

**EVALUATION OF A COMMUNITY-BASED ANTIRETROVIRAL THERAPY
DELIVERY PROGRAM FOR ADULTS IN OKONGO DISTRICT, NAMIBIA:
2007-2017**

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KEYWORDS

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Program Evaluation

Adherence

Retention

Viral Suppression

Health Information

ABBREVIATIONS

AIDS	Acquired Immunodeficiency Syndrome
ANC	Antenatal Care
ART	Antiretroviral Therapy
ARV	Antiretroviral
CACs	Community Adherence Clubs
CAGs	Community ART Groups
C-BART	Community Based Antiretroviral Therapy
CBOs	Community-Based Organisations
CDDP	Community ART Distribution Points
CD4	Cluster of Differentiation 4
COREQ	Consolidated Criteria for Reporting Qualitative Research
CPT	Cotrimoxazole Preventive Therapy
EDT	Electronic Dispensing Tool
ePMS	Electronic Patient Monitoring System
EWI	Early Warning Indicator
EWIs	Early Warning Indicators
F-BART	Facility Based Antiretroviral Therapy
HBC	Home-Based Care
LTFU	Lost to Follow Up
IPT	Isoniazid Preventive Therapy
MEDITECH	Medical Technology
MeSH	Medical Subject Heading
MMD	Multi-month Dispensing
MOHSS	Ministry of Health and Social Services
MPR	Medication Possession Ratio
MSF	Médecins Sans Frontière
NAMPHIA	Namibia Population-based HIV Impact Assessment
PCB	Patient Care Booklet
PCC	Population, Concept, Context
PMTCT	Prevention of Mother-to-Child Transmission
PLHIV	People Living with HIV

PODI	Poste de distribution Communautaire
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analysis
TB	Tuberculosis
VL	Viral Load
VS	Viral Suppression
WHO	World Health Organization

ABSTRACT

Namibia implemented a community-based ART (C-BART) delivery program in the Okongo District of the Ohangwena Region in northern Namibia in 2007. A C-BART site is a fixed, designated place in the community where ART services are provided on scheduled dates. The WHO recommends differentiated models of ART service delivery for stable patients at the facility and community levels. C-BART models are reported to increase patients' adherence and retention in care, with the ultimate goal of achieving viral suppression (VS).

By the end of April 2017, eighteen (18) C-BART sites were established in the Okongo district. At the time of the study, the effectiveness of the C-BART program had not been evaluated.

Aim: The study aimed to assess the effectiveness of the C-BART program on improving treatment outcomes (adherence to ART, retention in care, viral load suppression and survival) in comparison to facility-based ART(F-BART) and to describe patients' and healthcare providers' experiences of and challenges with implementing C-BART in the Okongo district.

Methodology: A multi-phased, mixed-method study was conducted. The phases included a scoping review of the community-based ART delivery program in sub-Saharan Africa with narrative synthesis; a validation study to assess the completeness and accuracy of patient medical records from the electronic Patient Management System (ePMS); a retrospective cohort analysis of ART patients seen at the Okongo District Hospital, F-BART and the 18 C-BART sites; and a descriptive qualitative study to describe experiences and challenges of implementing C-BART based on patients, HCWs and policymakers' and managers' perspectives.

Findings: The scoping review identified 16 published studies in sub-Saharan Africa from 2006-2018. Results demonstrated the similarity yet uniqueness of each of these models. The involvement of PLHIV networks, family members, support groups and patients as actors are the mechanics that make C-BART models work. Adherence to treatment, retention in care and viral suppression were key outcome measures assessed to describe the model's effectiveness. Organising patients in small self-formed and self-managed groups of 20-50 was reported to be effective in achieving group cohesion and commitment. In most studies, optimal treatment outcomes were achieved, but these waned after two years.

A validation study, including 10% of electronic records for patients seen at the facility-based and community-based sites, was done to determine the completeness of the electronic Patient Management System, the source database for the retrospective cohort analysis. In addition, data elements extracted from ePMS were compared to the data in the Patient Care Booklet (PCB) for accuracy. As a result, the overall completeness of data elements in ePMS at F-BART was 95.50% and 88.83% C-BART, respectively. The accuracy of data elements in ePMS was 98.96% % for F-BART and 99.61% for C-BART, respectively. The study rejected the null hypothesis and accepted the alternative hypothesis that F-BART and C-BART ePMS data are 80% or more complete and accurate. Based on the Chi-square test results, the overall difference in completeness and accuracy of data in C-BART and F-BART ePMS were not statistically significant.

