

Home Delivery of Antiretrovirals as an Option for Mitigating Challenges in Accessing HIV Medication in Anambra State, Nigeria

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ABSTRACT

Home delivery has the potential to enhance access to antiretroviral therapy (ART). This study aimed to compare the impact of an ARV home delivery model on patients' viral load outcomes against facility refills. Three hundred sixteen (316) HIV-diagnosed patients were recruited for the study, with 158 from each of two randomly selected hospitals in Anambra that met the qualifying criteria. Participants were randomly assigned to the intervention or control group using the web-based random number generator, each participant's received ARV medications at home every three months and viral load tests every six months over two years. Their outcomes were compared to a control group receiving facility-based care. Statistical analyses included the Chi-square test, Fisher's exact test, and independent t-test, with a two-sided p-value of <0.05 signifying significance. All participants were included in the analysis (intention to treat). Patients' willingness to pay for this service was assessed using a contingent valuation approach with the payment card technique. On recruitment, most clients were females. Also, majority of the clients had a basal viral load range of 21-10,000 cp/mL, with 74.7% at the intervention group and 81.7% at the control group. By 6th and 12th month, 69.0% and 70.9% of the intervention group achieved a viral load of <20 cp/mL, compared to 69.6% and 71.2% at the control group. These differences were not statistically significant (p-values of 0.07 and 0.09). At 18th and 24th months, 84.0% and 78.0% of the intervention group achieved viral load suppression of <20 cp/mL, while the control group had rates of 89.1% and 79.1%. These results were statistically significant, with p-values of 0.04 and < 0.001, respectively. On trial exit, majority of clients (89.7% in the control group and 85.9% in the intervention group, p < 0.001) expressed a willingness to pay for the home delivery service. Home delivery of ARVs positively impacts viral load outcomes, and patients are willing to pay this service.

Keywords: Home delivery, ARV, HIV, and Randomized controlled trial

INTRODUCTION

The Human Immunodeficiency Virus (HIV) remains a significant threat in Sub-Saharan Africa (SSA), affecting over 25.5 million individuals in 2016[1]. The anticipated future increase in cases will further strain individuals and healthcare systems in the region. To facilitate universal access to antiretroviral therapy (ART), the World Health Organization (WHO) eliminated CD4 cell count requirements from its 2016 treatment guidelines[2]. Access barriers and noncompliance with antiretroviral therapy (ART) notably hinder treatment effectiveness[3]. Ensuring ongoing access to HIV treatment is crucial for the potential eradication of this public health issue[3-5].

In 2020, Africa accounted for about 67% of the global disease burden[3.6], with approximately 1.9 million people living with HIV in Nigeria[7]. In 2019, around 60% of adults with HIV had access to antiretroviral therapy (ART), but this declined in 2020 due to challenges from COVID-19 and insecurity, undermining progress in HIV treatment[8]. Many countries implemented social distancing and lockdown measures during the pandemic, severely disrupting access to ART. These restrictions hindered essential health services, including ART for HIV patients[9-12]. Additionally, in countries like Nigeria, healthcare staff were reassigned to the COVID-19 response, leading to a shortage of regular services. Healthcare facilities faced further limitations due to travel restrictions, clinic closures, and fears of infection[13-16]. The pandemic posed serious global health security challenges, restricting access to healthcare and necessitating alternative service delivery methods for people living with HIV to prevent increased morbidity and mortality from treatment interruptions[17,18]. In response, the World Health Organization (WHO) recommended that countries implement measures to ensure the continuity of essential health services, including HIV care, during disruptions[19].

Nonetheless, for these disruptions to be averted, the implementation of measures to guarantee uninterrupted healthcare services became a vital focus for delivering effective HIV/AIDS treatment during this period. This effort was seen in a study in Nigeria in which it was found that factors such as convenience issues, long wait times, and high transportation cost, along with insecurity and the COVID-19 pandemic, significantly affected access to and adherence to antiretroviral therapy[4,21-23]. Consequently, home delivery of antiretrovirals is the most effective solution for individuals living with HIV on antiretroviral therapy, as it reduces the need for patients to visit healthcare facilities[4]. However, there is a lack of research on how this delivery model affects the viral load status of these patients. This study aimed to evaluate the impact of home delivery of antiretrovirals on the viral load outcomes of HIV patients in Anambra State, Nigeria, while also exploring patient willingness to pay for this delivery model.

