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JOURNAL OF THE INTERNATIONAL AIDS SOCIETY

Differentiated service delivery for HIV during COVID-19: lessons and opportunities

Guest Editors: Anna Grimsrud, Peter Ehrenkranz, Izukanji Sikazwe
Supplement Editor: Marlène Bras

Volume 24, Supplement 6, October 2021

WILEY

Acknowledgements

The Guest Editors – Anna Grimsrud, Peter Ehrenkranz and Izukanji Sikazwe - would like to thank all of the authors who responded to our request for contributions, prepared manuscripts, and participated in the rigorous review and selection process. We wish that many more studies could have been included, and hope that this effort to compile the latest evidence and around how differentiated service delivery (DSD) for HIV has been adapted and accelerated in response to COVID-19 will encourage more science and further implementation. We also thank the editors and staff of the *Journal of the International AIDS Society* for thoughtful guidance, rigorous support, and encouragement throughout the process and the reviewers for their constructive inputs.

Support

This supplement was supported by IAS – the International AIDS Society – and its Differentiated Service Delivery programme, thanks to funding from the Bill & Melinda Gates Foundation. The content is solely the responsibility of the authors and does not necessarily represent the views of the funding agency.

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JIAS
JOURNAL OF THE INTERNATIONAL AIDS SOCIETY

Grimsrud A et al. *Journal of the International AIDS Society* 2021, **24**(S6):e25807
http://onlinelibrary.wiley.com/doi/10.1002/jia2.25807/full | https://doi.org/10.1002/jia2.25807

EDITORIAL

Silver linings: how COVID-19 expedited differentiated service delivery for HIV

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Keywords: community; COVID-19; differentiated service delivery; HIV; multi-month dispensing; self-care; services; virtual medicine

Received 21 July 2021; **Accepted** 19 August 2021

> "In the rush to return to normal, use this time to consider which parts of normal are worth rushing back to."
> – Dave Hollis, author

As we write this Editorial at the beginning of July 2021, the World Health Organization (WHO) has reported that the African continent is experiencing its worst week of the COVID-19 pandemic and that COVID-19 cases are rising in all six of the WHO's global regions [1, 2]. There is a serious imbalance in global distribution of COVID-19 vaccines with only 1% of people in Africa and low-income countries being fully vaccinated and 85% of doses globally having been administered in high- and upper-middle-income countries [1, 3]. Amid this recent surge of infections and the inequities in access to vaccines, it is increasingly clear that the cycles of COVID-19 waves are likely to continue until the virus that causes COVID-19 transitions from pandemic to endemic [4].

Africa is home to the largest number of people living with HIV – two-thirds of the 38 million people living with HIV reside in on the continent, with 20.7 million people living with HIV in East and southern Africa alone [5]. Many sub-Saharan African countries have experienced an increased strain on their existing health infrastructure, including on human resources for health, since the onset of the COVID-19 pandemic, prompting countries to move swiftly to ensure uninterrupted supply of antiretroviral therapy (ART) and limit visits to health facilities for people on ART [6]. As a result, many of the previous barriers to the implementation of differentiated service delivery (DSD) models for HIV treatment, such as a recent documented undetectable viral load [7, 8], were unlocked, at least temporarily. With the rapid adaptation of national policies on HIV delivery to the realities of COVID-19 restrictions and lockdowns, eligibility for entry in DSD for HIV treatment models was expanded, longer refills of ART were prescribed and dispensed, virtual models of care were innovated, and the role of community models for HIV treatment delivery was reinforced. Additionally, ways to expand DSD services beyond treatment to encompass HIV testing and prevention services were explored.

In November 2020, we published a call for abstracts for both quantitative and qualitative data on the impact of these adaptations with the intention of drawing attention to the changes made to DSD for HIV in response to COVID-19. Evidence was needed to understand the effect of the temporary measures being implemented on health outcomes among people living with HIV.

Since our call, data have emerged that alleviates some of the initial concern that COVID-19 would lead to interruptions in HIV treatment delivery and result in considerable increases in morbidity, mortality and HIV incidence [9]. The November 2020 UNAIDS global AIDS update emphasized that while COVID-19 had led to decreases in access to HIV prevention, testing and consequently ART initiation, the number of people on ART has continued to increase with 27.5 million people on treatment worldwide at the end of 2020 [10]. Similarly, data from the Kwa-Zulu Natal (KZN) province in South Africa found a 48% decrease in HIV testing and 46% reduction in new ART initiations but no marked change in the number of ART collection visits during South Africa's first lockdown (April-July 2020) [11].

In March 2021, WHO launched updated recommendations on service delivery that expand eligibility criteria for access to DSD for HIV treatment, re-validate recommendations to extend ART refills and clinic visits for those who are established on ART, promote integration of family planning and non-communicable disease management within HIV programmes and encourage tracing and re-engagement for those in a treatment interruption [12]. These guidelines are based on data collected before COVID-19, and therefore, more recent evidence will be critical to inform future updates for DSD that go beyond HIV treatment.

This supplement includes 11 articles from the more than 50 submissions received and addresses many of the areas we highlighted as being of particular interest. In this editorial,

we summarize six key themes that emerge from this supplement and what this new data add to our understanding of accelerating access to DSD for HIV before scoping the future for DSD.

1. Virtual support on mobile phones can accelerate ART initiation and facilitate monitoring in facilities and communities

In response to COVID-19, many digital platforms were utilized to reduce in-person delivery of services [13]. Data from Amatavete et al. in Thailand outline how telehealth follow-up after same-day ART initiation [14] led to positive outcomes in terms of referral to long-term treatment facilities and retention among those receiving phone follow-up compared to in-person follow-up. Virtual follow-up via telehealth was also part of the DSD adaptations in the United States Veterans Health Administration (VA) programme described below [15]

2. DSD for HIV treatment can benefit those recently started on ART and those on second-line regimens

Two articles within the supplement found non-inferior HIV-related health outcomes among populations previously unable to access DSD for HIV treatment. Pooling data from two trials in Lesotho and Zimbabwe, Fatti et al. found that those who were referred to out-of-facility DSD models for HIV treatment after only 6–12 months on ART had similar outcomes as compared to those who had been on treatment for a year or longer at the time of referral [16]. Further, this study found that those who had annual clinical visits had at least non-inferior outcomes compared to those with more frequent (every 3 months) in-person clinical consultations. This is important evidence, given that the updated WHO guidance still recommends clinic visits every 3–6 months [12]. Novel evidence on the outcomes of people on second-line ART within DSD for HIV treatment models is described in an article from KZN, South Africa [17]. No differences in retention or viral suppression were observed comparing clients on second-line ART referred to community treatment distribution models versus those remaining in clinic-based care.

3. Extended ART refill durations should be a new standard of care

Perhaps the most consistent innovation recommended for HIV services during COVID-19 has been to increase access to and duration of multi-month dispensing (MMD) of ART refills [18–20]. Using routinely collected data from 17 PEPFAR supported countries, Bailey et al. describe how the proportion of clients receiving 6 months of ART increased from 9% in April to June 2020 to 16% in the following quarter (July-September 2020) [21]. MMD uptake was also expanded among important specific populations, including for children less than 15 years of age, for whom 3-month dispensing of ART increased from 34 to 50% in the same period. An analysis of routine data from Zambia by Jo et al. provides additional nuance to the multi-country PEPFAR results [22]. While participation in any DSD treatment model increased in 2020, there were significant obstacles in terms of choice of model and in access to longer dispensing intervals related to challenges in the supply chain.

4. COVID-19 has emphasized the importance of expanding access to community-based services

Data from the scale-up of DSD for HIV treatment in Nigeria describes enrolment numbers and client health outcomes between 2018–2020 [23]. Of five models that were implemented, more than half of all clients referred participated in a community ART refill club (53%) and the largest increase in enrolment corresponded with the first COVID-19 wave in Nigeria. In India, Pollard et al. facilitated discussions with gay men and other men who have sex with men, female sex workers and transgender women in two provinces to identify preferences for delivery of HIV prevention, testing and treatment services [24]. Community-based approaches that are flexible were identified as critical for HIV prevention, testing and treatment services for the key populations interviewed in this study. In Botswana, two individual out-of-facility models for ART refills were explored: home delivery and collection from private pharmacies [25]. A pilot of home delivery through a courier service found that 84% of clients accepted home delivery with 91% of ART refills successfully delivered. Both prospective users and private pharmacies were approached in assessing the feasibility of ART refills from private pharmacies; 61% of the prospective users indicated interest and willingness to pay approximately USD$4/refill for two refills per year.

5. DSD for HIV is also relevant in more highly resourced settings

Data from the United States VA highlight adaptations made in the United States parallel to those seen in less resourced contexts [15]. Adaptations included an increase in virtual follow-up and the duration of ART refills. In 2020, virtual visits (predominantly by telephone) increased to 68% compared to 27% in 2019 and 50% of ART refills were for 3-month ART refills or longer compared to 38% in 2019. Along with other published data from HIV providers in San Francisco [13], this VA data supports the acceptability of using virtual means to provide HIV services.

6. DSD is applicable for HIV prevention and tuberculosis treatment

While much of DSD has historically focused on differentiating HIV treatment for those established on treatment, COVID-19 has also accelerated adaptations to other parts of the HIV care continuum including prevention. In Zimbabwe, Matambanadzo et al. present data on how demand for pre-exposure prophylaxis (PrEP) among sex workers increased during COVID-19 lockdowns and was overcome through home delivery, extended PrEP dispensing and support via WhatsApp through providing mobile data and airtime [26]. Further, DSD must not be limited to HIV or HIV treatment alone. In the one commentary in the supplement, Tran et al. argue for the expansion of DSD for HIV treatment models to include tuberculosis treatment [27]. We agree—and while policy provisions were made in some countries to align HIV services and the delivery of other health commodities like family

planning or medications for non-communicable diseases, very little data on the implementation of these policies are available [6, 28].

REMAINING GAPS IN THE EVIDENCE AND SCOPING THE FUTURE OF DSD FOR HIV AND BEYOND

Many of the remaining gaps require data from implementation science, such as the paucity of evidence available on the integration of HIV services with other disease areas [29]. Further analyses of routine data on how COVID-19 adaptions impacted outcomes are also encouraged, including the effect of earlier access to MMD, particularly from ART initiation as well as for specific populations namely children and adolescents, those who are pregnant and breastfeeding and migrant populations. More data would also be welcome describing the perspectives and experiences of both recipients of care and healthcare providers of COVID-19 adaptations to HIV service delivery. In addition, costing and financing data is missing—particularly relevant in making the argument for adaptations to be sustained.

In summary, the articles in this supplement contribute to a growing evidence base showing that modifications made in response to COVID-19 should not be temporary, but rather part of a better service delivery system going forward that meets the needs of recipients of care. Indeed, COVID-19 has quickened acknowledgement across diverse stakeholders that DSD is not just for people who are established on ART. Rather, COVID-19 has presented an opportunity for a shift toward scale up of self-care models in general—not just for HIV, but also for tuberculosis, chronic diseases like hypertension and diabetes, and routinely provided services like family planning. The key components of DSD for HIV treatment of reducing the number of clinical visits, separating them from a decreased frequency of drug dispensing and prioritizing out-of-facility models apply to all of these purposes. Constraints within many supply chains were compounded by COVID-19 but should not prevent wider implementation of MMD or DSD models in general.

Highlighted in this supplement are the important roles of community-based services and virtual platforms (telephone, SMS and videoconferencing) in decreasing barriers for accessing critical aspects of the clinical visits as well as the resources required to provide it. These shifts may indeed represent a silver lining to the pandemic—a renewed focus on leveraging improvements in health systems, including supply chain and information technology, to provide high quality person-centred care.

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COMPETING INTERESTS

AG is a Deputy Editor of the Journal of the International AIDS Society. PE is an employee of the Bill & Melinda Gates Foundation.

AUTHORS' CONTRIBUTIONS

All authors were involved in the conceptualization of the article. AG wrote the first draft. All authors approved the final submission.

ACKNOWLEDGEMENTS

Thank you to Lina Golob for providing inputs on the draft manuscript and Nelli Bazarova for supporting the referencing.

FUNDING

AG's efforts was funded by the Bill & Melinda Gates Foundation INV002610. PE is an employee of the Gates Foundation. IZ is an employee of CIDRZ, with funding from PEPFAR, Bill & Melinda Gates Foundation and the NIH.

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Amatavete S et al. *Journal of the International AIDS Society* 2021, **24**(S6):e25816
http://onlinelibrary.wiley.com/doi/10.1002/jia2.25816/full | https://doi.org/10.1002/jia2.25816

RESEARCH ARTICLE

Evaluation of the integration of telehealth into the same-day antiretroviral therapy initiation service in Bangkok, Thailand in response to COVID-19: a mixed-method analysis of real-world data

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Abstract

Introduction: Same-day antiretroviral therapy (SDART) initiation has been implemented at the Thai Red Cross Anonymous Clinic (TRCAC) in Bangkok, Thailand, since 2017. HIV-positive, antiretroviral therapy (ART)-naïve clients who are willing and clinically eligible start ART on the day of HIV diagnosis. In response to the first wave of the coronavirus disease 2019 (COVID-19) outbreak in March 2020, telehealth follow-up was established to comply with COVID-19 preventive measures and allow service continuation. Here, we evaluate its implementation.

Methods: Pre-COVID-19 (until February 2020) clients who initiated SDART received a 2-week ART supply and returned to the clinic for evaluation before being referred to long-term ART maintenance facilities. If no adverse events (AEs) occurred, another 8-week ART supply was provided while referral was arranged. During the first wave of COVID-19 (March–May 2020), clients received a 4-week ART supply and the option of conducting follow-up consultation and physical examination via video call. Clients with severe AEs were required to return to TRCAC; those without received another 6-week ART supply by courier to bridge transition to long-term facilities. This adaptation continued post-first wave (May–August 2020). Routine service data were analysed using data from March to August 2019 for the pre-COVID-19 period. Interviews and thematic analysis were conducted to understand experiences of clients and providers, and gain feedback for service improvement.

Results: Of 922, 183 and 321 eligible clients from the three periods, SDART reach [89.9%, 96.2% and 92.2% ($p = 0.018$)] and ART initiation rates [88.1%, 90.9% and 94.9% ($p<0.001$)] were high. ART uptake, time to ART initiation and rates of follow-up completion improved over time. After the integration, 35.3% received the telehealth follow-up. The rates of successful referral to a long-term facility (91.8% vs. 95.3%, $p = 0.535$) and retention in care at months 3 (97.5% vs. 98.0%, $p = 0.963$) and 6 (94.1% vs. 98.4%, $p = 0.148$) were comparable for those receiving in-person and telehealth follow-up. Six clients and nine providers were interviewed; six themes on service experience and feedback were identified.

Conclusions: Telehealth follow-up with ART delivery for SDART clients is a feasible option to differentiate ART initiation services at TRCAC, which led to its incorporation into routine service.

Keywords: HIV; same-day antiretroviral therapy; differentiated care; telehealth; linkage to care COVID-19; Asia

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

Received 22 March 2021; **Accepted** 19 August 2021

1 | INTRODUCTION

Same-day antiretroviral therapy (SDART) initiation in which HIV treatment is started on the same day as HIV diagnosis is a safe and promising intervention to accelerate linkage to care. SDART is endorsed by the World Health Organization as a strategy in ending the HIV epidemic [1]. However, since available healthcare resources have been allocated to testing, treatment and mitigation of the coronavirus disease 2019 (COVID-19) pandemic, the decreased rates of HIV testing [2–4], pre-exposure prophylaxis [5,6] and post-exposure prophylaxis prescription [7–9], as well as antiretroviral therapy (ART) dispensation [4] were reported. With the increased perceived risk and fear of acquiring COVID-19, many clients viewed these HIV services as non-essential [10,11], which resulted in clients not accessing the services.

In Thailand, the first wave of the COVID-19 outbreak occurred during January–July 2020 [12] with a total of 3298 confirmed cases and 58 deaths [13]. The number of new infections escalated in March 2020 [14], which promptly led the Thai Government to issue a National Emergency Decree [15] and a nationwide curfew [16]. The implementation of these policies contributed greatly to the fall of local transmission in April 2020 and a drop to near zero cases in mid-May 2020 [17]. During this time in Thailand, new governmental recommendations were launched to support the adaptation of HIV and related services to allow their continuation [18–20]. However, no recommendation on ART initiation service was put forth. Timely ART initiation was already challenging pre-COVID-19 epidemic due to difficulty in obtaining baseline laboratory results and a requirement for multiple pre-ART counselling sessions to promote long-term adherence. Despite HIV care being free in Thailand, people living with HIV (PLHIV) can only access free services at the specific healthcare facility where they are registered through their national health insurance and, in some cases, may require to change their facility coverage to another more convenient facility. These complicated requirements might contribute to loss to follow up [21–24], adverse clinical events [25] and onward HIV transmission prior to ART initiation [25,26] that have been reported worldwide. The added barriers of social distancing, provincial border lockdown and avoiding of non-essential hospital visits during the COVID-19 pandemic were anticipated to aggravate linkage to care [27].

The Institute of HIV Research and Innovation (IHRI) has piloted the SDART initiation service at the Thai Red Cross Anonymous Clinic (TRCAC) since July 2017. It was the first SDART initiation hub in the country where ART-naïve, HIV-diagnosed people who were willing and clinically eligible could start ART on the same day as HIV diagnosis free of charge, regardless of their insurance coverage. This service was provided by a multidisciplinary team of non-specialist physicians, nurses, pharmacists, counsellors and peer navigators. The navigators, including but not limited to men who have sex with men (MSM), transgender women (TGW) and PLHIV, played an essential role in assisting PLHIV in retaining in care and overcoming the health system barriers. In early March 2020, the SDART provider team foresaw the aforementioned barriers of the COVID-19 pandemic to SDART initiation and planned service adaptations to reduce the risk of COVID-19 spread while optimizing linkage to care. This became the first differentiated ART initiation model available under the changed reality of health service delivery in the COVID-19 period.

This study evaluates the integration of telehealth into the SDART initiation service at TRCAC in Bangkok, Thailand, by describing service outcomes in the pre-, during and post-first waves of the COVID-19 epidemic and comparing the clinical outcomes of clients who received in-person and telehealth follow-up.

2 | METHODS

2.1 | Study design and participants

This is a sub-study of an observational cohort study of all clients who tested HIV positive and underwent the routine SDART initiation service at TRCAC, which is a standalone HIV/sexually transmitted infection testing centre and an SDART initiation hub located in the centre of Bangkok, Thailand. This analysis evaluated the outcomes of the SDART initiation service from three periods: pre- (1 March 2019–31 August 2019), during (1 March 2020–15 May 2020) and post-first waves of the COVID-19 epidemic (16 May 2020–31 August 2020). All clients who tested HIV positive at TRCAC were screened for SDART eligibility: being ART-naïve, not participating in another study and ability to attend follow-up visit (pre-COVID-19 epidemic only). Eligible clients were included in this analysis.

2.2 | SDART initiation procedure pre-COVID-19 epidemic

The SDART initiation procedure started after the client received the first positive HIV result (Architect HIV Ag/Ab Combo, Abbott, Germany, or Elecsys HIV combi PT, Roche Diagnostics GmbH, Germany) at TRCAC. The clients received post-test counselling and were assessed for eligibility and willingness to start SDART by the counsellor. Those who consented received phlebotomy for HIV confirmatory [Rapid Test for Anti-HIV (Colloidal Gold Device), Beijing Wantai Biological Pharmacy Enterprise Co., Ltd., China, and Serodia HIV-1/2, Fujirebio Inc., Japan] and baseline pre-ART laboratory tests (CD4 cell count, complete blood count, alanine aminotransferase, creatinine/creatinine clearance, urine analysis, Treponema pallidum hemagglutination, rapid plasma reagin, hepatitis B surface antigen, hepatitis C antibody and cryptococcal antigen for those with CD4 count < 100 cells/mm^3). The clients travelled to receive a chest X-ray at a nearby hospital. Afterwards, the clients met with a peer navigator to receive HIV diagnosis confirmation, screening for psychosocial readiness using Patient Health Questionnaire-9 and pre-ART initiation counselling, including adherence counselling. The date that this process takes place is referred to as the care engagement date, which due to logistics might not be on the same date as HIV diagnosis. A nurse and a physician then collected medical history and performed a physical examination to rule out tuberculosis (TB), cryptococcal meningitis and other serious illnesses that might

interfere with ART initiation. GeneXpert MTB/RIF assay was performed for clients who were suspected of TB. If serious opportunistic infections (OIs) or illnesses were suspected, clients were referred to their registered healthcare facility for OI investigation, treatment and/or ART initiation. Clients who were clinically eligible were prescribed ART (tenofovir disoproxil fumarate 300 mg, emtricitabine 200 mg and efavirenz 600 mg once daily) as per national guidelines [28].

After SDART initiation, clients were scheduled for a follow-up visit after 2 weeks, during which they received baseline laboratory results, physical examination and ART side effect assessment and/or management. Adverse events (AEs) included grades 1–3 [29]. If needed, ART regimen was modified. Otherwise, ART refill was provided, and the referral process was initiated in which the navigator assisted in the change in facility coverage process and accompanied the clients to their long-term ART maintenance facility upon request. The SDART process, from ART initiation to referral, lasted approximately 2.5 months for each client. After referral, the navigator continued to follow up the clients remotely by calling, messaging and/or checking their ART status in the online national HIV database, NAPPLUS, to confirm successful referral to the ART maintenance facility. The navigator will also follow up with clients to assess their retention for up to 2 years after ART initiation.

Those diagnosed with HIV but were ineligible for SDART or were eligible but not willing to start SDART received confirmatory HIV tests and were referred to their preferred hospital with the assistance of the navigator.

2.3 | Adaptation of SDART initiation service in response to COVID-19

The SDART initiation service models before and in response to COVID-19 are presented according to the differentiated service delivery (DSD) framework [30] in Figure 1. The ability to attend a follow-up visit at TRCAC was dropped from the eligibility criteria as the telehealth follow-up option was added to allow follow-up via video call using the LINE application. This application has been very popular in Thailand for instant communication with free audio and video calls. Those who lacked the skills in using the application or had limited access to high-speed internet for video calls were allowed to use audio-only calls and send photographs of additional laboratory test reports or their visible symptoms via LINE chat. ART refill was done via mail. The clients paid a delivery fee of 100 Thai baht (approximately US$3). The refill duration at the initiation visit was adjusted from 2 to 4 weeks to ensure adequate ART supply until the follow-up visit. Insurance transfer was offered at the initiation visit instead of at follow-up. The adapted SDART initiation service flow is shown in Figure 2.

2.4 | Statistical analysis

Data were stratified into pre-, during and post-first waves of the COVID-19 epidemic. Outcome measures included demographic characteristics, baseline CD4 cell count, SDART eligibility rate, SDART reach rate [31], ART initiation rate, duration to initiate ART, follow-up visit completion rate, AE rate, duration to change facility coverage, referral completion rate and retention rates at months 3 and 6. Descriptive analysis summarized the client characteristics, service outcomes and clinical outcomes using proportions, mean, standard deviation, median and interquartile range. Pearson's chi-square and Fisher's exact tests were used to determine the relationship between categorical variables. One-way ANOVA was used to compare means between the three periods. Kruskal–Wallis equality-of-populations rank test was applied to test equality of median distribution across groups. An independent samples *t*-test was used to compare means between in-person and telehealth follow-up groups. Univariate and multivariate logistic regression analyses were conducted to explore the associated factors with receiving telehealth follow-up. A *p*-value of <0.05 was considered as statistically significant.

Statistical analysis was conducted with Stata version 15.0 (StataCorp, College Station, TX, USA).

2.5 | Qualitative assessment

In October 2020, after the telehealth follow-up was continued as part of routine service delivery, a small subset of clients who completed telehealth follow-up and SDART providers were interviewed to assess their experiences and feedback for the purpose of service improvement. Interview participants were conveniently selected to represent the clients and each cadre of providers until the point of data saturation. The clients were interviewed by the navigators via LINE chat, which is a communication channel already used to communicate and form rapport between clients and navigators. The providers were interviewed in-person by navigators and program officers. The interview questions can be found in Appendix S1. Interview transcripts were generated, and thematic analysis was conducted manually by three program officers following the framework analysis outlined by Braun and Clarke. Each officer reviewed the entirety of the transcripts, generated codes from the relevant data and developed potential themes independently. Afterwards, they convened to discuss and finalize the themes, sub-themes and quotes to demonstrate each sub-theme [32]. Selected quotes in Thai were translated verbatim into English.

2.6 | Ethical consideration

This study was approved by the Institutional Review Board of the Faculty of Medicine, Chulalongkorn University (IRB158/56). The informed consent was waived as the routine service data were collected as secondary data with no personal identifiers. Interviewed participants provided verbal consent.

3 | RESULTS

A total of 1728 clients were screened for SDART eligibility during the study periods: 1084 pre-, 238 during and 406 post-first waves of the COVID-19 epidemic. Of these, 922 (85.1%), 183 (76.9%) and 321 (79.1%) were eligible for SDART, respectively. Their characteristics are shown in Table 1.

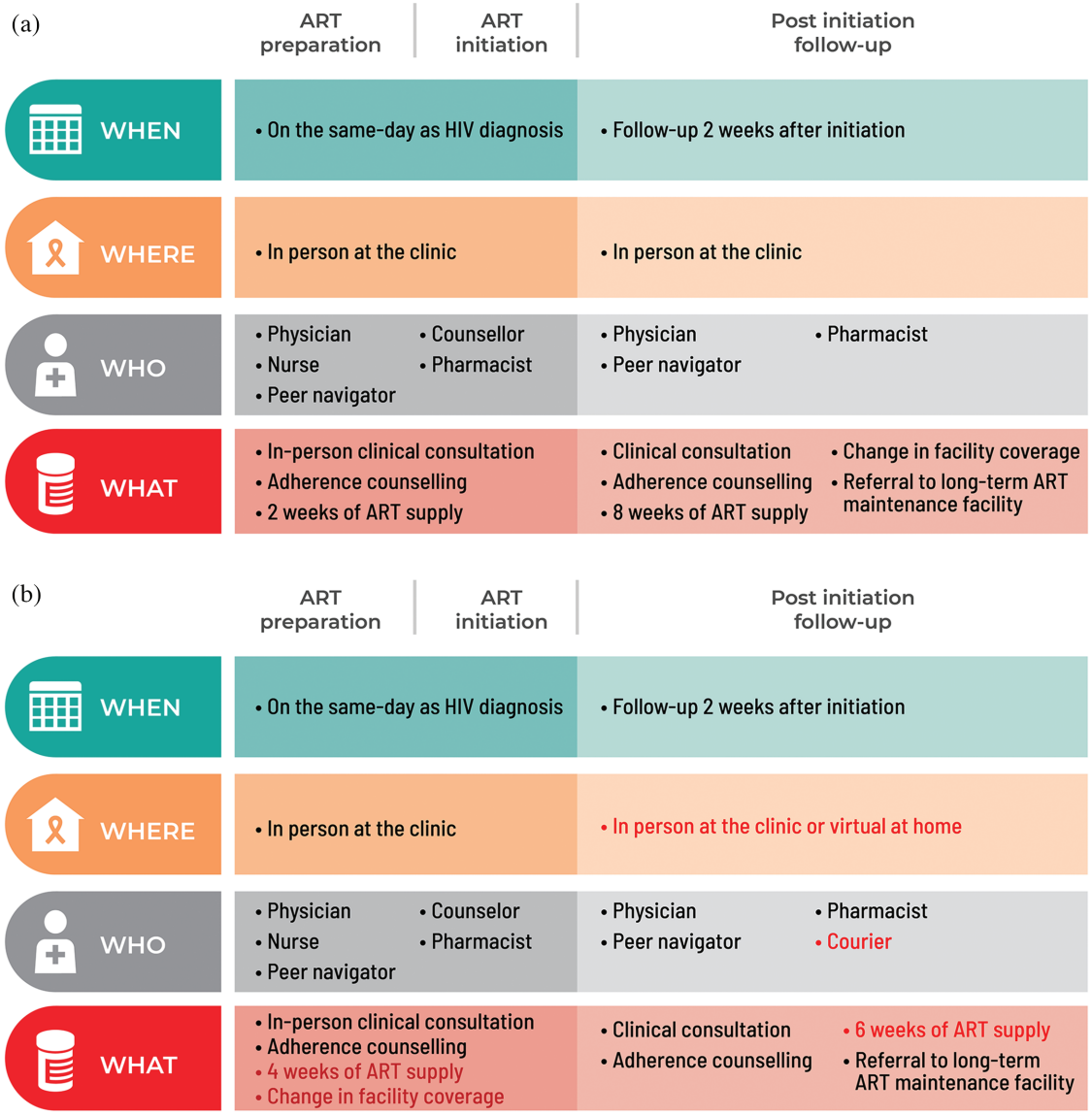

Figure 1. Differentiated same-day antiretroviral therapy (SDART) initiation service before and in response to coronavirus disease 2019 (COVID-19). The components of SDART initiation service models before (a) and in response to (b) COVID-19 are presented according to the differentiated service delivery framework with the red text indicating where the adaptation occurred. The service is divided into three parts: ART preparation, ART initiation and post initiation follow-up, with each part describing the timing, location, provider and frequency of services delivered. Abbreviation: ART, antiretroviral therapy.

The service outcomes of eligible clients pre-, during and post-first waves of the COVID-19 epidemic are shown in Table 2.

Table 3 shows the characteristics of 434 clients who received in-person follow-up (64.7%) and telehealth follow-up (35.3%) between 1 March and 31 August 31 2020. Univariate logistic regression analysis found no statistically significant factors associated with receiving telehealth follow-up. Therefore, multivariate analysis was not conducted.

Table 4 shows the clinical and service outcomes of clients who received in-person follow-up and telehealth follow-up. For clinical outcomes, 12.8% and 3.3% of clients receiving in-person and telehealth follow-up, respectively, experienced AEs. Rash was the most common AE; all were grades 1 and 2. Two clients experienced grade 3 dizziness and were managed in-person. The rates of successful referral to long-term ART maintenance facility and retention at months 3 and 6 were similar for both groups.

Six clients (two heterosexual females, two MSM and two TGW) who completed telehealth follow-up and nine providers (two physicians, three navigators, one counsellor, one pharmacist, one nurse and one administrative officer) were interviewed. Thematic analysis yielded six themes on the experiences of and feedback on receiving and providing telehealth follow-up: service access and inequity, cost and

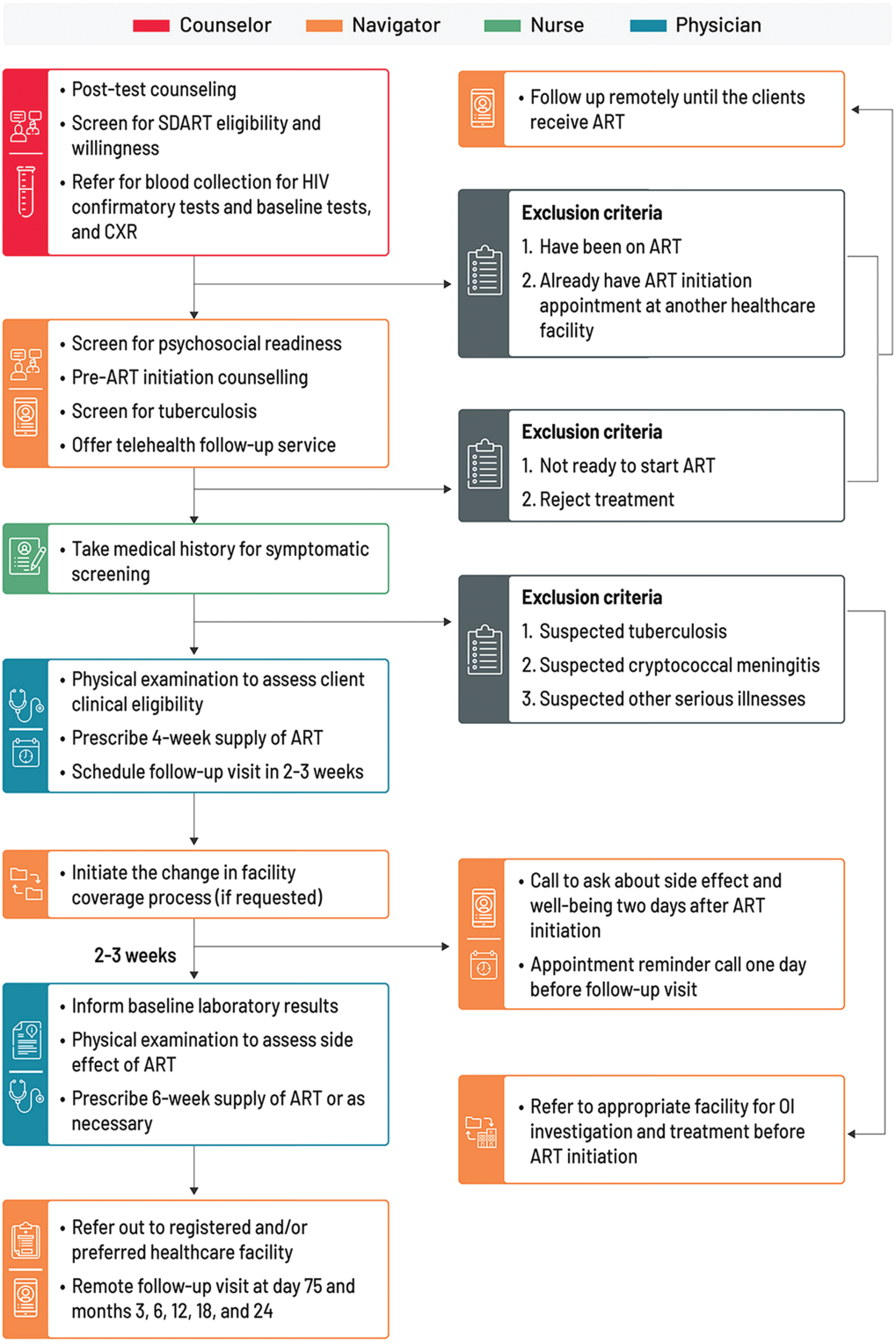

Figure 2. Same-day antiretroviral therapy (SDART) initiation service flow during and post-first waves of the coronavirus disease 2019 (COVID-19) epidemic. The SDART initiation service flow outlines the tasks conducted by the four main teams of SDART providers, which are counsellors, peer navigators, nurses and non-specialist physicians, from the ART initiation visit to the follow-up visit and the remote follow-up processes. Abbreviations: ART, antiretroviral therapy; CXR, chest X-ray; NAPPLUS, National AIDS Program Plus; OI, opportunistic infection; SDART, same-day antiretroviral therapy.

Table 1. Characteristics of same-day antiretroviral therapy (SDART) eligible clients in the pre-, during and post-first waves of the coronavirus disease 2019 (COVID-19) epidemic

	Pre-first wave (*N* = 922)	During the first wave (*N* = 183)	Post-first wave (*N* = 321)	*p*-value
Age (years), Mean (SD)	31.1 (9.3)	31.3 (10.0)	30.6 (8.2)	0.587*
Age group				0.581**
<25 years old	282/922 (30.6%)	50/183 (27.3%)	91/320 (28.4%)	
≥25 years old	640/922 (69.4%)	133/183 (72.7%)	229/320 (71.6%)	
Assigned sex at birth				0.965**
Male	802/922 (87.0%)	160/183 (87.4%)	278/321 (86.6%)	
Female	120/922 (13.0%)	23/183 (12.6%)	43/321 (13.4%)	
Population				0.449**
Heterosexual	219/922 (23.8%)	46/183 (25.1%)	76/321 (23.7%)	
MSM	658/922 (71.4%)	122/183 (66.7%)	227/321 (70.7%)	
TGW	45/922 (4.8%)	15/183 (8.2%)	18/321 (5.6%)	
Insurance				0.168**
UCS	380/913 (41.6%)	74/180 (41.1%)	139/319 (43.6%)	
SSS	371/913 (40.6%)	78/180 (43.3%)	130/319 (40.8%)	
CSMBS	52/913 (5.7%)	17/180 (9.4%)	16/319 (5.0%)	
Other schemes	2/913 (0.2%)	0/180 (0%)	0/319 (0%)	
Pay out of pocket	107/913 (11.7%)	10/180 (5.6%)	32/319 (10.0%)	
No scheme	1/913 (0.1%)	1/180 (0.6%)	2/319 (0.6%)	
CD4 cell count group (cells/mm$^{3)}$				0.241**
≤100	125/922 (13.6%)	25/183 (13.7%)	52/321 (16.2%)	
101–349	408/922 (44.3%)	76/183 (41.5%)	154/321 (48.0%)	
≥350	389/922 (42.1%)	82/183 (44.8%)	115/321 (35.8%)	

*One-way ANOVA.
**Pearson's chi-square test.
Abbreviations: COVID-19, coronavirus disease 2019; CSMBS, Civil Servant Medical Benefit Scheme; MSM, men who have sex with men; SD, standard deviation; SSS, Social Security Scheme; TGW, transgender women; UCS, Universal Coverage Scheme.

time-saving, confidentiality and stigma, COVID-19 preventive measures, DSD and service management through teamwork (Table 5).

4 | DISCUSSION

To our knowledge, our SDART initiation service is the first differentiated ART initiation model that has integrated telehealth, which makes it suitable for the COVID-19 era. Our findings show that SDART reach was about 90% throughout the pre-, during and post-first waves of the COVID-19 epidemic. The rates of ART initiation, duration of ART initiation and rates of follow-up completion improved over time with over 90% successful referral to long-term ART maintenance facility and retention rates. After the integration of the telehealth follow-up, about 35% of clients received this option with comparable referral and retention success of over 90%.

High SDART service performance throughout the three periods could be attributed to the integration of the telehealth follow-up option because it allowed clients who otherwise might not be able to attend the in-person visit to be eligible, accept SDART initiation and stay in care. However, only about 35% received telehealth. This might be due to the small scale of the first wave of the COVID-19 epidemic in Thailand and the swift response supported by the existing public health infrastructure [12] that allowed the continuation of some in-person services. Our clients and providers who were interviewed indicated that having telehealth as an additional option to conduct follow-up increased the service access, saved time and cost, improved confidentiality and reduced stigma. This might lead to an increase in the follow-up completion rate, which is in line with existing literature that shows a decline in missed visits with few people missing the telehealth visit [33]. Our providers viewed telehealth as highly appropriate for the COVID-19 period, as telehealth can help minimize the risk of acquiring COVID-19 through social contact in clinic setting and during travel [34,35].