The retrospective cohort study included a sample of 504 patients in C-BART and 2,161 patients in F-BART. Adherence among patients in C-BART and F-BART was high at 83.8% and 80%, respectively. Based on the date of patients' down-referral to C-BART, more patients were retained in C-BART at 12 months (96.8%) compared to 85.4% in F-BART. Most (89.5%) patients were retained in care in C-BART at 60 months, then in F-BART (61.6%) for the same duration. When retention analysis was conducted using the date ART started, retention was high in F-BART for 3-6 months' cohorts compared to C-BART. However, retention was high at 48-60 months among C-BART cohorts. Viral suppression <1000 copies/ml at 12 months was 99% in C-BART and 95.9% in F-BART. C-BART patients (93.1%) were more likely to be fully suppressed (viral load <400 copies/ml), compared to 86% in F-BART. The Chi-square test results suggest that C-BART is a protective factor for patient retention for long-term care.

A descriptive qualitative study was conducted through semi-structured in-depth interviews of C-BART patients, focus group discussions with healthcare workers and key informant interviews of managers and policymakers to describe the context and implementation of C-BART. Thematic analysis of five main themes and subthemes exploring C-BART site utilisation: perspective towards C-BART sites, service provider roles and preparation, service provider experiences, and recommendations for C-BART sites. Patients and community members confirmed reduced travel and related costs for follow-up care and that money previously spent on transport was used for other basic needs, including food. The study further reported inadequate infrastructures, late arrival of HCWs and patients at C-BART sites, and intermitted stockout of antiretroviral medicines (ARV) at C-BART sites as barriers to using C-BART sites. Proximity, ease of access, consistent C-BART visit schedule, support of traditional leaders, and presence of community health workers or volunteers are facilitators to utilising C-BART.

Conclusion: The study demonstrated the effectiveness of the C-BART program in retaining patients in care and achieving viral suppression for a more extended period of up to 60 months. In addition, the study revealed the suitability of the electronic management system for ART patients for longitudinal research, but it highlighted the need to improve data quality in some aspects. We recommend conventional, proper buildings or prefabricated structures to enhance privacy at C-BART sites to improve utilisation, especially for men and young people.

DECLARATION

I declare that **“Evaluation of community-based antiretroviral therapy delivery program for adults in Okongo district, Namibia: 2007-2017”** is my own work. It has not been submitted for any degree or examination to any university, and that all the sources that I have used or quoted have been indicated and acknowledged by complete references.

Naemi N. Shoopala

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CHAPTER 1

INTRODUCTION

1.1 Background

At the end of 2022, an estimated 39 million people globally were living with HIV, according to the Joint United Nations Program on HIV and AIDS (UNAIDS) [1], [2]. In addition, an estimated 29.8 million PLHIV were enrolled on ART at the end of June 2021 due to the rapid scale-up of antiretroviral therapy (ART) [1], [2]. By the same token, an estimated 67% of the world PLHIV (19 million) and more than half of those receiving ART (9 million) were living in sub-Saharan Africa [3]. The percentage of PLHIV in sub-Saharan Africa on ART increased from 45% in 2016 to 76% in 2022, of which 71% are virally suppressed [1], [2].