METHODS

Area of the Study

The study, a randomized, controlled experiment with a balanced design (1:1), took place at two different missionary hospitals in Anambra State, in southeast Nigeria. The study lasted two years, specifically from September 2020 to March 2023. In 2010, Anambra State, Nigeria, exhibited an HIV prevalence rate of 2.4%, ranking sixth in the nation for HIV transmission among those aged 15 to 49 years. A recent study from the Anambra State Aids Control Agency (ANSACA) highlighted the increasing prevalence of HIV transmission in the state[26]. In this context, many approaches for differentiated HIV care delivery have been used in the state to successfully mitigate this issue[26].

St. Charles Borromeo Specialist Hospital Onitsha is a missionary healthcare center and the biggest private hospital on Africa's west coast. It is owned by the Catholic Archdiocese of Onitsha and was established in 1964 and the hospital offers multidisciplinary services[27]. Iyien Missionary Hospital was founded in 1907 by the Church Missionary Society's Niger medical mission in Ozalla, Onitsha, providing healing for the sick. It became a university teaching hospital in 2022[28]. The two mission hospitals were selected because they have a HEART to HEART comprehensive center with a high HIV patient load[27,28].

Sample sizes and sampling techniques

The sample size was determined using an online sample size calculator from the Clinical and Translational Science Institute of the University of California, San Francisco. The percentage of individuals with viral load suppression above 1000 copies or more per milliliter of blood served as the basis for calculating the sample size. Assuming a standard deviation of 50% (increase in undetected viral load in the intervention arm compared to the control arm), a two-sided significance level of 5%, a 50% population outcome, and an effect size of 0.5, a minimum sample size of 264 participants was considered to be acceptable for the study. An additional 20% of the estimated sample was added to the minimum sample size of 264 in order to account for potential dropouts and loss to follow-up. This gave a sample size of 316 people, with 158 participants in each group.

Randomization

Three hundred sixteen (316) patients diagnosed with HIV, with 158 from each institution, were recruited for the study from two randomly chosen hospitals in Anambra, having satisfied the qualifying criteria. A web-based random number generator, Randomizer, was used to produce two sets of numbers within the range of 1 to 316. Each set of 158 numbers. Set 1 denoted the intervention group, while Set 2 denoted the control group. Participants were allocated consecutive numbers based on the recruiting order. A person not involved in sampling or data analysis executed the allocation procedure, using the participants' identifying numbers to determine their assigned group. However, the intervention in question, the home delivery of antiretroviral drugs, does not allow for blinding, as the delivery workers directly administer the pills to the participants' residences.

Eligibility Criteria

All stable individuals who have been on ART for at least six months and have a viral load of more than 1000 copies per milliliter of blood meet the inclusion criteria. Participants were excluded if they were pregnant at the time of enrollment, under 18 years of age, had missed visits, had an undiscovered viral load or a viral load below 20 copies per milliliter of blood, withdrew permission, or resided outside the state.

Study Procedure

The research assistant was in charge of explaining the study to the recruited participants (if they signed the permission form indicating their assent). The research assistant gathered data to facilitate the home delivery of their medications, including delivery locations, preferred days of the week, and the most accessible phone numbers, and then recommended those who provided their assent to the doctor. After reviewing the participant's most recent viral load from his or her folder, the doctor requested a baseline plasma viral load. If a doctor recommends that an enrolled participant is eligible for home delivery, the home delivery personnel (HDP) transported a three-month pre-packaged ARV in an appropriate package form with a participant identifier to the participant's selected delivery location via public transportation. Participants collaborate to choose the delivery locations, as long as the drug is given in a way that maintains confidentiality.

By the time of trial enrollment, participants in the intervention arm were instructed to go to the hospital for a viral load test every six months, unless they had a medical issue that needed to be attended to by a doctor. The HDPs report back to the pharmacist and the physician after every medication delivery, and the physician determines whether to revisit the patient in three months. The intervention group provides participants with a phone number for emergencies or urgent consultations before their next scheduled session. The control group received their medications from the HIV treatment facility according to standard protocol, and they underwent biannual evaluations of their viral load and Cluster Differentiation (CD4) count, just like the intervention group. Routine data were gathered, and the patient had the freedom to withdraw from the experiment at any moment. At the end of the study, i.e., at the 24-month the patients in the intervention

group were assessed for their level of satisfaction and their willingness to pay for the home delivery of their ARV medication.