Our regression analysis did not identify any characteristics associated with receiving telehealth follow-up. This might point to the consistent uptake of telehealth across clients of different ages, populations and socio-economic backgrounds. However, the thematic analysis revealed that a small

Table 2. Service outcomes of same-day antiretroviral therapy (SDART) eligible clients in the pre-, during and post-first waves of the coronavirus disease 2019 (COVID-19) epidemic

	Pre-first wave (*N* = 922)	During the first wave (*N* = 183)	Post-first wave (*N* = 321)	*p*-value
SDART reach	829/922 (89.9%)	176/183 (96.2%)	296/321 (92.2%)	0.018*
ART initiation	730/829 (88.1%)	160/176 (90.9%)	281/296 (94.9%)	<0.001*
Median (Q1, Q3) duration from HIV diagnosis to ART initiation (days)	1 (0, 4)	1 (0, 2)	0 (0, 2)	<0.001**
Median (Q1, Q3) duration from care engagement to ART initiation (days)	1 (0, 2)	0 (0, 1)	0 (0, 1)	0.001**
Follow-up visit completion	706/730 (96.7%)	157/160 (98.1%)	277/281 (98.6%)	<0.001*
In-person follow-up	706/706 (100%)	102/157 (65.0%)	179/277 (64.6%)	
Telehealth follow-up	N/A	55/157 (35.0%)	98/277 (35.4%)	
Median (Q1, Q3) duration from care engagement to successful change in facility coverage (days)	17 [14,21]	14.5 (0, 17)	0 (0, 12)	<0.001**
Referral to long-term ART maintenance facility among those with ≥ 2.5 months follow-up time				0.451*
Successful	663/706 (93.9%)	147/157 (93.6%)	254/277 (91.7%)	
Not Successful	43/706 (6.1%)	10/157 (6.4%)	23/277 (8.3%)	
Retention at month 3 among those reached month 3				0.666***
In care	678/706 (96.0%)	154/157 (98.1%)	265/277 (95.7%)	
LTFU	17/706 (2.4%)	1/157 (0.6%)	8/277 (2.9%)	
Discontinued ART	11/706 (1.6%)	2/157 (1.3%)	4/277 (1.4%)	
Retention at month 6 among those reached month 6				0.014***
In care	690/706 (97.7%)	151/157 (96.2%)	165/173 (95.4%)	
LTFU	11/706 (1.6%)	2/157 (1.3%)	8/173 (4.6%)	
Discontinued ART	5/706 (0.7%)	4/157 (2.5%)	0/173 (0%)	

*Pearson's chi-square test.
**Kruskal–Wallis equality-of-populations rank test.
***Fisher's exact test.
Abbreviations: ART, antiretroviral therapy; COVID-19, coronavirus disease 2019; LTFU, loss to follow up; Q1, the first quartile; Q3, the third quartile; SDART, same-day antiretroviral therapy.

group of ageing clients and inexperienced technology users had difficulty accessing telehealth follow-up. While the telehealth follow-up further increased the health access to some populations, it might further exacerbate health inequity in others that might be overlooked. A study conducted in the United States prior to the pandemic found that PLHIV who were on ART >10 years, had lower education, had lower income, had higher HIV stigma perception and were unfamiliar with technology were less likely to use telehealth [36]. Another recent study raised a concern regarding telehealth for those without access to high-speed internet and telephones [37]. These technological difficulties were recognized by our providers, and the option for audio-only call was posed as a backup plan for those who were unable to participate in video calls. This strategy was used in clinics in the United States as well [33,35]. Nevertheless, these technological barriers must be further addressed, such as by providing telehealth tools and training on how to use them, to ensure that everyone has the opportunities and confidence to use telehealth.

Our study reported similar proportions of clients receiving telehealth follow-up during and post-first waves of the COVID-19 epidemic. This differed from a trend analysis

Table 3. Characteristics of clients and factors associated with receiving telehealth follow-up

	In-person follow-up (*N* = 281)	Telehealth follow-up (*N* = 153)	*p*-value	Univariate logistic regression model	
				Crude OR (95% CI)	*p*-value
Age (years), Mean (SD)	31 (8.9)	30 (8.3)	0.679*	1 (0.97–1.02)	0.678
Age group			0.804**		
<25 years old	80/280 (28.6%)	42/153 (27.5%)		0.95 (0.61–1.47)	0.804
≥25 years old	200/280 (71.4%)	111/153 (72.5%)		1	–
Assigned sex at birth			0.140**		
Male	246/281 (87.5%)	126/153 (82.4%)		1	–
Female	35/281 (12.5%)	27/153 (17.6%)		1.51 (0.87–2.60)	0.142
Population			0.336**		
Heterosexual	64/281 (22.8%)	44/153 (28.8%)		1	–
MSM	199/281 (70.8%)	98/153 (64.1%)		0.72 (0.46–1.13)	0.149
TGW	18/281 (6.4%)	11/153 (7.2%)		0.89 (0.38–2.06)	0.784
Insurance			0.375***		
UCS	119/281 (42.3%)	65/153 (42.5%)		1.06 (0.68–1.63)	0.806
SSS	116/281 (41.3%)	60/153 (39.2%)		1	–
CSMBS	19/281 (6.8%)	11/153 (7.2%)		1.12 (0.50–2.50)	0.784
Pay out of pocket	25/281 (8.9%)	16/153 (10.5%)		1.24 (0.61–2.49)	0.551
No scheme	2/281 (0.7%)	1/153 (0.6%)		0.97 (0.09–10.88)	0.978
CD4 cell count group (cells/mm^3)			0.349**		
≤100	31/281 (11.0%)	20/153 (13.1%)		1.03 (0.54–1.97)	0.918
101–349	149/281 (53.0%)	70/153 (45.8%)		0.75 (0.49–1.15)	0.190
≥350	101/281 (35.9%)	63/153 (41.2%)		1	–

*Independent samples *t*-test.
**Pearson's chi-square test.
***Fisher's exact test.
Abbreviations: 95% CI, 95% confidence interval; CSMBS, Civil Servant Medical Benefit Scheme; MSM, men who have sex with men; OR, odds ratio; SD, standard deviation; SSS, Social Security Scheme; TGW, transgender women; UCS, Universal Coverage Scheme.

conducted in the United States that found a shift from heavy/moderate use of telehealth in April 2020 to minimal use in September 2020 [38]. Moreover, the linkage to care experience is critical in laying the groundwork for and facilitating engagement in care [39], and the telehealth follow-up has altered this experience. Several studies raised concerns regarding telehealth on loss of communication and support [34,36,37], and negative consequence on retention and virologic suppression [40]. Nonetheless, our results indicated that the telehealth follow-up was comparable or even superior to the in-person follow-up for the short-term outcomes (i.e. AEs, referral success and retention at months 3 and 6). Therefore, further study is needed to assess the long-term effects and usefulness of telehealth. Lastly, the feasibility of telehealth was largely due to the client-centred design and good management, as well as the coordinated and enabling policies from the local public health agencies [19,41], which were not available prior. Ongoing policies are needed to preserve and sustain this practice after the end of the pandemic [42]. Cost-effectivenessstudies are also needed to assess the scalability and facilitate advocacy for telehealth interventions for SDART.

As Thailand faced a worsened COVID-19 epidemic in 2021, less PLHIV were linked to care. This occurred particularly among those who were diagnosed at non-ART initiation facilities and those who required OI investigation and/or treatment as referral to healthcare facilities with infectious disease care and ART initiation capability became more challenging as the COVID-19 epidemic control has been prioritized over HIV treatment. Thus, while the telehealth follow-up option has shown that it allowed the continuation of SDART initiation service in 2020, more efforts are needed to adapt the ART initiation service to severe epidemic situation, such as by incorporating telehealth for ART initiation, to prevent a delay in linkage to care for PLHIV.

This study has several limitations. Although the telehealth follow-up proved feasible at a SDART initiation hub in Bangkok, this finding might not be readily applicable to other settings because the first wave of the COVID-19 epidemic in Thailand was relatively well-contained and TRCAC did not partake in COVID-19 testing and treatment actions. To translate this knowledge to other settings, the service model must be further tailored to suit specific implementation environments, including the demographic and health system factors, as well as the intensity of the local COVID-19 epidemic, to ensure implementation success. The literature we found on the integration of telehealth into HIV care services came from urban settings in developed and developing countries,

Table 4. Comparison of clinical and service outcomes of clients who received in-person and telehealth follow-up

	In-person follow-up (*N* = 281)	Telehealth follow-up (*N* = 153)	*p*-value
AEs	36/281 (12.8%)	5/153 (3.3%)	0.589*
Rash	34/36 (94.4%)	5/5 (100%)	
Dizziness	2/36 (5.6%)	0/5 (0%)	
Referral to long-term ART maintenance facility among those with 2.5 months of follow-up time			0.535**
Successful	258/281 (91.8%)	143/153 (93.5%)	
Not successful	23/281 (8.2%)	10/153 (6.5%)	
Retention at month 3 among those reached month 3			0.963*
In care	274/281 (97.5%)	150/153 (98.0%)	
LTFU	5/281 (1.8%)	2/153 (1.3%)	
Discontinued ART	2/281 (0.7%)	1/153 (0.7%)	
Retention at month 6 among those reached month 6			0.148*
In care	192/204 (94.1%)	124/126 (98.4%)	
LTFU	9/204 (4.4%)	1/126 (0.8%)	
Discontinued ART	3/204 (1.5%)	1/126 (0.8%)	

*Fisher's exact test.
**Pearson's chi-square test.
Abbreviations: AE, adverse event; ART, antiretroviral therapy; LTFU, loss to follow-up.

which could possibly be a literature bias. We chose to use a widely available and free communication application that was already installed on the smartphones of most people in Thailand for the telehealth follow-up in order to optimize the limited resources and rapidly launch the adapted service. Further service improvement should focus on the security of telehealth communication platform and the equity in accessing telehealth technology. In this analysis, we used routine service data to illustrate the real-world implementation. As a result, some data and variables were missing, especially in the during and post-first waves, as the continuation of service delivery was prioritized over the introduction and collection of new variables. An important missing variable was the reach of telehealth follow-up, which would be a useful piece of information in order to understand its demand. While the qualitative assessment revealed mostly positive feedback on the telehealth follow-up, the sample was conveniently selected and might not represent all clients and providers, particularly from those clients who did not receive telehealth follow-up. Further implementation research is needed to document the integration process in order to better translate this knowledge to other implementers.

5 | CONCLUSIONS

Timely service adaptation allowed telehealth integration into the SDART initiation service and offered follow-up options that suited the COVID-19 situation. This resulted in high SDART reach and uptake, reduced ART initiation duration and uptake of the telehealth follow-up option with favourable short-term outcomes. While its long-term outcomes must still be assessed, telehealth has safely improved accessibility to SDART initiation services during the first wave of a relatively well-contained COVID-19 epidemic in Thailand. Further service implementation should focus on increasing its inclusivity, training for quality improvement and advocacy for sustainability. Adaptation to other settings requires further tailoring to specific implementation environments to ensure success. Further SDART initiation service adaptation is also needed to allow service continuation during a more severe COVID-19 epidemic that Thailand faced in 2021.

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COMPETING INTERESTS

All authors declare no competing interests related to this work.

AUTHORS' CONTRIBUTIONS

SA and SL drafted the original manuscript. SA, SL and RR developed the analysis plan. SA, NP, ST, PS, PP, NP and RR designed and directed the study. NP, ST, CH, JS and CP implemented the service and led data collection. SA, SL, LS, TP, NP and SS analysed the data. SA, SL, NT, ST, PS, CH, JS, CP, LS, TP, NP, SS, MA, SM, PP, NP and RR read and approved the manuscript. SA and SL revised the manuscript according to comments received. SA, SL, NT, ST, PS, CH, JS, CP, LS, TP, NP, SS, MA, SM, PP, NP and RR have read and approved the final manuscript.

Table 5. Experiences of and feedback on receiving and providing telehealth follow-up

Themes	Sub-themes	Quotes
Service access and inequity	Transport challenge	"[The telehealth follow-up] was great. I lived in other province and it was inconvenient for me [to travel] to pick up my medication in Bangkok". – MSM client 1
	Time limitation	"Follow-up via video call was easy and convenient. It's suitable for people who have to travel long-distance or have limited free time. They can access the follow-up service without taking a leave from work". – MSM client 2
	Inexperienced technology users	"Sometimes the clients gave the wrong [LINE] ID or they didn't know their own ID because their children or grandchildren set it up for them.…So when we asked for their ID, they could not give it to us, and some of these clients decided they would just come to the clinic [for the in-person follow-up] instead". – Peer navigator 1
	No access to tools to conduct telehealth	"We [offered] telehealth follow-up to all clients but some clients could not choose this option because they didn't have a smartphone or internet, or they didn't have a suitable space for conducting video call, so these clients would just come to the clinic [for follow-up]". – Physician 1
	Financial burden brought by COVID-19	"Some clients had [financial] problem because the economic crisis during the COVID-19 pandemic made them short of money. There were many clients like this but they didn't tell us about their situation, and we kept reminding them [to transfer] the fee [for ART delivery] every day". – Peer navigator 1
Cost and time-saving	Reduce transport cost	"[Telehealth follow-up option] saves the overall cost for HIV treatment, including [the cost to] travel to the healthcare facility". - Administrative officer
	Reduce time spent in the clinic	"The telehealth integrated same-day ART initiation service is appropriate for the new normalcy of [service delivery during] the COVID-19 pandemic. It's very beneficial and convenient for clients … for instance, it reduces the waiting time in the clinic". – Nurse
	Reduce opportunity cost	"The pro [of telehealth follow-up visit] is that the clients don't have to take time off work, which meant that it doesn't impact with their bonus payment and doesn't cause problem for those who have just started a new job". – Peer navigator 1
Confidentiality and stigma	Privacy and confidentiality	"[The telehealth follow-up] provides a sense of privacy for people living with HIV, especially for those who don't feel comfortable going to see a physician [at the clinic] because they don't want to be around other people or are concern about running into someone they know at the clinic. Therefore, being able to consult with the physician via telehealth can help keep their secret". – Pharmacist
	Judgement from society	"ART client should have the option to receive the service that is private in order to help reduce problems of social pressure and stigma from some healthcare providers". – Peer navigator 1
	Data security	"I want to see a development of a [new telehealth] platform that we can use instead of LINE application to increase the security and anonymity [of client data]". – Physician 2
COVID-19 preventive measures	Clinic decongestion	"[Telehealth follow-up] helps reduce the number of clients in the clinic, which is appropriate for the ongoing COVID-19 pandemic". – Pharmacist
	Avoiding non-essential travel	"Telehealth follow-up stops clients from having to travel [to the clinic] and this helps improve the access to ART and medical services". – Counselor
Differentiated service delivery	Client-centred design	"We needed to find a way for clients to get their ART and receive the [medical services] as if they came to the clinic. This led to the [incorporation of] the telehealth follow-up via video call. We chose the technological tools that are widely available, which are smartphone and LINE application. If the clients could not do telehealth because they didn't have a phone or internet, they could still come to the clinic, given how small the outbreak was in our country". – Physician 1

(*Continued*)

Table 5. (Continued)

Themes	Sub-themes	Quotes
	Client preference	"During [the first wave of] COVID-19 outbreak, there was a recommendation to limit non-essential travel so many clients chose the telehealth follow-up option. After [the first wave], more clients chose to come to follow-up at the clinic. Most clients that lived in Bangkok and most clients that wanted to see a doctor face-to-face preferred to [come to the clinic] for a one-stop service, meaning [see a doctor and] refill their medication in one-go. There were not many clients that chose the telehealth follow-up after [the first wave] because many clients preferred to talk to the doctor in-person over via video call". – Peer navigator 3
Service management through teamwork	Service orchestration	"When [administrative officer's name] came into help.… she could manage everything because she understood the system and how we all worked. We [navigators] only had to…send a summary of clients in each day to her via email with the e-receipt and prescription attached…and [administrative officer's name] would work with the finance team … and the pharmacist team, so all the steps are linked … and that made a good working system". – Peer navigator 1
	Provider network	"Some clients who initiated ART on the same day but did not want to refill ART at their registered hospital [were referred to Public Health Center 28], and some clients that could not receive same-day ART initiation had to start ART at the Public Health Center 28.… Some of these clients might live in other province and the provincial borders were close [during the COVID-19 outbreak]. So, I planned with the Public Health Center 28 team … that I would mail the ART to the clients, their staff would follow up with the clients, the doctor would prescribe the medication, and the center would cover all mailing costs". – Peer navigator 2
	Difficulty scheduling a video call	"I had to mediate [between doctors and clients]. Sometimes the client was ready [for a video call] and I didn't understand why the doctor would not start the call already, or when the doctor was ready but the client wouldn't pick up the call but they just told me via LINE that they were available". – Peer navigator 1

Abbreviations: ART, antiretroviral therapy; COVID-19, coronavirus disease 2019; ID, identification; MSM, men who have sex with men.

ACKNOWLEDGEMENTS

We would like to thank all study participants for their trust in our services and to the staff members at IHRI and TRCAC who have contributed to the provision of SDART initiation service.

FUNDING

This study was supported by the US Agency for International Development (USAID) and US President's Emergency Plan for AIDS Relief (PEPFAR) through the Linkages Across the Continuum of HIV Services for Key Populations cooperative agreement (AID-OAA-A-14-0045) managed by FHI 360.

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SUPPORTING INFORMATION

Additional information may be found under the Supporting Information tab for this article:
Appendix S1. Interview questions

McGinnis KA et al. *Journal of the International AIDS Society* 2021, **24**(S6):e25810
http://onlinelibrary.wiley.com/doi/10.1002/jia2.25810/full | https://doi.org/10.1002/jia2.25810

RESEARCH ARTICLE

HIV care using differentiated service delivery during the COVID-19 pandemic: a nationwide cohort study in the US Department of Veterans Affairs

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Abstract

Introduction: The Department of Veterans Affairs (VA) is the largest provider of HIV care in the United States. Changes in healthcare delivery became necessary with the COVID-19 pandemic. We compared HIV healthcare delivery during the first year of the COVID-19 pandemic to a prior similar calendar period.

Methods: We included 27,674 people with HIV (PWH) enrolled in the Veterans Aging Cohort Study prior to 1 March 2019, with ≥1 healthcare encounter from 1 March 2019 to 29 February 2020 (2019) and/or 1 March 2020 to 28 February 2021 (2020). We counted monthly general medicine/infectious disease (GM/ID) clinic visits and HIV-1 RNA viral load (VL) tests. We determined the percentage with ≥1 clinic visit (in-person vs. telephone/video [virtual]) and ≥1 VL test (detectable vs. suppressed) for 2019 and 2020. Using pharmacy records, we summarized antiretroviral (ARV) medication refill length (<90 vs. ≥90 days) and monthly ARV coverage.

Results: Most patients had ≥1 GM/ID visit in 2019 (96%) and 2020 (95%). For 2019, 27% of visits were virtual compared to 64% in 2020. In 2019, 82% had VL measured compared to 74% in 2020. Of those with VL measured, 92% and 91% had suppressed VL in 2019 and 2020. ARV refills for ≥90 days increased from 39% in 2019 to 51% in 2020. ARV coverage was similar for all months of 2019 and 2020 ranging from 76% to 80% except for March 2019 (72%). Women were less likely than men to be on ARVs or to have a VL test in both years.

Conclusions: During the COVID-19 pandemic, the VA increased the use of virtual visits and longer ARV refills, while maintaining a high percentage of patients with suppressed VL among those with VL measured. Despite decreased in-person services during the pandemic, access to ARVs was not disrupted. More follow-up time is needed to determine whether overall health was impacted by the use of differentiated service delivery and to evaluate whether a long-term shift to increased virtual healthcare could be beneficial, particularly for PWH in rural areas or with transportation barriers. Programmes to increase ARV use and VL testing for women are needed.

Keywords: COVID-19; extended refills; HIV; veterans; virtual visits

Received 18 March 2021; **Accepted** 19 August 2021

1 | INTRODUCTION

The United States (US) Department of Veterans Affairs (VA) provides healthcare at no or low cost to eligible veterans and is delivered mainly through VA clinics and facilities. The VA benefits from one of the most highly developed health information systems in the world [1] and is one of the first US healthcare systems to create extensive virtual healthcare infrastructure including telephone and video visits (henceforth referred to as "virtual") [2,3]. With the emergence of the COVID-19 pandemic, changes in healthcare delivery became immediately necessary [4,5], and the VA responded quickly by expanding virtual care [2,6–10]. On 19 March 2020, the VA issued guidance for "Alternative Telehealth Communication Technologies During COVID19 National Emergency" [11]. This guidance outlined the preferred modes of communication including VA Video Connect and government-furnished phones, and also allowed for the use of alternative technologies to "augment clinical activities related to providing care to patients" during

the COVID-19 pandemic [11]. By June 2020, 58% of VA visits were virtual compared to 14% prior to March 2020 [12].

The VA is the largest provider of HIV care in the United States [1,13]. People with HIV (PWH) need consistent HIV healthcare engagement to maintain antiretroviral (ARV) medication adherence and HIV-1 plasma RNA viral load (VL) suppression [14–16]. Substance use screening is also an important component of HIV care [17]. Since 2015, the World Health Organization has promoted "differentiated service delivery" for PWH to simplify access to care and to reduce time spent in healthcare facilities [18]. One study reported that 5% of PWH at three VA sites used telehealth during the 3–4 years prior to the COVID-19 pandemic [19]. The pre-pandemic criteria for virtual visits prioritized patients who were virologically suppressed but had transportation or clinic distance challenges.

During in-person visits, patients are typically screened by support staff annually about health related items including alcohol and tobacco use [20] prior to seeing the clinician. In contrast, during virtual visits clinicians are expected to administer these screenings in addition to adjusting to the use of technology and any corresponding trouble-shooting issues for themselves or patients [2]. For those who utilize alcohol and tobacco use data collected via screenings, this transition to increased use of virtual visits during the COVID-19 pandemic could potentially lead to gaps in information and care.

Among women receiving HIV care within the VA, a lower percentage had ARV coverage and suppressed VL compared to men with HIV [21], and some studies have identified an association between race/ethnicity and lower virtual healthcare use [22]. Whether the impact of the COVID-19 pandemic on HIV healthcare varies by race/ethnicity and/or gender is unknown.

Understanding how the pandemic has impacted HIV healthcare service utilization, ARV adherence and substance use disorder screening can inform efforts to maintain continuity of care for PWH and other chronic health conditions using differentiated service delivery. More specifically, examining the impact of healthcare changes for PWH may provide broader insights into the implications of virtual care models for other chronic diseases as well as for maximizing healthcare resources and/or helping overcome barriers to care such as distance to clinic and/or lack of mobility or transportation [5]. Our main goals were to compare among PWH during and prior to the COVID-19 pandemic: (1) HIV healthcare delivery and (2) frequency of alcohol and tobacco use screening. Secondary aims included (1) comparing HIV healthcare delivery by race/ethnicity and gender and (2) evaluating diagnoses for alcohol use disorder (AUD) and tobacco use/smoking during and prior to the pandemic.

2 | METHODS

2.1 | Data source – Veterans Aging Cohort Study

The Veterans Aging Cohort Study (VACS) is a national cohort of 60,055 PWH and 125,122 age-matched, race/ethnicity-matched, sex-matched and clinical site-matched people without HIV who were identified in the US VA electronic health record in the fiscal years 1997–2020 using a modified existing algorithm [1]. Data were extracted from the VA Corporate Data Warehouse, a national repository that incorporates data from clinical and administrative systems into a data warehouse structure [23]. This study was approved by the Institutional Review Boards of the VA Connecticut Healthcare System and Yale University School of Medicine and has been granted a waiver of informed consent.

Within VACS, we identified PWH who entered care prior to 1 March 2019 with evidence of at least one outpatient VA healthcare encounter of any type including, but not limited to, general medicine (GM), infectious disease (ID), emergency care, mental health, pharmacy and laboratory from 1 March 2019 to 28 February 2021, and were alive at the end of the study period (28 February 2021). Due to the emerging body of evidence regarding health needs for persons infected with SARS-CoV-2, we excluded 1524 PWH who had an indication of a positive SARS-CoV-2 PCR laboratory test up to 28 February 2021. The analytic sample included 27,674 PWH.

2.2 | Variable definitions

Age, race/ethnicity and sex were determined as of 1 March 2019. We identified GM/ID clinic visits related to HIV primary care (VA clinic stop codes: 27, 170, 172, 301, 310, 318, 319, 323, 324, 338, 348, 349, 350, 311). Virtual (video or telephone) visits were determined based on methodology adapted from Ferguson and colleagues [12]. HIV-1 RNA VL was categorized as suppressed (≤50 copies/ml), detectable (>50 copies/ml) and not measured. ARV pharmacy fill/refill length was categorized as <60, 60–89 and ≥90 days.

We identified PWH who were screened with the Alcohol Use Disorder Identification Test-Consumption (AUDIT-C) and for tobacco use history via the clinical reminder system [19,20]. Unhealthy alcohol use was based on AUDIT-C ≥ 4 for men or ≥3 for women [24]. Tobacco use was identified as current, past or never based on responses to two clinical reminder questions: "Do you smoke cigarettes or use tobacco every day, some days, or not at all"?; and those who responded "not at all" were asked about former or never use. For those with multiple responses per year, we used the response representing the highest level of use. Additionally, we identified for each year those with at least one outpatient International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10) diagnosis code for AUD using codes F10.1x, F10.2x [25] or tobacco use/smoking using codes Z72.0x, F17.21, Z87.891.

2.3 | Analyses

For each month of 1 March 2019 to 29 February 2020 (2019) and 1 March 2020 to 28 February 2021 (2020), we summarized counts of GM/ID clinic visits (in-person vs. virtual), HIV-1 RNA VL tests, ARV prescriptions by length, AUDIT-C administered and tobacco use responses collected. We also calculated the percentage of patients with ARV coverage for each month based on prescription fill dates, days, supply and an additional half day supply was added to approximate lag time and overlap of fills.

For each period in 2019 and 2020 we calculated the percentage of individuals with ≥1 clinical encounter (by type),

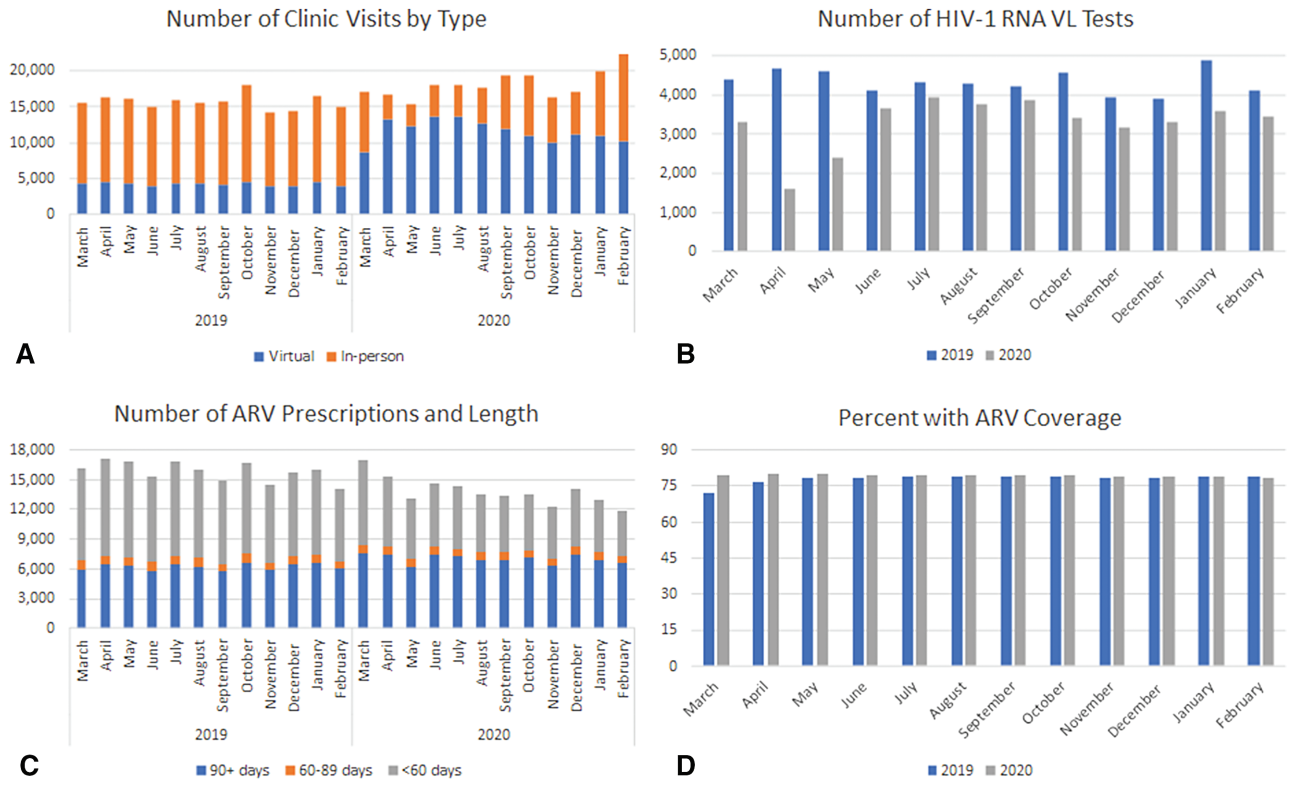

Figure 1. Healthcare services among 27,674 PWH in 2019 and 2020
ARV, antiretroviral therapy; VL, viral load; 2019, 1 March 2019 to 28 February 2020; 2020, 1 March 2020 to 29 February 2021.

≥1 HIV-1 RNA VL test (by detectable/suppressed) and any ARV use. We determined whether having ≥1 clinical encounter, ≥1 HIV-1 RNA VL test, or any ARV use varied by race/ethnicity and gender. Additionally, we calculated the percentage screened for AUDIT-C and tobacco use along with corresponding responses for each year. Lastly, we calculated the percentage with an ICD-10 diagnosis for alcohol use disorder (AUD) or smoking/tobacco use for each year.

3 | RESULTS

Of the 27,674 PWH enrolled in VACS prior to March 2019 and with at least one healthcare encounter in 2019 or 2020, the median age was 59 years (range = 23–97), 96% were men, 45% non-Hispanic Black (Black), 35% non-Hispanic White (White), 8% Hispanic, 3% other (American Indian, Asian, Pacific Islander or mixed race) and 9% unknown (Table 1). Almost everyone had at least one healthcare encounter of any type in 2019 (99%; 27,493) and 2020 (98%; 27,107). For all months except May, there were more visits in 2020 than in 2019 (Figure 1a). The transition to a higher percentage of virtual visits started in March 2020 and continued throughout February 2021 (Figure 1a). In 2019, 27% of visits were virtual compared to 64% in 2020. Of the virtual visits, 99% and 92% were by telephone (vs. video) in 2019 and 2020, respectively. Considering GM/ID clinics specifically, almost all patients had at least one virtual or in-person GM/ID clinic visit in 2019 (96%) and 2020 (95%) and this was similar for those of Black, White and Hispanic race/ethnicity and for men and women. For those of other or unknown race/ethnicity, the percentage with at least one GM/ID encounter in 2020 was slightly lower – 93% and 91%, respectively (Table 2). Compared to men, women were less likely to have in-person visits (91% vs. 95% in 2019 and 77% vs. 80% in 2020) and more likely to have virtual visits (62% vs. 57% in 2019 and 92% vs. 89% in 2020). Having any GM/ID clinic visits was similar by gender in both years ranging from 94% to 96% (Table 2).

There were fewer HIV-1 RNA VL tests in 2020, particularly in the months of April and May (Figure 1b). In 2019, 82% had VL measured compared to 74% in 2020. Of those with VL measured, 92% and 91% had suppressed VL in 2019 and 2020, respectively. The percentage of PWH with VL measured in 2019 was similar among those of Black, White and other race/ethnicity (82%–83%), and slightly higher among Hispanic PWH (86%) and lower among those with unknown race/ethnicity (70%). The pattern was similar for 2020; the percentage with VL in 2020 was similar among those of Black, White and other race/ethnicity (73%–75%), and slightly higher among Hispanic PWH (78%) and lower among those with unknown race/ethnicity (63%) (Table 2). Compared to men, women were less likely to have VL measured in 2019 (73% vs. 82%) and 2020 (67% vs. 74%) (Table 2).

Table 1. Characteristics of people with HIV in the Veterans Aging Cohort Study (*n* = 27,674)

Characteristics		
Mean age in years (SD)	59 (12.1)	
Race/ethnicity (%)		
Black	45	
White	35	
Hispanic	8	
Other	3	
Unknown	9	
Gender (%)		
Men	96	
Women	4	
	Year	
HIV healthcare (%)	2019	2020
GM/ID visit		
Any	96	95
In person	95	80
Virtual	57	89
HIV-1 RNA VL test detectable	6	7
HIV-1 RNA VL test suppressed	76	67
No test	18	26
On ARVS	85	84
Alcohol use (%)		
AUDIT-C – clinical reminder		
0 (no use)	35	29
1–3/1–4 (some use)	30	23
>3/>4 (unhealthy use)	10	7
Not asked	25	40
Alcohol use disorder diagnosis	11	9
Tobacco use/smoking (%)		
Clinical reminder		
Current	27	20
Past	23	19
Never	24	21
Not asked	26	40
Diagnosis	20	18

Abbreviations: ARV, antiretroviral therapy; AUDIT-C, Alcohol use disorder identification test-consumption; GM/ID, general medicine/infectious diseases; SD, standard deviation; VL, HIV-1 RNA viral load; 2019, 1 March 2019 to 28 February 2020; 2020, 1 March 2020 to 29 February 2021.

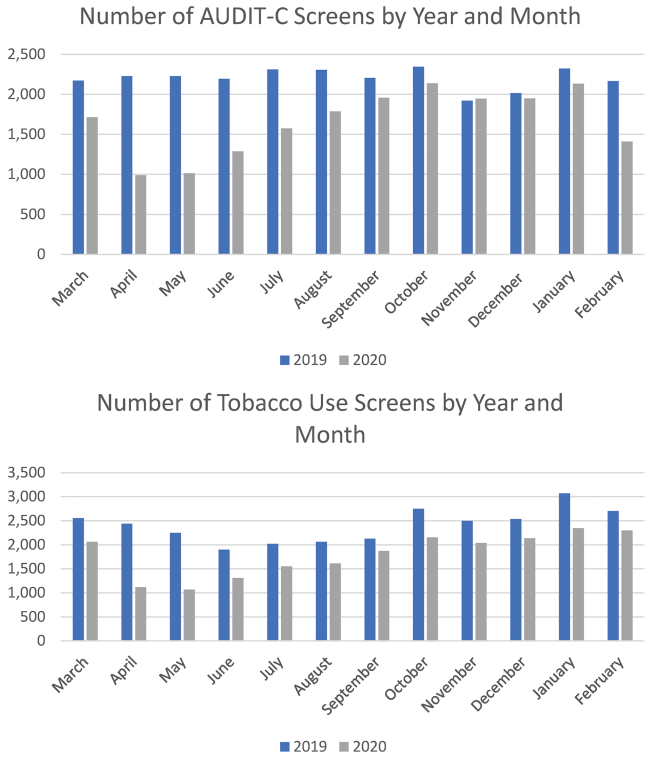

Figure 2. Screening for alcohol and tobacco use among 27,674 PWH in 2019 and 2020
AUDIT-C, Alcohol Use Disorder Identification Test-Consumption; 2019, 1 March 2019 to 28 February 2020; 2020, 1 March 2020 to 29 February 2021.

There were fewer ARV refills in all months of 2020 compared to 2019 except for in March. However, the percentage with a refill of ≥90 days was higher for all months in 2020 (Figure 1c). Overall, in 2020 51% of refills were for ≥90 days compared to 39% in 2019. Even though there was a lower number of refills in 2020 compared to 2019, because average prescription length was longer, ARV coverage was similar for all months of 2019 and 2020, ranging from 76% to 80% for all months except for March 2019 (72%) (Figure 1d). In 2019 and 2020, 85% and 84% had any ARV use, respectively. The percentage with ARV coverage was similar for those of Black, White, Hispanic and other race/ethnicity for both 2019 and 2020 (ranging from 85% to 86%). For those of unknown race/ethnicity, only 75% had any ARV use in both years (Table 2). Women were less likely than men to have ARV coverage in 2019 (75% vs. 85%) and 2020 (74% vs. 85%). There was little change in ARV coverage for either gender during the study period (Table 2).

AUDIT-C was collected less frequently for all months in 2020 compared to 2019, but only slightly less frequently in November and December (Figure 2). The AUDIT-C was completed for 75% of PWH in 2019 and 60% in 2020 (Table 1). In 2019, 10% had an AUDIT-C score indicating unhealthy alcohol use compared to 7% in 2020. In 2019, of those who only had a virtual visit, 25% had AUDIT-C responses compared to 73% of those with only an in-person visit. However, in 2020 the percentage with AUDIT-C responses was similar for those with only virtual compared to only in-person visits (44% vs. 46%). In 2019, 10% had an AUD diagnosis compared to 8% in 2020.

Tobacco use was collected less frequently for all months in 2020 compared to 2019 (Figure 2). The tobacco use items collected through the clinical reminder system were completed for 74% in 2019 and 60% in 2020. In 2019, 27% reported current tobacco use and 23% past tobacco use; in 2020, 20% reported current tobacco use and 19% reported

Table 2. HIV healthcare by race/ethnicity and gender in 2019 and 2020 (*n* = 27,674)

		GM/ID visit						VL		On	
		Any (%)		In person (%)		Virtual (%)		Measured (%)		ARVs (%)	
Race/ethnicity	*N*	2019	2020	2019	2020	2019	2020	2019	2020	2019	2020
Black	12,577	96	95	96	81	56	90	83	75	85	85
White	9759	96	95	96	81	59	90	82	75	86	85
Hispanic	2167	96	95	95	82	60	91	86	78	86	86
Other	713	96	93	94	78	60	87	83	73	86	85
Unknown	2485	93	91	91	71	53	84	70	63	75	75
Gender											
Men	26,661	96	95	95	80	57	89	82	74	85	85
Women	1013	94	95	91	77	62	92	73	67	75	74

Abbreviations: ARV, antiretroviral therapy; GM/ID, general medicine/infectious diseases; VL, HIV-1 RNA viral load; 2019, 1 March 2019 to 28 February 2020; 2020, 1 March 2020 to 29 February 2021.

past tobacco use (Table 1). In 2019, of those with only virtual visits, 21% had any tobacco use responses compared to 72% of those with only an in-person visit. However, in 2020 the percentage with tobacco use information was more similar for those with only virtual compared to only in-person visits (46% vs. 44%). In 2019, 17% had a tobacco use diagnosis compared to 15% in 2020.

4 | DISCUSSION

In response to the COVID-19 pandemic, the US VA ramped up the use of virtual visits (over 90% of virtual visits were telephone based) and increased refill length for ARVs for PWH. Despite a lower level of in-person care and HIV-1 RNA VL tests during the pandemic, the percentage with suppressed HIV-1 RNA VL remained similar (among those for whom it was measured) and access to ARVs was maintained. HIV healthcare before and during the pandemic was similar for those of Black, White, Hispanic and other race/ethnicities and for men and women. However, alcohol and tobacco use screening occurred less frequently among PWH with the increased use of virtual care during the pandemic.