In 2013, the estimated HIV prevalence in Namibia was 14% among the general adult population (15-49 years) [4]. The HIV prevalence declined to 12.6% by 2017 [5] and further to 11.0% by 2022 [6], [7]. It is further estimated that 220,000 Namibians were living with HIV in 2022 [6], and it was also established that HIV-related deaths declined from over 5,000 to 3,000 deaths per annum from 2012 to 2022 [7]. Early access to HIV testing improved, and people were diagnosed earlier, as did early initiation of ART, viral load monitoring, prophylaxis against opportunistic infections, and prompt treatment. Namibia has made good strides in controlling the HIV pandemic. Based on the 2017 NAMPHIA Study, Namibia surpassed some of the UNAIDS 90-90-90 targets, having achieved 86% of PLHIV knowing their HIV positive status, 96.4% on ART and 91.3% virally suppressed by 2017 [5]. The country also achieved 95% - 97% - 94% of the UNAIDS 95-95-95 cascade by 2022 [7], making Namibia one of the few countries in Africa that have achieved the UNAIDS ambitious targets toward ending AIDS as a public health threat by 2030 [8]. In a similar sense, improvement in care has been observed, especially cervical screening through the see-and-treat approach, reduced cervical deaths among women living with HIV [9], [10]. Consequently, the successful implementation of the prevention of mother-to-child transmission also reduced infant deaths attributed to HIV [11], [12]. It was further detected that the introduction of Gene X-pert diagnostic technology also brought positive changes and commendable improvement in the diagnosis of Tuberculosis among PLHIV, leading to prompt treatment [13], [14], [15]. In addition, Namibia adopted the “Treat-all”, also known as “test-and-treat” strategy for ART initiation in 2016 to ensure universal access to ART for all PLHIV [16]. All these factors contribute to the decline in HIV-related deaths.

1.1.1 Overview of the WHO HIV treatment guidelines

The WHO introduced ART guidelines for adults and adolescents in 2002, with subsequent revisions in 2003, 2006 and 2010. The revisions to the guidelines contain recommendations on when to start ART, standard revised regimens, and approaches to monitoring immunological response, i.e. increase in CD4 count and viral suppression [17]. The changes to the guidelines were informed by advances in science and the human rights agenda for managing HIV. Over the years, the revision of the guidelines primarily focused on changes in the eligibility criteria for initiating patients on ART, their choices of ART regimens, clinical monitoring, management of opportunistic infections and laboratory monitoring for different populations and age groups and settings [17]. Notable changes in the WHO ART guidelines include recommendations of starting patients on ART when they develop clinical AIDS or stage 4, or at a CD4 count below 200 cell/mm³ and the latest is the “Treat-all” strategy [17], [18], [19].

1.1.2 The UNAIDS fast-track targets to achieve epidemic control

In an endeavour to achieve epidemic control, the UNAIDS fast-track targets were announced to ensure that by 2020, 90% of PLHIV should know their HIV status; 90% of the diagnosed PLHIV should receive ART; and 90% of those receiving ART should achieve viral suppression [20]. Sustained and consistently high adherence rates to ART and retention in care are necessary to ensure patients achieve viral suppression [21], [22], [23]. However, the rapid scale-up of ART was associated with overcrowded facilities and setbacks derailing and working against adherence and retention of patients in care [24]. Therefore, the sharp increase in PLHIV on ART exacerbates the abovementioned challenges [24]. The UNAIDS upgraded from fast-track targets to ambitious levels with a goal of ending AIDS as a public health threat by 2030 by ensuring that 95% of PLHIV should know their HIV status; 95% of the diagnosed PLHIV should receive ART; and 95% of those receiving ART should achieve viral suppression [25]. It is, therefore, against the nuanced hindsight that the need to strengthen strategies that promote patient retention arises.

1.1.3 National HIV treatment program in Namibia

There were only 10,200 PLHIV on ART in Namibia by 2004, and this increased to 161,000 by 2016 [5]. Furthermore, the global UNAIDS estimates indicate that 200,00 PLHIV received ART in Namibia in 2021 [26]. Namibia completed a population-based HIV survey in 2017. The Namibia Population HIV Impact Assessment (NAMPHIA) tested for HIV and viral load

suppression among adults 15-64 years (n = 16,939). The NAMPHIA results indicate significant progress towards the 90-90-90 target. The national HIV prevalence is reported to be 12.6%. The HIV incidence decreased from 0.8% to 0.4% in the last five years. Furthermore, it was reported that eighty-six percent (86.0%) of the adult population are aware of their HIV positive status, 96.4% are on ART, and 91.3% achieved virological suppression [5]. Achieving the UNAIDS fast-track targets is a mammoth task, considering that Namibia is a vast country with a population density of 2.8 people per km², with 52% of the population living in rural areas [4]. The burden of HIV among the rural population is relatively high, especially in Zambezi (23.7%), Omusati (17.4%), Kavango (17%), Oshana (16.1%), and Ohangwena (15.6%)[27]. In essence, most communities lack a public transport system, making it difficult, if not impossible, for the patients to travel to the district hospitals for a clinic visit. Hence, differentiated care models, particularly community-based models, offer promising results to improve access to and service utilisation.