Training for Home Delivery Personnel

Home delivery personnel (HDP) for the home delivery model were four community health extension workers who also work in the hospital. They received five days of training from: (1) the National ART training curriculum; (2) the World Health Organization (WHO) guideline on stigma management; (3) the World Health Organization consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection: recommendations for a public health approach; and (4) the WHO community home delivery manual. The HDPs received training on maintaining strict secrecy throughout medicine delivery. They also received training on conducting participant interviews and overseeing adherence to antiretroviral treatment throughout medication administration. An HIV care services specialist conducted the training. The main outcome measures compared the HIV viral load suppression from greater than 1000 copies per milliliter of blood to the undetectable viral load at baseline, six, twelve, eighteen, and twenty-four months for both the intervention and control groups. The secondary result i.e. the willingness to pay out of pocket for the home delivery service, was assessed by adopting a questionnaire use in a study from the protocol by Nnenna et al in 2022[22].

Data Collection

A research assistant collected the baseline data at each recruiting center, while home delivery staff collected the follow-up data. A random test was performed to ensure completeness.

Data Analysis Technique

The obtained data were checked for correctness, encoded in an Excel spreadsheet, and analyzed using the Statistical Package for the Social Sciences (SPSS) version 26. The collected questionnaires were verified for consistency (the physical copies) by one of the researchers. The demographic data was reported as frequency (percentage or mean $\pm$ The study utilized standard deviation and analyzed dichotomous measurements between the intervention and control groups through the chi-square test and Fisher's exact test, while continuous measurements were compared using an independent t-test. A two-sided p-value of 0.05 was used to denote statistical significance. All individuals were included in the trial (intention to treat).

That is participants were analyzed based on the group they were randomly assigned to, regardless of whether they received the treatment or not. For the willingness to pay, a logistic regression analysis was conducted to evaluate the effect of the sociodemographic characteristics on the willingness to pay for the home delivery of ARVs.

Ethical Considerations

The research received approval from the Nnamdi Azikiwe University Teaching Hospital Health Research Ethics Committee (NAUTH/CS/66/VOL. 13/VER III/23/2020/011) on October 2, 2020. The Pan Africa Trial registry, accessible at <http://www.pactr.org/PACTR202004535536808>, has registered the trial under the number PACTR202004535536808, dated April 8, 2020. The trial was conducted in accordance with the principles established in the Declaration of Helsinki. All identifying information was managed with the utmost discretion. The informed consent form was completed by the participants, who were also made aware that they might leave the experiment at any moment at any stage.

RESULTS

Three hundred and sixteen (316) participants were recruited in the randomized controlled study, with 158 assigned to the intervention and control arms respectively (Table 1). Male individuals made up 53.85% of

the control group at enrollment, whereas female participants made up 60.8% of the intervention group. There was no significant difference in the mean age or gender of participants between the two arms (p-value 0.32). The mean ages of the participants in the intervention and control arms were 38+1.14 vs 40+1.08, $p = 0.35$. Most people were on the first-line ART regimen, Tenofovir/Lamivudine/Dolutegravir (88.8% for the intervention and 73.4% for the control).

Table 1. Socio-demographic Characteristics of the Intervention and Control Groups