The finding of increased virtual visits for PWH from 27% in 2019 to 64% in 2020 is consistent with findings of other (non-HIV specific) studies earlier in the pandemic [2,12] as well as with VA guidance and support in the form of additional training and tablets that were provided for virtual visits. Ferguson et al. reported that virtual visits increased from 14% prior to COVID-19 to 58% in June 2020; they also noted that virtual visits were more common among those with higher clinical or social needs [12]. During the pandemic, the VA Central Office recommended that newly diagnosed PWH with an opportunistic infection, low CD4 count, or serious ARV adverse event should be seen in an expedited matter in-person or virtually, depending on patient preference. In-person visits in ID clinics were restricted to patients with urgent care needs without COVID-19 symptoms, patients presenting for same day ARV and routinely scheduled patients who were considered high risk (e.g., active opportunistic infections, high VL and low CD4 count).

The number of VL tests was particularly low in April and May 2020 (early in the pandemic). While routine VA laboratory testing was available throughout the pandemic, but with a transition from mostly "walk-in" phlebotomy in close quarters to socially distanced appointments and limited to provider-defined essential blood draws early in the pandemic.

While the number of ARV prescriptions was lower in 2020 compared to 2019, the percentage of prescriptions over 90 days was greater in 2020 compared to 2019. ARV prescriptions were refilled automatically (mostly via mail service) regardless of prior appointment attendance (encouraged but not mandatory) or whether laboratory testing was done. The VA has one of the most highly rated prescription mail order services that was providing around 80% of VA outpatient medications even before the start of the COVID-19 pandemic [26,27]. This differentiated service delivery likely contributed to ARV coverage being maintained throughout the pandemic.

Several studies have reported that those of Black and Hispanic race/ethnicity have been disproportionately negatively impacted by COVID-19 with regard to testing, positivity rates and the vaccine rollout [28–30]. In this study of PWH receiving care in the VA, we found that HIV care during and prior to the COVID-19 pandemic was similar by race/ethnicity except for those of unknown race/ethnicity and this is consistent with a previous study that reported that HIV clinical management and adherence in the VA was similar by race/ethnicity [31]. Because having unknown race/ethnicity in the VA is also associated with having fewer VA visits, this finding is difficult to interpret, but may suggest less engagement in VA care.

While having any type of GM/ID visit was similar during and prior to the COVID-19 pandemic and by gender, we did identify differences in HIV care by gender. During both time periods, women were less likely than men to have in-person GM/ID visits, to have VL measured and to be covered by ARVs. This finding is consistent with a previous study of the HIV care continuum using US VA data [21].

AUDIT-C and smoking/tobacco use screenings were administered to a substantially lower percentage of PWH during the COVID-19 pandemic. Before the pandemic, clinical staff usually administered the screenings during in-person visits. It is likely that during the pandemic, in-person visits were

more focused on urgent issues and, therefore, routine screening questionnaires may not have been administered as frequently (this could be similarly true for virtual visits in 2019). Early in the pandemic, nurses triaged and screened only in-person visits, leaving providers to add these screenings to their workflow. These findings indicate that providers were able to adapt to administering the screenings during virtual visits without the same level of support staff. This is likely emblematic of a rapid uptake of virtual care modalities to replace in-person visits in 2020, as opposed to ad hoc, urgent or interim virtual assessments in 2019, which would be less likely to include routine preventive healthcare. Alcohol and tobacco use screening was done less frequently in 2020 during both in-person and virtual visits and this represents an important area for improvement.

Later in the pandemic, nurses started calling, triaging and screening patients before virtual visits. However, the timing and process for this change likely varied by site, may not be reflected in these data, and warrants follow-up research. Although providers took on the additional workload of administering the alcohol/tobacco screenings during virtual visits, this may not be an efficient or effective use of time in the long term. Integrating the use of support staff during virtual visits may be a way to improve screening. While ARV coverage was maintained during the pandemic, the lower frequency of substance use screening may have deleterious implications for other preventive care measures and to overall health outcomes in the coming months–years.

This study has some limitations. We excluded 2689 people who died or tested positive for SARS-CoV-2 during the study timeframe, which could have excluded PWH who were particularly vulnerable. Compared to those excluded, the 27,674 included were slightly more likely to be women (3.7% vs. 2.9%), younger (mean = 58.7 vs. 61.1 years) and less likely to be of Black race (45% vs. 51%). Most of the PWH are men so results for women may not generalize to non-VA PWH populations. However, we believe these concerns are addressed in the results by race/ethnicity and gender (Table 2). The similar percentage with detectable HIV-1 RNA VL between 2019 and 2020 should be interpreted with caution because there is a higher percentage without measured VL in 2020 and missing VL may be associated with lower ARV use. Additional follow-up time is needed to determine whether those without a VL measurement in 2020 are of similar health status as those without a VL measurement in 2019. However, it is reassuring that ARV coverage is similar before and during the pandemic and suggests that aspects of the differentiated service delivery during the COVID-19 pandemic may be worth continuing post-pandemic. Of note, ARV coverage was lower for March 2019 than for any other month, and we surmise this is because we included those identified in VACS up to 1 March 2019 and there are likely some PWH who were new to HIV care up to this date.

5 | CONCLUSIONS

With the emergence of the COVID-19 pandemic, the US VA substantially increased the use of virtual (mostly telephone) visits and longer refills (mostly by mail) for ARVs, maintaining a high percentage of patients with suppressed VL among those with VL measured. Despite a lower level of in-person services for PWH during the pandemic, access to ARVs was not disrupted. More observation time is needed to determine whether the health of PWH, measured by VL suppression, CD4 cell count, comorbidity diagnoses and other long-term outcomes, was impacted by the differentiated service delivery and to evaluate whether a long-term shift to increased use of virtual healthcare could be beneficial, particularly for those in rural areas or with transportation barriers. Findings could have long-term implications for more efficient HIV care in general, perhaps involving longer prescription fills, greater use of mail in prescription services, fewer in-person visits and less frequent VL tests.

Future research should evaluate whether newly diagnosed PWH had more challenges achieving VL suppression during the COVID-19 pandemic. In the short term, it is reassuring that the level of GM/ID visits and ARV use remained consistent and that healthcare during this period of the US COVID-19 pandemic was similar for PWH of Black, White, Hispanic and other race/ethnicities. However, a concerning finding is that ARV use and VL testing were lower for women than men both before and during the pandemic. Further studies are needed to evaluate the assessment of and treatment for HIV and substance use during the COVID-19 pandemic.

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COMPETING INTERESTS

VCM received research grants from Gilead Sciences and ViiV, and served as an advisory board member for Eli Lilly and Company and Novartis. Otherwise, the authors declare that they have no competing interests.

AUTHORS' CONTRIBUTIONS

KAM, ACJ, KMA, JPT, JTKJr, CTR, VCM, EH, FK and RY contributed to the conception and design MS, LSP and FK were responsible for data acquisition. KAM, ACJ, KMA, JPT, JTKJr, EH, CT R, JE and LS Park contributed to the analysis and interpretation. All authors contributed to the first draft or to critical edits and revisions of a subsequent draft. All authors have approved the final version of the manuscript and have agreed to be accountable to all aspects of the work.

ACKNOWLEDGEMENTS

We sincerely thank Dr Erica Abel and Dr Abeer Moanna for providing valuable information regarding changes to VA healthcare in response to the COVID-19 pandemic.

FUNDING

This study was funded by the National Institute on Alcohol Abuse and Alcoholism (grants U24-AA020794, U01-AA020790 and U10-AA013566-completed), Emory University Center for AIDS Research (grant P30AI050409) and the United States Department of Veterans Affairs Health Services Research & Development (grant C19 21-287). The funders of this study had no role in study design, data collection, analysis, interpretation and presentation or in the decision to submit the

manuscript for publication. Views presented in the manuscript are those of the authors and do not reflect those of the Department of Veterans Affairs, or the US Government.

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JIAS JOURNAL OF THE INTERNATIONAL AIDS SOCIETY

SHORT REPORT

Community-based differentiated service delivery models incorporating multi-month dispensing of antiretroviral treatment for newly stable people living with HIV receiving single annual clinical visits: a pooled analysis of two cluster-randomized trials in southern Africa

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Abstract

Introduction: Differentiated service delivery (DSD) models for HIV treatment decrease health facility visit frequency and limit healthcare facility-based exposure to severe acute respiratory syndrome coronavirus 2. However, two important evidence gaps include understanding DSD effectiveness amongst clients commencing DSD within 12 months of antiretroviral treatment (ART) initiation and amongst clients receiving only single annual clinical consultations. To investigate these, we pooled data from two cluster-randomized trials investigating community-based DSD in Zimbabwe and Lesotho.

Methods: Individual-level participant data of newly stable adults enrolled between 6 and 12 months after ART initiation were pooled. Both trials (conducted between August 2017 and July 2019) had three arms: Standard-of-care three-monthly ART provision at healthcare facilities (SoC, control); ART provided three-monthly in community ART groups (CAGs) (3MC) and ART provided six-monthly in either CAGs or at community-distribution points (6MC). Clinical visits were three-monthly in SoC and annually in intervention arms. The primary outcome was retention in care and secondary outcomes were viral suppression (VS) and number of unscheduled facility visits 12 months after enrolment. Individual-level regression analyses were conducted by intention-to-treat specifying for clustering and adjusted for country.

Results and Discussion: A total of 599 participants were included; 212 (35.4%), 128 (21.4%) and 259 (43.2%) in SoC, 3MC and 6MC, respectively. Few participants aged <25 years were included (n = 32). After 12 months, 198 (93.4%), 123 (96.1%) and 248 (95.8%) were retained in SoC, 3MC and 6MC, respectively. Retention in 3MC was superior versus SoC, adjusted risk difference (aRD) = 4.6% (95% CI: 0.7%–8.5%). Retention in 6MC was non-inferior versus SoC, aRD = 1.7% (95% CI: −2.5%–5.9%) (prespecified non-inferiority aRD margin −3.25%). VS was similar between arms, 99.3, 98.6 and 98.1% in SoC, 3MC and 6MC, respectively. Adjusted risk ratio's for VS were 0.98 (95% CI: 0.92–1.03) for 3MC versus SoC, and 0.98 (CI: 0.95–1.00) for 6MC versus SoC. Unscheduled clinic visits were not increased in intervention arms: incidence rate ratio = 0.53 (CI: 0.16–1.80) for 3MC versus SoC; and 0.82 (CI: 0.25–2.79) for 6MC versus SoC.

Conclusions: Community-based DSD incorporating three- and six-monthly ART refills and single annual clinical visits were at least non-inferior to standard facility-based care amongst newly stable ART clients aged ≥25 years.
ClinicalTrials.gov: NCT03238846 & NCT03438370

Keywords: antiretroviral treatment; cluster-randomized trial; COVID-19; differentiated service delivery; multi-month dispensing; operational research

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

Received 9 March 2021; **Accepted** 24 August 2021

1 | INTRODUCTION

Multi-month dispensing (MMD) of antiretroviral treatment (ART) is a component of a number of differentiated service delivery (DSD) models that extends the period between ART refills to three- or six-monthly [1]. MMD increases the efficiency of overburdened health systems in resource-limited settings and is preferred by ART clients as the burden and costs of frequent facility visits are reduced [2,3]. In the COVID-19 era, reducing facility visit frequency and enabling ART receipt outside of health facilities are crucial DSD adaptations to safeguard both ART clients and healthcare workers from severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection [4,5]. Safely scaling-up DSD to as great a number of ART clients as possible in resource-limited settings with high HIV prevalence is an urgent priority for health systems facing both pandemics of HIV and COVID-19 [4].

DSD models incorporating MMD have recently been found to be non-inferior to standard-of-care ART provision in three cluster-randomized trials (CRTs) in southern Africa [6–8]. However, in these and other studies, participants received ART for prolonged time periods before commencing DSD (up to median 7 years) with very few who initiated DSD within 12 months of ART initiation [7,9–11]. Without empirical evidence being available, it is currently unclear whether the safety and effectiveness of DSD is generalizable to newly stable clients within 12 months of ART initiation [12]. In some countries, eligibility to receive DSD and MMD has been reduced to 6 months from ART initiation; however, MMD eligibility remains at 12 months after ART initiation according to national policy in many sub-Saharan African countries and India [13]. Defining these eligibility criteria has important consequences for ART clients, noting that inadequate time since ART initiation was the most frequent reason for ineligibility for MMD in a recent study from Zambia and Malawi [14].

Regarding the frequency of clinical visits, the World Health Organization (WHO) currently recommends that clinical visits be offered three- to six-monthly for people established on ART [15]. Some countries have, however, reduced health facility visit frequency to only once annually (including in a CRT from South Africa [7]), which limits potential SARS-CoV-2 exposure and reduces burdens and costs for health systems and ART clients [16]. However, little randomized evidence regarding the safety and effectiveness of single annual clinical visits for newly stable ART clients is available. To investigate the effectiveness of community-based DSD for ART clients initiating DSD specifically within 12 months of ART initiation with single annual facility visits, we pooled data from two large operational research CRTs investigating DSD to increase the sample of newly stable participants.

2 | METHODS

Individual-level participant data (IPD) from two CRTs in Zimbabwe and Lesotho were pooled. The aim of both trials was to assess whether community-based DSD models incorporating MMD are non-inferior to standard-of-care facility-based ART provision for stable ART patients. The trials were conceptualized and implemented concurrently, had similar protocols, similar inclusion criteria, similar intervention and control arms, and similar hypotheses and outcomes, thus, data from the trials were suitable for pooling. The trials are described in detail elsewhere [6,8,17,18]. Briefly, both trials were three-arm, parallel, unblinded, pragmatic, non-inferiority CRTs. Each arm in both trials consisted of ten health facilities (clusters) as follows:

- **Control arm (SoC)**: Participants received standard-of-care ART and clinical consultations at three-monthly intervals at facilities.
- **Intervention arm 1 (3MC)**: Participants received ART at three-monthly intervals in community ART groups (CAGs) with annual facility visits and clinical consultations.
- **Intervention arm 2 (6MC)**: Participants received ART at six-monthly intervals in CAGs (Zimbabwe) or community distribution points (Lesotho) with annual facility visits and clinical consultations.

Study facilities (n = 60) were public health facilities in eight districts of the two countries. Clusters were allocated to the arms in each country with randomization stratified by urban/rural location and hospital/primary healthcare clinic. Adults (≥18 years) were eligible for enrolment if they were stable on ART, defined as receiving standard first-line ART for ≥6 months and having a suppressed viral load (VL) (<1000 copies/mL) within the last 12 months, without active opportunistic infections or comorbidities requiring facility visits more frequently than six-monthly, and who were not pregnant or postpartum. Recruitment commenced in August 2017 and follow-up was completed in July 2019. In Zimbabwe and Lesotho, national ART guidelines had recently been modified to allow ART clients to be eligible for DSD from 6 months after ART initiation, which differed from the prevailing WHO guidelines which recommended DSD eligibility from 12 months after ART initiation [19]. As we were specifically interested in outcomes amongst those who enrolled ≤12 months following ART initiation, analyses were restricted to those who initiated ART between 6 and 12 months previously.

The model of care for each arm is given in detail in Table S1. After 12 months, all participants were scheduled to receive a clinical consultation, VL testing and ART supply at the facility, where VL results were reported as unsuppressed, patients were recalled to the clinics. The trials were embedded in routine healthcare services with no interference by study staff in the healthcare models.

The primary outcome was the proportion remaining in ART care 12 months after enrolment by intention-to-treat including participants in each arm as per baseline allocation. Retention in care is a critical indicator of ART program success [20]. The principal hypothesis was that retention for both intervention arms would be non-inferior versus control (SoC) with a non-inferiority margin of −3.25% (risk difference [RD]), as per the original trials. Secondary outcomes were proportions achieving viral suppression (VS) after 12 months, and the number of unscheduled facility visits between months 0 and 12. As VL testing infrastructure scale-up was incomplete in these countries during the study, VS was a secondary

Table 1. Characteristics of participants at enrolment according to study arm

	SoC (control) (n = 212)	3MC (n = 128)	6MC (n = 259)	All participants (n = 599)
Age (years), median (IQR)	38.6 (32.2–48.1)	42.6 (35.7–50.7)	39.8 (32.1–49.6)	39.8 (32.8–49.6)
Age categories, n (%)				
18–24 years	15 (7.1)	4 (3.1)	13 (5.0)	32 (5.3)
25–49 years	151 (71.2)	91 (71.1)	189 (73.0)	431 (72.0)
≥ 50 years	46 (21.7)	33 (25.8)	57 (22.0)	136 (22.7)
Female, n (%)	118 (55.7)	96 (75.0)	167 (64.5)	381 (63.6)
Duration from ART initiation to study enrolment, months, median (IQR)	10.5 (8.9–11.6)	9.8 (8.2–11.3)	10.5 (9.1–11.5)	10.4 (8.7–11.5)
Time from HIV diagnosis to ART initiation, months, median (IQR)	0 (0–1.7)	0 (0–20.2)	0 (0–5.5)	0 (0–2)
WHO clinical stage				
Stage I or II	184 (86.8)	105 (82.0)	206 (79.5)	495 (82.6)
Stage III	23 (10.9)	19 (14.8)	51 (19.7)	93 (15.5)
Not recorded	5 (2.4)	4 (3.1)	2 (0.8)	11 (1.8)
CD4 cell count, cells/μL, median (IQR)	485 (289–654)	460.5 (310–716)	513.5 (318–640)	486 (306–654)
Weight, kg, median (IQR)	60.8 (55–67)	62 (54.7–74.9)	60.8 (54–70)	61 (54.3–69.8)
Year of ART initiation, median (IQR)	2016 (2016–2017)	2017 (2016–2017)	2017 (2016–2017)	2017 (2016–2017)
Disclosed HIV status, n (%)	200 (94.3)	119 (93.0)	246 (95.0)	565 (94.5)
Unemployed, n (%)	123 (58.0)	77 (60.2)	125 (48.3)	325 (54.4)
Married, n (%)	121 (57.1)	61 (47.7)	154 (59.5)	336 (56.2)
Currently drinks alcohol, n (%)	47 (22.2)	18 (14.1)	48 (18.5)	113 (18.9)
Facility type				
Primary healthcare clinic, n (%)	151 (71.2)	108 (84.3)	181 (69.9)	440 (73.5)
Hospital-based facility, n (%)	61 (28.8)	20 (15.6)	78 (30.1)	159 (26.5)
Location				
Rural, n (%)	153 (72.2)	70 (54.7)	211 (81.5)	434 (72.5)
Urban, n (%)	59 (27.8)	58 (45.3)	48 (18.5)	165 (27.5)
Country				
Lesotho, n (%)	118 (55.7)	51 (39.8)	150 (57.9)	319 (53.3)
Zimbabwe, n (%)	94 (44.3)	77 (60.2)	109 (42.1)	280 (46.7)

SoC-participants received three-monthly dispensing of ART at the facility. 3MC-participants received 3 months' supply of ART in community ART groups (CAGs). 6MC-participants received 6 months' supply of ART in CAGs or at community distribution points. ART: antiretroviral treatment; IQR: interquartile range; WHO: World Health Organization.

outcome and we used participants with available VL results as the denominator for VS analyses.

Retention in care was defined as one-participant attrition, where attrition was defined as either death (all-cause) or loss to follow-up (LTFU). LTFU was defined as no ART collection for >90 days after the last missed scheduled ART collection date. Participants not arriving for the scheduled 12-month visit were considered retained if collecting ART within 90 days following the appointment date. Participants transferring-out were censored at the date of transfer. VS was defined as VL <1000 copies/mL. Those eligible for outcome VL testing were enrolled participants excluding those who died, were lost to-follow-up or who had transferred-out. Unscheduled facility visits were defined as any visit to the study clinics for any reason outside of visits scheduled by the assigned model of care.

For the main outcomes analyses, we performed "one-stage" IPD meta-analyses (stratified by trial), being appropriate when few trials are included, when participant numbers are small or when outcome events are rare [21–24]. These analyses are detailed in the Supporting information. As an additional analysis for the primary outcome, a "two-stage" meta-analysis of IPD was performed by estimating cluster-adjusted RDs separately for each trial and then combining these to estimate pooled RDs using random-effects meta-analysis. Heterogeneity was assessed using the I^2 statistic and forest plots. Ethical approval was provided by the Stellenbosch University Health Research Ethics Committee, reference S20/05/128.

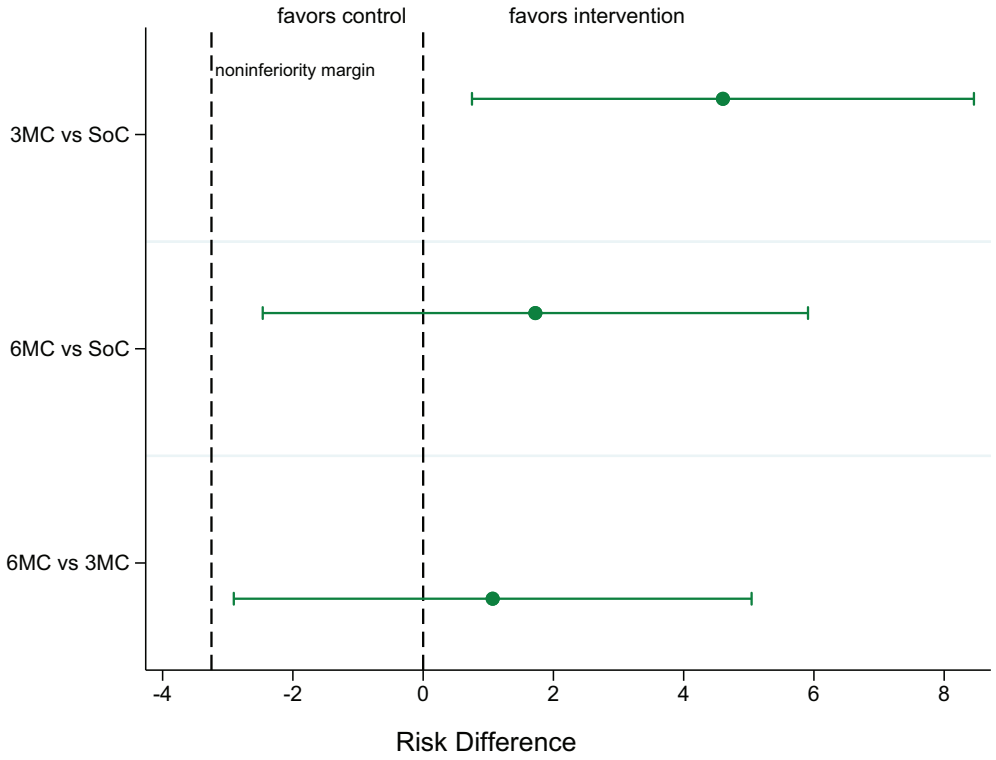

Figure 1. Arm comparisons of the primary outcome (retention in antiretroviral treatment care).
Effect measures are risk differences with 95% confidence intervals. SoC-participants received three-monthly dispensing of ART at the facility. 3MC-participants received three months' supply of ART in community ART groups (CAGs). 6MC-participants received 6 months' supply of ART in CAGs or at community distribution points.

3 | RESULTS AND DISCUSSION

Data of 5336 participants from Lesotho and 4800 from Zimbabwe were pooled (total of 10,136 participants) (Figure S1). Amongst these, 9537 were enrolled >12 months after ART initiation and excluded. Thus, 599 participants enrolled between 6 and 12 months after ART initiation were included; 212 (35.4%), 128 (21.4%) and 259 (43.2%) in arms SoC, 3MC and 6MC, respectively. Baseline clinical variables were similar between arms. Little variation between arms was apparent regarding time from ART initiation until study enrolment (Table 1). Few participants aged <25 years were included (n = 32).

After 12 months, retention was similar in all arms, 198 of 212 (93.4%), 123 of 128 (96.1%) and 248 of 259 (95.8%) in SoC, 3MC and 6MC, respectively (Table 2). In regression analyses adjusted for randomization variables and trial, retention in 3MC was superior versus SoC, adjusted risk difference (aRD) = 4.6% (95% CI: 0.7–8.5%) and retention in 6MC was non-inferior versus SoC, aRD = 1.7% (95% CI: −2.5 to 5.9%) (Figure 1). 6MC was also non-inferior versus 3MC. Few participants transitioned off the intervention arms due to requiring increased frequency of ART dispensing; 0.8% and 0.8% in 3MC and 6MC, respectively (Figure S1). We noted that retention amongst the small sample of participants aged <25 years was reduced and that in this age group retention in 6MC was reduced versus SoC (Tables S2 and S3). Gender was not associated with retention in this analysis, and gender was not an effect modifier.

The additional analyses using the "two-stage" approach for the primary outcome showed similar results to the "one-stage" approach, with heterogeneity being low. Estimated pooled RDs were 2.9% (95% CI: −1.0 to 6.8%) for 3MC versus SoC (I^2 = 0%; p = 0.84); and pooled RD = 2.6% (95% CI: −2.1 to 7.2%) for 6MC versus SoC (I^2 = 33%; p = 0.22) (Figures S2 and S3).

VL result availability at 12 months varied dramatically between districts (7-93%) and sites (0%-100%). Amongst those eligible for VL testing, 72.2, 59.0 and 42.4% had available VL results in SoC, 3MC and 6MC, respectively. Amongst these, VS was high and similar by arm, 99.3, 98.6 and 98.1% in SoC, 3MC and 6MC, respectively. Regression analyses confirmed that VS was similar between arms (Table 2). Differences in VS by age category were not apparent (Table S4).

Participants in all arms had few unscheduled facility visits between months 0 and 12 with little variation between arms. In regression analyses, intervention arms did not increased incidence of unscheduled facility visits (Table 2).

In this analysis of pooled data from two CRTs, including stable ART clients receiving ART for 6–12 months, retention was non-inferior amongst participants receiving three- and six-monthly community-based MMD with single annual clinical

Table 2. Comparison of 12-month study outcomes between arms

	Retention in ART care (primary outcome)[a]						Viral suppression[b]						Unscheduled facility visits[c]					
	Enrolled, N	Retained, n (%)	Unadjusted estimates		Adjusted estimates[d]		Tested, n/N (%)[e]	Suppressed n (%)	Unadjusted estimates		Adjusted estimates[d]		No., mean (SD)[f]	Unadjusted estimates		Adjusted estimates[d]		
			RD (95% CI)	*p*	RD (95% CI)	*p*			RR (95% CI)	*p*	RR (95% CI)	*p*		IRR (95% CI)	*p*	IRR (95% CI)	*p*
SoC	212	198 (93.4)	Ref	–	Ref	–	143/198 (72.2)	142 (99.3)	Ref	–	Ref	–	0.28 (0.83)	Ref	–	Ref	–
3MC	128	123 (96.1)	2.9% (-1.8 to 7.5%)	0.23	4.6% (0.7 to 8.5%)	0.02	72/122 (59.0)	71 (98.6)	0.99 (0.97–1.02)	0.73	0.98 (0.92-1.03)	0.41	0.13 (0.49)	0.51 (0.13–1.92)	0.32	0.53 (0.16-1.80)	0.31
6MC	259	248 (95.8)	2.3% (-1.5 to 6.1%)	0.24	1.7% (-2.5 to 5.9%)	0.42	103/243 (42.4)	101 (98.1)	0.99 (0.96–1.01)	0.33	0.98 (0.95-1.00)	0.10	0.25 (0.67)	0.84 (0.24–2.92)	0.79	0.82 (0.25-2.79)	0.76
6MC (vs 3MC)	259	248 (95.8)	-0.6% (95% CI: −4.5 3.3%)	0.77	1.1% (-2.9 to 5.0%)	0.60	103/243 (42.4)	101 (98.1)	0.99 (0.96–1.03)	0.64	1.0 (0.94–1.07)	0.96	0.25 (0.67)	1.55 (0.56–4.22)	0.40	1.65 (0.58-4.74)	0.35

[a]Risk differences were estimated using binomial population-averaged generalized estimating equations using an exchangeable correlation structure stratified by trial, specifying for clustering by facility, using robust standard errors, and using a small cluster size variance correction. The measured intracluster correlation coefficient for retention was <0.001.

[b]Risk ratios were estimated using log-binomial population-averaged generalized estimating equations using an exchangeable correlation structure stratified by trial, specifying for clustering by facility, using robust standard errors, and using a small cluster size variance correction.

[c]Population-averaged Poisson regression models were used to estimate incidence rate ratio's stratified by trial, specified for clustering by facility and using robust standard errors.

[d]Adjusted estimates were adjusted for primary healthcare clinic/hospital-based facility and rural/urban geolocation.

[e]Those tested for viral load /those eligible for viral load testing at 12 months. Those eligible for viral load testing were enrolled participants less those who died, were lost to-follow up or who had transferred-out prior to 12 months after enrolment.

[f]Number of unscheduled facility visits between months 0 to 12 of study.

SoC-participants received three-monthly dispensing of ART at the facility. 3MC-participants received three months' supply of ART in community ART groups (CAGs). 6MC-participants received 6 months' supply of ART in CAGs or at community distribution points. ART, antiretroviral therapy; CI, confidence interval; IRR, incidence rate ratio; RD, risk difference; Ref, reference category; RR, risk ratio.

visits for those aged ≥25 years. VS was similar, and unscheduled facility visits were not increased, which is reassuring as facility visits increase the risk of exposure to SARS-CoV-2. This suggests that eligibility for community-based DSD models incorporating MMD may be safely extended to include newly stable ART clients in southern Africa to allow greater numbers of people to benefit from these models, which are also particularly relevant in the COVID-19 era.

Strengths of our study include the randomized design that included 60 facilities in eight high HIV-prevalence districts of southern Africa. Study limitations include the relatively small sample size that resulted in reduced power and limited precision of effect measures. Although study power was reduced, we did not increase the non-inferiority margin compared to the original trials (in order to increase power) as we did not want to jeopardize the relatively strict criterion for non-inferiority as defined by the original trials. The sample of participants aged <25 years was particularly small, thus, conclusions regarding this age group could not be drawn. Studies including larger sample sizes of this age group need to be conducted to ascertain if overall results are generalizable to this group. VL result availability was lower in the intervention arms; however, this was likely heavily influenced by highly variable VL testing infrastructure at different sites and districts of the study areas, reflecting differing public VL testing scale-up that occurred during the study period. Further research in areas with good access to VL testing services should be conducted to establish if VL completion rates for out-of-facility models are acceptable amongst newly stable ART clients. In addition, outcomes beyond 12 months after enrolment were not measured. Further studies, including larger sample sizes and having longer participant follow-up durations, should be conducted to validate study findings.

4 | CONCLUSIONS

Amongst newly stable ART clients receiving ART for 6–12 months, community-based DSD models incorporating three- and six-monthly ART refills with single annual clinical visits were at least non-inferior to standard three-monthly facility-based care amongst those aged ≥25 years. These models should be considered for scaling in light of both the COVID-19 pandemic and to allow more people to benefit from these patient-centred models. Few participants aged <25 years were included, and further research to ascertain if community-based DSD models effectively retain newly stable ART clients in this age group should be conducted. Further research is also needed to assess whether community-based DSD models are suitable for those who have initiated ART within 6 months.

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COMPETING INTERESTS

The authors declare that they have no conflict of interest.

AUTHORS' CONTRIBUTIONS

GF, NNM, AT, BBT, CL, CC, AG designed the research study. GF, NNM, AT, BBT, TK, KM, CC, AG performed the research. GF and TM analyzed the data. GF wrote the paper. All authors have read and approved the final manuscript.

ACKNOWLEDGEMENTS

The authors wish to acknowledge the Zimbabwe Ministry of Health and Child Care; EQUIP Health; the Organization for Public Health Interventions and Development Zimbabwe; FHI360 Zimbabwe; Population Services International Zimbabwe; the Lesotho Ministry of Health; Christian Health Association of Lesotho; the Elizabeth Glaser Paediatric AIDS Foundation; Lesotho Network of AIDS Services Organisation; and participants and health facility staff.

FUNDING

President's Emergency Plan for AIDS Relief through the United States Agency for International Development EQUIP mechanism (Grant number AID-OAA-A-15-00070).

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SUPPORTING INFORMATION

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

Table S1. Brief description of the model of care for each arm of the trials

Table S2. Individual-level factors associated with participant retention in ART care 12 months after enrolment (primary outcome)

Table S3. Arm comparison of retention in care after 12 months stratified by age category

Table S4. Arm comparison of viral suppression after 12 months stratified by age category

Figure S1. Study flow diagram

Figure S2. Forest plot of estimated pooled risk difference of retention in ART care at 12 months for arm 3MC vs. SoC

Figure S3. Forest plot of estimated pooled risk difference of retention in ART care at 12 months for arm 6MC vs. SoC

Lewis L et al. *Journal of the International AIDS Society* 2021, **24**(S6):e25802
http://onlinelibrary.wiley.com/doi/10.1002/jia2.25802/full | https://doi.org/10.1002/jia2.25802

JIAS JOURNAL OF THE INTERNATIONAL AIDS SOCIETY

RESEARCH ARTICLE

Differentiated service delivery for people using second-line antiretroviral therapy: clinical outcomes from a retrospective cohort study in KwaZulu-Natal, South Africa

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Abstract

Introduction: Evidence is needed to guide the inclusion of broader groups of people living with HIV (PLHIV) in differentiated service delivery (DSD) programmes. We assessed treatment outcomes among PLHIV on second-line regimens in a community antiretroviral therapy (ART) delivery programme, compared to those who remained at clinics.

Methods: Using data from 61 public clinics, we did a retrospective cohort study among PLHIV receiving second-line ART following rollout of the Centralized Chronic Medicines Dispensing and Distribution (CCMDD) programme in KwaZulu-Natal, South Africa. We included PLHIV from the timepoint when they were first eligible, though not necessarily referred, for community ART within CCMDD and followed them for 18 months. We used multivariable logistic regression to compare 12-month attrition and viraemia between clients referred for community ART and those remaining in clinic care.

Results: Among 209,744 PLHIV aged ≥ 18 years who collected ART between October 2016 and December 2018, 7511 (3.6%) received second-line ART. Of these, 2575 (34.3%) were eligible for community ART. The median age was 39.0 years (interquartile range 34.0–45.0) and 1670 (64.9%) were women. Five hundred and eighty-four (22.7%) were referred for community ART within 6 months of meeting eligibility criteria. Overall, 4.5% [95% confidence interval (CI) 3.0–6.6%] in community ART and 4.4% (95% CI 3.5–5.4%) in clinic care experienced attrition at 12 months post eligibility for community ART. Two thousand one hundred and thirty-eight (83.0%) had a viral load recorded 6–18 months after becoming eligible, and of these, 10.3% (95% CI 7.7–13.3%) in community ART and 11.3% (95% CI 9.8–12.9%) in clinic care had viraemia ≥ 200 copies/ml. In separate regressions adjusted for age, gender, district, time on second-line ART, nucleoside reverse transcriptase inhibitor backbone and year of eligibility, no differences in the odds of attrition [adjusted odds ratio (aOR) 1.02, 95% CI 0.71–1.47] or viraemia (aOR 0.91, 95% CI 0.64–1.29) were observed between those in community ART and those remaining in clinic care.

Conclusions: We found good outcomes among PLHIV who were stable on second-line regimens and referred for community ART. Efforts to expand DSD access among this group should be prioritized.

Keywords: antiretroviral therapy; differentiated service delivery; HIV; retention in care; second line

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

Received 22 March 2021; **Accepted** 29 July 2021

1 | INTRODUCTION

South Africa has the largest antiretroviral therapy (ART) programme globally with more than 5 million clients receiving ART [1]. In September 2016, the country adopted the policy of universal test and treat, which aims to provide ART to all 7.8 million people living with HIV (PLHIV) regardless of CD4 count [2]. To efficiently achieve universal ART and the UNAIDS 95-95-95 targets, the country has implemented the Centralized Chronic Medicines Dispensing and Distribution (CCMDD) programme [3,4], which has been used to support the rollout of both community- and facility-based differentiated ART delivery [5]. In the community-based ART delivery programme, PLHIV can collect ART in more convenient locations, such as community pickup points and private pharmacies, rather than at clinics [3,4,6,7]. There is a growing body of evidence supporting the use of such differentiated ART delivery programmes among PLHIV who are stable on first-line

ART [8,9], in order to provide more efficient, client-centred care and decongest clinics.

The coronavirus disease 2019 (COVID-19) pandemic has led to calls to widen access to differentiated ART delivery, to facilitate ART provision through the pandemic, to reduce congestion and thereby COVID-19 infection risk in clinics and to free up clinic resources to focus on COVID-19 [10]. One such measure includes expanding eligibility to include people who are stable on second-line ART. In South Africa, second-line ART has been included in the CCMDD programme since inception, in contrast to several other countries which restrict differentiated ART delivery to first-line ART only, and there are little data evaluating differentiated ART delivery outcomes among PLHIV on second-line ART. These clients may benefit from increased clinic support, because they previously had treatment failure, and second-line ART regimens are more complex, with worse side effect profiles. Therefore, in this study, we investigate whether, among PLHIV on second-line ART who were potentially eligible for differentiated care, those who were referred into community ART had similar outcomes to those who continued to collect treatment in public clinics.

2 | METHODS

2.1 | Study design and setting

We performed a retrospective cohort analysis using routinely collected anonymized electronic data from between 1 October 2016 and 30 June 2020 in KwaZulu-Natal, South Africa. We used data from 56 urban clinics run by the eThekwini Municipality Health Unit and data from five rural clinics in the uMkhanyakude District in northern KwaZulu-Natal. These clinics were selected from existing collaborations and to provide data from both rural and urban settings. KwaZulu-Natal has an estimated HIV prevalence of 27% among adults aged 15–49 years [11]. ART is provided freely at all public sector clinics using South African National Guidelines, with viral load testing at 6 and 12 months after ART initiation, and annually thereafter [12]. Clients with virological failure, defined as two viral loads >1000 copies/ml more than 2–3 months apart, were recommended to switch to a second-line ART regimen. Typically, those failing first-line tenofovir disoproxil fumarate-based regimens would be switched to zidovudine, lamivudine and lopinavir/ritonavir, while those failing first-line zidovudine or stavudine-based regimens would be switched to tenofovir, emtricitabine and lopinavir/ritonavir [12]. In clients with contraindications to tenofovir (e.g. renal impairment) or zidovudine (e.g. anaemia), abacavir was sometimes used.

Prior to April 2020, PLHIV were eligible for CCMDD if they were 18 years or older, had been on the same ART regimen for more than 12 months and if their two most recent viral load measurements were undetectable and taken more than 6 months apart [13]. In addition, clients with tuberculosis (TB), pregnancy, uncontrolled hypertension or diabetes, or other medical conditions requiring regular clinical consultations, were ineligible. Clients referred for community ART would be given 2 months of ART supply at the clinic, with subsequent 2 monthly ART deliveries using the CCMDD programme at a community pickup point of their choice [7]. They would then be reviewed at the clinic every 6 months. Clients who continued to collect ART from the clinic (due to ineligibility for CCMDD, client choice, implementation problems or healthcare workers not deeming community ART delivery to be appropriate) would be seen approximately 2 monthly at the clinic. Although the rollout of CCMDD in KwaZulu-Natal began in June 2016 [14], we allowed for gradual implementation by starting the study period in October 2016.