1.1.4 Differentiated care models for antiretroviral therapy delivery

The WHO recommends differentiated care models of ART delivery for stable patients at the facility and community level [17]. The facility models include fast-tracking of patients, task shifting, task-sharing, Multi-month scripting, Multi-month Dispensing (MMD) and facility-based adherence clubs. MMD garnered attention in recent years because it allows patients to have fewer clinical and pharmacy visits. MMD also works well for cross-border patients, Seafers and those who travel away from home for extended periods. Community-based models entail task-shifting, adherence to clubs and groups and community-based ART (C-BART) delivery. The fundamental principle of the *out-of-facility* care model is bringing services closer to where the people live [28], [22], [29], [30], [31]. In 2016, the WHO released consolidated guidelines recommending differentiated ART delivery models, including refills for antiretroviral (ARV) medicines [17].

The differentiated care model framework is four-faceted, mainly centred around WHO is providing (providers/actors) or receiving care (beneficiaries); WHERE are services provided (physical location); WHEN (frequency) is it provided; and WHAT package of services is provided [32]. The component of interest informs the variations in the models of interest or challenges that a specific program is trying to address, whether it is (i) the location of service, (ii) the type of services delivered, (iii) the cadre of healthcare provider; and/or (iv) frequency of service provisions (Table 1).

Table 1: Differentiated ART delivery models and benefits

Key Objective	Appointment spacing and fast-track ARV refill	At enrolment into care		Community-ART distribution points	Community-ART groups
		Facility-based clubs	Community-based clubs		
Patient Perspective					
Reduce cost (time and transport)	Yes	Yes	Yes	Yes	Yes
Increase peer support	No	Yes	Yes	Yes	Yes
Enhance community participation	No	Potentially	Potentially	Potentially	Yes
Healthcare Perspective					
Reduced Workload					
Nurse	Yes	Yes	Yes	Yes	Yes
Pharmacist	Yes	Yes	Yes	Yes	Yes
Counsellor/Health Worker/ Peer Support	N/A	No	No	No	No
Maintain and improve Healthcare					
Retention	Yes	Yes	Yes	Yes	Yes
Improve the self-management of patients	Yes	Yes	Yes	Yes	Yes

(Source: WHO, 2016)[17]

1.2 Models of Community-based ART Delivery

The community-based ART delivery models have been associated with improved retention in care and virological and immunologic outcomes [24], [29], [33]. It was further seconded that these community-based models include community-based adherence clubs, community ART groups, and community ART distribution points [17], [29], [34], [35].

1.2.1 Community-based adherence clubs

Community-based adherence clubs (CACs) were established in South Africa for stable patients who have been on ART for more than 12 months and have fully suppressed viral loads at <400 RNA copies/ml [30], [36]. They were mainly established to decongest the primary healthcare clinics and reduce attrition by reducing the frequency and intensity of patient visits to the clinic, reducing the patients' waiting time and the workload for healthcare providers [17]. The CACs consisted of 25-30 members and were managed by a lay facilitator or community health worker and they met every second month at a community venue.

1.2.2 Community ART groups

Community ART groups (CAGs) models were implemented in Mozambique [37], [38], [39], [40], [41]. A CAG consisted of six stable ART patients. Each group member visits the clinic every six months for clinical review and collects ARVs for other group members. Unlike the CACs, the CAGs also monitor treatment outcomes, and if a problem is identified, the patient is then referred to the clinic by other CAG members [29], [30], [33], [34], [42].