Demographic characteristics		Intervention Group (%)	Control Group (%)	Total (%)
Gender	Female	96 (60.80)	85(53.8)	181 (57.28)
	Male	62 (39.20)	73(46.2)	135 (42.72)
Marital status	Single	63 (39.90)	56(35.4)	119 (37.67)
	Married	70 (44.30)	80(50.6)	150 (47.47)
	Divorced	0 (0.00)	5(3.16)	5(1.58)
	Widowed	25 (15.80)	17(10.7)	42(13.29)
Age (years)	18-27	2 (1.30)	9(5.70)	11(3.48)
	28-37	21 (13.30)	16(10.1)	37 (11.71)
	38-47	93 (58.90)	115(72.)	208 (65.82)
	≤48	42 (25.70)	18(11.3)	60(18.99)
Education	Primary School	20 (12.74)	33(20.8)	53 (16.77)
	Secondary School	46 (29.30)	50(31.6)	96 (30.47)
	Higher institution	71 (51.59)	37(23.4)	108 (34.18)
	No formal education.	9 (5.10)	38(24.0)	47 (14.87)
Occupation	Student	7 (4.46)	19(12.0)	26 (8.23)
	Govt. Employee	18 (11.46)	27(17.0)	45(14.24)
	Self-Employed	40 (25.48)	30(18.9)	70 (22.15)
	A private sector employee	81 (51.59)	60(37.9)	141 (44.62)
	Unemployed	4 (2.55)	17(10.7)	23 (7.27)
	Retired	7 (4.46)	5(3.16)	13(4.11)
Earnings per month (Nigerian naira)	≤18,000 (US\$15)	45(28.48)	50(32.6)	95 (30.06)
	18,001-50,000(US\$15-US\$14.7)	55 (35.03)	60(37.9)	115 (36.39)
	50,001-100,000(US\$14.7-US\$83.3)	33 (20.89)	34(21.5)	67 (21.20)
	100,001-200,000(US\$83.3-US\$166.7)	22 (14.02)	12(7.59)	34 (10.76)
	200,001-500,000(US\$166.7-US\$416.7)	0 (0.00)	2(1.27)	2(0.63)
	≥500,001(US\$416.7)	0 (0.00)	0 (0.00)	0 (0.00)
Senatorial zone	Anambra North	118 (74.70)	131(82.)	249 (78.80)
	Anambra Central	36 (22.80)	27(17.0)	63 (19.93)
	Anambra South	4 (2.50)	0 (0.00)	4(1.27)

*@ August 2023 \$1 = ₦1500 in Nigerian black market (<http://www.exchangerates.org.uk>)

For the viral load outcome, the plasma viral load findings of patients who had their medication at the facility (group 2, also known as the control) and those who had their prescription refill at home (group 1, also known as the intervention) were compared (Table 2). At enrollment, the plasma viral load values for the participants mostly fell within the range of 21–1000 cp/mL, accounting for 81.7% for the control group and 74.7% for the intervention group. There is no statistically significant difference between the intervention and control means (means = 3.7, standard deviation of ± 0.9), at a p-value of 0.41. After using ART for six months, some intervention participants (69.0%) and control participants (69.6%) achieved a plasma viral load of less than 20 cp/ml. The standard deviation was ± 0.98 , the mean difference was 2.3, and the p-value was 0.07. At the 12-month, 70.9% of participants in the intervention group and 71.92% of those in the control group had a

plasma viral load result of less than 20 cp/ml, with a mean difference of 1.9 ± 1.1 and a p-value of 0.09. Interestingly, a significant difference with a mean difference of 1.70 ± 0.92 and a p-value of 0.04 was observed in both groups in the 18th month.

At the 24-month, 89.1% of the intervention group and 79.0% of the control group had achieved an undetectable viral load. The results, with a p-value of 0.00 and a mean of 1.5, were statistically significant. Furthermore, we reported maintaining 305 individuals in care—149 in the control group and 156 in the intervention group. Furthermore, the majority of patients (86.7% for the intervention group and 67.7% for the control group) continued to take dolutegravir, tenofovir, and lamivudine. For the secondary outcome, 89.7% of the intervention participants against 85.9% of the control participants reported they were willing to pay (WTP) for services which was statistically significant at a p value of <0.001

Table 2: Impact of home delivery of antiretrovirals on primary and secondary outcomes