2.2 | Participants

We included PLHIV on second-line ART meeting CCMDD eligibility criteria captured in the routine clinic database during the period from 1 October 2016 to 31 December 2018. We used the date on which the second suppressed viral load (<200 copies/ml) was taken as baseline, because this was when eligibility could have been first established. We included only those who had at least one clinic visit in the 6 months following eligibility, at which point they could have been referred to either community ART or continued in clinic care. Using the routine clinic data, we excluded individuals who were pregnant or had TB, but it was not possible to identify other medical conditions which may preclude them from inclusion in the community ART programme, such as uncontrolled hypertension or uncontrolled diabetes. Clients were followed up for 18 months after the first point at which eligibility was established.

2.3 | Data sources and data management

We used de-identified data extracted from TIER.net, an electronic register in which demographic, clinical and clinic visit data are recorded for all clients initiating and receiving ART in the South African public sector [15]. The register includes data on viral loads, ART regimens, pregnancy and TB status, and referral to the community ART programme. TIER.net data are compared monthly against clinic registers and a subset of clinical charts. Data were checked and cleaned with duplicated records, visits and ART entries removed and ART regimens were rationalized to remove systematic inconsistencies. We did not use the TIER.net lost to follow-up outcome, as this can be inconsistent [16], and generated our own attrition variable (defined below). Since data were anonymized, data of patients who transferred care to or from another clinic could not be accessed, and 'silent transfers' could not be detected. We analysed anonymized data using R 4.0 (R Foundation for Statistical Computing, Vienna, Austria) and SAS, version 9.4 (SAS Institute Inc).

2.4 | Variables

The primary exposure of interest was a binary variable measuring referral into the community ART programme. PLHIV who were referred within 6 months of eligibility being established were assigned to the community ART group, and those with no referral were assigned to the clinic ART group. Participants in both groups were receiving second-line ART. Those who were referred to the community ART programme more than 6 months after eligibility was established were assigned to the clinic ART collection group, because of their limited exposure to the community ART programme.

The primary outcomes were attrition and viraemia at 12 months after becoming eligible for community ART. Since the exposure group included clients referred up to 6 months after becoming eligible, the minimum exposure time to community ART at 12 months post eligibility was 6 months. A client was defined as experiencing attrition at 12 months if there was no record of clinic attendance between 12 and 18 months after baseline. Clients who were documented as being transferred to another clinic within 12 months of baseline were assigned a missing value for their attrition outcome as clinic attendance at another clinic could not be matched to baseline data. Patients were defined as having viraemia if they had a viral load $\geq$ 200 copies/ml 12 months after baseline. We used a window of 6–18 months for the 12-month viral load because measuring and recording viral loads can be inconsistent in routine healthcare settings [17]. Those with no viral load recorded between 6 and 18 months were assigned a missing value for the viraemia outcome.

Baseline variables that were potentially confounders to the association between community ART referral and outcomes were incorporated in the analysis. These included age, gender, urban or rural district, year in which CCMDD eligibility was established, time on second-line ART, nucleoside reverse transcriptase inhibitor (NRTI) backbone and most recent CD4 count value, taken within the past 2 years. For those clients who were transferred into the clinic from another facility while already receiving second-line ART and were missing a second-line ART start date, we used 30 days before their transfer-in date as the second-line ART start date.

2.5 | Statistical analysis

Baseline and follow-up characteristics of the cohort were summarized using median and interquartile range (IQR) values for continuous variables and using frequencies and percentages for categorical variables. A Fisher's exact test was used to compare baseline categorical variables of those referred to community ART to those remaining in clinic care. We used generalized estimating equations with a logit-link and an exchangeable working correlation structure to test the association between the covariates and the outcomes of, first, attrition and second, viraemia, accounting for clinic-level correlation. Univariable and multivariable regression results are reported. Covariates included in the models were selected based on data availability and clinical significance. As recent CD4 count data were available for only 54.9% of the cohort, it was excluded as a covariate from the main analysis but included in a complete case sensitivity analysis. In a second sensitivity analysis for the attrition outcome, clients who had been transferred to another clinic within 12 months of baseline were included and classified as experiencing attrition. For the viral load outcome, a further sensitivity analysis was performed excluding those who had a follow-up viral load measured less than 12 months after baseline.

2.6 | Ethical approval

This work was approved by the University of Kwazulu-Natal Biomedical Research Ethics Committee (BE646/17), KwaZulu-Natal Department of Health's Provincial Health Research Ethics Committee (KZ_201807_021), eThekwini Municipality Health Unit and the Bethesda Hospital Ethics Committee, with a waiver for informed consent for analysis of anonymized, routinely collected data.

3 | RESULTS

3.1 | Cohort characteristics

Among 209,744 PLHIV aged $\geq$ 18 years who collected ART between October 2016 and December 2018, 7511/209,744 (3.6%) received second-line ART (Figure 1). Of these, 4936/7511 (65.7%) were excluded from analysis as they failed to meet one or more of the community ART programme eligibility criteria captured in the routine clinic database. One thousand six hundred and twenty-six of these were clients with a suppressed viral load while on second-line ART, but had no previous suppressed viral load recorded in the previous 6–24 months. A further 11/7511 (0.1%) were excluded as they did not have a clinic visit within 6 months of eligibility at which they could have been referred to the community ART programme. The remaining 2575/7511 (34.3%) were included in the analysis as they were receiving second-line ART and potentially eligible for the community ART programme during the baseline period of October 2016 and December 2018. The median age of this cohort was 39.0 years (IQR 34.0–45.0) and 1670 (64.9%) were women (Table 1). The majority (n = 2389, 92.8%) resided in urban districts.

Overall, 584/2575 (22.7%) were referred to the community ART programme within 6 months of becoming eligible. The estimated proportion of clients referred into the community ART programme increased with each year in the baseline period from 8.8% in 2016 to 24.0% in 2017 and 25.8% in 2018. The baseline distributions of age, gender, district, NRTI backbone and time on second-line ART of those referred for community ART were similar to those who remained in clinic care. However, a larger proportion of those receiving community ART had a CD4 count greater than 500 (47.2% vs. 34.9%, p<0.001). 166/1991 (8.3%) clients were referred late for community ART at more than 6 months after baseline eligibility and so were included in the clinic care group for analysis.

3.2 | Attrition

By 12 months, 79/2575 (3.1%) of clients had been transferred to another clinic. Of the remaining 2496, 4.5% [95% confidence interval (CI) 3.0–6.6%] of those receiving community ART for a minimum of 6 months and 4.4% (95% CI 3.5–5.4%) of those in clinic care experienced attrition at 12 months [crude odds ratio (OR) 1.01, 95% CI 0.71–1.45], (Table 2). After adjusting for age, gender, district, time on second-line ART, NRTI backbone and year of eligibility in a multivariable regression, there was no difference in 12-month attrition between those referred for community ART and those in clinic care [adjusted odds ratio (aOR) 1.02, 95%

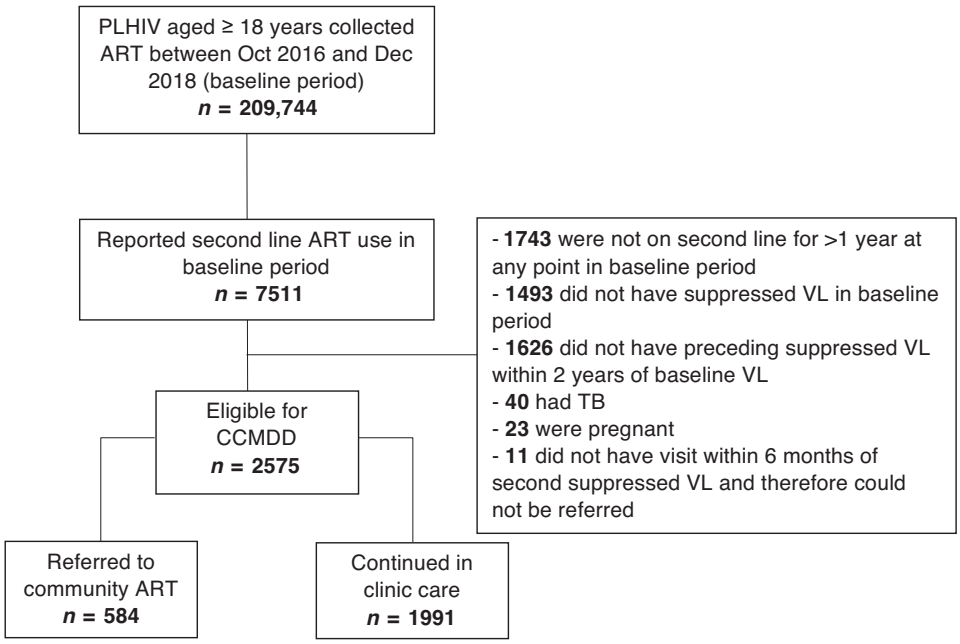

Figure 1. Participant flowchart. ART, antiretroviral therapy; CCMDD, Centralized Chronic Medicines Dispensing and Distribution; PLHIV, people living with HIV; TB, tuberculosis; VL, viral load.

CI 0.71–1.47]. In addition, no differences in 12-month attrition were observed in a sensitivity analysis adjusting for CD4 count and all aforementioned covariates (n = 1366, aOR 1.17, 95% CI 0.77–1.77), (Table S1). In a further sensitivity analysis including all clients who were transferred to another clinic, attrition was lower in the community ART group versus clinic care (n = 2575, aOR 0.73, 95% CI 0.54–0.99), (Table S2).

3.3 | Viraemia

A total of 2138 (83.0%) had a follow-up viral load recorded at a median of 12 (IQR 11–12) months after becoming eligible for community ART. 14.9% in the community ART group and 17.6% of those in clinic care were missing a viral load result (Table 1). At follow-up, 10.3% (95% CI 7.7–13.3%) of PLHIV referred for community ART compared to 11.3% (95% CI 9.8–12.9%) in clinic care had viraemia (OR 0.89, 95% CI 0.64–1.24), (Table 3). After adjusting for age, gender, district, year of eligibility, time on second-line ART and NRTI backbone, referral for community ART was not found to be significantly associated with the odds of viraemia (aOR 0.91, 95% CI 0.64–1.29). In separate sensitivity analyses, adjustment for CD4 count in the multivariable regression (n = 1143, aOR 1.21, 95% CI 0.75–1.94), (Table S3), and exclusion of clients with a viral load taken before 12 months (n = 1111, aOR 0.68, 95% CI 0.43–1.05), (Table S4), did not alter findings. Although not the main objective of this analysis, in the multivariable model, there was an association between an abacavir-based second-line regimen and viraemia (aOR 1.78, 95% CI 1.21–2.63).

4 | DISCUSSION

In this retrospective cohort study of 61 public sector clinics in South Africa, we found that among PLHIV receiving second-line ART, those who were referred into a community differentiated ART delivery programme had comparable retention in care and viral load outcomes to those who continued to collect ART in clinics. While these data were collected before the COVID-19 pandemic, it has implications for countries which are looking to expand access to differentiated ART delivery as part of efforts to continue ART provision during COVID-19, and beyond.

There are few data regarding outcomes of people receiving second-line ART in community differentiated ART delivery programmes, and none that compare outcomes with people who continue treatment at clinics. A cohort study in South Africa assessed outcomes among 165 clients with viraemia who recently resuppressed and were referred into facility- or community-based adherence clubs [18]. The study included 105 clients known to be on second-line ART. Overall retention in care was 94.8% (95% CI 89.8–97.4%) and viral suppression was 83.9% (95% CI 76.8–88.9%) at 12 months. A study in Mozambique of 699 clients who were on second- or third-line regimens and attending community adherence clubs found very high retention in care at 12 months (98.9%, 95% CI 98.2–99.7%) and 12-month viral suppression of 85.8% (95% CI 83.1–88.2%) [19]. Although these two studies did not include a comparator group that continued to receive standard care in clinics, results from the differentiated ART delivery groups are similar to retention in care and viral suppression outcomes seen in the community ART programme

Table 1. Baseline and follow-up characteristics of clients on second-line ART who met community ART programme eligibility criteria, split by referral into the community ART programme (*N* = 2575)

		Referred to community ART programme (*n* = 584)	Continued at clinic (*n* = 1991)
Baseline characteristics			
Age, median (IQR)		39 (35–45)	39 (34–45)
Age, *n* (%)	<30	55 (9.4)	206 (10.3)
	30–39	246 (42.1)	823 (41.3)
	40–49	203 (34.8)	686 (34.5)
	≥50	80 (13.7)	276 (13.9)
Gender, *n* (%)	Female	384 (65.8)	1286 (64.6)
District, *n* (%)	Urban	540 (92.5)	1849 (92.9)
Year of baseline observation, *n* (%)	2016	30 (5.1)	310 (15.6)
	2017	309 (52.9)	977 (49.1)
	2018	245 (42.0)	704 (35.4)
Second-line protease inhibitor	Lopinavir/ritonavir	581 (99.5)	1980 (99.5)
	Atazanavir	3 (0.5)	11 (0.5)
NRTI backbone[a]	Tenofovir	165 (28.2)	514 (25.8)
	Zidovudine	377 (64.6)	1315 (66.1)
	Abacavir/other[b]	42 (7.2)	162 (8.1)
Months on second-line ART, median (IQR)		28.5 (18–50)	26 (16–45)
Months since viral load measure preceding baseline viral load, median (IQR)		11 (8–13)	11 (8–13)
Most recent CD4 count at baseline, median (IQR)		449 (260–622)	385 (237–555)
Most recent CD4 count at baseline, *n* (%)	< = 200	34 (11.3)	176 (15.8)
	201–350	70 (23.2)	277 (24.9)
	351–500	55 (18.3)	272 (24.4)
	>500	142 (47.2)	389 (34.9)
	Missing	283	877
Months since most recent CD4 count at baseline, median (IQR)		9 (0–15)	9 (0–15)
Months to community ART referral from baseline	At eligibility	193 (33.1)	
	1–3 months post eligibility	277 (47.4)	
	4–6 months post eligibility	114 (19.5)	
Follow-up characteristics			
Months to viral load follow-up measurement, median (IQR)		12 (11–12)	12 (11–12)
Missing viral load follow-up value, *n* (%)		87 (14.9)	350 (17.6)

[a]Tenofovir typically combined with emtricitabine, zidovudine and abacavir typically combined with lamivudine.
[b]All but two clients were on abacavir.
ART, antiretroviral therapy; IQR, interquartile range; NRTI, nucleoside reverse transcriptase inhibitor.

in our study (95.5% and 89.7%, respectively). In our study, only 34% of people receiving second-line ART were eligible for CCMDD, largely due to not being on second line for >12 months, or not having a known suppressed viral load in the past year. Eligibility criteria for the adherence clubs in the Mozambican and South African cohorts were less strict than in our cohort, with only 6 months on an ART regimen required [19], and only one suppressed viral load needed [18,19]. Applying these criteria to our cohort would have enabled a further 1626 clients to be eligible for differentiated ART delivery, and these changes have been adopted for all people on ART in new South African guidelines from March 2020, which also allow longer intervals between community ART pickups and less frequent clinic visits [20]. Selective eligibility criteria may explain some of the good outcomes seen among clients on second line in both clinic care and differentiated ART delivery services. However, these good outcomes may also reflect the fact that burdensome clinic visits could have contributed to clients having originally failed first-line regimens, and easier access through second-line community ART may enhance retention and viral suppression.

While our study demonstrates good outcomes for people receiving second-line ART in CCMDD, we cannot be sure that these findings would hold true under the new less

Table 2. Multivariable logistic regression model of attrition among people living with HIV who are receiving second-line ART and eligible for referral into the community ART programme (*N* = 2496)

		No recorded visit 12–18 months after baseline, *n* (%) or median (IQR)	OR (95% CI)	Adjusted OR (95% CI)
Age at baseline		39.5 (33–45)	1.00 (0.98–1.02)	1.01 (0.99–1.03)
Gender	Female	75 (4.7)	1.15 (0.83–1.6)	1.21 (0.87–1.67)
	Male	35 (4.0)	1	1
District	Rural	6 (3.4)	0.71 (0.35–1.45)	0.75 (0.35–1.62)
	Urban	104 (4.5)	1	1
Year of baseline observation	2016	14 (4.2)	0.86 (0.56–1.34)	0.87 (0.55–1.39)
	2017	52 (4.1)	0.83 (0.55–1.25)	0.84 (0.55–1.27)
	2018	44 (4.9)	1	1
NRTI backbone at baseline	Tenofovir	28 (4.2)	1.00 (0.63–1.58)	1.05 (0.64–1.72)
	Abacavir/other	14 (7.0)	1.71 (0.94–3.11)	1.7 (0.94–3.1)
	Zidovudine	68 (4.2)	1	1
Months on second line at baseline		25 (14–46)	1.00 (0.99–1.004)	1.00 (0.99–1.005)
Referred into community ART programme	Yes	26 (4.5)	1.01 (0.71–1.45)	1.02 (0.71–1.47)
	No	84 (4.4)	1	1

ART, antiretroviral therapy; CI, confidence interval; IQR, interquartile range; NRTI, nucleoside reverse transcriptase inhibitor; OR, odds ratio.

Table 3. Multivariable logistic regression model of viraemia (≥200 copies/ml) among people living with HIV who are receiving second-line ART and eligible for referral into the community ART programme (*N* = 2138)

		Viral load ≥ 200 copies/ml 6-18 months after baseline, *n* (%) or median (IQR)	OR (95% CI)	Adjusted OR (95% CI)
Age at baseline		39 (33–44)	0.99 (0.97–1)	0.99 (0.97–1.01)
Gender	Female	151 (10.8)	0.94 (0.7–1.27)	1.03 (0.74–1.45)
	Male	85 (11.6)	1	1
District	Rural	11 (7.1)	0.63 (0.51–0.78)	0.83 (0.65–1.05)
	Urban	225 (11.3)	1	1
Year of baseline observation	2016	26 (8.9)	0.67 (0.42–1.06)	0.66 (0.38–1.13)
	2017	114 (10.6)	0.83 (0.62–1.1)	0.86 (0.64–1.16)
	2018	96 (12.5)	1	1
NRTI backbone at baseline	Tenofovir	45 (7.9)	0.67 (0.48–0.92)	0.78 (0.55–1.11)
	Abacavir/other	29 (17.3)	1.7 (1.16–2.5)	1.78 (1.21–2.63)
	Zidovudine	162 (11.6)	1	1
Months on second line at baseline		22 (16–36.5)	0.99 (0.99–1)	1.00 (0.99–1.00)
Referred into community ART programme	Yes	51 (10.3)	0.89 (0.64–1.24)	0.91 (0.64–1.29)
	No	185 (11.3)	1	1

ART, antiretroviral therapy; CI, confidence interval; IQR, interquartile range; NRTI, nucleoside reverse transcriptase inhibitor; OR, odds ratio.

strict eligibility criteria, and in particular with longer intervals between ART collection which require a more robust ART supply chain. During COVID-19, concerns around ART supply chains, including for second-line regimens, were more pronounced [21]. Our study has some limitations due to the pragmatic use of programmatic data. Firstly, assignment to the exposure groups was non-random and selection bias may have occurred. Although our analysis adjusted for available demographic and clinical confounders, unmeasured confounders may have meant that clients who were referred for

community ART were more stable than those who continued in clinic care, and therefore more likely to have better outcomes. Our definition of eligibility was limited to using data on eligibility criteria stored in the TIER.net database, which excluded criteria on pre-existing medical conditions of clients. Consequently, there may have been some clients included in the clinic-care group in the cohort who were not eligible for community ART. If these participants had poorer clinical outcomes than those eligible for community ART, a comparison of the two groups would be biased towards better outcomes among those in the community ART programme. However, we adjusted for NRTI backbone, which is likely a proxy for co-morbidity [22], and our result was unchanged. An abacavir-based NRTI backbone was associated with viraemia, which may reflect the negative impact that co-morbidities can have on treatment outcomes. We used a 6-month window for a clinic visit to define retention in care at 12 months [23]. As clients in the community ART programme are expected to return to clinic every 6 months, compared to 2 monthly in the clinic group, our attrition window may have biased against community ART clients. Despite this, we found low levels of attrition in the community ART group. Outcomes were measured 12 months after first eligibility for community ART, meaning our results may not reflect longer term outcomes. One hundred and sixty-six clients who were referred for community ART more than 6 months after eligibility were assigned to the clinic care group, as they would have had less than 6 months in community ART by 12 months of follow up. Under the alternate hypothesis that outcomes for clients in the community ART programme will be better than those in clinic care, inclusion of these clients in the clinic care group may have biased outcomes in the two groups to be more similar.

Our findings are reassuring that clients who are virally suppressed on second-line ART can be referred safely into community ART programmes and have good clinical outcomes. For ART programmes where this is not already practiced, our findings should encourage policy changes to allow people receiving second-line ART to benefit from differentiated ART delivery. This is important both in the context of COVID-19, to reduce health service use and risk of SARS-CoV-2 transmission [10], and for ART programmes in general, as they move towards more client-centred care [24]. Introducing second-line ART into community ART programmes requires the addition of new ART supply chains, as second-line regimens can be more complex than single tablet fixed dose combinations that are commonly used in first-line ART [25]. We note that the proportion of those eligible who were actually referred for community ART rose slowly with time, but remained low. Anecdotally, clinicians at study clinics were sometimes reluctant to refer people on second line due to a perceived need for increased monitoring, and concerns regarding the supply of second-line drugs both in clinics and at community pickup points [26]. Therefore, supply chains for second-line regimens must be guaranteed if they are to be successfully included in community ART programmes. Further work is needed to identify why referrals remained low in our clinics, and also to assess longer term outcomes among larger cohorts, and the impact of the more recent changes to CCMDD, particularly in the context of COVID-19.

5 | CONCLUSIONS

In this retrospective cohort study of routinely collected data, we demonstrate that among PLHIV on second-line ART, those who were referred for a community differentiated ART delivery programme had similar clinical outcomes compared to those who remain in clinic care. While our findings are limited by the potential for unmeasured confounding, they support the use of community ART delivery which may provide a more convenient and efficient service for clients receiving second-line ART. As this may also reduce the burden on clinic resources constrained by the COVID-19 pandemic, efforts to accelerate the rollout and strengthen community ART delivery among PLHIV on second-line ART should continue.

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COMPETING INTERESTS

The authors declare no competing interests.

AUTHORS' CONTRIBUTIONS

JD and NG conceived the analysis. HN, KG, MD, YS and LH oversaw second-line ART and CCMDD programme implementation. TK, SM, MD, YS, KG and HN oversaw data collection. LL and JD analysed the data. LL and JD drafted the manuscript. All authors critically reviewed and edited the manuscript and consented to final publication.

ACKNOWLEDGEMENTS

We would like to thank the staff and patients at eThekwini Municipality and Bethesda Hospital primary care clinics.

FUNDING

This work was supported by a COVID-19 Adaptations to Differentiated Service Delivery grant from the International AIDS Society and a Fast Track Cities Implementation Science grant from the International Association of Providers of AIDS Care (IAPAC) (2021-ISG-Y1-10004). JD is supported by the Wellcome Trust (grant number 216421/Z/19/Z).

DATA SHARING

The data used for this analysis cannot be shared publicly because of legal and ethical requirements regarding use of routinely collected clinical data in South Africa. Researchers may request access to the data from the eThekwini Municipality Health Unit and Bethesda Hospital (contact details obtainable upon request to corresponding author).

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SUPPORTING INFORMATION

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

Table S1. Multivariable logistic regression model of attrition among people living with HIV who are receiving second-line ART and eligible for referral into the community ART programme, excluding those missing CD4 count data (N = 1,366)

Table S2. Multivariable logistic regression model of attrition among people living with HIV who are receiving second-line ART and eligible for referral into the community ART programme, including those transferred to another clinic as lost to care (N = 2,575)

Table S3. Multivariable logistic regression model of viremia (≥200 copies/ml) among people living with HIV who are receiving second-line ART and eligible for referral into the community ART programme, excluding those missing CD4 count data (N = 1,143)

Table S4. Multivariable logistic regression model of viremia (≥200 copies/ml) among people living with HIV who are receiving second-line ART and eligible for referral into the community ART programme, excluding those with viral load measured less than 12 months after baseline eligibility (N = 1,111)

Bailey LE et al. *Journal of the International AIDS Society* 2021, **24**(S6):e25794
http://onlinelibrary.wiley.com/doi/10.1002/jia2.25794/full | https://doi.org/10.1002/jia2.25794

JIAS JOURNAL OF THE INTERNATIONAL AIDS SOCIETY

SHORT REPORT

The impact of COVID-19 on multi-month dispensing (MMD) policies for antiretroviral therapy (ART) and MMD uptake in 21 PEPFAR-supported countries: a multi-country analysis

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Abstract

Introduction: Increasing access to multi-month dispensing (MMD) of antiretroviral therapy (ART) supports treatment continuity and viral load suppression for people living with HIV (PLHIV) and reduces burden on health facilities. During the COVID-19 response, PEPFAR worked with ministries of health to scale up MMD and expand eligibility to new groups of PLHIV, including children and pregnant/breastfeeding women. We analysed PEPFAR program data to understand the impact of the policy changes on actual practice.

Methods: We conducted a desk review in 21 PEPFAR-supported countries to identify and collect official documentation released between March and June 2020 addressing changes to MMD guidance during the COVID-19 response. MMD coverage, the proportion of all ART clients on MMD, was assessed in the calendar quarters preceding the COVID-19 response (Q4 2019, October–December 2019; and Q1, January–March 2020) and the quarters following the start of the response (Q2 2020, April–June 2020; Q3 2020, July–September, 2020; Q4 2020, October–December 2020). We used the two-proportion Z-test to test for differences in MMD coverage pre-COVID-19 (Q4 2019) and during implementation of COVID-19 policy adaptations (Q2 2020).

Results and discussion: As of June 2020, 16 of the 21 PEPFAR-supported countries analysed adapted MMD policy or promoted intensified scale-up of MMD in response to COVID-19. MMD coverage for all clients on ART grew from 49% in Q4 2019 pre-COVID-19 to 72% in Q2 2020 during COVID-19; among paediatric clients (< 15), MMD coverage increased from 27% to 51% in the same period. Adaptations to MMD policy were associated with a significantly accelerated growth in the proportion of clients on MMD ($p < 0.001$) for all populations, irrespective of age and dispensing interval.

Conclusions: Access to MMD markedly expanded during the COVID-19 pandemic, supporting treatment continuity while mitigating exposure to COVID-19 at health facilities. This model is beneficial in public health emergencies and during disruptions to the healthcare system. Outside emergency contexts, expanded MMD eligibility extends client-centred care to previously excluded populations. The success in expanding MMD access during COVID-19 should motivate countries to recommend broader MMD access as a new standard of care.

Keywords: ART; COVID-19; MMD; PEPFAR; treatment continuity; viral load

Received 23 March 2021; **Accepted** 29 July 2021

1 | INTRODUCTION

Policies permitting multi-month dispensing (MMD) of antiretroviral therapy (ART) have become increasingly common, allowing people living with HIV (PLHIV) to reduce the frequency of ART pickups. In 2016, the World Health Organization (WHO) recommended less frequent medication pickup (3- to 6-month intervals) for clients "stable on ART" and reinforced the provision of MMD, particularly 6-month multi-month dispensing (6MMD), for clients responding well to treatment in the updated 2021 guidelines [1,2]. MMD has an important impact on individual treatment success and there is a growing body of literature showing improved treatment continuity and viral load suppression for people in MMD models [3–5]. Extended ART dispensing intervals improve client satisfaction and ease the burden on stretched health facilities by reducing health worker workloads and decongesting clinics [6–9]. MMD, specifically 6MMD, is also associated with cost savings to both the healthcare system and patients [10].

The United States President's Emergency Plan for AIDS Relief (PEPFAR) encourages MMD as a key strategy for

promoting client-centred differentiated care and treatment continuity [11]. The scope of MMD policies, eligibility criteria and implementation varied greatly across PEPFAR-supported countries prior to the COVID-19 pandemic; however, MMD uptake was increasing globally and PEPFAR was promoting MMD as a minimum program requirement per its 2019 Country Operational Plan guidance [12]. An internal 2020 PEPFAR MMD policy analysis, which reviewed MMD policies in national HIV treatment guidelines in 21 PEPFAR-supported countries, revealed that most countries permitting MMD limited it to adults who were "stable on ART", though the definition of "stable on ART" differed slightly across countries and did not always align with the 2016 WHO definition, which requires: receiving ART for at least 1 year, no current illnesses or pregnancy, a good understanding of lifelong adherence and evidence of treatment success [1].

In March 2020, in anticipation of COVID-19-related disruptions in supply chain, facility operations and patient mobility, PEPFAR released technical guidance highlighting reinforcement and expansion of MMD as a means to mitigate potential exposure to COVID-19 at health facilities and protect HIV treatment continuity during the pandemic [13]. Also beginning in March 2020, several PEPFAR-supported countries began disseminating updated MMD guidelines for expanded access to MMD. PEPFAR worked with ministries of health to institute and implement these guidelines during the COVID-19 response.

PEPFAR used an iterative process to ensure a sufficient supply of antiretrovirals (ARVs) to scale MMD, including: analysing stock levels using the electronic Logistics Management Information System (eLMIS), placing early orders, developing and implementing ARV distribution plans and conducting regular follow-up with site pharmacists. PEPFAR also supported health worker trainings on the updated MMD guidelines, conducted supportive supervision visits to health facilities and utilized MMD focal persons to review client registers and identify clients eligible for MMD.

We analysed PEPFAR program data to understand the impact of the policy changes on actual practice and explored the potential benefits of adopting COVID-19 adaptations to MMD policy and broader MMD access as the standard of care.

2 | METHODS

2.1 | COVID-19 MMD policy analysis

We conducted a desk review with support from PEPFAR colleagues at overseas United States (US) government missions to identify and collect official documentation released between March and June 2020 addressing MMD guidance during the COVID-19 response. We reviewed the documentation against pre-COVID guidelines noting any changes to the policy. Policy adaptations were: longer dispensing intervals; expanded eligibility criteria, including changes to minimum time on ART, age requirements, viral load status, treatment regimen type, pregnancy and breastfeeding status, and "stable on ART" status; and intensification or promotion of MMD without actual policy change.

2.2 | MMD data collection and analysis

PEPFAR programs routinely collect quarterly MMD data from PEPFAR-supported ART sites in over 20 countries and three regional programs using ministry of health clinical data collection tools, electronic medical records or program monitoring tools and report the data in PEPFAR's electronic data reporting system. Due to country-specific reporting limitations, South Africa, Ukraine, Botswana and Namibia were excluded, leaving 21 PEPFAR-supported country programs included in this analysis. The Asia, West Africa and western Hemisphere Regional PEPFAR programs were also excluded due to the disproportionately small size of the programs and incomplete data.

All PEPFAR-supported clients on treatment are categorised as receiving one of three ARV-dispensing frequencies: less than 3 months, 3–5 months (3–5MMD) and 6 or more months. PEPFAR defines MMD as receiving at least 3 months of ARVs and disaggregates MMD data by dispensing interval (3–5MMD and 6MMD) and by sex and coarse age disaggregates (15+ and <15 years). We looked at MMD coverage, the proportion of all ART clients on MMD, receiving MMD in the quarters directly preceding the global COVID-19 response (Q4 2019, October–December 2019; and Q1 2020, January–March 2020) and the immediate quarters following the start of the global COVID-19 response (Q2 2020, April–June 2020; Q3 2020, July–September; and Q4 2020, October–December 2020).

We also performed a two-proportion *z* test in R to test for differences in MMD coverage pre-COVID in Q4 2019 and during implementation of COVID-19 adaptations in Q2 2020. We compared Q4 2019 rather than Q1 2020 to Q2 2020 in the *z* test as some COVID-19 adaptations were already being implemented in March at the end of Q1 2020.

2.3 | Viral load data collection

PEPFAR also collects quarterly viral load testing data from laboratory or medical records for all clients on ART. PEPFAR calculates viral load suppression as the proportion of documented viral load results from adult and paediatric ART patients who have been on ART for at least 3 months with a viral load result of <1000 copies/ml.

2.4 | Ethical approval

This was an analysis of facility-level aggregated program data and did not require Institutional Review Board approval or consent.

3 | RESULTS AND DISCUSSION

3.1 | COVID-19 adaptations to MMD policy

We identified documentation of MMD policy adaptations or directives to scale-up MMD for 16 of the 21 PEPFAR-supported countries in the analysis. Specific policy adaptations varied with some countries recommending MMD for nearly all ART clients, while other countries enacted narrower policy adaptations that expanded eligibility for specific subpopulations or increased dispensing intervals (Table 1).

Table 1. Country-specific COVID-19 adaptations to MMD policy [14–32]

Country	Pre-COVID-19 MMD policy/practice	COVID-19 adaptation category	
		Increased dispensing intervals	Expanded eligibility details
Burundi	3MMD for clinically stable[a,b]	No	3MMD for clinically stable and unstable clients, children and PBFW on first-line regimen; 2MMD for clients on second- or third-line regimen
Cote d'Ivoire	3-6MMD for clinically stable[b,c]	No	3MMD for new ART initiators and clinically unstable clients
Democratic Republic of the Congo (DRC)	3MMD for clinically stable[a]	6MMD	3MMD for new clients who have been on ART for 3 months; 6MMD for clients on ART for > 3 months
Dominican Republic	No policy	6MMD	6MMD for clinically stable clients; 3MMD for clinically unstable clients
Eswatini	3MMD for clinically stable[a,b]	6MMD	3MMD for virally suppressed children > 2 years; 3MMD for all clients on first-line TLD; 3MMD for stable, virally suppressed clients on second-line DTG-based regimens; 6MMD for all clients on first-line TLE; 3MMD for eligible, new ART initiators
Ethiopia	3-6MMD for clinically stable[b]	No	3MMD for PBFW, paediatrics, new ART initiators, clients on second- and third-line ART and clinically unstable clients not needing readmission
Kenya	3MMD for clinically stable[a,b]	No	Up to 3MMD for all PLHIV regardless of age and viral load status (does not include PBFW and new-ART initiators)
Lesotho	3MMD for clinically stable[a,b]	6MMD	3–6MMD for all eligible clients including stable children > 2 years, adolescents and PBFW
Malawi	3-6MMD for clinically stable[a]	6MMD	6MMD for clients > 20 kg, new ART initiators (on ART for 3 months) and suppressed VL in the last 6 months is not required; 3MMD for PBFW
Mozambique	3MMD for clinically stable[a,b]	No	3MMD for new ART initiators (on ART for 3 months), children > 2 years and PBFW
Uganda	3MMD for clinically stable[a,d]	No	No age limits for 3MMD (this does not include clients on second- or third- line ART, new ART initiators, virally non-suppressed clients, lactating mothers with babies < 6 months and the very sick)
Zambia	3-6MMD for clinically stable[a,b]	6MMD	3MMD for children 2–10 years; 6MMD for adolescents 10–19 years; 3–6MMD for clients with comorbid conditions; 3MMD for clients failing treatment and receiving enhanced adherence counselling; All health facilities providing ART must ensure recipients of care in contact with the facility receive 6MMD
Zimbabwe	3MMD for clinically stable[a]	6MMD	6MMD for priority groups: PLHIV > 50 years, clients with comorbidities and adolescents
Haiti	3-6MMD for clinically stable[a,d]	No policy change, but guidance issued to intensify scale-up of MMD	
South Sudan	3-6MMD for clinically stable[a]	No policy change, but guidance issued to intensify scale-up of MMD	
Tanzania	3-6MMD for clinically stable[a]	No policy change, but guidance issued to intensify scale-up of MMD	
Angola	3MMD for clinically stable[a,b]	Unknown/official documentation not located	

(*Continued*)

Table 1. (Continued)

Country	Pre-COVID-19 MMD policy/practice	COVID-19 adaptation category: Increased dispensing intervals	COVID-19 adaptation category: Expanded eligibility details
Cameroon	3-6MMD for clinically stable[a]	Unknown/official documentation not located	
Nigeria	3-6MMD for clinically stable[a,b]	Unknown/official documentation not located	
Rwanda	3MMD for clinically stable[a,d]	Unknown/official documentation not located	
Vietnam	3MMD for clinically stable[c]	Unknown/official documentation not located	

[a]Minimum age and/or weight requirements.
[b]Pregnant and/or breastfeeding women not included.
[c]Age requirements not specified.
[d]First- or second-line ART only.
ART, antiretroviral therapy; DTG, dolutegravir; MMD, multi-month dispensing; PBFW, pregnant/breastfeeding women; PLHIV, people living with HIV; TLD, tenofovir lamivudine dolutegravir; TLE, tenofovir lamivudine efavirenz; VL, viral load; 3MMD, 3-month multi-month dispensing; 6MMD, 6-month multi-month dispensing.

Table 2. Proportion and absolute number of all ART clients on MMD in 21 PEPFAR-supported countries (October 2019–December 2020)

Quarter	Clients on ART	3–5MMD (%)	6MMD (%)	Total MMD (%)
Q4 2019	10,372,711	4,180,036 (40%)	913,525 (9%)	5,093,561 (49%)
Q1 2020	10,703,679	5,198,528 (49%)	1,014,704 (9%)	6,213,232 (58%)
Q2 2020[1]	11,121,591	6,134,728 (55%)[a]	1,917,047 (17%)[b]	8,051,775 (72%)[c]
Q3 2020	11,476,916	6,196,129 (54%)	2,308,130 (20%)	8,504,259 (74%)
Q4 2020	11,656,878	6,227,107 (53%)	2,517,943 (22%)	8,745,050 (75%)

[1]Two-proportion Z-test comparing MMD % for Q2 2020 (COVID-19) versus Q4 2019 (pre-COVID-19): (a) for 3–5 MMD, $p<0.001$; (b) for 6MMD, $p < 0.001$; and (c) for total MMD, $p < 0.001$.
ART, antiretroviral therapy; MMD, multi-month dispensing; PEPFAR, the United States President's Emergency Plan for AIDS Relief; 3-5MMD, 3-5-month multi-months dispensing; 6MMD, 6-months multi-month dispensing.

3.2 | Changes in MMD coverage

MMD policy adaptations implemented during the COVID-19 response (Q2 2020) were associated with a significantly accelerated growth in MMD coverage ($p < 0.001$), irrespective of age or dispensing interval. MMD coverage for all clients on ART grew substantially from 49% (5,093,561/10,372,711) in Q4 2019 pre-COVID-19 to 72% (8,051,775/11,121,591) in Q2 2020 during COVID-19; and among paediatric clients, MMD coverage grew from 27% (142,580/524,546) in Q4 2019 to 51% (270,984/531,538) in Q2 2020. Across MMD dispensing intervals, 3–5MMD for all clients on ART increased from 40% (4,180,036/10,372,711) in Q4 2019 to 55% (6,134,728/11,121,591) in Q2 2020; and among paediatric clients, 3–5MMD increased from 24% (127,261/524,546) to 45% (238,561/531,538) in the same period. The proportion of clients on ART receiving 6MMD increased from 9% (913,525/10,372,711) in Q4 2019 to 17% (1,917,047/11,121,591) in Q2 2020; and among paediatric clients, 6MMD coverage doubled from 3% (15,319/524,546) to 6% (32,423/531,538) in the same period (Tables 2 and 3).