1.2.3 Community ART distribution points

In the Democratic Republic of Congo, community ART distribution points (CDDP) were brought into existence because patients faced numerous challenges, including, but not limited to, the cost of transport, stigma and discrimination associated with going to ART clinics [29] [35]. However, the benefits of community ART models described above entail improved retention in care, reduced loss to follow-up, virological suppression and improved survival, similar to those reported from facility-based models [29]. Hence, as countries strive towards universal access to ART and strategies to retain patients in care, community-based ART models are and will continue to be vital strategies to achieve these goals [33].

1.3 Key Outcomes of Interest in Evaluating Antiretroviral Therapy Programs

ART delivery programs seek to improve outcomes, such as retention in care, adherence, immunologic (CD4) evolution, virological suppression and survival [29], [43], [44].

1.3.1 Retention in care

The definition of *retention in care* encompasses the patient remaining engaged in ART protocol once enrolled in care; that the patient is alive and on ART at the same facility, or formally transferred out to another ART facility, and thus is assumed to be on ART [45], [46]. Furthermore, retained patients are those who are alive and on ART at the end of the follow-up period. This follow-up period could be 6, 12, 24, or 36 months after initiating ART [45]. In the same vein, the WHO defines retention in care as the number of patients retained on the first-line regimen at the 12-month date [28].

Patients who died, were lost to follow-up and stopped/discontinued ART were considered not retained [28], [45]. The recommended target for retention in care at 12 months after ART

initiation is >85%, which is considered an excellent performance; 75-85% is fair, and <75% is categorised as poor performance [28].

It was also noted that factors influencing patient retention in care include individual/patient-related factors, medication-related, health system, and socio-economic and structural-related factors [24], [29], [47], [24], [29], [47], as outlined in Table 2.

Individual/patient-related factors: In terms of gender (sex), males are reported to have low adherence and retention in care compared to females [48], [49]. Older age group ≥ 50 years were more likely to be retained in care and adhere to ART than those ≤ 50 years old and younger, especially those in the 18-29 and 30-39 years old categories [50]. In the same vein, patient's health beliefs, especially cultural preferences for treatment, traditional versus Western medicine, may affect patients' adherence and retention in care; because of their beliefs [51], patients may default on clinic visit appointments and /or on taking their ARVs as prescribed. Patients with low health literacy levels may have a limited understanding of why they need to return to the clinic for follow-up and why they need to take medicines [40], [52], [53], unlike those with high literacy levels, who will be more self-efficacious and reliant on making medical decisions [53]. Patients with a mental health and substance abuse [54] history may have limited decision-making capacity.

Medication-related factors: Patients with simplified medication dosing are reported to be more adherent than those with complex regimens or taking more pills. Similarly, patients who experience severe side effects and toxicities [55] are more likely to drop out of and default from treatment [52]. The type of ARV regimen, frequency and timing of taking ARVs, ARV formulation and taste may also affect patients' adherence and retention in care [48].

Health System Factors: A shortage of healthcare staff may result in long waiting times for patients, and patients may be deterred from going for follow-up visits if they have to wait for long periods. In addition, limited available staff may spend less time with the patient to assess them properly for side effects and other problems, affecting their adherence to treatment and attending clinic visits. The service delivery model influences patients' adherence and retention [30], [42]. Patients seen in various differentiated service delivery models, such as the community adherence groups and community distribution centres [30], [56] were found to be retained. Similarly, patients who are fast-tracked, receive care closer to their home [34], have treatment buddies, or receive multi-month scripts are more likely to adhere and be retained in care [48], [57].

Socio-economic Factors: Even in settings where ARVs are provided at no cost to the patient, patients still require transport to get to the facility; hence, poverty remains a factor that affects adherence to clinic appointments and leads to interrupted access to ARVs and adherence [34], [35]. Patients reported more side effects when they took ARVs on an empty stomach [21]. Hence, food security affected adherence [58], [59]. Decentralised service delivery improves adherence and retention in care. Distance to clinics and health centres, lack of transport, the high cost of transport [38], [55], [60], travel time [55], [60], work commitment and childcare responsibilities are some of the identified socio-economic factors that affect adherence and retention [35]. Patients, especially the unemployed and patients in low-income brackets, prioritise livelihood over ART [21].