Intervals (Months)	Characteristics of Participants	Intervention	Control	p-value
Baseline	Mean Age of participants $\pm$ SD	38.5 $\pm$ 1.14	40.1 $\pm$ 1.08	0.35
	Gender of Participants			
	Male	62 (39.2%)	85 (53.8%)	0.32
	Female	96 (60.8%)	73 (46.2%)	
	ART medication at baseline			
	TDF/3TC/DTG	139 (88.8%)	116(73.4%)	
	ABC/3TC/DTG	17 (10.0%)	41 (25.9%)	
	ABC/3TC/EFV	1 (0.6%)	1 (0.0%)	
	Plasma viral load (cp/mL)			
	<20	0 (0.0%)	0 (0.0%)	0.41
	21-10000	118 (74.7%)	129 (81.7%)	
	>10001	40 (25.3%)	29 (18.4%)	
	The mean difference in viral load is $\pm$ SD.			3.7 $\pm$ 0.9
6 months	Plasma viral load (cp/mL)			
	<20	109 (69.0%)	110 (69.6%)	0.07
	21-10000	45 (28.5%)	43 (27.3%)	
	>10001	4(2.6)	5 (3.2%)	
	The mean difference in viral load $\pm$ SD.			2.3 $\pm$ 0.98
	Number of Participants retained in care	158/158	158/158	
12 months	Plasma viral load (cp/mL)			
	<20	112 (70.9%)	113 (71.2%)	0.09
	21-10000	44 (28.2%)	34 (11.9%)	
	>10001	0 (0.0%)	5 (3.2%)	
	Mean difference in viral load $\pm$ SD			1.90 $\pm$ 1.1
	Number of Participants retained in care	156/158	152/158	
18 months	Plasma viral load (cp/mL)			
	<20	131 (84.0%)	117 (78.0%)	0.04*
	21-10000	25 (16.0%)	28 (18.7%)	
	>10001	0 (0.0%)	5 (3.2%)	
	Mean difference in viral load $\pm$ SD			17.0 $\pm$ 0.92
	Number of Participants retained in care	156/158	150/158	

24 months (Trial Exit)	Gender of Participants			
	Male	60 (38.0%)	76 (48.1%)	0.23
	Female	96 (60.8%)	73 (46.2%)	
	ART Medication at Exit of Trial			
	TDF/3TC/DTG	137 (86.7%)	107 (67.7%)	
	ABC/3TC/ATV	17 (10.0%)	41 (25.9%)	
	ABC/3TC/EFV	1 (0.6%)	1 (0.2%)	
	Plasma viral load (cp/mL)			
	<20	139 (89.1%)	118 (79%)	<0.001
	21-10000	17 (10.9%)	27 (18.1%)	
	>10001	0 (0.0%)	4 (2.7%)	
	Number retained in care	156/158	149/158	
	Number willing to pay for HD	140 (89.7%)	128 (85.9%)	<0.001

*p-value < 0.05

Key: SD: Standard deviation, HAART: High active antiretroviral therapy, TDF: Tenofovir (300mg) , 3TC: Lamivudine(300mg), DTG: Dolutegravir(50mg), ABC: Abacavir(600mg) EFV: Efavirenz (600mg), cp/mL: copies per milliliter, HD: Home delivery

Patient education level significantly impacts trial respondents' willingness to pay (WTP) for ARV delivery, with an odds ratio of 1.7 (95% CI: 1.04-2.80, p=0.03). Table 3 shows no significant difference in WTP for home delivery of ARVs across sociodemographic variables like gender, age, marital status, income, patient satisfaction, and health insurance. Employment also notably influences WTP, with an odds ratio of 1.9 (95% CI: 1.10-3.38, p=0.02). Furthermore, monthly income affects WTP at an odds ratio of 1.58 (95% CI: 1.00-2.44, p=0.05).

Table 3: Logistic regression of the intervention groups' demographic characteristics and their willingness to pay for ARV home delivery service

Demographic characteristics	Willingness to pay (yes = 1, no = 0), n = 108 OR* (95% CI [†])	p-value
Gender	0.8 (0.33-2.20)	0.74
Age	1.5 (0.91-2.38)	0.12
Occupation	1.9 (1.10-3.38)	0.02 [‡]
Resides	0.6 (0.23-1.31)	0.18
Education	1.7 (1.04-2.80)	0.03 [‡]
Marital status	0.78 (0.48-1.25)	0.30
Insured	1.0 (0.00-xx)	0.99
Earnings	1.58 (1.00-2.44)	0.05 [‡]
Income Description	1.13 (0.58-2.18)	0.73
Patient satisfaction with a facility refill	0.88 (0.73-1.10)	0.15

*OR-Odds ratio, [†]CI-confidence interval, [‡]p-value <0.05

A multiple binary regression analysis (Table 4) revealed no significant differences in WTP among various groups based on employment, monthly income, or education level. The item analysis indicates that 37.3% of

HIV clients earned between 18,000 and 50,000 Nigerian naira (US\$15-US\$41.7) per month, with nearly half (51.3%) reporting that their income was insufficient for their needs.

