.1)	7 (50.0)
Types of clients served at the HIV facilities ^b								
	Children (0–9 years of age)	157 (89.7)	20 (66.7)	6 (75.0)	21 (100.0)	71 (95.9)	27 (96.4)	12 (85.7)
	Adolescents/young adults (10–24 years of age)	165 (94.3)	25 (83.3)	7 (87.5)	21 (100.0)	71 (95.9)	28 (100.0)	13 (92.9)
	Adults—general population (≥ 20 years of age)	152 (86.9)	19 (63.3)	7 (87.5)	21 (100.0)	73 (98.6)	25 (89.3)	7 (50.0)
	All age groups	134 (76.6)	10 (33.3)	5 (62.5)	21 (100.0)	69 (93.2)	24 (85.7)	5 (35.7)

^aBased on publicly available information by country.

^bEach subgroup was captured as a binary variable and answer yes is presented. All other variables are mutually exclusive and sum up to 100%.

Table 2. Differentiated service delivery (DSD) implementation at healthcare facilities for HIV clients, by the International epidemiology Databases to Evaluate AIDS region

Characteristic	Subgroups	Overall N = 175 (100%) N (%)	Asia-Pacific n = 30 (17.1%) n (%)	Latin America n = 8 (4.6%) n (%)	Central Africa n = 21 (12%) n (%)	East Africa n = 74 (42.3%) n (%)	Southern Africa n = 28 (16%) n (%)	West Africa n = 14 (8%) n (%)
Provision of DSD ^a	Yes	133 (76.0)	8 (26.7)	3 (37.5)	17 (81.0)	69 (93.2)	25 (89.3)	11 (78.6)
	No	42 (24.0)	22 (73.3)	5 (62.5)	4 (19.0)	5 (6.8)	3 (10.7)	3 (21.4)
Type of DSD provided ^b	HIV testing	81/133 (60.9)	3/8 (37.5)	3/3 (100.0)	9/17 (52.9)	45/69 (65.2)	15/25 (60.0)	6/11 (54.5)
	ART initiation	79/133 (59.4)	4/8 (50.0)	1/3 (33.3)	8/17 (47.1)	42/69 (60.9)	17/25 (68.0)	7/11 (63.6)
	HIV treatment	121/133 (91)	6/8 (75.0)	0/3 (0.0)	17/17 (100.0)	65/69 (94.2)	23/25 (92.0)	10/11 (90.9)
	All three services	64/133 (48.1)	1/8 (12.5)	0/3 (0.0)	8/17 (47.1)	36/69 (52.2)	14/25 (56.0)	5/11 (45.4)
Standard frequency of refills for clients who are stable on ART/MMD ^a	Monthly	24 (13.7)	10 (33.3)	3 (37.5)	0 (0.0)	6 (8.1)	4 (14.3)	1 (7.1)
	Every 3 months	122 (69.7)	15 (50.0)	3 (37.5)	18 (85.7)	65 (87.8)	13 (46.4)	8 (57.1)
	Every 6 months	17 (9.7)	4 (13.3)	1 (12.5)	2 (9.5)	2 (2.7)	5 (17.9)	3 (21.4)
	Other	12 (6.9)	1 (3.3)	1 (12.5)	1 (4.8)	1 (1.4)	6 (21.4)	2 (14.3)
DSD for HIV treatment models offered								
Clients served via DSD for HIV treatment ^c	Clients presenting/returning to care with advanced HIV disease ^d	61/121 (50.4)	4/6 (66.7)	0 (0.0)	3/17 (17.6)	38/65 (58.5)	12/23 (52.2)	4/10 (40.0)
	Clients presenting/returning to care when clinically well	80/121 (66.1)	1/6 (16.7)	0 (0.0)	7/17 (41.2)	50/65 (76.9)	16/23 (69.6)	6/10 (60.0)
	Clients clinically stable on ART	110/121 (90.9)	2/6 (33.3)	0 (0.0)	15/17 (88.2)	61/65 (93.8)	23/23 (100.0)	9/10 (90.0)
	Clients on ART with virologic/therapeutic failure ^d	69/121 (57.0)	4/6 (66.7)	0 (0.0)	5/17 (29.4)	38/65 (58.5)	15/23 (65.2)	7/10 (70.0)

Abbreviations: ART, antiretroviral therapy; DSD, differentiated service delivery; MMD, multi-month dispensing.