Socio-cultural Factors: Social relationships, social support interventions, and peer and family support [60], [61] are reported to motivate patients to adhere [62]. Similarly, patients who have disclosed their HIV status are more likely to adhere because of the support system of significant others [62], whereas patients who experience some form of stigma and discrimination [38], [61] and those experiencing gender-based violence are reported to have more adherence challenges [63].

Clinical factors: Patients who initiated ART with a very low baseline CD4 (<50 cells/mm³) are more likely to adhere to treatment [57]. Having experienced severe diseases was reported to be a motivational factor to remain in care [53]. However, some patients who initiated ART at a high baseline CD4 > 200 cells/mm or baseline WHO Stage 3 and 4 were less likely to be adherent [57]. Patients diagnosed with TB disease and on TB treatment were reported to be less likely to adhere to ARVs due to pill burden and the likelihood of experiencing side effects [64].

Table 2: Factors influencing adherence and retention in care

Category	Factors/determinants
Individual/patient-related factors	<ul style="list-style-type: none"> • Sex; age; • Health beliefs; • Level of health literacy level • Self-efficacy; • Mental health and substance abuse
Medication-related factors	<ul style="list-style-type: none"> • Medication dosing; • Side effects and toxicities; • Type of ARV regimen
Health system factors	<ul style="list-style-type: none"> • Staff shortages; • Waiting time; • Service delivery model
Socio-economic Factors	<ul style="list-style-type: none"> • Poverty and food security; • Distance to clinics and health centres, lack of transport; high cost of transport, travel time • Work commitment and childcare responsibilities
Socio-cultural Factors	<ul style="list-style-type: none"> • Social relationships; social support interventions & family support • Disclosure status, stigma and discrimination; • Gender based violence
Clinical factors	<ul style="list-style-type: none"> • Baseline CD4 <50cells/mm ; Baseline CD4 > 200 cells/mm • Baseline WHO Stage 3 & 4; • TB disease diagnosis

Sources: [24], [29], [47]

1.3.2 Adherence to antiretroviral therapy

It was further reiterated that adherence to medications (ART) is the extent to which the person's (patient) behaviours coincide or correspond with the agreed-upon recommendations from the healthcare providers [65]. The patient on ART can take the prescribed dose of medications at the right time, following any instructions given [66]. Therefore, the goal of adherence is to have the patient consistently take their medication every day and in the correct dose as prescribed to achieve viral suppression [67]. Therefore, several approaches are used to assess and measure patients' adherence to ART, including patient self-reporting, pharmacy dispensing records, pill counts and clinic visit-based systems [28]. The self-reported adherence method involves asking the patients how many doses they missed in the last week or the last 30 days; however, it is prone to recall bias [28], [44].

In equal measure, pill count is another pill-based and pharmacy method used to estimate adherence. Pill counting involves counting how many pills the patient has at the follow-up compared to the interval prescribed plus the buffer medicines [28], [68]. Unique technology

exists, such as the Medication Event Monitoring System (MEMS), an electronic bottle cap-based system that monitors each date and time a bottle was opened and wirelessly sends this information to a secured web-based server [28], [69], but it requires substantial system investment. Based on the data captured during the pharmacy dispensing and on-time clinic appointment, on-time pill pick-up are two objective measures, demonstrating close to accurate prediction of virological and drug-resistance outcomes [28]. Therefore, the WHO suggested an optimal level of $\geq 80\%$ for an on-time clinic appointment.

1.3.3 Virological suppression

Virological suppression is defined as the reduction of viral activities of HIV [70]. The virological suppression measurement is determined by viral load laboratory assays used to test plasma HIV-1 RNA. The test indicates the number of HIV-1 RNA copies per millilitre of blood plasma. This is used as an accurate proxy of the HIV-1 RNA in the cell and the magnitude of the virus replication [71]. Therefore, the viral load measurement is used to assess the disease progression for individuals infected with HIV [28]. The current study defines virological suppression as viral load measurements < 1000 copies/ml [27], and total virological suppression as viral load measurements < 400 copies/ml [16].