MMD growth slowed considerably following the Q2 2020 surge, likely due to select countries achieving saturation of MMD enrolment among eligible clients or disruptions to the ARV supply chain due to COVID-19, but total MMD coverage continues to grow across the PEPFAR program. There is a drop-off in the proportion of clients receiving 3–5MMD starting in Q3 2020 and continuing in Q4 2020 and a subsequent increase in the proportion of clients receiving 6MMD as programs begin transitioning more clients from 3–5MMD to 6MMD.

3.3 | Changes in MMD coverage in select countries

Notable increases in MMD coverage among PEPFAR-supported clients were observed in a number of countries during the COVID-19 response; though tests of statistical significance were not performed on individual countries. In Ethiopia and the Democratic Republic of the Congo (DRC),

Table 3. Proportion and absolute number of paediatric (<15 years) ART clients on MMD in 21 PEPFAR-supported countries (October 2019–December 2020)

Quarter	Paediatric clients on ART	3–5MMD (%)	6MMD (%)	Total MMD (%)
Q4 2019	524,546	127,261 (24%)	15,319 (3%)	142,580 (27%)
Q1 2020	525,128	165,620 (32%)	16,055 (3%)	181,675 (35%)
Q2 2020[1]	531,538	238,561[a] (45%)	32,423[b] (6%)	270,984[c] (51%)
Q3 2020	537,126	242,968 (45%)	38,792 (7%)	281,760 (52%)
Q4 2020	532,239	244,351 (46%)	39,814 (7%)	284,165 (53%)

[1]Two-proportion Z-test comparing MMD % for Q2 2020 (COVID-19) versus Q4 2019 (pre-COVID-19): (a) for 3–5 MMD, $p < 0.001$; (b) for 6MMD, $p < 0.001$; and (c) for total MMD, $p < 0.001$.

where the governments recommended MMD for nearly all ART clients starting in March and April 2020, respectively; total MMD coverage in Ethiopia was 41% in Q4 2019, climbed to 79% in Q2 2020, and reached 89% in Q4 2020; and in DRC, total MMD coverage was 35% in Q4 2019, increased to 88% in Q2 2020 and reached 94% in Q4 2020. Among clients < 15 years of age, total MMD coverage in Ethiopia increased from 14% in Q4 2019, tripled to 58% in Q2 2020 and increased to 72% in Q4 2020; and in DRC, paediatric coverage increased from 16% in Q4 2019, quadrupled to 83% in Q2 2020 and increased further to 89% in Q4 2020 [16,20]. In Mozambique, where COVID-19 adaptations specifically addressed eligibility for children over 2 years of age, MMD coverage among clients < 15 years was 9% in Q4 2019, increased four-fold to 38% in Q2 2020 before dipping slightly to 35% in Q4 2020 [26]. In Zambia, where the government issued guidance in March 2020 to provide 6MMD to stable clients over 10 years of age, 6MMD coverage started at 26% in Q4 2019, doubled to 54% in Q2 2020 and increased slightly to 55% in Q4 2020 [31].

3.4 | Changes in treatment outcomes

PEPFAR program data indicate that as MMD eligibility criteria and enrolment expanded, virologic suppression rates remained high. Across the 21 countries, virologic suppression was 90% in Q4 2019 and Q1 2020 before MMD expansion (6.6 and 6.9 million clients, respectively) and steadily increased from 91% in Q2 2020 (7.0 million clients), to 92% in Q3 2020 (7.4 million clients) and to 93% in Q4 2020 (8.1 million clients). Among clients < 15 years old, virologic suppression was 71% in Q4 2019 (286,000 clients) and steadily increased to 80% in Q4 2020 (326,000 clients). Consistently increasing rates of viral suppression were maintained across nearly all 21 countries.

3.5 | Limitations

This study has a number of limitations. First, PEPFAR began collecting MMD data in Q4 2019 giving us only two quarters of data (Q4 2019; Q1 2020) to establish a baseline prior to the COVID-19 response; and several countries began implementing adaptations to MMD policy in March of Q1 2020. Second, MMD was a PEPFAR priority prior to COVID-19 and uptake was increasing globally. Third, the COVID-19 MMD policy desk review and analysis may not have captured all country-specific policy changes; the absence of a documented country policy adaptation does not mean one did not exist, only that we could not find one. Fourth, the viral load results are promising but will need to be monitored over a longer time in order to assess impact. Lastly, we recognize that MMD is just one enabler of differentiated service delivery for HIV treatment in a suite of services and is part of an overall strategy to separate clinical care from drug distribution.

4 | CONCLUSIONS

The COVID-19 adaptations to MMD policy created an enabling environment for accelerating MMD uptake and extending dispensing intervals, particularly among clients < 15 years of age. Increasing access to MMD for children, pregnant and/or breastfeeding women, clients not meeting the criteria for "stable on ART" and new ART initiators supports treatment continuity while mitigating potential exposure to COVID-19 at health facilities. Early evidence suggests that this model is beneficial in public health emergencies and during disruptions to the healthcare system. Outside emergency contexts, expanded MMD eligibility extends client-centred care to previously excluded populations promoting improved client satisfaction, virologic suppression and treatment continuity. With millions of new clients receiving the benefits of MMD, the global HIV community can move beyond limiting these policy changes to temporary protective measures during a global pandemic and consider institutionalizing them to become the new standard of care, even as COVID-19 subsides.

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COMPETING INTERESTS

There are no competing interests.

AUTHORS' CONTRIBUTIONS

The initial concept for this commentary was conceived by all authors (LEB, GKS, CG, PA, MD and JRC). LEB, GKS and CG contributed to the initial outline. LEB, GKS

and CG contributed to the initial manuscript content. MD conducted the statistical analysis in R. LEB, GKS, CG, MD and PA contributed to the revisions. All authors (LEB, GKS, CG, PA, MD and JRC) approved the final commentary.

ACKNOWLEDGEMENTS

We would like to thank our PEPFAR colleagues based throughout United States Embassies and members of the U.S. Government interagency MMD short-term technical team who supported efforts to collect and share MMD policy changes during the COVID-19 response.

FUNDING

This article was made possible by the support of the American people through the U.S. President's Emergency Plan for AIDS Relief (PEPFAR).

DISCLAIMER

The views expressed in this article are those of the authors and do not necessarily reflect the view of the U.S. President's Emergency Plan for AIDS Relief, the U.S. Agency for International Development, the U.S. Office of the Global AIDS Coordinator and Health Diplomacy, the United States Army, the Department of Defense, Henry M. Jackson Foundation for the Advancement of Military Medicine or the U.S. Government.

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Jo Y et al. *Journal of the International AIDS Society* 2021, **24**(S6):e25808
http://onlinelibrary.wiley.com/doi/10.1002/jia2.25808/full | https://doi.org/10.1002/jia2.25808

JIAS JOURNAL OF THE INTERNATIONAL AIDS SOCIETY

SHORT REPORT

Changes in HIV treatment differentiated care uptake during the COVID-19 pandemic in Zambia: interrupted time series analysis

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Abstract

Introduction: Differentiated service delivery (DSD) models aim to improve the access of human immunodeficiency virus treatment on clients and reduce requirements for facility visits by extending dispensing intervals. With the advent of the COVID-19 pandemic, minimising client contact with healthcare facilities and other clients, while maintaining treatment continuity and avoiding loss to care, has become more urgent, resulting in efforts to increase DSD uptake. We assessed the extent to which DSD coverage and antiretroviral treatment (ART) dispensing intervals have changed during the COVID-19 pandemic in Zambia.

Methods: We used client data from Zambia's electronic medical record system (SmartCare) for 737 health facilities, representing about three-fourths of all ART clients nationally. We compared the numbers and proportional distributions of clients enrolled in DSD models in the 6 months before and 6 months after the first case of COVID-19 was diagnosed in Zambia in March 2020. Segmented linear regression was used to determine whether the outbreak of COVID-19 in Zambia further accelerated the increase in DSD scale-up.

Results and discussion: Between September 2019 and August 2020, 181,317 clients aged 15 or older (81,520 and 99,797 from 1 September 2019 to 1 March 2020 and from 1 March to 31 August 2020, respectively) enrolled in DSD models in Zambia. Overall participation in all DSD models increased over the study period, but uptake varied by model. The rate of acceleration increased in the second period for home ART delivery (152%), ≤2-month fast-track (143%) and 3-month MMD (139%). There was a significant reduction in the enrolment rates for 4- to 6-month fast-track (−28%) and "other" models (−19%).

Conclusions: Participation in DSD models for stable ART clients in Zambia increased after the advent of COVID-19, but dispensing intervals diminished. Eliminating obstacles to longer dispensing intervals, including those related to supply chain management, should be prioritized to achieve the expected benefits of DSD models and minimize COVID-19 risk.

Keywords: antiretroviral treatment; COVID-19; differentiated service delivery; HIV service delivery; multi-month dispensing; Zambia

Received 22 March 2021; **Accepted** 3 August 2021

1 | INTRODUCTION

In 2020, an estimated 16.4 million people living with human immunodeficiency virus (PLHIV) and taking antiretroviral treatment (ART) in sub-Saharan Africa risked treatment interruptions because of COVID-19 due to closing or limiting of human immunodeficiency virus (HIV) services, antiretroviral supply chain disruptions, transportation or travel restrictions and/or overwhelmed service providers [1]. Maintenance of ART services — in addition to continued case identification and prompt initiation of newly diagnosed PLHIV on lifelong treatment — is critical to protect the progress that has been made towards HIV epidemic control [2].

One potential solution to the disruptions caused by COVID-19 is differentiated service delivery (DSD), a "client-centered approach that simplifies and adapts HIV services across the cascade to serve the needs of PLHIV better and reduce unnecessary burdens on the health system" [3]. DSD has emerged as a key strategy for HIV programmes in resource-limited settings, as DSD models can lessen the burden of HIV treatment on clients and providers by extending medication dispensing intervals, reducing requirements for

Table 1. Description of each of the evaluated differentiated service delivery models implemented in Zambia between September 2019and August 2020[a]

Differentiated service delivery model	Description
Fast-track (≤2 months, 3 months, 4–6 months)	A model that creates a separate queue, kiosk, or procedure at a facility to speed up service delivery for stable clients [5]. In Zambia, this typically involves a separate and shorter queue for quick dispensing when a clinical visit is not indicated.
Multi-month dispensing (MMD) (3 months, 4–6 months)	Any model in which the primary goal is to dispense medications for a longer duration than is done under standard care (usually 3 or 6 months) [5]. Dispensing is typically done alongside a clinical facility-based visit.
Community adherence group (CAG)	Group of ±6 people, based on residential proximity or client preference, meet monthly at a designated place in the community. Members collect medication at clinical appointments for other CAG members, in a rotating fashion [4].
Home ART delivery	Trained community health workers (CHWs) linked to facilities conduct home visits to deliver ART, conduct health screening, monitor adherence and refer clients as required. All community services are captured on a tablet-based SmartCare linked Community HTC (HIV testing and counseling) or Community ART module [4].
Others	There are a number of additional models currently enrolling clients in Zambia, but all at a relatively small scale. These models include: ART dispensing after/before (standard clinic) hours, weekend clinic, scholar (i.e. expanded hours, focused on school-going youth), central dispensing unit, community ART distribution points/pharmacy, health post, mobile ART distribution (in hard-to-reach areas) and rural/urban adherence groups (i.e. pre-packed ART dispensed by a healthcare worker in a group setting outside of typical clinic hours).

[a]Eligibility for all models was identical – "stable" adult clients (except for the scholar model, which was aimed at school-going adolescents). Eligibility did not change as a response to the pandemic.
ART, antiretroviral therapy.

facility visits and adjusting the location of service delivery [4]. These adjustments also minimise client contact with healthcare facilities and other clients [5], a high priority during the COVID-19 pandemic.

In Zambia, the Ministry of Health began promoting DSD models for ART in 2016, with participation gradually increasing over time [6]. By February 2021, roughly a quarter of the country's nearly 1 million clients were recorded as having ever been enrolled in a DSD model [7]. The models offered in Zambia included multi-month dispensing (MMD), fast-track medication pickup, community adherence groups (CAGs) and home ART delivery, with healthcare facilities varying widely on which of these or other models they adopted (Table 1). Three-month dispensing has been the standard of care for stable clients [8], though it has not been universally implemented. The Ministry of Health introduced 6-month dispensing in 2019 [9]. When the country's first SARS-CoV-2 infection was confirmed in March 2020, the Ministry of Health doubled down on the implementation of 6-month dispensing for all patients from ART initiation, with the exception of 3-month dispensing for those aged 2–10 [10]. Other models became more or less attractive in the face of COVID-19 risks and restrictions, depending on whether they required clients to meet as groups (e.g. CAGs) or reduced the need for public interaction (e.g. home delivery). In this study, we assessed the association between the COVID-19 pandemic and Zambia's response to it and the rate of change of enrolment in DSD models in the 6-month period before and after diagnosis of the first SARS-CoV-2 case.

2 | METHODS

To assess how DSD model enrolment, by model type, changed before and after the start of the COVID-19 pandemic, we conducted a retrospective review of SmartCare, Zambia's national electronic medical record system. As of February 2021, 737,411 clients were recorded in SmartCare as currently on ART, representing roughly three quarters of all ART clients in the country. The remaining quarter of clients attend facilities that do not yet utilize SmartCare. We accessed records for all clients aged 15 or older who newly enrolled in any DSD model between September 2019 and August 2020 at any of 737 health facilities across all 10 provinces. Children younger than the age of 15 were not included in the study protocol, given that when the protocol was written, children were not eligible for DSD models. We collapsed the many

DSD models recorded in SmartCare into eight groups based on the location and duration of medication dispensing: ≤2-month fast-track, 3-month fast-track, 4- to 6-month fast-track, 3-month MMD, 4- to 6-month MMD, CAGs, home ART delivery and all others. A description of each model can be found in Table 1 [11].

We first describe the basic characteristics of clients enrolled by DSD model before and after the introduction of COVID-19 in Zambia to determine whether enrolment in models has changed in terms of location (urban/rural, level of health facility) or in the age or sex distribution of clients enrolling. For each of the DSD model groups, we calculated the number of DSD enrolments by month from September 2019 to August 2020. To assess the effect of the COVID-19 pandemic on DSD care utilisation, we conducted an interrupted time series analysis using a segmented regression. Segmented regression has been previously used to evaluate changes at any defined point in time [12]. In our analysis, we compared the change in slope between the cumulative number of clients enrolled in DSD before 1 March 2020, compared to 1 March through August 2020 (i.e. before and after 1 March 2020), the approximate date when COVID-19 was first diagnosed in Zambia [13]. We used the following segmented regression model: $DSD_t = \beta_0 + \beta_1 time + \beta_2 covid_t + \beta_3 time \cdot covid_t$, where *time* is in months, and *covid* is a dummy variable indicating whether the current time is pre- or post-COVID. The outcome *DSD* is the cumulative number of clients enrolled in DSD at time *t*. β_3 indicates the slope change following the intervention, which we then tested whether there was a significant change in β_3 before and after 1 March 2020; a significant change in slope would suggest that DSD utilisation changed substantially during the COVID-19 pandemic. All analyses were performed at a two-sided significance level of 0.05. Finally, we estimated percentage changes in participation between the periods for each model group based on the mean slope. Data analysis was conducted in R version 4.0.2. (The R Project for Statistical Computing, Vienna, Austria.)

2.1 | Ethics

This study protocol was approved by ERES Converge IRB (Zambia), protocol number 2019-Sep-030; the Human Research Ethics Committee (Medical) of the University of Witwatersrand, protocol number M190453; and the Boston University IRB H-38823 for the use of data with a waiver of consent.

3 | RESULTS AND DISCUSSION

Participation in DSD models before and after the introduction of COVID-19 in March 2020 is presented in Table 2. Between September 2019 and August 2020, 181,317 clients aged 15 or older were recorded as being newly enrolled in DSD models in Zambia in the SmartCare electronic medical record system. These include 81,520 before and 99,797 on or after 1 March 2020, an overall increase of 22.4%. However, uptake varied widely by model. For example, the number of clients most substantially increased for home ART delivery (168%), 3-month MMD (96%), ≤2-month fast track dispensing (69%) but decreased for 4- to 6-month fast-track dispensing (−26%) and other models (−20%). Between the two periods, 3-month dispensing increased from 13% to 21% of all DSD enrolments, ≤2-month fast-track from 7% to 10% and home ART delivery from 1% to 2%. While 4- to 6-month fast-track declined, 4- to 6-month MMD increased between the two time periods, due to the greater increase in DSD enrolment in rural areas where fast-track is seldom implemented.

The proportion of all DSD enrolments in 4- to 6-month fast-track fell from 23% to 14%. There was no change in the proportions of clients enrolled in 4- to 6-month MMD (38% of all DSD enrolments in both periods). Participation of clients enrolled in rural areas increased for ≤3-month fast-track, 3-month MMD, CAGs and others. Home ART delivery was the only model to see a relative increase in the proportion of clients enrolled in urban areas (Table 2). There were no significant differences between the two time periods in the composition of the population enrolled in terms of sex or age.

Participation in DSD models accelerated over the study period. Comparing the periods before and after 1 March 2020, segmented linear regression models demonstrated an acceleration in the rate of increase (significant increases in slope) in participation during the COVID-19 pandemic for home ART delivery (152% change in slope between periods, *p*-value <0.001), ≤2-month fast-track (143%, $p < 0.001$) and 3-month MMD (139%, $p < 0.001$). Three-month fast-track showed both an immediate increase in numbers enrolled (155% from 6278 to 9729) and a significant acceleration in the rate of increase (60%, $p = 0.03$) between the two periods. In contrast, there were significant decelerations in the increase in enrolment for 4- to 6-month fast-track (−28%, $p = 0.01$) and for "other" models (−19%, $p < 0.001$) (Figure 1).

Over the course of 2020, the COVID-19 pandemic was associated with accelerated participation in DSD models in Zambia, though with uneven increases across the models. Most new clients enrolled in ≤2-month fast track, 3-month MMD, 4- to 6-month MMD, CAGs or home ART delivery. On the other hand, the increase in DSD enrolment was slower for the 4- to 6-month fast-track and "other" models. Participation in home ART delivery increased the most (168%), but it still accounted for only a small proportion of all participation (2%). Recommendations that high-risk individuals remain at home, to minimise their exposure to SARS-CoV-2, may potentially explain the expansion of home delivery models. We also found an immediate jump in enrolment for ≤2-month and 3-month fast-track on 1 March 2020 and an increase 1 month later for home ART delivery.

Although 3- to 6-month dispensing is Zambia's national policy for stable patients, the proportion of clients newly enrolled in 4- to 6-month DSD models fell between the two time periods, while ≤3-month dispensing increased for new DSD model enrolees. Another study at the United States President's Emergency Plan For AIDS Relief (PEPFAR)-supported sites found that 6-month dispensing had been expanded to 56% of clients ($n = 561,409$) by July 2020, an increase from

Table 2. Percentage change in numbers of clients enrolled in DSD models before and after COVID-19 introduction in Zambia (*n* = 181,317)

Parameters	Number of clients (proportion change %)	Location		Healthcare level			Sex			
		Urban	Rural	Health post	Clinic	Hospital	Male	Female		
All models	Before[a]	81,520 (100%)	64,997	16,523	4587	49,619	27,314	28,562	46,808	42 (11)
	After[b]	99,797 (100%)	75,424	24,373	5218	58,403	36,176	36,386	59,587	41 (12)
	%Δ[c]	22%	16%	48%	14%	18%	32%	27%	27%	–
≤2-month fast-track dispensing	Before	6005 (7%)	4405	1600	302	4202	1501	2078	3927	40 (12)
	After	10,163 (10%)	7205	2958	618	6854	2691	3654	6509	39 (11)
	%Δ	69%	64%	85%	105%	63%	79%	76%	66%	–
3-month fast-track dispensing	Before	6325 (8%)	5788	537	318	3973	2034	2067	4258	41 (10)
	After	6917 (7%)	6140	777	350	4360	2207	2427	4490	41 (11)
	%Δ	9%	6%	45%	10%	10%	9%	17%	5%	–
4- to 6-month fast-track dispensing	Before	19,112 (23%)	18,283	829	2013	10,026	7073	6481	12,631	43 (10)
	After	14,168 (14%)	13,627	541	975	7553	5640	5172	8996	43 (10)
	%Δ	−26%	−25%	−35%	−52%	−25%	−20%	−20%	−29%	–
3-month MMD	Before	10,743 (13%)	8215	2528	410	7101	3232	3744	6999	41 (11)
	After	21,101 (21%)	14,812	6289	1122	13,030	6949	7564	13,537	41 (12)
	%Δ	96%	80%	149%	174%	83%	115%	102%	93%	–
4- to 6-month MMD	Before	30,832 (38%)	22,447	8385	998	19,689	10,145	11,246	19,586	44 (11)
	After	38,120 (38%)	28,260	9860	1439	21,576	15,105	14,172	23,948	43 (11)
	%Δ	24%	26%	18%	44%	10%	49%	26%	22%	–
Community adherence groups	Before	2885 (4%)	1595	1290	112	1628	1145	917	1968	45 (11)
	After	3483 (3%)	1362	2121	133	2220	1130	1231	2252	45 (11)
	%Δ	21%	−15%	64%	19%	36%	−1%	34%	14%	–
Home ART delivery	Before	721 (1%)	444	277	240	132	349	283	438	39 (12)
	After	1929 (2%)	1472	457	288	838	803	686	1243	39 (12)
	%Δ	168%	232%	65%	20%	535%	130%	142%	184%	–
Others	Before		3820							40 (13)
	After	3916 (4%)	2546	1370	293	1972	1651	1480	2436	39 (13)
	%Δ	−20%	−33%	27%	51%	−31%	−10%	−15%	−23%	–

[a]Before: September 2019 to February 2020.
[b]After: March 2020 to August 2020.
[c]Percentage change in participant numbers between before and after periods.
DSD, differentiated service delivery; MMD, multi-month dispensing.

fewer than 50,000 in September 2019 in Zambia [7]. PEPFAR global data, excluding South Africa, showed a similar trend across its global programmes with an increase in 3- to 6-month dispensing from 46% in December 2019 to 69% by the end of June 2020 [14]. The smaller relative increase in 4- to 6-month dispensing in this analysis compared to the general nationwide (e.g. not DSD enrolee specific) dispensing data for Zambia, as well as global PEPFAR data, is likely due to the fact that we focused solely on patients newly enrolling into a DSD model (i.e. their first interaction with a DSD model only). This analysis is thus not reflective of the total scope of 4- to 6-month dispensing during the COVID-19 pandemic, but of new DSD enrolees alone. It is possible that new DSD enrolees receive ≤3-month dispensing at first, but then switched to 4- to 6-month dispensing during the pandemic period [15].

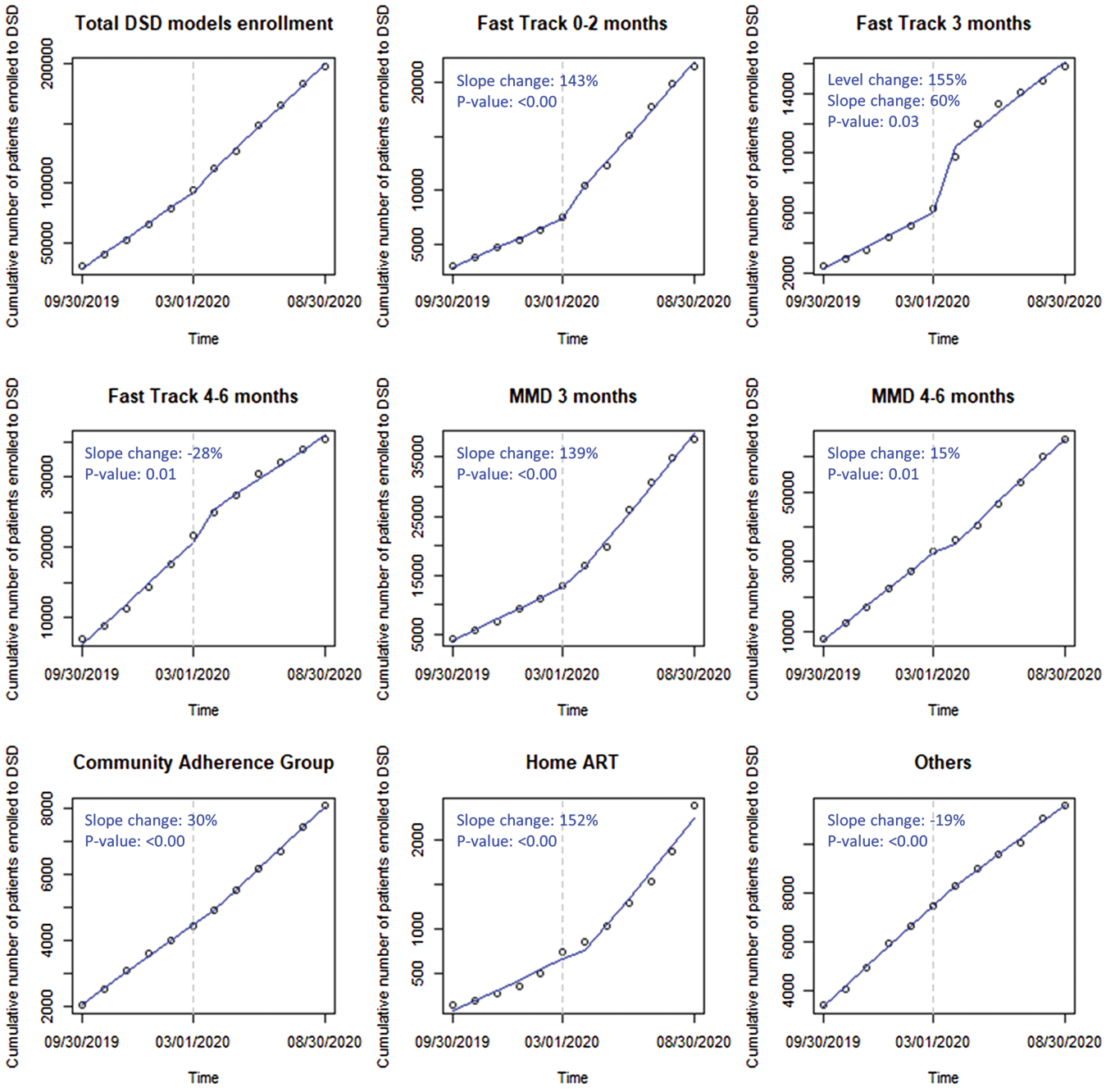

Figure 1. Interrupted time series scatter plot and slope lines for the DSD models before (September 2019 to February 2020) and after (March 2020 to August 2020) 1 March 2020 in Zambia. ART, antiretroviral therapy; DSD, differentiated service delivery; MMD, multi-month dispensing.

Our study has several limitations. We relied entirely on routinely collected medical record data from the SmartCare system, which covers only about three quarters of Zambia's ART facilities. It is possible that healthcare facilities without SmartCare differ from those in our data set in ways that would affect our outcomes. For example, facilities without SmartCare may be more poorly resourced or more remotely located than those with SmartCare, characteristics that could lead to differential uptake of DSD models. While interrupted time series analysis allows the ability to control for secular trends in the data (unlike pre/post cross-sectional studies) using population-level data with clear graphical presentation of results, this analysis does not illustrate how and why the introduction of COVID-19 resulted in different scale-up patterns by DSD models and whether and to what extent the temporal changes may differ by setting. Future research may examine the drivers and barriers of MMD from both the demand and supply-side aspects in the context of COVID-19

to improve continuation of care. Moreover, we have not considered retention in and switching between the DSD models or care more generally. Future work should aim to understand how this rapid acceleration of DSD model uptake has affected overall initiation and retention in care from a longitudinal cohort population perspective.

4 | CONCLUSIONS

Based on national electronic medical record data for clients enrolled in DSD models in Zambia from September 2019 to August 2020, our findings suggest that the introduction of the COVID-19 pandemic was associated with an acceleration in the scale-up of DSD models for clients on ART in Zambia. Efforts to eliminate obstacles to longer dispensing intervals should be prioritised to achieve the expected benefits of DSD models and minimise COVID-19 risk. This process has already begun in Zambia, where the government is now recommending relaxation of eligibility criteria for MMD, such that all clients initiating ART to receive a 3-month or 6-month supply of medications immediately, allowing them to delay their first follow-up visit for 3 months or 6 months after initiation [16]. Evaluating the impact of this evolution in DSD guidelines will be a high priority for the coming years.

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COMPETING INTERESTS

The authors declare that they have no conflicting interests.

AUTHORS' CONTRIBUTIONS

YJ, SR, and BEN conceived the study. YJ, SR, KTLS and BEN designed the study. BP, MM, HS, PH, MMM and PLM led study data collection. YJ, KTLS analysed the data and SR, ANH, BEN contributed to data analysis. YJ, SR, KTLS and BEN wrote the first draft of the manuscript. All authors reviewed and edited the manuscript. All authors have read and approved the final manuscript.

ACKNOWLEDGEMENTS

The funder had no role in study design, data collection and analysis, decision to publish or preparation of the manuscript.

FUNDING

Funding for the study was provided by the Bill & Melinda Gates Foundation through OPP1192640 to Boston University. Youngji Jo was supported by the Ruth L. Kirschstein National Research Service Award, National Institutes of Health T32 Training Grant (grant number: T32 AI052074-14).

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JIAS JOURNAL OF THE INTERNATIONAL AIDS SOCIETY

RESEARCH ARTICLE

Differentiated service delivery models among PLHIV in Akwa Ibom and Cross River States, Nigeria during the COVID-19 pandemic: descriptive analysis of programmatic data

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Abstract

Introduction: The rapid increase in the number of people living with HIV (PLHIV) on antiretroviral therapy (ART) in Akwa Ibom and Cross River states in Nigeria led to overcrowding at clinics. Patients were devolved to receive ART refills through five differentiated service delivery (DSD) models: fast-track (FT), adolescent refill clubs (ARCs), community pharmacy ART refill programs (CPARPs), community ART refill clubs (CARCs) and community ART refill groups (CARGs) designed to meet the needs of different groups of PLHIV. In the context of COVID-19-related travel restrictions, out-of-facility models offered critical mechanisms for continuity of treatment. We compared retention and viral suppression among those devolved to DSD with those who continued standard care at facilities.

Methods: A retrospective cohort study was conducted among patients devolved to DSD from January 2018 to December 2020. Bivariate analyses were conducted to assess differences in retention and viral suppression by socio-demographic characteristics. Kaplan–Meier assessed retention at 3, 6, 9 and 12 months. Differences in proportions were compared using the chi-square test; a *p*-value of <0.05 was considered significant.

Results: A total of 40,800 PLHIV from 84 facilities received ART through the five models: CARC (53%), FT (19.1%), ARC (12.1%), CPARP (10.4%) and CARG (5.4%). Retention rates at 6 months exceeded 96% for all models compared to 94% among those continuing standard care. Among those using DSD, retention rate at 12 months was higher among adults than children (97.8% vs. 96.7%, $p = 0.04$). No significant sex differences in retention rates were found among those enrolled in DSD. Viral suppression rates among PLHIV served through DSD were significantly higher among adults than children (95.4% vs. 89.2%; $p < 0.01$). Among adults, 95.4% enrolled in DSD were virally suppressed compared to 91.8% of those in standard care ($p < 0.01$). For children, 89.2% enrolled in DSD were virally suppressed compared to 83.2% in standard care ($p < 0.01$).

Conclusions: PLHIV receiving ART through DSD models had retention but higher viral suppression rates compared to those receiving standard care. Expanding DSD during COVID-19 has helped ensure uninterrupted access to ART in Nigeria. Further scale-up is warranted to decongest facilities and improve clinical outcomes.

Keywords: differentiated service delivery; people living with HIV; treatment retention; viral suppression; COVID-19; Nigeria

Received 23 March 2021; **Accepted** 19 August 2021

1 | INTRODUCTION

Globally, over 38 million people are living with HIV and 26 million are currently receiving lifelong antiretroviral therapy (ART) [1]. In 2016, the World Health Organization recommended a "test and treat" approach for all people newly diagnosed with HIV [2]. This recommendation was based on scientific evidence that early ART initiation reduces morbidity and mortality among people living with HIV (PLHIV) [3–5]. This expanded eligibility for treatment, while necessary to save lives, stretched already overburdened health systems in resource-limited settings, such as Nigeria. To address this situation, complementary differentiated service delivery (DSD) models were introduced in addition to the routine hospital service delivery models in high-burden countries. The DSD models implemented support the attainment of the global targets for HIV treatment while maintaining optimum quality of care [6] for PLHIV.

Although core principles of DSD are provision of client-centred care and achieving health system efficiencies, variations in model implementation by location, settings, HIV population and individual client characteristics are expected [7–9]. In addition, for optimal outcomes, DSD models should be constantly adapted to address challenges of access, and quality of care and treatment outcomes for PLHIV [10]. Sub-populations of PLHIV, such as pregnant and breastfeeding women, adolescents and children, men and key population members, may have different needs. Other individual characteristics of PLHIV accounted for during the design included clinical stage of disease and living environment. Across service characteristics (provider, location, frequency and intensity of care), different treatment delivery models are aimed at providing more client-centric services [9].

Data from other studies suggest that DSD models for PLHIV are more resource efficient and do not compromise patient care [11,12]. Uganda successfully implemented a DSD model using community drug distribution points for clients who were on ART for more than 3 months, showed good adherence (95%) and a CD4 count greater than 350 cells/mm^3 [13]. Mozambique implemented patient-managed community ART groups that led to significant improvement in ART retention and other treatment outcomes [10]. In South Africa, a high-volume ART site provided multi-month dispensing to stable clients through the fast-track (FT) model resulting in significant reduction in client waiting time with better retention and satisfaction [3].

PLHIV in Nigeria, as in other countries in sub-Saharan Africa, face significant challenges accessing ART [14,15]. In Akwa Ibom (HIV prevalence 5.5%) and Cross River (HIV prevalence 2.2%) states, the high HIV burden and geographic access challenges further constrain access [16]. To close treatment gaps in these two states, the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) through the United States Agency for International Development (USAID) funded the Strengthening Integrated Delivery of HIV/AIDS Services (SIDHAS) project to drive the surge implementation [17]. The surge response resulted in a marked increase in the number of PLHIV receiving ART in the two states. This increase in patient load was not accompanied by a corresponding increase in the number of healthcare workers (HCWs) at the public health facilities, which led to long wait times and overcrowding. To address this, starting in 2016, the project instituted DSD models to provide options for clients who wished to be devolved from the facilities. The rate of uptake of the devolvement options increased with the onset of COVID-19 in February 2020.

The COVID-19 outbreak in Nigeria was first reported on 27 February 2020, when the first confirmed case was announced by the Nigeria Center for Disease Control [18]. As of 17 February 2021, a total of 161,074 cases and 2018 deaths were reported by the Nigeria CDC. Several measures were instituted by the government, including total lockdowns in some states, restrictions on interstate movement, school closures, workplace restrictions and bans on social gatherings to help curb the spread of the virus. These restrictions prompted concerns about treatment interruption among PLHIV and necessitated a targeted intervention to encourage more patients to devolve from their usual treatment site to suitable DSD models to minimize the risk of exposure to COVID-19 for HCWs and patients.

The objective of this study was to compare retention and viral load suppression among PLHIV in Akwa Ibom and Cross River states who received their ART refills through DSD models with those who continued to receive refills through standard care at facilities.

2 | METHODS

2.1 | SIDHAS project

The SIDHAS project supports the Government of Nigeria (GON) in implementing comprehensive HIV services in Akwa Ibom and Cross River states. The goal is to sustain cross-sectional integration of HIV and AIDS services with tuberculosis (TB) services by building the capacity of GON staff to deliver high-quality, comprehensive, preventive care and treatment and other related services. The project, which began in 2011, currently provides technical support to 151 health facilities (123 public, 26 private-for-profit and 2 faith-based organizations) and 83 community pharmacies.

In the SIDHAS project, five DSD models were introduced to provide ART refills to the growing number of PLHIV on treatment. For the purpose of devolvement, stable clients were those who had been on ART for >12 months, had achieved at least 90% adherence, were VL suppressed (<1000 copies/ml) as at the time of the devolvement and had no opportunistic infections. The characteristics of the DSD models are summarized in Table 1. These models were designed to meet the unique needs of different groups and were introduced at different times.

2.2 | Data collection

For this study, de-identified data were extracted from Lafiya Management Information System (LAMIS), an electronic medical record database, that houses routine programmatic data collected from PLHIV who access services at SIDHAS-supported health facilities. These service delivery data are collected using standardized paper-based forms at each patient encounter and then entered into LAMIS by facility staff. The database was reviewed, and all PLHIV who were enrolled in one of the DSD models up to 30 December 2020 were selected for inclusion in the study. Data extracted for each patient included basic demographic information: age and sex; and clinical information: DSD models to which they were devolved, date devolved and recent viral load test results at the time of the study. The extracted data contained no patient names or any other personal identifying information that could be used to identify individual patients. The extracted data were subjected to internal consistency checks and assessed for outliers, which were removed prior to analysis.

2.3 | Data quality measures

At the end of each day, patient data initially captured on paper are entered into LAMIS by data entry clerks attached to each clinic. The data were summarized at the end of each

Table 1. Description of models of HIV treatment

Building blocks of service delivery	Clinical consultations	ART refills	VL sample collection	Psychosocial support
Model	Standard of care			
Eligibility (who)	All patients are eligible			
When	Fixed working hours, normal wait time			
Location of services (where)	Health facility			
Fees	None			
Services provided	+	+	+	+
Model	Fast-track			
Eligibility (who)	Only stable patients are eligible			
When	Fixed working hours, patients served within 5 min of arrival at facility			
Location of services (where)	Health facility			
Fees	None			
Services provided		+	+	+
Model	Adolescent refill clubs			
Eligibility (who)	Adolescents and young adults (10–24 years of age)			
When	Fixed after work hours on selected days			
Location of services (where)	Facility			
Fees	None			
Services provided		+	+	+
Model	Community pharmacy ART refill programs (CPARPs)			
Eligibility (who)	Stable adults (18 years and older)			
When	Flexible			
Location of services (where)	Private pharmacies in the community			
Fees	Yes			
Services provided		+		+
Model	Community ART refill groups (CARGs)			
Eligibility (who)	All patients linked through family or group membership			
When	Flexible hours			
Location of services (where)	Client's homes			
Fees	None			
Services provided		+		+
Model	Community ART refill clubs (CARCs)			
Eligibility (who)	All patients			
When	Flexible			
Location of services (where)	Convenient community locations, that is clinics and schools			
Fees	None			
Services provided	+	+	+	+

ART, antiretroviral therapy; VL, viral load.

week showing the number of individuals who accessed different services. All data were validated internally on a regular basis following established processes for data quality assurance setup by the SIDHAS project. Summary reports submitted to the project were compared with source documents, such as registers and other intake forms in the facilities to ensure consistency. If discrepancies were observed in the data, then reasons for the discrepancies were ascertained, noted and the data in LAMIS were adjusted to ensure consistency with the source document.