^aMutually exclusive variables sum up to 100%. All other variables are binary and answer yes is presented.

^bDenominator based only on facilities providing DSD.

^cDenominator based only on facilities providing any DSD for HIV treatment models.

^dDefinitions: Advanced HIV disease: CD4 < 200 cells/mm³ and/or WHO Clinical Stage 4 disease. Virologic failure: "unstable clients" on ART > 1 year.

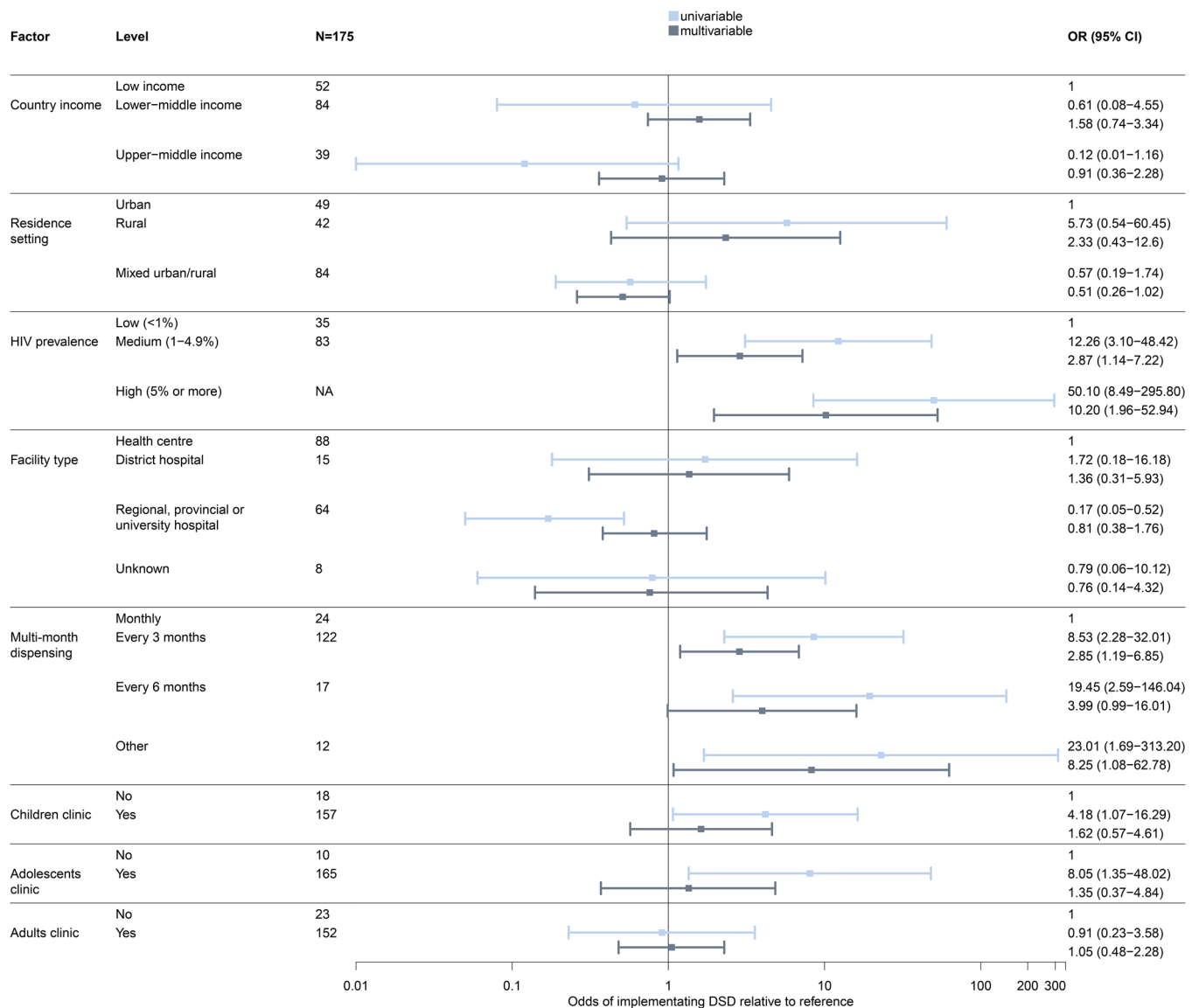


Figure 3. Univariable and multivariable model exploring factors associated with differentiated service delivery implementation. The adjusted model accounts for all factors listed in the figure.