Table 4: Multiple binary logistic regression of the intervention groups' demographic characteristics and their willingness to pay for ARV home delivery service

Demographic characteristics	NO	YES	Willingness to pay (OR)*	p-value
Occupation				
Student	6 (5.10)	1 (0.63)	2.4 (0.00 - xx)	0.99
Government employee	8 (5.10)	10 (7.64)	3.0 (0.00 - xx)	0.99
Self-employed	12 (7.64)	28 (17.83)	4.7 (0.00 - xx)	0.99
Private sector employee	21 (13.38)	61 (38.8)	2.4 (0.00 - xx)	0.99
Unemployed	2 (1.27)	2 (1.27)	8.1 (0.00 - xx)	0.99
Retired	4 (2.55)	3 (1.91)		Ref
Education				
Primary school	8 (5.10)	12 (7.64)	0.41 (0.13-1.22)	0.10
Secondary school	15 (9.55)	30 (19.11)	0.53 (0.18-1.43)	0.22
Tertiary institution	21 (13.38)	60 (38.21)	0.83 (0.32-1.45)	0.25
No formal education	8 (5.10)	1 (0.64)		Ref
Earnings per month				
≤18,000(US\$15)				0.99
18,001-50,000(US\$15-US\$41.7)	18 (11.46)	27 (17.20)	0.0 (0.0-xx)	0.99
50,001-100,000(US\$41.7-US\$83.3)	15 (9.55)	40 (25.48)	0.0 (0.0-xx)	0.99
100,001-200,000(US\$83.3-US\$166.7)	8 (5.10)	25 (15.92)	0.0 (0.0-xx)	0.99
200,001-500,000(US\$166.7-US\$416.7)	3 (1.91)	20 (12.74)	0.0 (0.0-xx)	0.99
≥500,001(US\$416.7)	0 (0.00)	0 (0.0)	0.0 (0.0-xx)	Ref

*@ August 2023 \$1 = ₦1500 in Nigerian black market (<http://www.exchangerates.org.uk>) *OR-Odds ratio
@ 95% CI, † CI-confidence interval

DISCUSSION

This study used a randomized control trial to examine the impact of home delivery of antiretroviral therapy (ART) on viral load outcomes among HIV patients in Anambra State, Nigeria, over a two-year period. The finding indicates that home delivery significantly improved patient outcomes, particularly in terms of viral load suppression, compared to regular prescription refill by patient. Also, on the trial exit, the HIV clients' willingness to pay for the home delivery of the antiretrovirals was assessed, and most of the clients showed a willingness to pay for the delivery model.

Both intervention and control groups showed a gradual decline in viral load from the baseline. By the 6th month, the intervention group exhibited a somewhat increase in the proportion of patients with undetectable viral loads, while the control group had a remarkable increase. Although there was a slight drop in viral load at the 12-month mark for both groups, the mean difference was not statistically significant. However, by the 18th month, the differences became statistically significant in favor of the intervention group, continuing through the 24th month.

The home delivery approach involved healthcare workers delivering ARVs directly to stable HIV patients, which enhanced patient-centered care. Previous studies in Uganda, primarily involving newly initiated ART patients, did not show significant differences in viral load outcomes after six months or during the 36-month follow-up period [29,30]. In contrast to this study, both previous trials relied on a single ART clinic. In rural Uganda, the first trial deployed trained and recruited community health workers to deliver medication to patients' homes. Similarly, the trial's second phase took place in an urban sub-district of Uganda, comparing

the same cohort of patients receiving ART home delivery with those attending a physician-staffed hospital[29]. The study showed that patients who received their ARV at home were more likely to achieve viral suppression. The Zakumumpaet al., study in 2021 differed from the Anambra state study in that it relied on newly recruited patients for the trial, potentially leading to a lack of documented or established ARV adherence among the clients[29].