2.4 | Data analysis

Individuals were considered to still be in care if their next pickup date for ART from their designated pickup point (for the DSD group) or the health facility (for the non-DSD group) was after 31 December 2020. Individuals were classified as virally suppressed if their viral load was <1000 copies/ml.

Time-based cohorts of patients devolved to the DSD models were created based on the simplified cohort analysis approach, commonly used during routine ART program monitoring [19]. With this approach, patients were placed in different cohorts based on the dates on which they were enrolled in one of the DSD models. Patients devolved during any given quarter (3-month period) were considered to be in the same cohort.

Descriptive statistics were used for characteristics of PLHIV who were enrolled in DSD models. Bivariate analyses were then conducted to assess differences in retention and viral suppression rates by socio-demographic characteristics. Kaplan–Meier was used to assess retention for up to 12 months for those individuals who were enrolled in the DSD models. The Log-rank test was used to assess differences in retention rates by age and sex across the DSD models. Differences in proportions of individuals who were virally suppressed across the DSD and non-DSD models were compared using chi-square test. All tests were considered significant with a *p*-value of < 0.05.

2.5 | Ethical consideration

This study was reviewed by the Protection of Human Subjects Committee at FHI 360 and was categorized as non-human subject research. The data for this study were collected from an existing project database that is used for routine patient management and program monitoring. The authors had no access to the patients or any personal identifying information for the individuals who were included in the study.

3 | RESULTS

3.1 | Patients and models

At the end of December 2020, a total of 133,644 PLHIV were receiving ART at SIDHAS-supported facilities in Akwa Ibom and Cross River states. Out of those, 40,800 (30.5%) had been devolved to receive ART refills through five DSD models, and 92,844 (69.5%) continued to receive ART at the facilities where they were enrolled. The rate of devolution started slowly but then increased significantly after June 2020 during the first wave of the epidemic in Nigeria (Table 2).

Most patients were devolved to the community ART refill club (CARC) model (Table 3). PLHIV less than 20 years old were significantly more likely than those older than 20 to have been devolved to one of the DSD models; 42% (2912/6904) of those less than 20 years old were devolved compared to 29.8% (37,888/126,904) of those 20 or older ($p < 0.05$). There were no significant differences in the proportion of males and females devolved to one of the DSD models.

Table 2. Number of PLHIV devolved at different times

Time period	Number (%) devolved
January 2018–December 2019	3250 (7.96%)
January–March 2020	3821 (9.4%)
April–June 2020	3359 (8.2%)
July–September 2020	12,528 (30.7%)
October–December 2020	17,842 (43.7%)
Total	40,800 (100%)

PLHIV, people living with HIV.

3.2 | Viral suppression

Overall viral suppression was higher among DSD participants compared to those who continued to receive standard care at facilities (94.9% vs. 91.5%; $p < 0.05$). Among patients on DSD, viral load suppression rate was highest among those devolved to the FT model (98%) and lowest for those assessing care through the adolescent refill club (ARC) (90%) (Table 4).

Viral suppression rates were consistently higher among persons on DSD compared to those receiving the standard care (Table 5). Among persons 20 years or older, 95.4% of those enrolled in DSD were virally suppressed compared to 91.8% receiving standard care ($p < 0.01$). Similarly, for those younger than 20 years, 89.2% enrolled in DSD were virally suppressed compared to 83.2% who received ART at clinics ($p < 0.01$). Among females, 94.7% of those enrolled in DSD were virally suppressed compared to 91.7% receiving standard care ($p < 0.001$). A higher proportion of males enrolled in DSD (95.3%) were virally suppressed compared to males receiving standard care (90.9%) ($p < 0.001$).

3.3 | Retention in care

Among those who were devolved to DSD (Figure 1), retention rates at 12 months were significantly higher among those who were 20 years or older compared to those less than 20 years ($p = 0.004$). No significant differences in 12-month retention rates were found between males and females ($p = 0.592$).

Table 6 summarizes retention among PLHIV based on the simplified cohort analysis approach. With this analysis, we found that retention rates drop off as cohorts "age". Among the cohort followed up for 3 months, retention was 99.5%; in the 6-month cohort, 98.4%; in the 9-month cohort, 97.0%; and for those in the 12-month cohort, retention dropped to 89.5%.

4 | DISCUSSION

In this paper, we describe DSD models and compare viral suppression and retention among PLHIV who were devolved to receiving care through various DSD models with those who continued in standard, facility-based care in two states in Nigeria. Close to one-third of patients (30.3%) were devolved to receive care through the five DSD models. Enrolment of patients into the different models increased over the 2-year period from January 2018 to December

Table 3. Characteristics of people receiving treatment through different methods

	CARC *n* (%)	FT *n* (%)	ARC *n* (%)	CPARP *n* (%)	CARGs *n* (%)	Standard care *n* (%)
Sex						
Male	8525 (39.6)	2208 (28.4)	979 (19.19)	1534 (36.2)	828 (37.9)	33,047 (35.5)
Female	13,000 (60.4)	5569 (71.6)	3933 (80.1)	2705 (63.8)	1355 (62.1)	59,961 (64.5)
Age (years)						
<20	721 (3.3)	193 (2.5)	1829 (37.1)	38 (0.9)	131 (6.0)	3992 (4.3)
≥20	20,867 (96.7)	7591 (97.5)	3098 (62.9)	4278 (99.1)	2054 (94.0)	89,016 (95.7)
Median (IQR)	35 (29–42)	37 (31–45)	20 (18–22)	41 (35–48)	34 (28–41)	36 (29–43)
Total	21,588	7784	4927	4316	2185	93,008

Abbreviations: ARC, adolescent refill clubs; CARC, community ART refill clubs; CARG, community ART refill groups; CPARP, community pharmacy refill programs; FT, fast track; IQR, inter-quartile range.

Table 4. Viral suppression rates for patients disaggregated by model of care

	Standard care *N* = 93,008	DSD model *N* = 40,800				
		ARC	CARC	CPARP	FT	CARG
Number who had VL test	63,093	3816	15,023	3455	7227	1793
Number suppressed	57,705	3420	14,185	3310	7089	1717
% suppressed	91%	90%	94%	96%	98%	96%

Abbreviations: ARC, adolescent refill clubs; CARC, community ART refill clubs; CARG, community ART refill groups; CPARP, community pharmacy refill programs; DSD, differentiated service delivery; FT, fast track; VL, viral load.

2020 with the most significant increase occurring in July 2020, which coincided with the peak of the first wave of the COVID-19 pandemic in Nigeria. The movement restrictions, physical distancing requirements, supply chain disruptions and financial difficulties brought on by the pandemic necessitated the transitioning of patients to other models of care that limit exposure of both patients and HCWs to COVID-19 [20]. The results of our study are consistent with others that have reported some clients are very amenable to receiving care and treatment out of the healthcare facility [21]. To inform scale up, it is important to continually review routinely collected data to understand how treatment outcomes in DSD models compared with the standard of care.

Overall, we found higher suppression but similar retention rates among patients enrolled in the DSD models compared to those who continued to receive services through standard care at the facilities. Viral suppression rates for patients devolved to the DSD models were 95% compared to 91%

Table 5. Viral suppression rates disaggregated by models of care and age group

Demographic characteristics	Standard care versus DSD	% virally suppressed	Number tested	*p*-value
Age				
< 20 years	Standard care	83.2	2889	<0.001
	DSD	89.2	2377	
20 + years	Standard care	91.8	60,364	<0.001
	DSD	95.4	28,937	
Sex				
Male	Standard care	90.9	21,254	<0.001
	DSD	95.3	10,496	
Female	Standard care	91.7	41,999	<0.001
	DSD	94.7	20,818	

Abbreviation: DSD, differentiated service delivery.

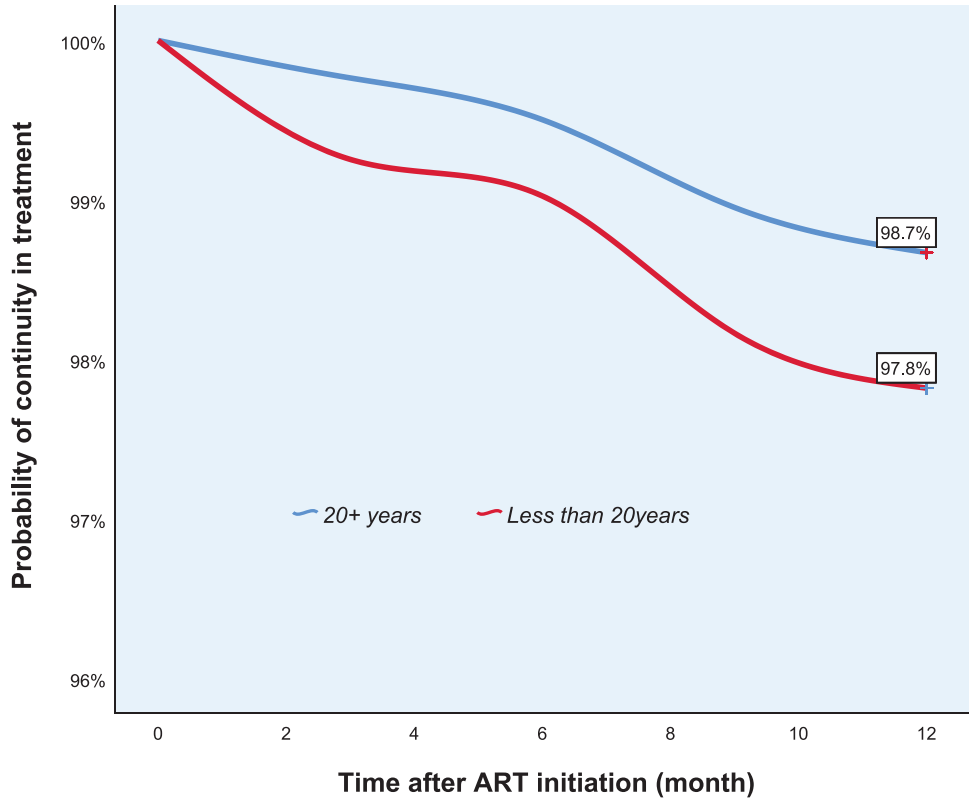

Figure 1. Twelve-month retention among patients on differentiated service delivery. ART, antiretroviral therapy.

among those who continued to receive standard care. Among models, viral suppression rates were highest with FT and lowest in the ARCs. The DSD models offer options for patients without compromising quality of care [22]. These models need to be continuously evaluated to ensure that they meet client needs and assure quality. The experience managing patients who were devolved before the COVID-19 outbreak helped to catalyze the rates at which patients were devolved and to maintain the quality of service. In the COVID-19 context, engagement with stakeholders is critical to avoid suboptimal outcomes [20]. The SIDHAS team offered clients a number of models in the two states to cater to the unique needs of clients. The CPARP and CARC models are critical for optimizing healthcare services, especially for patients living in remote areas with bad road networks and poor coverage of health facilities. Patients in these models are supported by HCWs who directly ensure they receive the same comprehensive healthcare package as provided at a health facility.

The cost of accessing treatment is a major factor affecting continued access to ART among patients on treatment [23]. While DSD models offer greater flexibility, out of facility models can, however, be more expensive than conventional facility care for equal or improved outcomes [24]. Donors and program managers would need to take this into account when planning and scaling up DSD. Retention rates among patients in the fee-paying CPARP model were 98.2%, which was marginally lower than those who continued to use the FT model care at the facilities for free. The CPARP model still offers an opportunity for busy patients in urban settings who are able to pay a small user fee. In other studies, user fees have had a mixed impact on access to services, especially in West Africa [25]. During the COVID-19 pandemic when movement was restricted and the cost of transportation increased, we observed increased enrolment in this DSD program.

Although DSD models were associated with high retention, implementing them in the middle of the COVID-19 pandemic would need some adjustments to ensure they meet the preferences of the patients to ensure optimal utilization [26]. The number of patients on antiretrovirals who chose different DSD models has implications for programming. The majority (78.6%) of patients in our project who were eligible for DSD continue to receive facility-based care either through standard care, FT or ARCs. The FT model, which requires patients to go to the health facility, nevertheless, ensures that the waiting time is reduced to the barest minimum. Reducing the waiting time helps improve treatment outcomes and may also act as a motivation to unstable clients who are assessing care at the health facility [22]. Retention was highest with the FT model highlighting its potential for patients who prefer facility models. Other authors have shown that some patients find it easier to access medication at facilities [27]. As multimonth dispensing, especially for 6-month supplies, scales up, the FT model holds promise. Waiting time in this model could be further reduced through introduction of automated lockers and prefabricated pharmacy in a box conveniently placed in less busy parts of a health facility. With this, patients on FT

Table 6. Retention rates for patients disaggregated by model of care

Retention by aggregated period – total DSD								
Period	**Elements**	**ARC**	**CARC**	**CPARP**	**Fast track**	**F-CARG**	**S-CARG**	**Total**
3 months (July–Sept 2020)	Number devolved	1921	7385	237	2266	592	171	12,572
	Number continued in treatment	1912	7347	235	2260	590	171	12,515
	% continued in treatment	99.5%	99.5%	99.2%	99.7%	99.7%	100.0%	99.5%
6 months (April–June 2020)	Number devolved	340	1805	739	404	82	28	3398
	Number continued in treatment	332	1775	728	400	82	28	3345
	% continued in treatment	97.6%	98.3%	98.5%	99.0%	100.0%	100.0%	98.4%
9 months (Jan–March 2020)	Number devolved	202	2637	476	270	326	0	3911
	Number continued in treatment	196	2540	465	270	322	0	3793
	% continued in treatment	97.0%	96.3%	97.7%	100.0%	98.8%	0%	97.0%
12 months (Oct–Dec 2019)	Number devolved	58	382	111	7	3	3	564
	Number continued in treatment	56	330	109	7	0	3	505
	% continued in treatment	96.6%	86.4%	98.2%	100.0%	0.0%	100.0%	89.5%

ARC, adolescent refill clubs; CARC, community ART refill clubs; CARG, community ART refill groups; CPARP, community pharmacy refill programs; DSD, differentiated service delivery.

can pick up their medication without having to register when they visit the clinic.

We found higher retention (98.2%) among children in the ARCs than their peers who continued to receive standard care at facilities (93.6%). This model, which offers adolescents a platform to relate and interact with their peers, gives them a sense of belonging and hope that may help address the viral suppression gaps among adolescents.

Our study had some limitations. We used programmatic data for this analysis and as such, there are a number of limitations. Firstly is the inherent selection bias as participants were not randomized to the respective DSD models but elected to join them when they were offered. Secondly, the eligibility criteria for the DSD models required clients to be stable on treatment. These clients would more likely also be retained in care and maintain their VL suppression. Thirdly,

the majority of the patients were devolved during the last 6 months, resulting in a relatively short follow-up period resulting in limited ability to make inferences about the longer term outcome across the DSD models. Finally, these data were not collected for research purposes and may contain some level of errors, including missing data and inconsistencies, that could affect generalizability of the results. Finally, data for other important confounding variables that could have affected the relationships were not collected and the relationships could not be adjusted for these. Consistent data quality assurance measures implemented by the project, including regular review of the data collection tools and mentoring of staff, helped mitigate this situation.

5 | CONCLUSIONS

PLHIV receiving ART through DSD models had better treatment retention and viral suppression rates than those receiving ART through standard care at facilities. Expanding DSD treatment models during the COVID-19 pandemic has helped ensure uninterrupted access to ART in Nigeria. Further scale-up of various DSD models is warranted to decongest facilities and improve clinical outcomes among PLHIV. These data, collected during routine program implementation, represent the real-world setting and provide an example of routinely collected data can be used to answer important research questions. Persons working in other settings who are thinking of adapting these models should use their data to adjust them to suit their unique context [28].

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COMPETING INTERESTS

The authors report no competing interests.

AUTHORS' CONTRIBUTIONS

OS, NP, PN, AI and MB conceptualized the study and supervised the analysis and interpretation of the data. CU, OA, PI and CO organized and prepared the data for analysis. AI, UA, OT and TB conducted the data analysis with the advice of OS, NP and PN. OS, NP, PN and AI wrote the first draft of the manuscript. KO, HK, SP, RC, EJ, IL and DO reviewed the draft and added content to specific sections. All authors contributed to data interpretation and approved the final version.

ACKNOWLEDGEMENTS

The authors acknowledge all those who were involved in the SIDHAS project in Nigeria, particularly the technical and strategic information staff members based at the various facilities.

FUNDING

This publication resulted in part from data collected during implementation of the PEPFAR-funded SIDHAS project in Nigeria (Cooperative Agreement Number: AID-620-A-11-00002).

DISCLAIMER

The content of this article represents the views of the authors and does not necessarily represent the views of the funder.

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http://onlinelibrary.wiley.com/doi/10.1002/jia2.25800/full | https://doi.org/10.1002/jia2.25800

JIAS JOURNAL OF THE INTERNATIONAL AIDS SOCIETY

RESEARCH ARTICLE

HIV service delivery in the time of COVID-19: focus group discussions with key populations in India

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Abstract

Introduction: There are limited data on the impact of COVID-19-associated disruptions and novel HIV service delivery strategies among key populations (KPs) in low- and middle-income countries. In March 2020, in response to COVID-19, the Government of India revised HIV service delivery policies to include community antiretroviral therapy (ART) distribution and multi-month dispensing (MMD) of ART for all people living with HIV (PLHIV).

Methods: To assess the acceptability of these adaptations and impact of the pandemic among KPs, we conducted focus groups in November–December 2020 with purposively sampled men who have sex with men (MSM), female sex workers (FSWs) and transgender women (TGW) in Telangana and Maharashtra. Seven discussions were conducted. Topics included HIV service access, risk behaviours, economic security and feedback to ensure service continuity. Inductive coding identified themes across topics.

Results: Forty-four individuals aged 20–49 years participated in discussions (13 MSM; 16 FSW; and 15 TGW). Twenty-four participants self-identified as living with HIV. People not living with HIV reported challenges in accessing HIV antibody testing at hospitals due to travel restrictions and fear of contracting COVID-19. Participants accessed HIV antibody testing using transportation arranged by community-based organizations after lockdowns eased. PLHIV reported uninterrupted ART refills and generally consistent adherence; however, there were experiences of delayed CD4 and HIV RNA testing. Participants shared appreciation for MMD as it saved time, money, and reduced exposure to COVID-19. Participants expressed gratitude for home deliveries which enabled ART access, yet shared concerns about home-based services causing confidentiality breaches with family/neighbours. Participants voiced preferences for community-based service provision due to proximity, convenient hours, and welcoming environments compared to public hospitals. Other requests included support for income, employment, nutrient-rich food and more accessible mental health, HIV, and other health services.

Conclusions: COVID-19 restrictions had a greater impact on access to HIV antibody, CD4, and RNA testing services compared to ART access. High acceptance of MMD and community-based services support the continued role of differentiated service delivery models to improve KP access to HIV antibody, CD4, RNA testing services, convenient ART retrieval, and integrated services beyond HIV, which may be critical for survival and wellbeing.

Keywords: COVID-19; DSD; HIV; India; key populations

Received 22 March 2021; **Accepted** 6 August 2021

1 | INTRODUCTION

India, with an estimated 2.35 million people living with HIV (PLHIV), bears the third largest burden of HIV globally [1]. HIV prevalence in India is disproportionately higher among key populations (KPs), or groups at higher risk of HIV who often face stigma and criminalization of their behaviours [2]. KPs in India with higher HIV prevalence compared to the general population prevalence of 0.22% include people who inject drugs (6.3%), transgender people (3.1%), men who have sex with men (MSM) (2.7%), and female sex workers (FSWs) (1.6%), based on the last round of national surveillance conducted in 2017 [3]. The national HIV program in India delivers free antiretroviral therapy (ART) from public centres, accessed by KPs and general populations alike. In 2018, India's National AIDS Control Organization (NACO) issued technical ART guidelines, which recommend differentiated care to KPs living with HIV who access ART at public centres

[4]. For HIV prevention, India maintains the targeted interventions program through government-funded, community-based organizations (CBOs). These programs provide a variety of KP-focused HIV prevention services, including community-based HIV and sexually transmitted infection (STI) screening, and commodity distribution (e.g. condoms, lubricant, needles/syringes, and opioid substitution therapy).

The first case of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) was reported in India on 30 January 2020; the number of cases escalated dramatically thereafter, reaching a peak of almost 100,000 cases per day in September, 2020 before declining. A second SARS-CoV-2 wave spiked in March–April 2021, exceeding 400,000 cases per day at its peak [5]. As of 30 June 2021, there were 30,411,634 total reported cases of COVID-19 in India, the second highest case count globally [5]. The sharp increase in cases during India's first wave was accompanied by a nationwide lockdown that was strictly enforced from March to May 2020. No public transport was operational, and travel was only allowed for essential services during restricted hours. Many government facilities providing HIV services were re-purposed to provide COVID-19 case management. Some states continued lockdowns with varying restrictions beyond May 2020. In India's second wave, no national lockdown was instituted but restrictions were regulated on a state-by-state basis.

NACO rapidly re-designed components of their program to ensure service continuity in response to the first wave of COVID-19. Pre-pandemic, ART in India was generally dispensed for 30 days through government facilities for all PLHIV, and only PLHIV who met criteria to be considered stable on treatment were eligible to receive multi-month dispensing (MMD). Prior to September 2018, MMD was approved for 2 months, then switched to 3-month MMD to be rolled out in phases for eligible PLHIV. As of March 2019, it was estimated that 46% of documented PLHIV on ART in India were receiving MMD [6]. In response to COVID-19 lockdown restrictions in March 2020, 3-month MMD became available for all PLHIV. Other policy adaptions in response to the pandemic included expanding home or community-based delivery of ART rather than facility pick-up, allowing ART pick-up from any public ART centre in the country rather than the centre where clients are registered, and issuing multi-day doses (5–7 days) of opioid substitution therapy [7]. The impact of COVID-19 and the government's response among KPs is largely unknown, but critical to ensure that gains with respect to HIV/AIDS epidemic control in India are not lost as a result of COVID-19.

We describe the findings from KP focus group discussions in two high HIV-burden Indian states to assess the impact of COVID-19 on access to HIV services among KPs to inform HIV programming and policy.

2 | METHODS

2.1 | Study setting

We facilitated KP focus group discussions in November–December 2020 to inform service delivery of a President's Emergency Plan for AIDS Relief (PEPFAR) program working to improve the HIV care continuum among KPs in select districts in the states of Maharashtra and Telangana. These states were chosen because they were identified by PEPFAR as states with high HIV burdens in India; Maharashtra has the highest estimated number of PLHIV in India (396,000) and Telangana has the fifth highest (158,000), as of 2019 [1]. These states together account for about a quarter of the HIV burden in India and contributed 16% of India's newly documented HIV infections in 2019 [3]. HIV transmission in these states is largely sexually driven. Among new HIV diagnoses with self-reported transmission routes in 2019–2020, 95% were sexually driven in Maharashtra and 97% were sexually driven in Telangana [3]. This is similar to most regions of India apart from the Northeast, where injection drug use is a major driver [3]. As of 30 June 2021, 20% of India's total COVID-19 cases (30,411,634) were in Maharashtra (6,061,404), the state which bore the highest COVID-19 burden nationally, and 2% were in Telangana (623,510) [5,8].

2.2 | Study population

KPs represented in this sample include MSM, FSW, and transgender women (TGW). Local CBOs who provide services tailored to one of these KP groups facilitated recruitment. They were chosen through a mapping exercise of KP-focused CBOs in the states of this study. Using a purposive sampling approach aimed at recruiting an information-rich, balanced sample across KP groups and HIV status [9], program staff worked with the CBOs to identify community members with whom they had existing relationships through service provision. Participants had to be 18 years or older, living in India since lockdowns, and self-identifying as one of the KP groups of interest.

2.3 | Study procedures

Semi-structured interview guides included questions related to four domains: HIV service access, risk behaviours, economic security, and feedback to ensure service continuity. Interview guides were pilot tested and modified accordingly prior to discussions with participants. Due to in-person COVID-19 restrictions and to maximize safety, program staff contacted potentially eligible participants by phone to conduct eligibility screening and obtain informed oral consent in the local language of participants. Discussions were organized to have individuals of the same KP group and HIV status as part of the same group. Due to COVID-19, discussions were either held over the phone using a conference-calling platform called Voice Snap or in-person with COVID-19 safety precautions. For remote discussions, participants called in by phone at the designated time. Facilitators were staff of the program who had experience working with KPs but were uninvolved with CBO service provision. Facilitators were trained in qualitative interviewing, including techniques to encourage full-group engagement and understanding over the phone, and led each discussion in local languages (Hindi in Maharashtra and Telugu in Telangana). Discussions were also attended by a note taker. Instead of their real names, participants used a pre-determined unique identification number or pseudonym to identify themselves. A total of seven focus group discus-

Table 1. Focus group discussion participant characteristics

	Total (*n* = 44)	MSM (*n* = 13)	FSW (*n* = 16)	TGW (*n* = 15)
Age [n(%)]				
20–29	17 (39)	6 (46)	4 (25)	7 (47)
30–39	18 (41)	3 (23)	9 (56)	6 (40)
40–49	9 (20)	4 (31)	3 (19)	2 (13)
HIV status [n(%)]				
Positive	24 (55)	7 (54)	10 (62.5)	7 (47)
Negative	20 (45)	6 (46)	6 (37.5)	8 (53)
State [n(%)]				
Maharashtra	18 (41)	6 (46)	6 (37.5)	6 (40)
Telangana	26 (59)	7 (54)	10 (62.5)	9 (60)

Abbreviations: FSWs, female sex workers; MSM, men who have sex with men; TGW, transgender women.

sions were conducted with 5–8 participants in each. All participants were compensated 500 Indian Rupees (~7 USD) for their time.

2.4 | Data analysis

Audio recordings of discussions were transcribed and translated to English by trained transcribers. One analyst reviewed transcripts on a rolling basis and developed emergent themes, which were reviewed by interviewers and note takers to confirm they represented their understanding of what participants shared. Two analysts developed a codebook using a constant comparison approach [10,11]. Codes were created inductively from initial transcripts across two a priori categories (experiences and perspectives). Codes were developed by comparing themes within each transcript and subsequent transcripts to determine whether a theme presented a new category, fit an existing category, or added nuance to an existing category. The codebook was added to and refined through this process, aided by discussion between analysts. Next, one analyst applied codes to all transcripts. Then, both analysts independently synthesized themes across codes, comparing similarities and differences between KP groups, HIV status groups, and geographies, and engaged in discussion to clarify findings. Coding was conducted using Dedoose Version 8.0.35 [12].

2.5 | Ethical clearances

This study was approved by the Johns Hopkins Bloomberg School of Public Health Institutional Review Board (protocol no. IRB00013169), as well the YR Gaitonde Centre for AIDS Research and Education Institutional Review Board (protocol no. YRG 339), the local IRB in India.

3 | RESULTS

Seven discussions were conducted with 44 participants (Table 1) – four in Telangana (two remotely, two in-person with COVID-19 safety precautions) and three in Maharashtra (all remote). Group size ranged from 5 to 8 participants. Thirteen participants were MSM, 16 were FSW, and 15 were TGW; 24 self-identified as living with HIV. Some MSM and TGW participants also engaged in sex work which became evident through discussion; however, this number was not explicitly documented. The median age of participants was 31 (range: 20–49).

We present themes across the following topics: pandemic impact on sexual behaviours, access to facility-based HIV testing and treatment services, experiences taking ART, preferences for service delivery, experiences with restricted mobility and limited livelihood, and perspectives about community needs.

3.1 | Pandemic impact on sexual behaviours

Participants expressed difficulty in finding and meeting sexual partners during the pandemic. Some reported completely stopping sexual activity and others engaged in sex with known partners as they were unable to meet new partners. "During the pandemic, we don't indulge in sex activities that much. We were scared of getting any infection". (MSM, age 49) Of those who engaged in sex work, including MSM and TGW, there was a decrease in sexual activity during the pandemic, but those who continued sex work or resumed after lockdown reported earning less due to reduced demand, inability to meet clients, and fear of COVID-19 exposure. TGW in Maharashtra who engaged in sex work reported changes in client interactions since the pandemic, such as clients asking if they have had a COVID-19 test and requiring them to wear masks during sex. One participant explained how clients now "prefer to have only anal sex because they are scared of getting Corona infection". (TGW, age 25)

Participants reported no change in condom use during COVID-19 compared to before. Across groups, participants consistently said that condoms are non-negotiable for safety. "We make sure that if there is no condom we don't engage in sexual activities. I feel that condom is most important". (MSM, age 35) MSM in both states reported a lack of reliable condom stock at public hospitals during COVID-19. However, all KP groups reported that CBOs helped maintain their supply of condoms.

3.2 | Access to facility-based HIV testing and treatment services

Disruptions from COVID-19 heightened several barriers for participants trying to access facility-based services for HIV antibody, CD4, and HIV RNA testing, compared to before the pandemic. Participants reported barriers to travel to facilities to get an HIV test or pick up ART, and confusion over which clinics were open or still offering these services given that hospitals had transitioned to treating COVID-19 patients:

> *Other health services were put on a back foot in front of COVID-19. I was willing to get my HIV test done but transport service was shut. So, in spite of having biannual HIV*

test due, I did not get tested and I felt that I shouldn't have missed it. (MSM, age 35)

Participants also mentioned avoiding HIV antibody testing because "there are so many Corona cases in government hospitals". (TGW, age 25) After lockdowns eased, some accessed HIV antibody testing through support of CBOs who helped make appointments and assist with transportation.

Disruptions in mobility and at health facilities resulted in delayed CD4 and HIV RNA tests for PLHIV. Hospitals cancelled CD4 test appointments or deferred them until after lockdown for multiple participants. One MSM, age 29, shared that he completed CD4 and HIV RNA testing at a public hospital post-lockdown, but experienced a delay in getting his results. Similar to HIV antibody testing support, CBO staff helped by providing transportation or accompanying participants over the pandemic to CD4 test appointments at public hospitals.

3.3 | Experiences taking ART

There were reported challenges in taking ART regularly during the pandemic among participants, most notably when living with family over lockdown:

I had faced problems while taking the medicines because my brothers were asking me, what are these medicines for and why I was taking them. I had to lie to my family members about the medicines. I also had difficulty in keeping the medicines at home. (MSM, age 40)

However, participants living with HIV generally reported taking ART regularly during COVID-19 without lapses in adherence.

Participants retrieved refills of ART either in-person at public ART centres or through home deliveries from CBOs. There were a few challenges in ART pick-up. One participant did not take ART for 15 days during lockdown after she ran out of pills, "I had gone to get my medicines, but they said that there is a shortage of medicines. So, I had to wait until the stock arrived". (FSW, age 30)

Despite these challenges, participants reported that new support mechanisms helped sustain ART access over the pandemic. KPs in both states reported receiving door-delivery of ART and expressed gratitude for the service, as it enabled them to maintain their stock. TGW in Maharashtra shared how a CBO in their area contacted them directly to ask about ART adherence and helped get them ART if needed. One participant described how his local CBO proved helpful especially after he tested positive for COVID-19:

I am thankful to them. As per medicines, I did not face any problems…[NGO name] delivered 3 boxes [of ART] to my house when I had informed that I have medicine shortage. By then I was COVID positive, they told me that there is no need to go out and delivered my medicines. (MSM, age 24)

A major change for participants living with HIV over the pandemic was receiving MMD, both through pick-ups and door deliveries. Participants across KP groups appreciated MMD, mentioning how it reduced trips to hospitals, saved money on travel expenses, and reduced disruptions in daily life, such as missing work:

It would be helpful if medicines are given for three months at a time. As we do private jobs, every month they might not give permission to go and get our medicines. They might have doubts that why are we asking permission every month on that particular date. (MSM, age 26)

Participants also shared concerns with MMD, mentioning that it could make it harder to keep their status a secret from others:

Taking medicines once in a month is good because if we have a stock of three months medicines, it will be difficult to hide them. What if someone sees them and tells others? If it is a single box with one month's medicines, it will be easy to hide. (FSW, age 30)

Participants reported misconceptions related to HIV, ART, and COVID-19. These included the idea that taking ART mitigated the risk of contracting SARS-CoV-2 infection, and living with HIV increased susceptibility to infection. Participants living with HIV shared how they were fearful of exposure especially as a person who is HIV positive, "We are at least living with HIV, if we get COVID we might perish. I am not sure if we will ever get treatment for it". (FSW, age 35) This fear made some question the safety of going to clinics to collect their ART.

3.4 | Preferences for HIV service delivery

Participants said that they would prefer to access services across the HIV cascade (i.e. HIV antibody testing, ART pick-up, CD4 and HIV RNA testing) through CBOs compared to public hospitals or clinics due to proximity, extended hours, and more welcoming environments. One participant shared his view that CBOs are well-placed to distribute ART and support on-time pick-ups compared to public hospitals:

[CBOs] have good accessibility and it is easier for them to do tracking. They can call up the members and remind about the medicine due date…It is better to hand over the responsibility to the community than going to [public hospital] and standing in the queue. (MSM, age 24)

Participants also preferred going to community-based service locations to avoid stigmatizing environments in public clinics. TGW in Telangana not living with HIV shared that they experience "odd looks" and "teasing" at public hospitals and staff do not take their health concerns seriously, so going to a CBO for HIV antibody testing is better than going to the hospital.

Participants shared conflicting opinions about home-based services initiated during lockdowns. There was appreciation for the convenience of home-delivery of ART and the perspective that this service delivery should continue. However, when sharing perspectives about whether or not other

services should hypothetically be delivered at home in the future, such as HIV antibody testing or CD4 testing, confidentiality concerns arose:

> *If they come home for [CD4] testing, the whole world will know about it…if the house owner comes to know about it, he will throw us out and nobody will give house for rent…Then we will have to shift to the forest. (FSW, age 35)*

> *We do not want [CD4] testing conducted at home…Most of us live with our family members and we do not want our family members to know about the testing. (MSM, age 24)*

Participants were open to the idea of telemedicine consultations (by phone or video call) as it saved time and money; however, there were reservations. One MSM, age 35, thought that a patient needs to meet a doctor physically to get better treatment. FSW and TGW both expressed concerns related to technology access, as many in their communities do not own a computer or smartphone.

3.5 | Experiences with restricted mobility

Difficulty to travel and move around during the pandemic emerged as a prominent theme across topics for KPs. Participants reported staying inside during lockdowns, as public transit was inaccessible and curfews were enforced. Restrictions affected participants" access to healthcare and resulted in a lack of clarity as to which pharmacies or service venues were operational. Participants either experienced or heard about harassment from police for travelling during lockdowns, which led to fear of leaving the house, "Females due to fear were not ready to go [to the hospital]…they used to say that police beat a lot…why unnecessarily get beat by police and come home?" (FSW, age 34)

3.6 | Experiences with limited livelihood

Another salient theme was how disruptions from the pandemic reduced income for participants, which caused stress and challenges to cover basic needs, including food and rent:

> *We used to have good food and be healthy. It used to [be] sufficient for us to survive. At times I also used to go to work. Now there is no money, [I] have taken loans and repaying them is difficult. We are facing lot of problems. (FSW, age 30)*

Prior to the pandemic, participants earned income from a variety of activities, including agriculture, daily wage jobs, and sex work. These income sources were far less lucrative over the pandemic, as earning opportunities reduced, travel was difficult, and activities produced less earnings. TGW reported challenges to earn money from begging, an important source of income in some TGW communities, "I go for begging at the signals, the vehicles are not giving us money…earlier we used to get 1,000 to 1,500 [rupees per day], now we get 200 to 300. It has become very difficult". (TGW, age 20)

Participants found alternative sources of income, such as this MSM, age 35, "We were not working during the lockdown. I learned how to run the sewing machine so I made masks to sell, and I earned a subtle income". Across groups, financial insecurity emerged as an ongoing point of stress post-lockdowns for participants and their communities.

3.7 | Perspectives about community needs

When discussing needs, participants requested help to find income opportunities, support to access government pensions they may be eligible for, skills training to find employment, and provision of nutrient-rich food or supplements for themselves and their families. One TGW described the impact which employment support could have in her community:

> *There are well-educated TG people who are getting decent jobs, and there are illiterate people with other skills sets. So if we get the proper opportunity, we can bring changes in our own life and stop begging and sex work. (TGW, age 36)*

Other trends for service priorities included COVID-19 testing, COVID-19 vaccine provision and mental health counselling. Participants also requested increased availability of HIV antibody testing, CD4 and HIV RNA testing, and accessible ART. Suggestions to make these services more available included subsidized or free travel to get to clinics for HIV-related services, and a mobile van to deliver ART and collect blood samples near people's homes.

4 | DISCUSSION

This qualitative assessment explored the impact of COVID-19 on HIV-related behaviours and HIV prevention and treatment access among MSM, TGW, and FSW in the high HIV-burden Indian states of Maharashtra and Telangana. We found that participants were appreciative of adaptations of the national AIDS program to ensure continuity of services, such as MMD and home/community-based ART delivery; however, participants encountered barriers to access facility-based testing services (HIV antibody testing as well as CD4 and HIV RNA testing) throughout the pandemic. A recurrent theme was the impact of COVID-19 on livelihood, which led to concerns with respect to securing food and housing.

Participants reported fewer sexual partners during the pandemic and tended to use condoms during sex, which may imply decreased HIV risk. In an online study in the United States, most MSM reported having the same or fewer sexual partners early in the pandemic, but 1% did increase their number of partners, and about a quarter indicated increased alcohol or other recreational drug use [13]. A different survey with MSM in the United States contrastingly found that MSM on average increased their number of sexual partners over the COVID-19 lockdown period, and those with increased substance use were significantly more likely to report increases in number of sexual partners [14]. Both surveys found that MSM maintained their pre-COVID condom usage, in parallel with participants in our study. More research is needed to ascertain the impact of COVID-19 on HIV risk among KPs by

investigating changes in sexual behaviours and substance use over the course of the pandemic.

Accessing facility-based testing services (i.e. HIV antibody and RNA testing) was a challenge for participants in this study. This experience is not unique to KPs in India. Emerging data on the impact of COVID-19 among MSM in various sites illustrate how HIV antibody testing has been harder to access [13,15,16], which was also seen in the United States, as the pandemic caused interruptions and declines in HIV/STI testing access [17]. HIV programs globally saw fewer clients living with HIV complete HIV RNA testing over the initial months of COVID-19 compared to pre-pandemic [18]. Public health programs can help restore testing service utilization by exploring innovative solutions, such as delivering testing through community health workers or incorporating HIV self-testing into service delivery [19–21]. These strategies may be particularly important to maintain access to HIV diagnosis and RNA testing for KPs, who already face socio-structural access barriers, especially if travel or facility disruptions from COVID-19 continue.