3.6 | Dedicated HIV clinics for specific population groups

Most facilities reported offering dedicated HIV clinics for pregnant or breastfeeding women (150/175, 86%) and clients with comorbidities or opportunistic infections (142/175, 81%) (Table 3). Overall, fewer facilities reported offering dedicated HIV clinics for key population groups with high HIV acquisition risk. Less than half of the facilities offered dedicated clinics for gay men and other men who have sex with men (57/175, 33%) or female sex workers (71/175, 41%), and less than a third offered dedicated clinics for transgender individuals (46/175, 26%), people who inject drugs (46/175, 26%) or incarcerated populations (47/175, 27%), with variations across regions.

4 | DISCUSSION

We analysed site-survey data from 175 HIV treatment and care facilities in 35 LMICs to assess the global implementation of DSD before the COVID-19 pandemic. Three-quarters of facilities reported providing DSD services in HIV care, with DSD more common for HIV treatment than for HIV testing or ART initiation, with variations across regions. While nearly 90% of facilities in Africa reported offering DSD services, outside of Africa it was less than a third, with none of the surveyed facilities in Latin America offering DSD for HIV treatment. Less than a tenth of facilities reported using 6MMD for clinically stable clients, with most facilities offering 3MMD. Less than half of the facilities reported dedicated care for key