Similar to studies in Uganda and Anambra, a study in rural Kenya found no difference in the number of stable ART patients with an undetectable viral load between those who received ART from home visits and those randomly assigned to standard facility-based ART[31-34]. This study, the first in Nigeria, integrates the intervention directly into the regular healthcare system just like the Uganda and Kenya trials, where a non-governmental organization manages the study's facilities[29,33]. Additionally, while the Uganda trial trained a new cadre of community health workers to deliver ART by motorbike, the Anambra State study trained pharmacy technicians who work at the same health facility where the participant receives their routine HIV care. These technicians have received some form of orientation on patient care and deliver medication refills by foot or public transport, this was done as a way to curtail stigma associated with accessing antiretrovirals[33]. Furthermore, while this trial enrolled a large number of clients from two hospitals and divided them into two arms (intervention and control), it only implemented the intervention at one clinic in Uganda and Kenya[29,33]. Finally, both the Uganda and Kenya trials were unable to rigorously assess the possibility of sustaining this model of care; on the other hand, this trial conducted both intervention and control arm in both centers and was able to evaluate patient willingness to pay for the service at the same time [23,35].

Unlike the studies conducted by Mash et al.,(2022 and 2021 respectively) and Bery et al., in 2019 in which executing the study had a huge challenge (like loss to follow up and lack of audit)the study in Anambra State overcame some of the above challenges by collecting clients' addresses on the day of enrollment, tracking the clients with phone calls on or before the day of drug delivery, giving the staff stipends for the delivery, and encouraging the delivery of the medications after the close of work[36-38]. Additionally, this study also effectively managed the issue of a reliable audit trail by opening trial folders for each participant separately from the hospital folders and by having pharmacists, who are also hospital staff, monitor each client's refill processes[36].

This study also assessed the willingness of HIV patients in the southern region of Nigeria to pay for home delivery of ARVs to or near their homes, and the research-developed study instrument was then administered to the trial participants upon trial exit. Upon trial exit, the majority of participants expressed their willingness to cover the cost of ARV delivery. Similar to this study, at trial exit, a significant number of participants expressed willingness to pay for home delivery services, reflecting their positive experiences with the model. This aligns with findings from Geldsetzer et al., conducted in 2020, indicating a broader acceptance of home delivery among patients[39,40]. This is because the participants had already experienced the benefits and advantages of the care model before the evaluation, which explains their positive response[39].

There are various disruptions in health service delivery in Nigeria and beyond; an example is the major decline in HIV care (40%) in over 500 health facilities across Africa and Asia since the covid-19 epidemic[6]. The result from this study backs up the World Health Organization's suggestions for flexible ways to improve access to care in Nigeria and it stresses how important home delivery is for sustaining availability of antiretrovirals (ART)[41,42]. Therefore it is imperative that the delivery of antiretroviral therapy to patients' homes or close to their homes serves as a measure for expanding access to care when access to health services that was/is disrupted by routine circumstances. In this study, the home delivery of medication offered a significant advantage to this group of patients on antiretroviral medication.

CONCLUSION

Home delivery of antiretrovirals in Anambra State, Nigeria, significantly reduces viral load in HIV patients compared to facility-based refill, with patients willing to pay an average of 1US\$ per delivery. This model

shows strong potential for improving HIV care in Nigeria and similar settings, and warrants further research and implementation to address healthcare access challenges

STUDY LIMITATIONS

This study has several limitations

- This study's findings are not generalization to the entirety of Nigeria due to its single-state setting.
- Patient attempts to transfer from the control to the intervention group were prevented by assigning patients to subgroups and individual healthcare workers for identification.
- The study did not investigate the impact of individual factors like adherence, adverse drug reactions, and stigma on the HIV care model.
- A cost-benefit analysis of the home delivery model was not conducted, limiting the assessment of its overall suitability

RECOMMENDATIONS

- Optimize home delivery of ARVs for stable HIV patients as part of routine care.
- National HIV program leaders should advocate for permanent policies supporting efficient ARV home delivery.
- Governments and partners should secure financing to sustain decentralized ARV home delivery services.
- Research is needed to assess the suitability of ARV home delivery based on individual patient needs related to adherence, adverse effects, and stigma.

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