Key barriers to ART pick-up reported by our participants are consistent with those reported from adults on ART in Kampala, Uganda, who reported that stay-at-home orders negatively impacted ART access due to transportation challenges, police violence, and fear of COVID-19 [22]. Despite these barriers, participants living with HIV in our discussions were overall able to maintain ART adherence. This speaks to the pandemic response of NACO to limit trips to routine ART distribution sites through MMD and expanded community-based outreach, and highlights the critical role of CBOs. Differential access to HIV testing and treatment services has also been observed in countries with generalized epidemics. A study in South Africa examining HIV service access across 65 clinics during the pandemic found that HIV antibody testing was more heavily impacted than ART provision [23]. Another study assessing the effect of COVID-19 on 1,059 health facilities in 11 African countries observed that HIV antibody testing decreased, but MMD and ART home delivery likely enabled ART adherence [24].

Adapting how HIV services are delivered to the unique needs of each person, or differentiated care, can help ensure uninterrupted service access for KPs as COVID-19 disruptions continue. Strong preferences among our participants, especially around door-deliveries and community-based HIV service delivery, highlight the importance of tailoring services to individuals' preferences and context [22,25]. These findings also re-affirm that "one size does not fit all", as evident from varied reactions to MMD and telemedicine. While the rapid transition towards virtual service delivery, MMD, and field-delivery of ART in response to the pandemic is a major step towards client-centred, decentralized HIV care, it is crucial to implement these approaches with the ability to tailor options to individual preferences [26,27].

Our findings can inform guidelines and policies which help expand community-based service provision and facilitate service access for KPs. As community-based ART dispensation models have been expanded over COVID-19 in India, developing guidelines for community service provision can facilitate standardized implementation and scale-up of such models at the district-level. These policies should incorporate recommendations to tailor delivery models to various KP groups and contexts by gathering community input, and accommodating preferences and concerns surrounding confidentiality.

Most HIV programs in India and globally have a vertical programming structure with the objective of delivering optimal HIV-associated services. The COVID-19 pandemic highlights the need to design client-centred programs and re-think vertical programming to integrate comorbidities, such as mental health and non-communicable diseases [28]. Our findings that COVID-19 exacerbated challenges for KPs to access basic resources are consistent with other settings [13,29,30]. Since basic needs, including housing and food, come before access to healthcare for many, HIV programs and policies should think more comprehensively for the benefit of KPs to include access to social support services in such times of public health emergencies. This is in line with recent calls for HIV programs to move towards comprehensive care, rather than a single-disease approach [31,32]. Catering to social determinants of health and people's most pressing needs may engage more people in services and contribute to favourable outcomes across the HIV cascade for KPs [33]. Policies and program approaches would benefit from further research investigating variations of service access and preferences across KP groups in India, especially those related to community-based service modalities and comprehensive care.

There are limitations to this study. Participants were recruited through CBOs which may limit generalizability to KPs who are not engaged in services. As opposed to in-person focus groups with face-to-face interaction, focus groups in our study held over the phone presented some challenges to natural conversation and rapport-building. In these remote discussions, participants could not see each other and there were a few instances where participants experienced phone connectivity issues. However, at the time of data collection, remote interaction was necessary as per local government restrictions and to prevent the spread of SARS-CoV-2. Although our sample size is small if disaggregated per KP group, our purposive sampling approach worked to optimize for information power and variation of KP group while considering implementation feasibility [34]. Our study did not recruit people who inject drugs, a group at higher risk for HIV infection in India. As the majority of HIV infections in India are sexually driven, especially in the states of Maharashtra and Telangana, it was challenging to incorporate people who inject drugs in our focus groups. Therefore, it is possible that people who inject drugs were impacted by COVID-19 in ways that are not captured in this manuscript. Also, as sex work was not the primary focus of our study, more research is needed to make direct inferences about the impact of COVID-19 on experiences with sex work among KPs in India. Although our study was only conducted in two Indian states, Maharashtra and Telangana are well-placed to represent other high-HIV burden states across India, except for the Northeast where HIV transmission is disproportionately driven by injection drug use, since public HIV services across India follow standardized national guidelines. While findings are likely not representative of KPs across all of India or globally, our study offers insight into the experi-

ences and perspectives of KPs given the pandemic in order to strengthen HIV prevention and treatment services.

5 | CONCLUSIONS

As COVID-19 continues to impact health services, ensuring continuity in HIV preventive and treatment services is paramount to maintain and build on progress made in the past two decades towards HIV epidemic control. This is especially needed for KPs in low- and middle-income countries, for whom disruptions from COVID-19 threaten to widen existing economic and societal disparities compared to general populations. Our findings support the need for differentiated service delivery to bridge gaps of access to facility-based testing, integrate comprehensive care with HIV services, and expand community-based services in ways that remain sensitive to individual preferences and varying community and environmental contexts.

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COMPETING INTERESTS

SSS received consulting fees and research grants and products for his institution from Gilead Sciences and research grant and product from Abbott Laboratories outside of the submitted work. SSS and SHM received consulting fees from Gilead Sciences outside of the submitted work. KHM has received research grants outside of the submitted work for his institution from Gilead, Merck and Janssen, and has served on scientific advisory boards for Gilead, Merck and ViiV focused on HIV prevention.

AUTHORS' CONTRIBUTIONS

AMM, SHM, SSS and RP designed the study, developed the data collection tools, and trained field teams. YAR, BRK, PM, CKV, AKS and AS led and supervised data collection. UG and RP conducted data analysis, and RP drafted the manuscript with key inputs from KHM and SSS. All authors read and approved the final manuscript.

ACKNOWLEDGEMENTS

We sincerely thank all discussion participants for their time and involvement. We also thank the program staff who conducted interviews and local CBOs who supported recruitment. We also acknowledge PEPFAR, USAID, NACO and the Maharashtra and Telangana State AIDS Control Societies for their support.

FUNDING

This project has been supported by the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) through a cooperative agreement through the United States Agency for International Development (USAID) under the terms of cooperative agreement #72038619CA00001.

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Mpofu M et al. *Journal of the International AIDS Society* 2021, **24**(S6):e25814
http://onlinelibrary.wiley.com/doi/10.1002/jia2.25814/full | https://doi.org/10.1002/jia2.25814

JIAS JOURNAL OF THE INTERNATIONAL AIDS SOCIETY

RESEARCH ARTICLE

Distribution of antiretroviral therapy through private pharmacies and postal courier services during COVID-19 in Botswana: acceptability and reach of two out-of-facility individual differentiated service delivery models

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Abstract

Introduction: The advent of COVID-19 has put pressure on health systems as they implement measures to reduce the risk of transmission to people living with HIV (PLHIV) and healthcare workers. For two out-of-facility individual differentiated service delivery (DSD) models, we assessed acceptability of antiretroviral therapy (ART) distribution through private pharmacies and reach of home delivery of ART through courier services during the COVID-19 pandemic in Botswana.

Methods: From 24 July to 24 August 2020, we conducted exit interviews with PLHIV receiving ART from 10 high-volume public facilities in Gaborone, and mapped and conducted an online survey with private pharmacies to assess willingness and capacity to dispense ART to PLHIV enrolled in the Botswana national ART program. We piloted ART home delivery from September 2020 to January 2021 in Gaborone and Kweneng East districts for PLHIV accessing ART at two Tebelopele Wellness Clinics. We used cascade analysis to measure the enrolment and eventual reach (percentage of those reached amongst those who are eligible) of ART home delivery.

Results: Sixty-one PLHIV and 42 private pharmacies participated. Of the PLHIV interviewed, 37 (61%) indicated willingness to access ART from private pharmacies and pay BWP50 (~US$4) per refill for a maximum of two refills per year. All private pharmacies surveyed were willing to provide ART, and 26 (62%) would charge a dispensing fee (range = BWP50–100; ~US$4–8) per refill. All pharmacies operated 12 h/day, 6 days/week and on public holidays. In the home delivery pilot, 650 PLHIV were due for refills, 69.5% (n = 452) of whom were eligible for home delivery. Of these, 361 were successfully offered home delivery and 303 enrolled (enrolment = 83.9%: female = 87.2%, male = 77.8%, p = 0.013). A total of 276 deliveries were made, a reach of 61%.

Conclusions: Providing ART through private pharmacies and home delivery was acceptable in Botswana during COVID-19. Surveyed pharmacies were willing and able to dispense ART to PLHIV attending public sector facilities for free or for a nominal fee. Additionally, using courier services for ART home delivery is a novel and viable model in countries with a reliable courier service like Botswana and should be scaled up, particularly in urban areas.

Keywords: ARV; Botswana; courier services; COVID-19; differentiated care; home delivery

Received 24 March 2021; **Accepted** 19 August 2021

1 | INTRODUCTION

People living with HIV (PLHIV) on antiretroviral therapy (ART) are required to visit healthcare facilities regularly for consultations or medication refills, which has become challenging during the COVID-19 pandemic. Governments have issued stay-at-home orders, curfews and lockdowns, making it difficult to access health services [1, 2]. In Zimbabwe, about 19% of PLHIV who attempted to get their ART refills were not successful during the lockdowns [3]. Similarly, 48% of PLHIV in China did not know how to access their HIV treatment during the COVID-19 lockdowns [4].

Visiting health facilities during COVID-19 is high risk due to congestion [5]. The U.S. Centers for Disease Control and

Prevention has recommended that "HIV facility visits should be limited to those deemed medically essential, to reduce the risk and burden to recipients of care and health care providers" [6]. For PLHIV, implementation of lockdowns and social distancing measures necessitated urgent enrolment into differentiated service delivery (DSD) models as safe alternatives for accessing ART [7, 8]. Out-of-facility individual DSD models for ART including through private pharmacies, home delivery (e.g., courier services) and smart lockers offer alternatives in the context of COVID-19 [9]. These models offer PLHIV convenient options for continuing treatment, decongest clinics, allowing for physical distancing and safeguarding PLHIV and healthcare workers [1,10]. Before the COVID-19 pandemic, the private sector models were implemented on a small scale, primarily to ensure treatment continuity, despite associated cost savings for governments and PLHIV [9].

While there is a dearth of studies on systematic dispensing of ART by private pharmacies and through home delivery to public sector PLHIV in low- and middle-income countries, there are some examples of successful implementation. Noncommunicable disease (NCD) medications have been delivered through courier and other models in South Africa [11, 12]. In Nigeria, PLHIV who utilized private pharmacies for refills had higher treatment continuity rates (88% vs. 73%) and higher viral suppression rates (100% vs. 80%) than those at facilities, while participating clinics were decongested by half [13]. During COVID-19 restrictions, ART was delivered through courier services to homes of PLHIV who were unable to reach treatment centres in Pakistan [3]; while in Ukraine, home delivery of ART and other medicines were successfully delivered through the country's two biggest postal operators [14]. In India, the postal service delivered drugs following government-imposed movement restrictions during COVID-19 [15].

Botswana has the third highest HIV prevalence in the world, with one in five adults aged 15–49 living with HIV [16]. The country adopted the World Health Organization's test-and-treat strategy in 2016 and expanded treatment eligibility regardless of CD4 count [17]. The resulting increase in the number of PLHIV on treatment stretched the already constrained public health resources. The country recorded its first confirmed COVID-19 case on 30 March 2020, and by 21 February 2021, 26,524 cumulative cases and 254 deaths had occurred [18]. Shifting of resources to respond to COVID-19 has exacerbated existing health system challenges. A national lockdown commenced on 2 April 2020 through May 20 [19]. These measures limited access to ART. To address these challenges in Botswana and other countries, the Meeting Targets and Maintaining Epidemic Control (EpiC) project funded by the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) through the United States Agency for International Development (USAID) provided support to identify and assess the acceptability of alternative ART delivery models and to pilot those deemed feasible. We determined the acceptability of ART distribution through private pharmacies and the reach of home ART delivery through courier services.

Table 1. Top ten high-volume ART clinics/facilities in Gaborone District-June 2020

Name of facility	Number of PLHIV on ART
Nkoyaphiri Clinic	4457
Bontleng Clinic	4434
Broadhurst Traditional Area Clinic	3972
Phase 2 Clinic	3885
Tsholofelo Clinic	3450
Tlokweng Main Clinic	3339
Extension 15 Clinic	2487
Lesirane Clinic	2271
Mogoditshane Clinic	2168
Gaborone West	2133

ART, antiretroviral therapy; PLHIV, people living with HIV.

2 | METHODS

2.1 | Study design and setting

In this study, we assessed two implementation science outcomes: (1) acceptability – defined as the perception among implementation stakeholders that a given treatment, service or innovation is agreeable, palatable or satisfactory [20]; and (2) reach – the absolute number, proportion and representativeness of individuals who participate in a given intervention, and reasons why or why not [21]. To determine the acceptability of the private pharmacy model, we interviewed PLHIV receiving ART from 10 high-volume public facilities in Gaborone. We also mapped and surveyed private pharmacies proximal to those facilities in Gaborone, Kweneng East and South East districts by administering an online questionnaire using Kobo toolbox [22].

We also designed and piloted delivery of ART to PLHIV's homes or alternative locations in Gaborone and Kweneng East districts through the Botswana Postal Services (BPS), the national courier service. BPS already has an ongoing contract with the Central Medical Stores for warehousing and distribution of drugs to health facilities in the country. Survey tools were adapted from tools developed by EpiC for use in nine countries (including Botswana) which are implementing different decentralized ART models [23]. We then assessed the proportion of eligible PLHIV reached with ART delivered at home or alternative location, through BPS as the main outcome of the pilot.

At the time of the assessment and pilot, out-of-facility ART distribution was not national policy. However, the assessments and pilot were authorized by the Botswana Ministry of Health and Wellness (MoHW) to inform national policy. The pilot was conducted at two USAID- and PEPFAR-supported Tebelopele Wellness Clinics (TWC) run by a local implementing partner.Table 2 shows how the proposed DSD models differ from the standard of care.

Table 2. Building blocks for standard of care, home and pharmacy ART delivery models

Model	When	Where	Who	What
Standard of care	3 monthly	Public ART clinic	Clinician	ART refill
				Adherence support
	6 monthly			Clinical consultation
				ART refill
				Viral load testing
Home ART delivery	3 monthly	Home	Courier services	ART delivery[a]
	6 monthly	Health facility	Clinician	Clinical consultation
				ART refill
				Adherence support[b]
				Viral load testing
Proposed pharmacy model	3 monthly	Private pharmacy	Private pharmacist	ART refill
				Adherence support
	6 monthly	Health facility	Clinician	Clinical consultation
				ART refill
				Adherence support[b]
				Viral load testing

[a]~50 pula per refill for each client was paid by EpiC for the pilot and later expected by the government or clients (if able and willing).
[b]Virtual support by clinic 3–6 monthly or as needed.
ART, antiretroviral therapy.

2.2 | Acceptability of ART distribution through private pharmacies

Acceptability was assessed through exit interviews with PLHIV and through a survey with private pharmacies.

2.2.1 | *PLHIV exit interviews*

From 24 July to 24 August 2020, structured interviews were conducted with PLHIV receiving ART services from the 10 highest-volume ART facilities in Gaborone. The interviews collected perspectives on ART distribution through private pharmacies, information on travel time to ART sites and to the nearest private pharmacy, waiting time for services, prior use of private pharmacies and interest in receiving refills through them, willingness to pay a dispensing fee and the range of fees they were willing to pay.

The PLHIV were purposively identified and informed about the study on the day they reported for their clinic visit. During recruitment, an EpiC staff member approached them and offered participation. Informed consent was obtained from those who agreed to participate prior to conducting the interview. Participant names were not recorded to ensure confidentiality. Participation was voluntary, and all PLHIV were informed that they could discontinue participation at any time and could decline to respond to any question. After a month, the interviews were stopped to minimize additional risk of COVID-19 for the interviewers and clients.

2.2.2 | *Pharmacy survey*

The survey was conducted with private pharmacy points of contact. The list of pharmacies, their location and points of contact were obtained from the Pharmacy Society of Botswana (PSB), a professional body of certified pharmacy practitioners. Prior to the selection of the pharmacies, PSB convened its members to sensitize them about the survey.

Using an online questionnaire administered using Kobo toolbox, we assessed their willingness to dispense ART to PLHIV enrolled in Botswana's national ART program; their dispensing fee (refill fee) if at a cost; adequacy of their infrastructure (counselling space, storage space, and security), documentation procedures; operating hours; and staff capacity to support the ART program. Piloting of the private pharmacy DSD model had not commenced at the time of this analysis pending MoHW permission.

2.3 | Reach of ART home delivery during pilot implementation

With concurrence from MOHW, two community-based TWCs were purposefully selected in Gaborone (urban) and Kweneng East district (semi-urban) to pilot ART home delivery through BPS. Tebelopele clinics were established in 2000 as HIV testing centres and in 2019, they started offering integrated HIV services including ART to underserved populations such as men who have sex with men (MSM), female sex workers (FSW), noncitizens and other populations.

Prior to starting home deliveries at TWCs, EpiC and BPS signed a memorandum of understanding for delivery of ART parcels to eligible PLHIV receiving care at the TWCs. BPS was engaged because it was already providing medication warehousing services for the MoHW and delivering parcels in communities where PLHIV reside. As such, ART parcels would not be seen as different from routine packages. A delivery fee of 50 Botswana pula (BWP) (~US$4), the amount BPS charges for a regular parcel was agreed upon. For this pilot, the delivery fee was paid by EpiC. TWC healthcare workers were trained on how to use the BPS's e-Waybill, the electronic data capture and parcel tracking system. Antiretroviral (ARV)

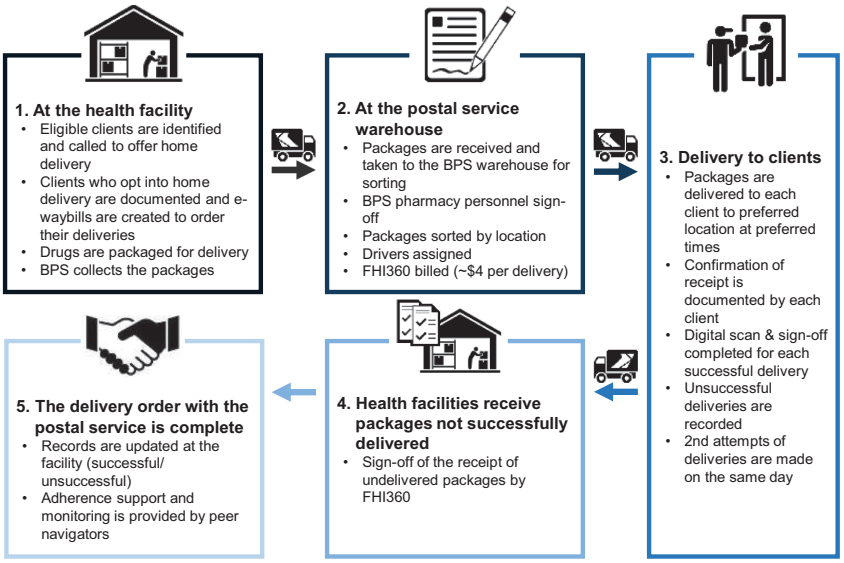

Figure 1. Flowchart of home delivery of ART through Botswana Postal Services (BPS)

drugs were packaged in standard BPS-branded packaging to ensure that they were indistinguishable from other parcels. To maintain confidentiality, BPS staff were also not aware of the specific medication(s) in the parcels.

From September 2020 to January 2021, eligible PLHIV who were established on ART were identified by reviewing their clinic records. PLHIV were considered established on ART if they had been on treatment for more than 6 months, had recent viral load of less than <400 copies/ml, had no current opportunistic infections, as per the Botswana National Treatment Guidelines. Eligible PLHIV were contacted by phone by the TWC nurse and offered the option of receiving their next ARV refill through BPS home delivery. Verbal consent was obtained, and the preferred physical address and time of delivery were confirmed. To prepare for each scheduled delivery, TWC staff completed an electronic form in e-Waybill and packaged the medications before contacting BPS for pick-up.

Figure 1 shows the home delivery process from eligibility assessment to delivery completion and documentation.

Medication parcels were scheduled for delivery a week before the actual refill due date.

The delivery parcel contained a 3-month supply of ART, an appointment card for the next clinic or ART refill date and a viral load test request form if a test was due before the next clinic appointment. The refill supply would cover the next 3 months until the next scheduled visit to the facility where they would get their next refill after clinical consultation. Botswana was beginning to transition to 6-monthly dispensing (6- MMD) when the first case of COVID-19 was reported which was then put on hold to better manage ART stocks given the anticipated shortages. We determined reach by collating the total number of packages that were successfully delivered as a proportion of those that were eligible.

2.4 | Data analysis

We conducted descriptive analysis to compare frequencies. Additionally, we used Chi Square to test the difference in home delivery acceptability and reach by sex, population group and citizenship. SPSS was used for analysis (IBM Corp. Released 2017. IBM SPSS Statistics for Windows, Version 25.0. Armonk, NY: IBM Corp).

2.5 | Ethical considerations

The pharmacy assessment received a nonresearch determination from FHI 360 Office of International Research and Ethics. Home delivery processes were nested within the TWCs' routine activities and aggregate data with no patient identifiers were collected. Confidentiality of medications and other personally identifiable information was further ensured by packing and sealing the medication at the TWCs, and using the same packaging used for all other parcels sent through BPS before it was retrieved by BPS drivers. The contents were not identifiable or known to BPS staff. Additionally, all BPS staff and drivers signed nondisclosure and confidentiality forms.

3 | RESULTS

3.1 | PLHIV exit interviews

A total of 61 PLHIV on ART were interviewed from 10 high-volume facilities in Gaborone. Of these, 57.4% (n = 35) were female, 52.4% (n = 32) were 40 years and older, and 60.7% (n = 37) had been on treatment for more than four years (Table 3).

Table 3. Demographic and clinical variable of the ART PLHIV who were interviewed

	Sex					
	Female		Male		Total	
	n = 35	%	*n* = 26	%	*N* = 61	%
Age group (years)						
<20	0	0	0	0	0	0
20–29	5	45.5	6	54.5	11	18.0
30–39	110	66.7	6	33.3	18	29.5
40+	190	62.5	12	37.5	32	52.5
Number of years on ART						
0–4	14	40	10	34.6	24	39.3
5–9	13	34.4	10	34.5	23	37.7
10+	8	22.9	6	19.2	14	22.9

ART, antiretroviral therapy; PLHIV, people living with HIV.

Table 4. PLHIV willingness to use private pharmacies for ARV pick-up

Measures	Frequency *n* = 61	%
Number of PLHIV who had used private pharmacies previously	26	42.6
PLHIV willing to use private pharmacies	37	60.7
PLHIV willing to use private pharmacies and pay a dispensing fee	27	44.3
Median dispensing fee PLHIV were willing to pay[a]	BWP50 (~US$4) Range = BWP50–100	

[b]Amongst those willing to pay.
ARV, antiretroviral; PLHIV, people living with HIV.

Twenty-six (43%) reported previous private pharmacy use (Table 4).

Of the PLHIV interviewed, 37 (60.67%) indicated willingness to access ART from private pharmacies; this number dropped to 27 (44.2%) if they would be expected to pay a dispensing fee. Amongst those willing to pay, 40% were willing to pay BWP50 (~US$4) per refill or a maximum of BWP100 per year.

Thirty-three (54.1%) PLHIV and 52 (85.2%) indicated that they lived within a 30-minute walking distance to the nearest public ART facility and private pharmacy, respectively. Most PLHIV (*n* = 39; 63.9%) indicated that the waiting time for HIV services at the ART facility was less than 1 h.

3.2 | Pharmacy survey

Forty-two private pharmacies in Gaborone, Kweneng East and South East districts participated in the survey (Table 5).

All private pharmacies were willing to provide ART on behalf of public facilities, although 26 (62%) indicated that they would require a dispensing fee of BWP60 [range: BWP50–100; (~US$ 4–8)] per refill, either paid directly by the PLHIV or by the MoHW. All 42 pharmacies were already dispensing ART to private clients. They reported having adequate space in their waiting area and a designated private

Table 5. Results of pharmacy survey and characteristics of participating pharmacies

	Frequency *n* = 42	%
Number of participating pharmacies by district		
Gaborone	33	78.6
Kweneng East	4	9.5
South East	5	11.9
Willingness to support ART distribution		
Number of private pharmacies willing to dispense ARVs on behalf of public facilities	42	100
Number of pharmacies who would charge a dispensing fee	26	61.9
Median dispensing fee	BWP60 (~US$4)	
Pharmacy capacity		
Pharmacies with qualified pharmacists	42	100
Pharmacies with waiting areas	42	100
Pharmacies with counselling rooms	42	100
Pharmacies already providing ART to private PLHIV	42	100
Pharmacies with latest ART guidelines	26	61.9
Pharmacies with adequate storage capacity	42	100
Median number of pharmacists per pharmacy	1 (Range = 1–5)	
Days of operation		
Weekdays (Monday–Friday)	42	100
Saturdays	42	100
Sundays and public holidays	33	78.5

ART, antiretrovial therapy; ARVs, antiretrovirals; PLHIV, people living with HIV.

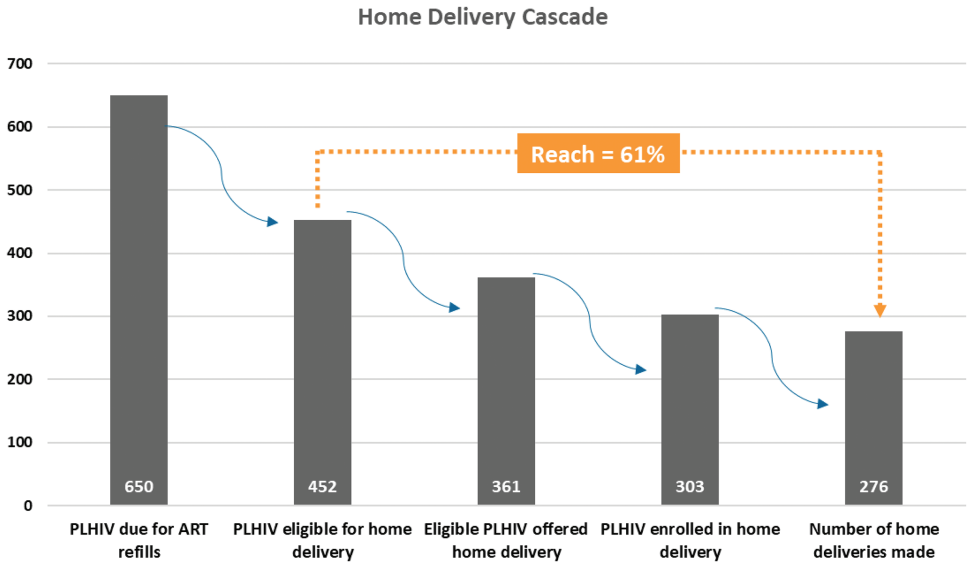

Figure 2. Cascade of home delivery of ART through BPS in Botswana, 22 September 2020–12 February 2021

area for counselling. They also operated at least 12 h per day on weekdays and were open on Saturdays. However, only 33 (78.5%) operated on Sundays and public holidays for limited hours.

3.3 | ART home delivery pilot

A total of 650 PLHIV were identified as due for refills for the period 22 September 2020–12 February 2021 in the two pilot clinics (Figure 2). Among those due for refills, 69.6% (452 out of 650) were found to be eligible for home delivery, 79.8% (361 out of 452) were successfully offered home delivery through BPS. The remaining 20.2% could not be contacted by phone.

Out of those who were eligible, the percentage reached with home deliveries was 61% although 83.9% (303 out of 361) initially enrolled. Of those offered home delivery, 13.6% (49 out of 361) were not interested at all, while an additional 13 (3.6%) were undecided or needed to consult with their partners. Reasons for declining home delivery included preference for the facility pickup (30%), was mobile with no stable delivery address (19%) and workplace constraints (15%). Twenty-seven (8.9%) parcels were returned to the facility because recipients were not at home or had decided to pick up their ART at the health facility before the delivery was made.

The enrolment for home delivery was higher amongst females (AR = 87.2%) than males (AR = 77.8%, $p = 0.01$) (Table 6). Enrolment was statistically equivalent between the general population and key population (KP) (specifically, MSM and FSW) ($p = 0.447$) and by citizenship ($p = 0.52$).

Table 6. Enrolment for home delivery of ART by sex, population group and citizenship

	Home delivery enrolment			
	Enrolled	Refused	Enrolment	*p* value
Sex				0.013
Females	184	27	87.2%	
Males	119	34	77.8%	
Total	303	61	100%	
Population group				0.447
General population	135	26	83.9%	
Key population[a]	168	35	82.8%	
Citizenship				0.517
Botswana citizens	142	29	83.0%	
Noncitizens	161	32	83.4%	

[a]MSM, FSW.

4 | DISCUSSION

We found high interest and acceptability of the pharmacy and home delivery models in Botswana, demonstrating that these models could ensure treatment continuation in the context of COVID-19. Botswana has made significant progress in its HIV response [24] with high treatment continuation (95%) and viral suppression rates (97%) [16]; an estimated 310,000 PLHIV are currently on ART [16], the majority through a few high-volume facilities. The burden on these facilities can be reduced by adding ART home delivery and private pharmacy distribution to current DSD models. The advent of COVID-19 coupled with the growing number of PLHIV established on ART in Botswana calls for the implementation of these innovative models that leverage the private sector.

Our assessment revealed several opportunities. First, private pharmacies in Botswana are already distributing NCD medications and are dispensing ART for private clients who pay out of pocket. They are willing and have the infrastructure to serve PLHIV enrolled in the national program. The high willingness to access ART refills through private pharmacies is encouraging considering that the majority of Batswana

living with HIV access ART services primarily through public facilities.

Second, the 50 BPS post offices already store and distributes medications (including ARVs) to regional distribution centres and hospitals. This thriving parastatal could be leveraged to support home delivery of ART. Overall, 83.9% of PLHIV who were offered home delivery of ART accepted, highlighting the potential for a courier DSD model. The home delivery model has long been a preferred method in other countries [25]. Expanding this model in Botswana would address stigma, since many people already receive their NCD medication through this approach. During the COVID-19 pandemic, the home delivery model can decongest public health facilities and, therefore, minimize the risk of COVID-19 to both PLHIV and healthcare providers. Furthermore, the decentralization of ART improves continuity in care [26]. Decentralization through the private sector has the potential of cost savings for governments, donors and, more importantly, PLHIV, as evidenced through modelling data [7].

DSD empowers PLHIV to find a model of care conducive to their lifestyle while decongesting the healthcare system [27]. The assessment provides data which can inform the design of more PLHIV-centred services. About 85% of PLHIV surveyed lived within 30-minute walking distance to a private pharmacy, thus using them as pick up points for out-of-facility individual DSD models could put services within convenient reach. All private pharmacies assessed had resident pharmacists, an attribute that will assure high-quality ART services. In addition, private pharmacies and home delivery could address the issue of waiting time for HIV services at heath facilities, which can be substantial at high-volume facilities [28]. The home delivery cuts down on travel costs and time spent at health facilities. Coupled with multi-month dispensing, these models would reduce the number of clinic visits and associated costs [25].

User fees are a major barrier to accessing services in both the public and private sectors for the majority of PLHIV [29, 30]. Our assessment found that less than half of the PLHIV were willing to obtain their ART refills from private pharmacies if they had to pay a dispensing fee. Importantly, the ART dispensing fee which was proposed by the private pharmacies was at par with the median fee proposed by PLHIV, indicating the viability of this option. Including user fees in the design of private sector programs increases their sustainability, reduces the need for significant donor or government subsidies but can result in lower uptake of services. However, the cost to PLHIV could be lowered by creating a business case with pharmacies and appealing to their corporate social responsibility. We also found through the pilot that the cost of home delivery was about the same as the dispensing fee proposed by pharmacies (~US$4 vs. US$5, respectively), making these two models roughly equivalent in cost. Educating PLHIV on each option's relative advantages and evaluating the models side by side would provide the government of Botswana with the relevant information for large-scale rollout.

The acceptability of the home delivery model was significantly higher amongst females, consistent with acceptability of other HIV services such as HIV testing, whose uptake tends to be lower amongst men [31, 32]. Our finding that there was no difference in acceptability rates by citizenship is positive, as the Botswana government aims to ensure equity in delivery of HIV services. The home delivery success rate in our pilot was high, at 91.1%. We ascribe this success to staff adherence to procedures, including contacting PLHIV prior to delivery and delivering the parcels at a time and place of their choosing.

Home delivery can also address stigma and discrimination faced by key population (KP). Though we did not find any significant difference in the acceptability of home delivery between the general population and KP (83.9% vs. 82.8%), it is well established that KP often experience stigma and discrimination in healthcare settings, resulting in decreased access to services [33, 34]. DSD models have been used to address this gap and enhance access [35]. However, the pilot was not designed to address this issue.

This assessment had some limitations. First, the use of private pharmacies for distribution of ART had not begun at the time of the study, and we were not able to compare the performance of this model with that of home delivery. Second, our sample size was small, in part due to limitations related to COVID-19. The pharmacies assessed were also located in urban areas. These models might apply differently to rural and urban settings, where acceptability may also vary. Last, the findings may have limited generalizability because of smaller sample sizes and geographical coverage.

During this analysis, discussions with the MoHW in Botswana were ongoing to expand the home delivery model beyond the TWCs to public health facilities, through private pharmacies and smart lockers. The MoHW is cognizant of its responsibility to pay for HIV services and is carefully reviewing lessons from the pilot as well as the cost implementations before making policy decisions or allowing further geographical expansion. EpiC is continuing to work alongside the MoHW to ensure seamless integration and national roll-out of these out-of-facility DSD models. MoHW approval could pave the way to maximize the potential of the more than 350 private pharmacies in the country, the 50 BPS post offices and their distribution networks for distribution of ART and other medications.

5 | CONCLUSIONS

Provision of ART through private pharmacies is acceptable to both PLHIV and the private pharmacy providers in Botswana. While the pharmacies would prefer to charge a fee, the cost is within the range PLHIV are also willing to pay making it feasible to implement this private sector model beyond NCD drugs which are distributed through private pharmacies on behalf of government. An alternative and novel model of using courier services for ART is viable in countries with a reliable courier service like Botswana and should be scaled up, particularly in urban areas. Scaleup of these models would decongest public health facilities, safeguard staff and PLHIV against COVID- 19, and free up space, financial and human resources to address the COVID-19 pandemic.

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COMPETING INTERESTS

The authors declare no competing interests.

AUTHORS' CONTRIBUTIONS

MM, TM, MG, WD and MB led the conceptualization of the paper and the writing of the methods section. GK, TM and MQ led the extraction, validation and cleaning of the program data and contributed towards data analysis and the writing of the methods and results sections. MM led the data analysis and writing of the introduction, results and discussion. MQ, JB, HS and MB wrote part of the introduction, the methods and the results, and LN contributed to writing the methods section. LK, HM and HMQ reviewed all sections of the manuscript. All authors read and approved the final manuscript.

ACKNOWLEDGEMENTS

Appreciation goes to EpiC and Tebelopele Wellness Clinic staff who worked tirelessly to make the assessments and pilot a success.

FUNDING

The EpiC Botswana project is implemented with funding from PEPFAR through USAID (agreement number 7200AA19CA00002) and in collaboration with the Botswana Ministry of Health and Wellness.

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Matambanadzo P et al. *Journal of the International AIDS Society* 2021, **24**(S6):e25813
http://onlinelibrary.wiley.com/doi/10.1002/jia2.25813/full | https://doi.org/10.1002/jia2.25813

SHORT REPORT

"It went through the roof": an observation study exploring the rise in PrEP uptake among Zimbabwean female sex workers in response to adaptations during Covid-19

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Abstract

Introduction: *Sisters with a Voice (Sisters)*, a programme providing community-led differentiated HIV prevention and treatment services, including condoms, HIV testing, pre-exposure prophylaxis (PrEP) and antiretroviral therapy linkage for sex workers, reached over 26,000 female sex workers (FSW) across Zimbabwe in 2020. Zimbabwe's initial Covid "lockdown" in March 2020 and associated movement restrictions interrupted clinical service provision for 6 weeks, particularly in mobile clinics, triggering the adaptation of services for the Covid-19 context and a scale up of differentiated service delivery (DSD) models. PrEP service delivery decentralized with shifts from clinical settings towards community/home-based, peer-led PrEP services to expand and maintain access. We hypothesize that peer-led community-based provision of PrEP services influenced both demand and supply-side determinants of PrEP uptake. We observed the effect of these adaptations on PrEP uptake among FSW accessing services in *Sisters* in 2020.

Methods: New FSW PrEP initiations throughout 2020 were tracked by analysing routine *Sisters* programme data and comparing it with national PrEP initiation data for 2020. We mapped PrEP uptake among all negative FSW attending services in Sisters alongside Covid-19 adaptations and shifts in the operating environment throughout 2020: prior to lockdown (January–March 2020), during severe restrictions (April–June 2020), subsequent easing (July–September 2020) and during drug stock-outs that followed (October–December 2020).

Results and discussion: PrEP uptake in 2020 occurred at rates <25% (315 initiations or fewer) per month prior to the emergence of Covid-19. In response to Covid-19 restrictions, DSD models were scaled up in April 2020, including peer demand creation, community-based delivery, multi-month dispensing and the use of virtual platforms for appointment scheduling and post-PrEP initiation support. Beginning May 2020, PrEP uptake increased monthly, peaking at an initiation rate of 51% (n = 1360) in September 2020. Unexpected rise in demand coincided with national commodity shortages between October and December 2020, resulting in restriction of new initiations with sites prioritizing refills.

Conclusions: Despite the impact of Covid-19 on the Sisters Programme and FSW mobility, DSD adaptations led to a large increase in PrEP initiations compared to pre-Covid levels demonstrating that a peer-led, community-based PrEP service delivery model is effective and can be adopted for long-term use.

Keywords: differentiated care; HIV prevention; PrEP; Sars-Cov2; sex workers; Zimbabwe

Received 16 March 2021; **Accepted** 19 August 2021

1 | INTRODUCTION

Much has been written about the negative effects of the Sars-Cov2 pandemic (Covid-19) on sex workers' livelihoods, wellbeing and access to healthcare [1–4]. Closure of entertainment venues, restrictions on personal mobility and clients' fears of contracting Covid-19 have reduced sex workers' incomes, while strain on health services and disruptions to supply chains decreased their access to healthcare, including HIV testing, prevention and treatment [5]. In some contexts, including Zimbabwe, sex workers have experienced increased stigma against them as potential "disease vectors", leading to harassment and violence, including from police [6,7]. There have been calls for policies and programmes to recognize sex workers' enhanced vulnerability and respond accordingly [3,8].

The need for ongoing flexibility during this time, however, also provided opportunities for introducing or scaling up existing differentiated service delivery (DSD) models that may

previously have been thought too costly or unfeasible to implement. It also refocused attention on the structural drivers of vulnerability [9,10]. Pre-exposure prophylaxis (PrEP) may be particularly well suited to testing new DSD approaches, given its recent introduction into national HIV programmes in many sub-Saharan African countries and initial slow uptake among some populations, including sex workers and adolescent and young women at particularly high risk [11–13]. Despite successful demonstration projects, PrEP initiation and retention continue to pose challenges to prevention programmes throughout the region, prompting calls for renewed efforts to increase uptake. One method for increasing uptake is by making it more easily available in community settings beyond health facilities [12].