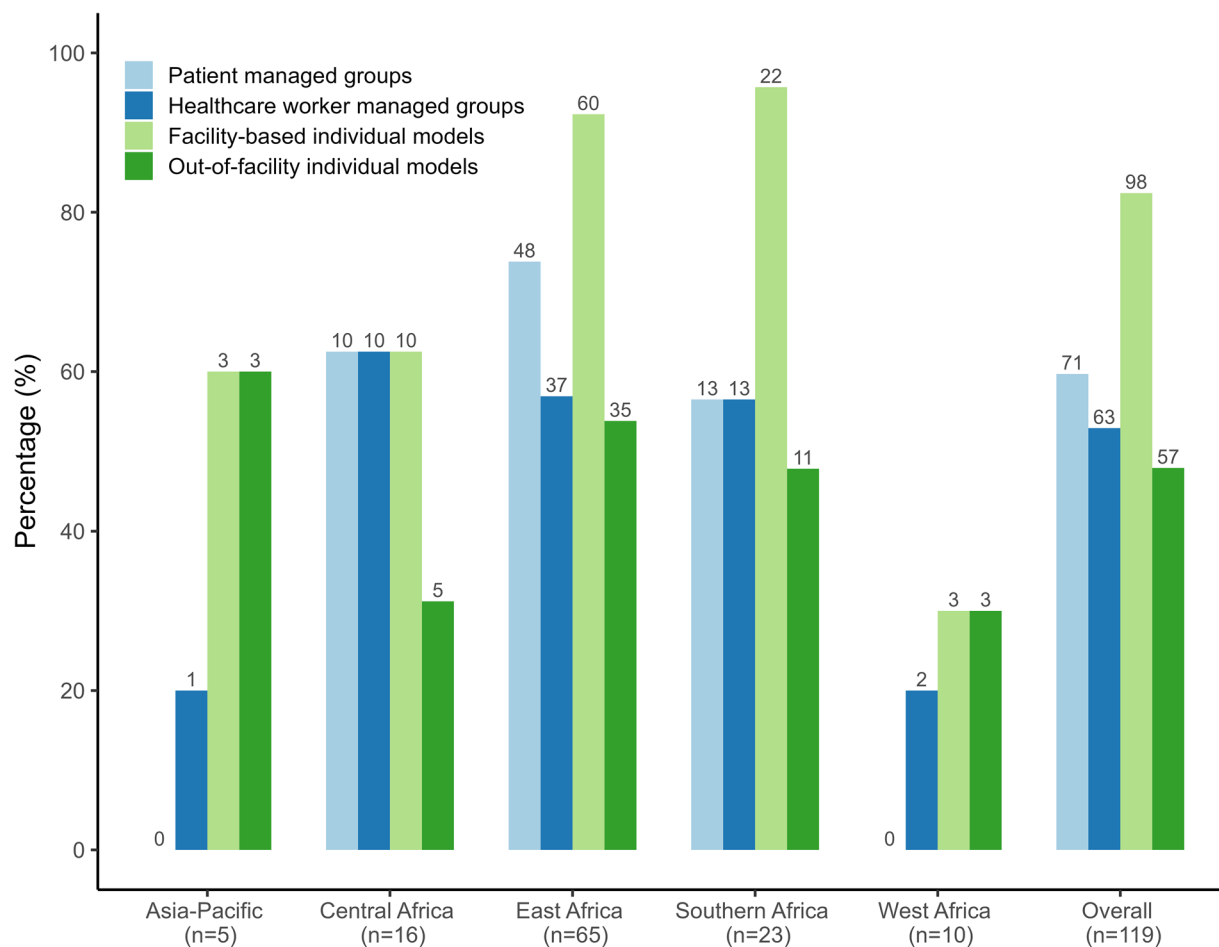


Figure 4. Availability of differentiated service delivery for HIV treatment models by the International epidemiology Databases to Evaluate AIDS region in 2019.

*None of the facilities in Latin America reported providing differentiated service delivery for HIV treatment.

population groups, such as female sex workers or people who inject drugs.

In our study, facility-based models were more frequently implemented than community-based models. While this result is consistent with previous studies reporting client's preferences for facility-based HIV services [19, 35–40], it is important to consider that such preferences may reflect what participants know and what is most accessible to them. In settings where facility-based individual models combine clinical visits with extended ART refills, this approach can reduce the time spent at the facility [41]. Combined with fast-track facility-based drug refills, MMD can provide a cost- and time-efficient way of accessing ART. In a study in Zambia, clinically stable HIV clients in urban settings preferred facility-based individual models over group or community-based ones because they offered extended MMD and fast-track visits [42]. However, implementing facility-based models can be challenged by limited resources, including dedicated personnel or space, particularly at smaller facilities [8, 9, 39]. In contrast, people living in rural areas of Zambia preferred community-based models, which saved them travel-associated time and costs [42]. Of note, clients of community-based HIV services

were shown to remain stable on care and maintain good adherence to treatment, without an increased risk of loss to follow-up than those in facility-based models [43].

Our finding that 3MMD was the most frequent ART refill interval, with 6MMD rarely available, is consistent with other studies conducted in LMICs showing that most ART programmes provided 2 or 3 months of ART refills between 2016 and 2019 [36, 44]. The advantages of longer ART refills for clients include time and cost savings, minimised work interruptions, and potentially diminished exposure to HIV-related stigma and discrimination, as clinic visits decrease [45, 46]. Studies comparing MMD strategies showed similar retention in care for 6MMD and 3MMD [47–49]. On the healthcare provision side, longer ART refill schedules can contribute to decongesting facilities and decreasing providers' workloads [45, 46]. One of the main obstacles to the implementation of 6MMD lies with the frequent drug stock-outs, especially in LMICs [9, 37].

We observed an association between higher HIV prevalence at country level and the implementation of DSD. HIV prevalence emerges as a determinant influencing the relevance and acceptability of DSD models within healthcare

Table 3. Availability of dedicated HIV clinics providing care to various population groups, by the International epidemiology Databases to Evaluate AIDS region

Population group	Overall N = 175 (100%) N (%)	Asia-Pacific n = 30 (17.1%) n (%)	Latin America n = 8 (4.6%) n (%)	Central Africa n = 21 (12%) n (%)	East Africa n = 74 (42.3%) n (%)	Southern Africa n = 28 (16%) n (%)	West Africa n = 14 (8%) n (%)
Pregnant/breastfeeding women	150 (85.7)	22 (73.3)	6 (75.0)	21 (100.0)	71 (95.9)	22 (78.6)	8 (57.1)
Family care clinics	86 (49.1)	15 (50.0)	2 (25.0)	16 (76.2)	30 (40.5)	18 (64.3)	5 (35.7)
Men	113 (64.6)	19 (63.3)	6 (75.0)	19 (90.5)	42 (56.8)	20 (71.4)	7 (50.0)
Clients with comorbidities or opportunistic infections	142 (81.1)	28 (93.3)	6 (75.0)	20 (95.2)	52 (70.3)	23 (82.1)	13 (92.9)
Female sex workers	71 (40.6)	16 (53.3)	5 (62.5)	18 (85.7)	21 (28.4)	9 (32.1)	2 (14.3)
Gay men and other men who have sex with men	57 (32.6)	20 (66.7)	7 (87.5)	9 (42.9)	13 (17.6)	6 (21.4)	2 (14.3)
Transgender individuals	46 (26.3)	18 (60.0)	6 (75.0)	5 (23.8)	10 (13.5)	6 (21.4)	1 (7.1)
People with substance use disorders	55 (31.4)	17 (56.7)	5 (62.5)	4 (19.0)	23 (31.1)	6 (21.4)	0 (0.0)
People who inject drugs	46 (26.3)	17 (56.7)	3 (37.5)	3 (14.3)	17 (23.0)	5 (17.9)	1 (7.1)
People with mental health disorders	85 (48.6)	21 (70.0)	4 (50.0)	14 (66.7)	28 (37.8)	16 (57.1)	2 (14.3)
Mobile populations	75 (42.9)	12 (40.0)	2 (25.0)	12 (57.1)	32 (43.2)	14 (50.0)	3 (21.4)
Incarcerated populations/prisoners	47 (26.9)	8 (26.7)	3 (37.5)	6 (28.6)	18 (24.3)	8 (28.6)	4 (28.6)
People living with disabilities	101 (57.7)	22 (73.3)	5 (62.5)	19 (90.5)	33 (44.6)	14 (50.0)	8 (57.1)

systems [50]. Regions facing a significant burden of diseases like HIV can exhibit a better implementation of DSD to better suit the various people's need, and thus to improve retention in care and clinical outcomes [51, 52]. Although in our model country income was not associated with DSD implementation, other studies have noted that upper- and lower-middle-income countries had rapidly implemented "treat all" and provided universal HIV treatment to PWH [53–56], accompanied by many interventions to accelerate treatment uptake. Moreover, other factors can influence the implementation of DSD such as national policies, research programmes and funding sources. Others have shown that facilities supported by external funding can embrace more DSD initiatives [37, 55, 57, 58]. Future research should further examine how economic and political dynamics influence the implementation and long-term sustainability of DSD.

In our study, few facilities offered dedicated clinics for key population groups. Key populations often suffer from limited access to a wide range of HIV services, especially if not targeted to their specific needs [2]. Consequently, key population groups are often at increased HIV acquisition risk and experience higher HIV prevalence than the general population, with lower access to ART [59, 60]. Discrimination and social exclusion can hinder access to HIV services for key population groups in countries where these populations are criminalised [61]. This highlights the need for dedicated services tailored to these groups, including prevention, testing, ART delivery and long-term prevention [61, 62]. Key population groups may be more likely to access HIV services in trusted environments, with tailored DSD models specifically addressing stigma and discrimination which are prominent concerns in these populations [5, 63, 64].

To our knowledge, this is one of few global analyses examining the implementation of DSD in LMICs [65]. The main strength of our study is that it captured the scale of DSD across a large sample of HIV care facilities in LMICs globally, using standardised questionnaires. However, our data do not provide information on the actual client-level uptake of DSD, its acceptability, nor its sustainability, which are essential elements to understand the success of implementation processes but were beyond the scope of this site-level survey. Furthermore, we acknowledge that while being a global consortium, leDEA is mainly comprised of large sites and programmes, including referral and university teaching hospitals that serve large numbers of clients and provide advanced or specialised HIV care. Facilities participating in leDEA are likely not representative of all facilities that provide HIV care within LMICs generally. Our survey results may overestimate the implementation of DSD in sub-Saharan Africa settings if rollout treatment guidelines lag at peripheral, lower-level facilities or among clinics serving key populations. Additionally, leDEA comprises only eight facilities in Latin America, which are selected based on the availability of electronic data. Another limitation of our survey is that it is self-reported, and thus subject to recall bias and social desirability bias. Moreover, our data may not fully reflect the current context due to evolving policies and healthcare practices. Our analysis focused on service delivery practices in 2019, 1 year prior to the COVID-19 pandemic, yet many sites accelerated the implementation of DSD strategies in response to the