In Zimbabwe, oral PrEP has been offered to sex workers since 2016, when the Ministry of Health and Child Care (MoHCC) adopted World Health Organization (WHO) guidelines. However, widespread access began in 2018 with phased rollout of a 2-year national Implementation Plan [14]. *Sisters with a Voice (Sisters)* is a nationally scaled, evidence-based comprehensive HIV prevention and treatment programme for sex workers implemented by the Centre for Sexual Health and HIV/AIDS Research (CeSHHAR) on behalf of the MoHCC and National AIDS Council (NAC) since 2009. *Sisters* reached over 26,000 female sex workers (FSW) yearly across Zimbabwe in 2019 and 2020 with HIV prevention and treatment and sexual and reproductive health services, relying on robust sex worker-led community mobilization to link sex workers to services, including provision of condoms, lubricants, HIV testing, PrEP and linkage to antiretroviral therapy. The strength of *Sisters* is its integrated model of government ownership, services delivered through a network of fixed-site and mobile clinics co-located within MoHCC clinics and sex worker leadership through 370 peer educators supported and supervised by outreach workers [15]. *Sisters* rolled out PrEP in April 2019, screening all HIV-negative female, male and transgender sex workers attending clinics and drop-in centres following a pilot introduction as part of a trial [16,17].

Initially, *Sisters'* PrEP implementation protocol specified that nurses should provide prevention, testing and counselling for all sex workers. All FSW who tested negative were screened for PrEP eligibility, and those who accepted were initiated on PrEP. Newly initiated FSW received 1 month's supply and were encouraged to return to the clinic at any time if they experienced adverse reactions, but otherwise advised to attend monthly follow-up visits for the first 3 months. After that, FSW were recommended to visit the clinic every 3 months for refills, adherence counselling, HIV testing, as well as checks for sexually transmitted infections and for other sexual and reproductive health services. Following the introduction of Covid-19 lockdown restrictions in late March 2020, *Sisters* was obliged to close all 10 permanent sites for 1 week and all mobile clinics for 6 weeks, re-opening them as "essential services" on 6 April 2020 and 18 May 2020, respectively. Subsequently, routine clinic visits were discouraged to "decongest" facilities.

To maintain and expand access to PrEP, services were shifted into the community with greater reliance on peer educators and outreach workers to create demand and provide follow-up support. This paper describes the Covid-19-related DSD adaptations made to the PrEP provision within *Sisters* and explores the effect of these on trends on PrEP uptake.

2 | METHODS

2.1 | Adapted approach to provision of PrEP

First, existing peer educators were trained on PrEP by their supervising outreach workers and encouraged to become advocates for PrEP within the sex work communities where they live and work. They disseminated information among their peers, dispelled myths and encouraged increased demand. The sex workers at highest risk, tracked weekly, were prioritized for PrEP discussions and referral to new community "access points" established outside the clinic, comprising agreed meeting points or sex workers' homes. As shown in Table 1, outreach workers and peer educators joined clinicians to form outreach teams that delivered community-based PrEP services.

Second, the use of telehealth was scaled up so that at week 1 and again when due for their 1-month follow-up clinic visit, sex workers received follow-up support from a clinician for side effects and adherence counselling via phone calls. Sex workers could report adverse events via phone and WhatsApp.

Third, ongoing virtual support through peer educators was introduced. We provided mobile data and "talk time" for peer educators, WhatsApp broadcast lists were set up and a communication structure created through which each outreach worker remotely monitored a group of local peer educators, each working with their allocated caseload of sex workers with whom they regularly engaged to address PrEP myths, encourage uptake and adherence, and check concerns. Finally, all PrEP re-supplies were provided for 3 months at a time, waiving the initial requirement for monthly clinic visits.

This adapted PrEP distribution model remained in place into 2021, providing an opportunity to take stock of its impact and identify lessons for future implementation once commodity supply is restored.

2.2 | Data collection and analysis

In this study, we included aggregated anonymized individual clinic data for all 19,407 FSW who presented to *Sisters* and tested negative in 2020 and all 6539 FSW initiated on PrEP during 2020. Data were collected from all FSW receiving services within *Sisters* at facility or within the community to whom a unique alphanumeric identifier was assigned based on personal data that can be easily recalled through a series of prompts – mother's first name, FSW's last name, date of birth, sex and district of birth – thus eliminating the necessity of any documentation or clinic card. Data were entered electronically into cloud storage and record synced daily, and as long as a sex worker provided the same information at each visit, her records were linked across services and sites. The data captured included: HIV testing, PrEP screening and initiation, each monthly and then quarterly visit, results from repeat HIV testing, any noted side effects, adverse outcomes and reported adherence. National PrEP initiation data used for comparison are as recorded in the DHIS2 system by MoHCC.

Table 1. Adaptations made (and sustained) in response to COVID-19

	PrEP Screening, initiation and early follow-up (0-3 months)			PrEP continuation (+3 months)	
Post Covid-19	**Screening**	**PrEP initiation visit**	**Initial follow-up**	**PrEP refill**	**Routine clinical follow-up**
WHEN *Service frequency*	At entry point, first clinic/DIC visit	First visit	One month visit, virtual follow up at 1 week for side effects/adverse events	Every 3 months if tolerating well	Every 3 months. SW receive virtual support for with monthly check ins
WHERE *Service location*	• Clinic • Drop in centre • Community	• Clinic • Drop in centre • Community	• Clinic • Drop in centre • Community/home	• Clinic • Drop in centre • Community/home	• Clinic • Drop in centre • Community/home
WHO *Service provider*	Nurses, outreach teams	Nurses, outreach teams	Nurses, outreach teams	Nurses, outreach teams	Nurses, outreach teams
WHAT *Service package*	Counselling on combination HIV prevention, HIV testing, eligibility screening, adherence counselling	Counselling on combination HIV prevention, Adherence, STI, ARV side effects, eligibility screening	Counselling on combination HIV prevention, Adherence, STI, ARV side effects, HIV Testing	Counselling on combination HIV prevention, Adherence, STI, ARV side effects, HIV testing every 3 months	Counselling on combination prevention, substantial risk screening adherence, assess for signs of acute HIV infections, STI, ARV side effects

ARV, antiretroviral; DIC, drop in centre; PrEP, pre-exposure prophylaxis; STI, sexually transmitted infection; SW, sex worker.

Ethical approval for this study was granted as part of the wider AMETHIST Consortium group of studies by the Medical Research Council of Zimbabwe (MRCZ/A/2559) and Liverpool School of Tropical Medicine (ref:19-115RS).

3 | RESULTS AND DISCUSSION

In total, 19,407 HIV-negative individual sex workers were screened for PrEP of whom 33.7% (n = 6539) accepted PrEP. Initiations were highest among sex workers aged 20–24 years at 33% (2152/6539), followed by 21% among those aged 25–29 (1382/6539). Lowest uptake was among FSW who were 40 years old or over, at 5% among the 40- to 44-year olds and under 2% for those 45 years and above. PrEP continuation data were only available for 5653 FSW (data for 10 out of 61 sites were unavailable). Retention at 1 month was 40% (n = 2269), 27% (n = 1509) at 3 months and 14% (n = 803) at 6 months.

Following Covid-19-related closures and amid continuing movement restrictions, adaptations to PrEP provision were introduced as facilities reopened, rapidly scaling up existing DSD models that shifted many routine functions from clinics to the community. 2020 PrEP uptake within *Sisters* ranged between 212 and 315 initiations per month until the emergence of Covid-19 in Zimbabwe. Beginning around May 2020, the uptake of PrEP consistently increased monthly, until it reached 1360 initiations in September 2020. Unfortunately, the unexpected rise in demand coincided with national commodity shortages from October to December 2020 due to delayed shipments. This stock rupture necessitated restrictions on new initiations with higher volume sites halting initiation altogether. Overall, we saw 746 PrEP initiations January–March 2020, prior to Covid-19, 1161 between April and June 2020 with most intense restrictions, 3084 following easing of restrictions from July to September 2020 and 1548 during October–December 2020 when drug stockouts were experienced. Despite the stock rupture, seroconversion was reported in 2/6539 FSW initiated on PrEP within *Sisters* in 2020. Low rates of seroconversion despite stockouts may have been due to prioritization of refills over new initiations between October and December 2020.

Figure 1 demonstrates the steep rise in PrEP uptake within *Sisters* following these adaptations.

Figure 1 also shows *Sisters'* increased contribution (63%) to national PrEP initiations between April and December 2020, compared with a contribution of 16% between January and March 2020 prior to adaptations within *Sisters*. Prior to the Covid-19 pandemic, PrEP initiations within the public sector and among other MoHCC implementing partners were four to five times higher than those within *Sisters*, suggesting DSD adaptations made within *Sisters* may have facilitated rapid recovery from the impact of Covid-19 not witnessed in settings where similar shifts to peer-led community-based delivery of PrEP services were not immediately possible.

FSW reported that the Covid-19 pandemic reduced their ability to procure clients due to a combination of factors, such as closure of bars, restaurants, truck stops and other sex work venues; restrictions on personal mobility; and clients' fears about contracting Covid-19 from sex workers. Anecdotal evidence suggests that a shortage of clients increased competition between sex workers, reducing their ability to negotiate

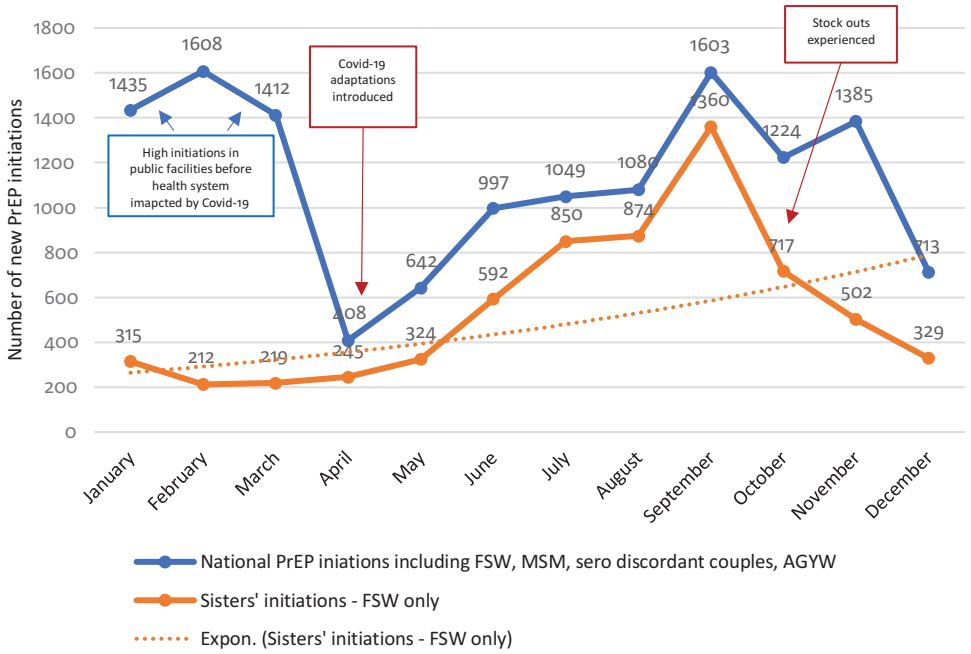

Figure 1. National and Sisters only PrEP initiations January–December 2020. AGYW, adolescents girls and young women; FSW, female sex workers; MSM, men who have sex with men; PrEP, pre-exposure prophylaxis.

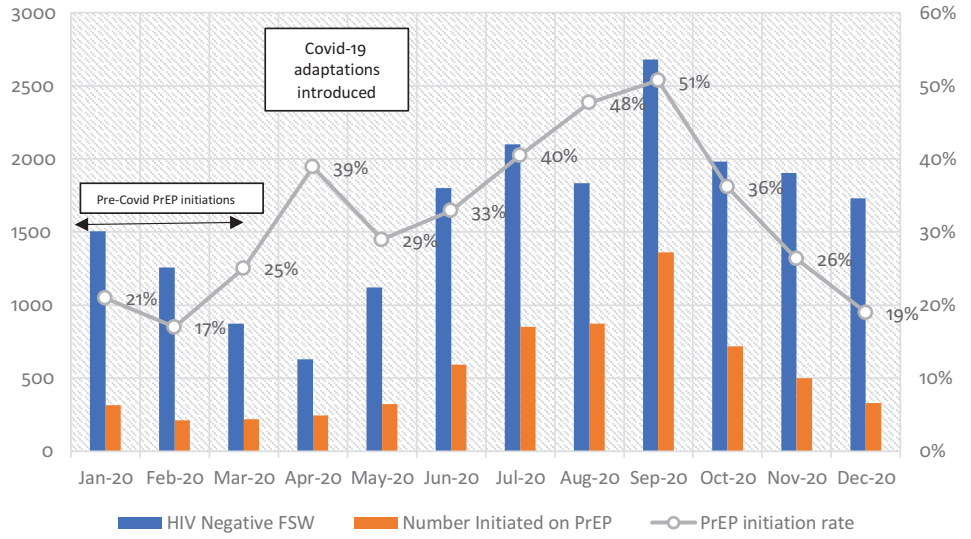

Figure 2. Sisters PrEP initiation rate January–December 2020. FSW, female sex workers; PrEP, pre-exposure prophylaxis.

condom use and thus heightening their concerns about HIV risk. Greater risk perception may have, in turn, increased sex workers' openness to PrEP as an alternative prevention strategy resulting in steady increase in PrEP initiation rates among negative FSW to a peak of 51% in September 2020 before stockouts were experienced as shown in Figure 2. Another factor likely to have contributed to interest is sex workers' reduced movement around the country. As transport hubs and borders were closed, with inter- and intra-city travel restricted, sex workers were unable to migrate out of Zimbabwe or move between locations in search of work.

4 | CONCLUSIONS

Globally, Covid-19 has disrupted healthcare across regions, including negatively affecting many HIV programmes and reducing access for vulnerable populations, such as sex workers [1,5]. In response, a range of adjustments to service delivery models are being introduced, offering an unexpected real-time experiment in DSD. Covid-19-related service disruptions to Zimbabwe's sex work programme services led to adaptations introduced in April 2020 and sustained throughout the year to scale-up community-based PrEP service

delivery, significantly boosting PrEP uptake among FSW within the national context. The experience of *Sisters* in Zimbabwe provides one example of how DSD adaptations to PrEP distribution protocols can lead to a rapid increase in its uptake among FSW. A peer-led, community-based PrEP service delivery model is effective and can be adopted for long-term use.

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COMPETING INTERESTS

The authors declare that they have no competing interests.

AUTHORS' CONTRIBUTIONS

PM led *Sisters'* Covid-19-related adaptations and conceived the idea for the paper. JB wrote the initial draft and coordinated contributions from other authors. HM and LC led analysis of programme data. FM and NG provided comments on early drafts. RS, AP and FC contributed to interpreting the data and re-writing text. All authors have read and approved the final version of the manuscript.

ACKNOWLEDGEMENTS

Simbarashe Mulingwa, Rumbidzai Makandwa, Florence Mutevedzi, Sitholubuhle Magutshwa, Sithembiso Dube, Juliet Mufuka. The programme activities and data collection described in this paper are implemented within the Adapted Microplanning: Eliminating Transmissible HIV In Sex Transactions (AMETHIST) study funded by The Wellcome Trust Grant 214280/Z/18/Z.

FUNDING

The Global Fund to Fight AIDS, TB and Malaria (GFATM), PEPFAR, USAID and the Elton John AIDS Foundation.

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JIAS JOURNAL OF THE INTERNATIONAL AIDS SOCIETY

COMMENTARY

Tuberculosis treatment within differentiated service delivery models in global HIV/TB programming

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Abstract

Introduction: Providing more convenient and patient-centred options for service delivery is a priority within global HIV programmes. These efforts improve patient satisfaction and retention and free up time for providers to focus on new HIV diagnoses or severe illness. Recently, the coronavirus disease 2019 (COVID-19) pandemic precipitated expanded eligibility criteria for these differentiated service delivery (DSD) models to decongest clinics and protect patients and healthcare workers. This has resulted in dramatic scale-up of DSD for antiretroviral therapy, cotrimoxazole and tuberculosis (TB) preventive treatment. While TB treatment among people living with HIV (PLHIV) has traditionally involved frequent, facility-based management, TB treatment can also be adapted within DSD models. Such adaptations could include electronic tools to ensure appropriate clinical management, treatment support, adherence counselling and adverse event (AE) monitoring. In this commentary, we outline considerations for DSD of TB treatment among PLHIV, building on best practices from global DSD model implementation for HIV service delivery.

Discussion: In operationalizing TB treatment in DSD models, we consider the following: *what* activity is being done, *when* or how often it takes place, *where* it takes place, *by whom* and *for whom*. We discuss considerations for various programme elements including TB screening and diagnosis; medication dispensing; patient education, counselling and support; clinical management and monitoring; and reporting and recording. General approaches include multi-month dispensing for TB medications during intensive and continuation phases of treatment and standardized virtual adherence and AE monitoring. Lastly, we provide operational examples of TB treatment delivery through DSD models, including a conceptual model and an early implementation experience from Zambia.

Conclusions: COVID-19 has catalysed the rapid expansion of differentiated patient-centred service delivery for PLHIV. Expanding DSD models to include TB treatment can capitalize on existing platforms, while providing high-quality, routine treatment, follow-up and patient education and empowerment.

Keywords: differentiated service delivery; HIV treatment; National TB and Leprosy Programme; patient-centred care; persons living with HIV; tuberculosis; tuberculosis treatment

Received 22 March 2021; **Accepted** 19 August 2021

1 | INTRODUCTION

Before severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the virus that causes coronavirus disease 2019 (COVID-19), tuberculosis (TB) was the world's deadliest infectious disease; TB remains the leading cause of death for people living with HIV (PLHIV) [1,2]. In 2019, an estimated 208,000 PLHIV died of TB globally. Only 71% of the estimated individuals with incident TB were treated, and treatment success only reached 56% among PLHIV [1]. Approximately 1.4 million fewer TB cases were reported globally in 2020 partly because COVID-19 reduced access to health facilities and triggered commodity stockouts [3–5]. While more data are needed to characterize and quantify the impact of COVID-19 on TB diagnosis, treatment and prevention, modelling studies have suggested that the number of people developing TB could increase by more than 1 million per year between 2020 and 2025 [1,6].

In HIV care, differentiated service delivery (DSD) includes tailored adaptations to meet the needs and preferences of PLHIV, while also streamlining care in the context of limited

human resources and infrastructure [7]. DSD models are increasingly being adopted, including recent scale-up of multi-month dispensing (MMD) options for antiretroviral therapy (ART) and TB preventive treatment (TPT) for patients supported through the US President's Emergency Plan for AIDS Relief [8–11]. To date, most DSD models have primarily served PLHIV considered "stable on ART" by reducing the frequency of clinic visits and ART dispensation (e.g. every 3–6 months) or by making services available in communities. DSD models improve patient retention and satisfaction, reduce patient costs (e.g. transportation or lost labour) and free up space and time in facilities for health providers to focus on PLHIV with new diagnoses or who require intensive care [7,9]. However, PLHIV with a TB disease diagnosis are often ineligible for these models because they are not considered "stable on ART", which necessitates biweekly or monthly visits to a health facility for close management and follow-up while they receive TB treatment [12–14]. To help patients with TB access care, the World Health Organization's Global TB Programme has prioritized patient-centred care, and directly observed treatment for TB has moved from strictly facility-based to community-based or remote/virtual models, though frequent and close interaction has remained a hallmark of this approach [14,15].

This paradigm is now changing in the context of COVID-19, which has pushed programmes to decrease patient contact with health facilities to reduce the risk of COVID-19 transmission for both patients and providers [8,9]. In HIV programmes, eligibility criteria have been expanded across many countries to ensure that all patients have a continuous supply of critical medications despite COVID-19 disruptions and lockdowns [8,9]. These policy changes have resulted in dramatic scale-up of MMD options for ART, cotrimoxazole and TPT paired with direct delivery to patient communities or homes and greater reliance on virtual treatment support for adherence and adverse event (AE) monitoring [8,16].

TB treatment delivery could also be adapted to this new environment to mitigate disruptions to patients' treatment courses and to support long-term gains in TB epidemic control [8,17–20]. Underscored by new Joint United Nations Programme on HIV/AIDS targets for 2025, the vision of DSD can promote sustainable patient-centred care by integrating treatment services for HIV and other diseases, such as TB [21,22]. Drawing on principles of HIV DSD, we propose that differentiated TB treatment for PLHIV – while ensuring appropriate TB clinical care, treatment support and AE monitoring – could be implemented and sustainably scaled and maintained after the COVID-19 pandemic. Although we propose scaling up TB treatment within HIV DSD models, this approach could also improve treatment outcomes for HIV-negative persons with TB, who comprise >90% of global TB cases. Similarly, while we focus on treatment of drug-sensitive TB, many of the principles described could be applied in all-oral treatment of drug-resistant TB. We describe overarching considerations for TB treatment delivery within DSD models, a conceptual example among PLHIV and an early implementation experience in Zambia among people treated for TB irrespective of HIV status.

2 | DISCUSSION

2.1 | General principles and considerations for incorporating TB treatment into differentiated HIV service delivery models

2.1.1 | DSD framework for TB treatment and alignment with HIV care

Important considerations for operationalizing TB treatment in DSD models include the following: *what* activity is being done, *when* or how often it takes place, *where* it takes place, *by whom* and *for whom* [23]. We propose the initial step in incorporating TB treatment into DSD models for PLHIV is to assess the policy and structure of current DSD models to determine how these could be leveraged and/or adapted. For PLHIV already established in a DSD model before receiving a TB diagnosis, minimizing changes to their chosen model by aligning timing and location of TB service delivery with HIV service delivery is integral to preserving the intent of DSD enrolment. Consultation with patients and civil society is critical to ensure that the patient-centred nature of a given model is optimized and adapted as needed.

2.1.2 | TB screening and diagnosis

Because expanding DSD models for PLHIV may mean less frequent facility-based interactions, routine high-quality screening for TB disease can be performed in other settings and/or virtually (e.g. through virtual platforms or mobile technology such as texting or telephone check-ins) [24]. Given their common symptomatology, TB symptom screening and evaluation could be coupled with COVID-19 screening and testing in or outside health facilities. TB symptom screening can be provided for PLHIV during standardized virtual follow-ups, community drug distribution or by patients themselves or treatment supporters (e.g. peer educators or community health workers). Confirmatory TB diagnostic testing, in contrast, is complicated, and should still be performed by a designated health provider in accordance with national guidelines. However, sputum specimens, samples for lateral flow urine lipoarabinomannan assays and digital chest X-rays could be collected in community settings to increase patient convenience by leveraging networks of treatment supporters and existing referral and transport systems (e.g. for HIV viral load or COVID-19 testing). National TB programmes have long used treatment supporters, including for sputum collection, and these innovations can be incorporated into new DSD models. Patient preferences of DSD modality, treatment supporter training, timely sample collection and referral of results for treatment evaluation (e.g. through point-of-care or reliable digital technologies) are important considerations.

2.2 | TB treatment initiation

2.2.1 | Medication dispensing

A key consideration in adapting TB treatment delivery is determining how many doses of TB medication will be dispensed at treatment initiation. If drug supply permits, longer

TB medication dispensing intervals – even if clinical disease severity necessitates more frequent clinical encounters – is the best practice to ensure uninterrupted treatment ("decoupling" refill frequency from clinical assessment frequency). One strategy could be to provide 2 months of TB medication at initiation to last through the full intensive treatment phase. Dispensation could occur at health facilities, community pharmacies, other community distribution points or in home-based settings (e.g. visit by supporter or mail delivery). Aligning TB medication and ART dispensing location and timing, including options for expanded pick-up hours or fast-tracked services (i.e. services for which patients do not need to see a clinician or provider to access) will substantially improve patient outcomes [25].

2.3 | Patient education and counselling at TB treatment initiation

With less frequent facility-based interactions between health providers and patients, collaborative discussions about what to expect in treatment, especially a focus on empowering patients to commit to treatment completion, are critically important at treatment initiation and throughout the treatment course [26–29]. Standardized and comprehensive education and counselling include emphasizing the importance of adherence to TB treatment and potential complications and consequences of missed doses or discontinuation. It is critically important that patients receive counselling and informational materials for home review on TB treatment related AEs, with clear instructions to contact a designated treatment supporter or health provider at the onset of any worrisome sign or symptom. Patient education should also include discussion of symptoms of immune reconstitution inflammatory syndrome, especially for those who are newly initiating ART. While provision of standardized counselling and education is not novel, it is not standard practice in many TB treatment programmes, but should be ensured.

2.4 | TB treatment management

2.4.1 | Medication dispensing

Timing, frequency and location of TB medication dispensing can be adapted to local context and patient needs and align with ART dispensing location and frequency. For example, after completing the intensive treatment phase with demonstrated response to treatment, a patient could return to the health facility and receive 4 months of TB medication to cover the entire continuation phase, with subsequent check-ins delivered in the community or virtually. If more frequent refill dispensation is needed, this could occur at alternative, more convenient locations and/or be performed by a designated alternate provider (e.g. pharmacist or treatment supporter).

2.4.2 | Monitoring treatment response and effectiveness

Despite reductions in facility-based encounters, changes in a patient's symptoms while on TB treatment can be monitored through frequent, standardized and virtual check-ins [30]. As with diagnosis, specimen collection to monitor bacteriologic response can be performed in the community setting. A 2-month follow-up clinic visit and visit at the end of treatment with a health provider would enable bacteriologic testing and physical examination to assess response to TB treatment.

In cases of TB treatment non-response, it is important to identify any underlying barriers to adherence or risk factors for drug resistance. The provider could then adapt the patient's management plan with more frequent in-person or virtual monitoring, additional diagnostic evaluation for drug resistance, a modified treatment regimen and/or adherence counselling and additional support.

2.4.3 | Monitoring adherence and AEs

For ongoing adherence counselling and AE monitoring, patients could be linked to a designated treatment supporter, existing support group, virtual support or some combination. [25,31,32]. Several modalities for virtual monitoring and support for TB patients have been shown to provide higher patient and provider satisfaction, cost savings and high rates of treatment adherence and completion [33–35]. Digital adherence technologies such as pill sleeves or boxes that provide a proxy for medication use may be another feasible and acceptable alternative [36]. The frequency of check-ins could vary depending on the patient's clinical status and preference as well as method of interaction (e.g. daily text messaging adherence reminders and AE screens could be paired with monthly video or phone discussions with a health provider).

2.5 | Recording and reporting

Characteristics of successful TB treatment programmes include appropriate and timely data collection, dissemination and use for continuous programme improvement. Programmes may need to create or adapt fields in patient charts, aggregate registers and electronic medical records to ensure capture of TB treatment model, drug dispensation, adherence and AE monitoring and treatment outcomes. Digital technologies and platforms can enable automated screening and adherence questionnaires to enhance reporting completeness; such platforms should be considered for patients with access to mobile phones [36]. As new options for TB treatment delivery are introduced, routinely assessing patient outcomes within each DSD model ensures model non-inferiority, patient satisfaction and continuous programme quality improvement.

2.6 | Examples of TB treatment integration into DSD models

2.6.1 | Conceptual model incorporating TB treatment into 3-month ART MMD

A conceptual model for incorporating TB treatment into standard MMD for ART is provided in the Figure 1A. After receiving a TB diagnosis, the patient is seen at the clinic and prescribed 1 or 2 months of intensive phase TB medications. With intensive counselling on adherence and potential AEs by the provider, the patient is linked to a treatment supporter. During the 2-month intensive phase, the patient

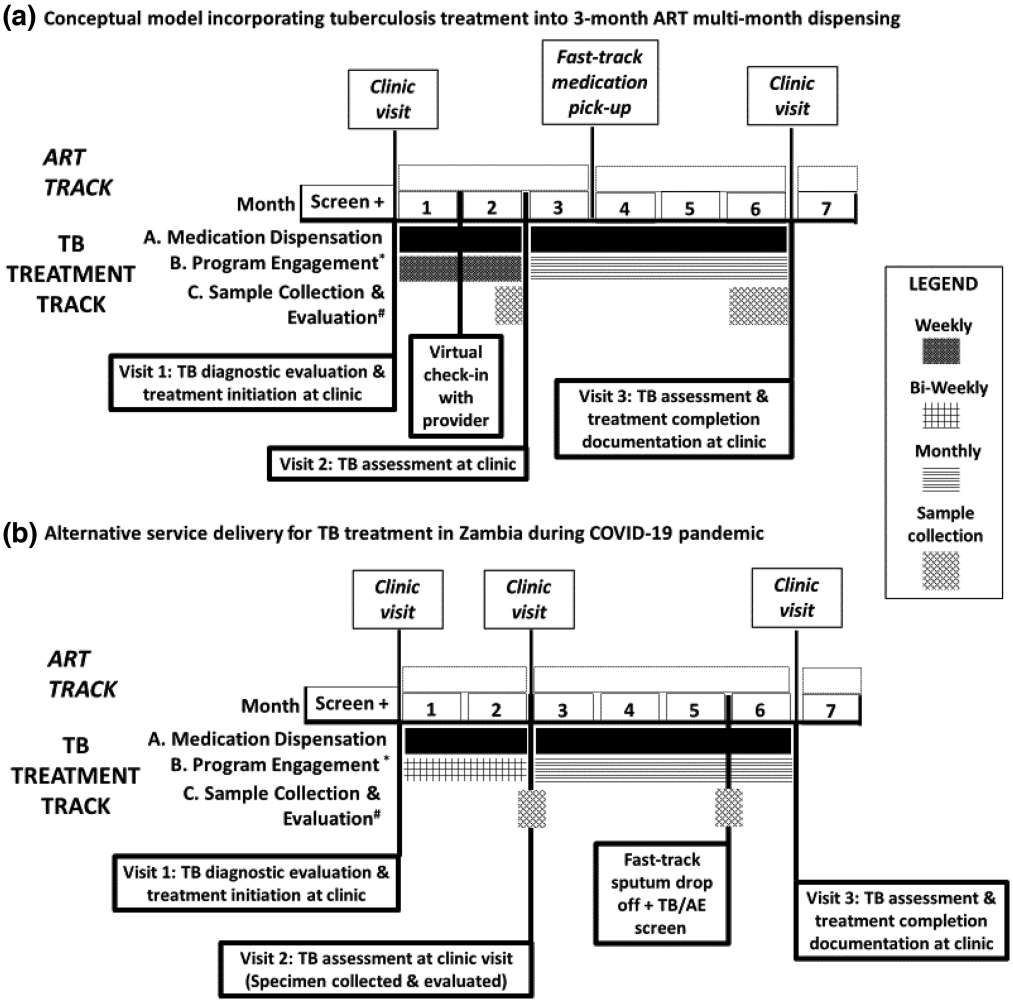

Figure 1. Examples of tuberculosis (TB) treatment integration in differentiated service delivery models; (A) This diagram defines the elements of the model and their timing/frequency. There are flexibilities inherent in this model with regard to who will carry out each task and in what setting. For example, medication dispensation could occur at the clinic, pharmacy or at community distribution points. Likewise, programme engagement (check-ins, adherence support) could be virtual, community-based or a combination of these. Sample collection and evaluation will most often be based in the clinic setting, but there may be models or specific situations that entail community-based specimen collection. For example, *Programme engagement consists of virtual or community contact by a treatment supporter to monitor for adherence and adverse events. #Sample is collected in the community and prior to clinic visit for a TB assessment. Fast track consists of clinic visits every 6 months with fast-track medication pick-up at 3 months in between clinic visits. HIV treatment: 6-month clinical visit per year and clinical services/medication refills are fast tracked (expedited) at 3 months. TB treatment: consists of three in-person clinic visits and one virtual check-in with a health provider. TB medication is dispensed twice, for 2 and 4 months. Sample collection and evaluation is performed prior to the TB assessment clinic visits. Programme engagement is conducted by a treatment supporter weekly during the intensive phase and monthly during the continuation phase. (B) HIV treatment: PLHIV receiving TB treatment through this model have their HIV medication aligned to the TB treatment arm for this 6-month period (2 months/4 months) then return to 6 months of dispensation following treatment completion. TB treatment: At treatment initiation, patients receive 2 months of intensive phase treatment (rifampin, isoniazid, pyrazinamide, ethambutol) and receive bi-weekly virtual check-ins. At month 2, patients return to clinic for evaluation and switch to continuation treatment (rifampin, isoniazid); if they are smear-negative and responding well to treatment, they receive 4 months of medication and virtual check-ins revert to monthly. If a patient has not converted to smear-negative status at month 2 or revert positive at month 5, they are evaluated for drug resistance and returned to TB treatment standard of care based in the clinic. AE, adverse event; ART, antiretroviral therapy; HIV, human immunodeficiency virus; PLHIV, persons living with HIV; TB, tuberculosis.

participates in weekly community-based or virtual AE screening and adherence counselling with a treatment supporter and a 1-month virtual check-in by the health provider. Before the 2-month clinic visit, sputum specimen collection occurs in the community for evaluation by smear microscopy and/or culture, in time for provider assessment and discussion of treatment effectiveness at that visit [37]. If the treatment is effective, the patient receives a 4-month supply of TB continuation phase treatment. At the patient's final TB clinic visit, the patient is evaluated for TB treatment completion and success by a provider (again requiring specimen collection before this visit). Automated adherence reminders via texting and virtual check-ins via phone calls occur at least weekly during the intensive phase and at least monthly throughout the continuation phase. These modalities could be strengthened with backup contact plans, either through contact with treatment supporters or through household visits [25,38]. Provision of dedicated mobile phones and airtime to clinic staff ensures consistent virtual follow-up. A variation in this model to further align TB and HIV treatment dispensation could be to dispense 4 months of TB treatment medication and ART at the 2-month clinic visit. It is important to document all encounters, especially community-based and virtual clinical encounters via paper-based or electronic systems. Throughout, the patient is engaged as a partner to maintain patient activation and self-efficacy, to maximize treatment success even as in-person clinical interactions may be limited.

2.6.2 | *Early Implementation in Zambia*

Within 3 months of implementation of COVID-19 mitigation measures in Zambia, TB diagnosis fell by 30% while TB treatment loss to follow-up increased slightly compared to previous years. In the context of COVID-19, Zambia modified delivery of TB treatment to address these challenges [39]. As shown in Figure 1B, updated guidance released in April 2020 allows MMD for drug-susceptible TB treatment (2 months at initiation followed by 4 months after clinical follow-up), fast-track sputum specimen drop-off at the facility (at month 5) and virtual (texting/phone) bi-monthly and monthly check-ins for symptoms and AEs during intensive and continuation phases, respectively. The guidance emphasizes selecting and educating a home-based treatment supporter to provide daily adherence support; however, the guidance does not explicitly mandate alignment of TB care with ART service delivery.

Several virtual discussions held with health staff across Zambia on implementation of new guidelines allowed for real-time troubleshooting. The National TB and Leprosy Program (NTLP) hosted a weekly TB Situation Room to monitor and mitigate the impact of COVID-19 on case-finding and other TB services. Using this virtual platform, they addressed commodity distribution issues and granted facilities maximum flexibility in implementing DSD models. Limited direct training was provided to the health providers and data clerks, which resulted in data irregularities and fewer virtual check-ins than planned. Virtual monitoring was complicated by lack of dedicated phones and airtime for TB departments and difficulty reaching patients. Since then, virtual trainings have been scaled up, and revised guidance has been developed to address these issues.

Since April 2020, Zambia's NTLP estimates that 80% of all health facilities providing TB services provide TB treatment through a DSD model, with nearly all their patients enrolled. Common model variations include 1-month drug dispensation during the intensive treatment phase and 2-month dispensation during the continuation phase because of stock limitations. Data from 10 early-adopter sites in Lusaka Province presented at a TB Situation Room meeting showed that all 1449 patients starting TB treatment between 1 March and 31 May 2020, were enrolled in some form of DSD model for TB treatment [39], and that all patients received at least one treatment support visit virtually or in the community. Among enrolled patients, 1396 (96.3%) had a documented treatment outcome, but 53 (3.7%) were lost to follow-up. Among those with a documented outcome, 1334 (95.6%) completed treatment, 56 (4.0%) died, 5 (0.4%) were diagnosed with drug-resistant TB and 1 (0.1%) discontinued treatment due to a severe AE.

After implementing this DSD model alongside the NTLP TB Situation Room which managed site-specific issues and challenges, TB case notification and treatment success rates have rebounded to level or surpass pre-COVID performance. Although these guideline changes were an emergency measure in response to the COVID-19 pandemic, the NTLP is planning more rigorous programme evaluations to assess patient outcomes and the impact and long-term utility of these adaptations.

3 | CONCLUSIONS

COVID-19 has catalysed rapid global scale-up of differentiated, patient-centred service delivery for PLHIV. Expanding DSD models to include TB treatment can capitalize on existing platforms while providing high-quality, routine treatment follow-up and patient education and empowerment. These efforts can be supported by existing networks of treatment supporters, systems for sample collection and transport and mobile technologies. Adapting the existing provider–patient interface for TB treatment could not only increase patient convenience and satisfaction but also reduce patient and health system costs and other barriers to adherence. Incorporating these options into health programmes would contribute to realizing the goal of integrated, patient-centred, sustainable care.

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COMPETING INTERESTS

The authors declare no conflicts of interest.

AUTHORS' CONTRIBUTIONS

CHT, BKM, IP and AT. Boyd conceived and wrote the first draft of the manuscript. PL, SS, IO, TA-S, SAM and AD reviewed and edited the final version of the manuscript.

ACKNOWLEDGEMENTS

The authors thank the staff at the Zambia Ministry of Health, Macarthur Charles and Bill Coggin. Salaries for Cuc H. Tran, Brittany K. Moore, Ishani Pathmanathan, Ikwo Oboho, Teeb Al-Samarrai, Susan A. Maloney, Anand Date and Andrew T. Boyd are supported by the US President's Emergency Plan for AIDS Relief (PEPFAR) through the US Centers for Disease Control and Prevention. The content and conclusions of this Commentary are those of the authors and do not necessarily represent the official position of the funding agencies.

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The *Journal of the International AIDS Society*, the official journal of the Society, provides a peer-reviewed, open access forum for essential and innovative HIV research, across all disciplines. All articles published by the *Journal of the International AIDS Society* are freely accessible online. The editorial decisions are made independently by the journal's Editors-in-Chief.

Website: www.jiasociety.org

eISSN: 1758-2652

Contact details

Editorial office:
Avenue de France, 23
CH-1202 Geneva
Switzerland

Email: editorial@jiasociety.org

Tel: +41 (0) 22 710 0800

Publisher

The *Journal of the International AIDS Society* is published by John Wiley & Sons Ltd on behalf of the IAS - International AIDS Society

John Wiley & Sons Ltd
9600 Garsington Road
Oxford, OX4 2DQ UK

Telephone: +44 1865 776868

Email: customer@wiley.com

Production Editor

Karthikeyan Thinakaran (email: kt@wiley.com)

Abstracting and Indexing Services

The *Journal of the International AIDS Society* is indexed in a variety of databases including PubMed, PubMed Central, MEDLINE, Science Citation Index Expanded and Google Scholar. The 2020 Journal Impact Factor is 5.396, Journal Citation Reports (Clarivate Analytics, 2021).

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