pandemic to minimise patient visits and maintain client retention in care [51, 66–68]. Moreover, our study did not explore novel DSD strategies implemented during the COVID-19 pandemic to maintain client retention in care while minimising visits to healthcare facilities [22, 23, 69]. For example, in countries supported by the United States President's Emergency Plan for AIDS Relief (PEPFAR), MMD increased access to ART during the COVID-19 pandemic [70]. Nevertheless, despite the age of our data, they are still relevant to the current push towards client-centred HIV care and provide a timely global overview of efforts being made towards DSD implementation across different settings. We acknowledge that newer developments may have influenced DSD implementation and should be considered when interpreting our findings. We also believe that collecting more data on specific DSD components is essential to better understand the nuanced impact of national policies across countries. At present, we are not using scales to assess DSD in the post-COVID era, and while comparisons with pre-COVID data may offer valuable insights, such analyses are not planned within the scope of this work. Finally, we recognise that our model exploring factors associated with DSD implementation combined data collected at facility and country levels, which may not reflect the exact same setting.

5 | CONCLUSIONS

Most of the HIV care facilities in LMICs had implemented a range of DSD for HIV treatment models by 2019. The majority offered facility-based models and 3MMD for clinically stable clients. Fewer facilities used community-based models and extended MMD. Efforts to expand DSD into HIV testing and ART initiation and offer extended MMD in resource-constrained settings would contribute to further alleviate the burden on healthcare services and PWH, while improving long-term adherence and retention in care.

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COMPETING INTERESTS

The authors have declared no competing interests.

AUTHORS' CONTRIBUTIONS

International epidemiology Databases to Evaluate AIDS performed the site-level survey. VK, CT, MS, BC, JH, TT, CWW, SMF, GM, YC-V, REL, IR, DMZ, KP, DMN, JP, KW-K, CBM, OET, SK, RAA, SMA, GF and KM provided survey data. MB designed the research study. NVFV, FH and EZ analysed the data. NVFV, EZ and MB wrote the first draft. CWW assisted with survey design. All authors have read and approved the final manuscript.

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DISCLAIMER

This work is solely the responsibility of the authors and does not necessarily represent the official views of any of the institutions mentioned above.

DATA AVAILABILITY STATEMENT

People interested in accessing the leDEA consortium data for research purposes may contact the corresponding author for more information or see our website at <https://www.iedea.org/>.

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SUPPORTING INFORMATION

Additional information may be found under the Supporting Information tab for this article:

Table S1: List of countries per region and number of facilities per country.

Table S2: Year of implementation of DSD for HIV treatment models.

Figure S1: Year of introduction of DSD for HIV treatment models by leDEA region.

Text S1: Acknowledgements.

Text S2: leDEA 2020 Site Assessment Survey.

VIEWPOINT ARTICLE

The need to differentiate at re-engagement: lessons from South Africa and Zimbabwe's re-engagement algorithms

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As HIV epidemics mature, effectively addressing interruptions in antiretroviral therapy (ART) becomes increasingly critical to reducing morbidity, mortality and transmission [1–3]. Prolonged disengagement from ART places significant demands on health systems, including the need to manage advanced HIV disease (AHD), higher rates of hospitalisation and preventable new HIV acquisitions.

Disengagement from HIV care is the result of individual, interpersonal and/or structural vulnerabilities combined with life disruptions, such as unexpected travel, that impact a person's ability to remain in care [4, 5]. Fortunately, many individuals are self-motivated to return to care. However, their timely re-engagement often depends on removing barriers and introducing valued facilitators [6, 7]. Data from Malawi and South Africa show that the majority of people attempt return within 3 months of missing a scheduled appointment, but more country-specific time-to-return data is needed [8, 9].

Disengagement occurs across the HIV care cascade, with proportionally more people disengaging during early ART but greater numbers disengaging thereafter. In mature, generalised HIV epidemics, disengagement is common among all population groups, reinforcing the need for broad, scalable approaches that improve re-engagement outcomes [3].

Re-engagement involves two main intervention categories: tracing to encourage return, and enhancing the return experience to reduce interruption length and repeat disengagement [5]. This viewpoint focuses on the latter by removing barriers and adapting service delivery to support re-engagement.

HIV programmes must first recognise that ART interruptions are common and prioritise facilitating easy, quick and sustained re-engagement [3]. Some individuals fear returning due to concerns about disappointing healthcare workers and experiencing punitive actions [6, 10, 11]. Respectful care for returning clients can reduce fear and promote timely return. Re-engagement guidance should emphasise same-day ART provision, avoiding multiple visits [7] or transfer documentation collection [11]. Long waiting times and penalisation for missed appointments should be monitored and penalisation [6, 7]. People re-engaging in care commonly previously struggled with frequent appointments, inconvenient locations and long wait times. Accelerating access to less-

intensive differentiated service delivery (DSD) can reduce client burden and help prevent future interruptions [6, 7]. Frequent clinical visits should be reserved for when clinically necessary.

Ministries of health are starting to implement guidance on managing people returning to care, focusing on respectful care and a shift away from one-size-fits-all intensified clinical management, with its monthly appointments and multiple adherence counselling sessions. Differentiating care pathways identify individuals who are simply “late” for their scheduled visit, with no or only a brief treatment interruption, and who can continue routine care, including in DSD models. They also identify those who require further assessment. Two key assessments at return guide further differentiation. First, clinical stability, assessed through signs of opportunistic infections, mental health concerns, AHD or an elevated viral load prior to disengagement. Second, time since the missed appointment which indicates potential interruption duration and AHD risk.

To illustrate how these programmatic considerations have been applied, we highlight the national re-engagement algorithms of South Africa and Zimbabwe—the first two countries to formalise differentiated re-engagement pathways in national guidelines – offering valuable lessons for other settings. These are shown in Figure 1.

South Africa defines re-engagement as missing an appointment and returning to care unwell or by more than 28 days [12]. Their algorithm (Panel A) distinguishes routine from re-engagement care [12]. People late by 28 days or less continue or enrol in DSD models. The viral load testing schedule remains unchanged. Those missing appointments for more than 28 days or self-identifying as unwell undergo a clinical assessment and, unless clinically indicated, continue or restart ART on the same day. Clinically unstable individuals, regardless of interruption duration, require a repeat CD4 test to identify AHD and their follow-up schedule is determined by need. Clinically stable individuals are assessed for time since the missed appointment, with CD4 testing required for those missing for more than 90 days. Those missing appointments by 29–90 days are managed similarly to individuals 28 days or less late. Both clinically unstable and “more than 90 days late” groups require a follow-up viral load test after 3 months

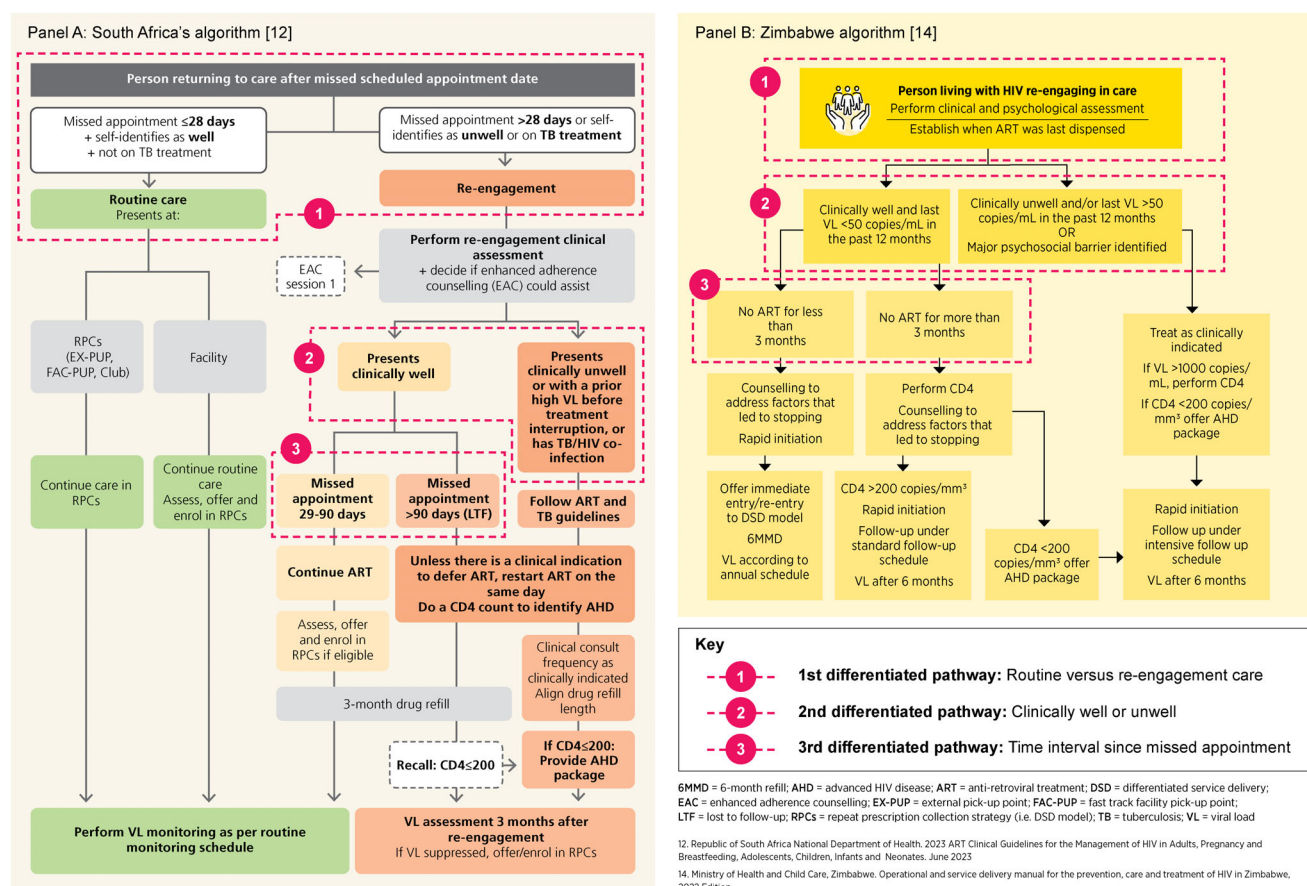


Figure 1. Algorithm-based differentiated clinical management and service delivery pathways at re-engagement.

and a 3-month ART refill unless earlier clinical care is needed. A month later, if suppressed, they are offered DSD enrolment.

Piloting an earlier version in nine health facilities revealed that engaged leadership, provider empathy and alignment with existing workflows were critical for successful adoption [13].

Zimbabwe defines re-engagement as stopping ART after a missed visit. A clinical assessment is required for everyone re-engaging to differentiate between those who are clinically stable and unstable (Panel B) [14]. For clinically stable individuals, those who are less than 3 months late are re-initiated within 7 days and (re)enrolled in DSD models after receiving adherence counselling sessions. The viral load testing schedules remain unchanged. Clinically unstable individuals include those who are unwell, have an elevated viral load within the past 12 months or have significant psychosocial challenges. They require a follow-up CD4 if the last viral load exceeded 1000 copies/ml, with their appointment schedule tailored to clinical needs. For all individuals more than 3 months late, CD4 counts are repeated to assess for AHD. Those with a CD4 count above 200 cells/mm³ follow the standard ART initiation schedule, with follow-up clinical reviews after 1, 3 and 6 months—after which a viral load test is done. At the subsequent visit, suppressed individuals are offered DSD models, including 6-month ART refills.

In an evaluation of the AHD screening component across 70 facilities, 23% of re-engaging clients received CD4 testing,

with 41% of those tested having CD4 < 200 cells/mm³. Staff shortages and commodity constraints posed challenges, particularly for point-of-care CD4 testing, while facilities trained on the use of the algorithm, conducted screening more confidently [15].

The South African and Zimbabwean algorithm-based differentiated pathways for re-engagement offer scalable approaches to facilitating efficient and durable return to care. By ensuring minimal disruption to individuals' lives through accelerated access to extended ART refills and less-intensive DSD, these approaches reduce the burden for clinically stable clients while ensuring necessary oversight for those with increased clinical needs, including AHD. Importantly, they ensure the re-engagement process is person-centred, with a focus on enhancing the return experience and mitigating barriers that may lead to prolonged or future interruptions. These adaptable approaches allow healthcare systems to address individual needs while optimising resources for broader population coverage.

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COMPETING INTERESTS

The authors declare that they have no conflict of interest.

AUTHORS' CONTRIBUTIONS

The concept for this commentary was developed by LSW, HB and AG. LSW wrote the first draft. All authors contributed and approved the final version.

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DATA AVAILABILITY STATEMENT

Data sharing is not applicable to this article as no datasets were generated or analysed during the current study.

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