Clinical factors affecting ART outcomes, including patient-related factors [52], virus characteristics and the regimen [52] or prescribing practices are outlined in Table 3 below. Patients with prior exposure to ARVs for PMTCT and those with a history of treatment interruptions and poor adherence to ART are likely to report poor treatment outcomes. Patients infected with viral mutations and drug-resistant strains respond suboptimal to ART. Inappropriate *prescribing practices* and the use of inappropriate regimens also give rise to suboptimal outcomes [48], [52], [53], [54], [57], [72].

Table 3: Clinical factors that determine treatment outcomes

Factor/Determinant	Description
Patient factors	<ul style="list-style-type: none"> • Prior exposure, e.g history of ARV for PMTCT • Treatment interruptions; Adherence to ART
Virus	<ul style="list-style-type: none"> • Mutations; drug resistant strains
Regimen practices and prescribing	<ul style="list-style-type: none"> • Inadequate dosage; inappropriate regimen

Source: [48], [52], [53], [54], [57], [72]

Other clinical factors

It was noted that baseline clinical characteristics, such as patients' body weight at ART initiation, baseline CD4 count and baseline WHO staging, are associated with treatment outcomes. Low baseline CD4 and advanced HIV disease staging were also associated with mortality and LTFU among patients on ART [53]. The risk of LTFU and mortality is high in patients with baseline WHO stage IV and a history of no IPT [52], [57].

1.3.4 Survival

The emergence of ART has improved survival for PLHIV, allowing patients to live longer and healthier. However, mortality and LTFU are commonly documented as a cause for non-retention in the ART program, especially in the first three months of initiating ART [53], [57]. In connotation to the above, the risk of developing HIV strains that are resistant to affordable, readily available ARVs is high among patients with poor adherence. Therefore, non-adherence is associated with poor survival for PLHIV [48]. In addition, factors such as comorbidity with TB or Hepatitis B, lower baseline CD4 cell count and high plasma HIV concentration also contribute to poor survival of PLHIV [48], [53], [54], [57], [72].

1.4 Okongo Community-based Antiretroviral Delivery Model

The Okongo district health management established a community-based ART delivery (C-BART) program in 2007 after realising that even when the ART services were decentralised to district hospitals and clinic level, access remained a serious challenge to some patients due to long distances, and the lack and cost of public transport. By the end of April 2017, there were 18 C-BART sites established in Okongo district. A C-BART site is a fixed designated place in the community where ART services are provided on scheduled dates (once in three months). Services are rendered in traditional make-shift structures in the communities and the package of services consists of clinical consultation follow-ups; ARV refill; provision of Cotrimoxazole Preventive Therapy (CPT) and Isoniazid Preventive Therapy (IPT) prophylaxis; viral load monitoring; and education, CD4 monitoring; and adherence counselling. Nurses and community counsellors deliver the ART services at C-BART sites from the Okongo District Hospital facility based ART clinic.

1.5 Problem Statement

Given that Namibia suffers a high income inequality, with high poverty levels particularly in the rural areas, it is hypothesized that many patients experience socioeconomic factors that may negatively influence adherence and retention to care by impeding regular access to health facilities and facility-based ART (F-BART). Although there have been anecdotal reports of the benefits of the C-BART programs in Namibia and elsewhere, no formal evaluation of the treatment outcomes of the C-BART program in Namibia has been conducted to date. It is, therefore, essential to assess whether the C-BART program produces treatment outcomes comparable to patients' outcomes at the F-BART program. There is also, therefore, a nascent need to evaluate whether the district ART program produces outcomes comparable to the rest of the country and other countries in the sub-Saharan Africa region.

1.6 Aims and Objectives of the Study

The study aimed to evaluate the effectiveness of the community-based ART (C-BART) delivery program in the Okongo District in Namibia on treatment outcomes (adherence to ART, retention in care, viral load suppression and survival) among adult (>15 years) patients in C-BART compared to those in the facility-based ART (F-BART) care, the standard model of care at the Okongo District Hospital.

The objectives of the study were:

- a) To map the evidence on the models of community-based ART delivery in sub-Saharan Africa.
- b) To assess, compare and describe treatment outcomes (adherence, viral suppression, retention in care, and long-term survival) of adult ART patients in the C-BART and the F-BART program in the Okongo District, Namibia.
- c) To assess the completeness and accuracy of the electronic Patient Management System (ePMS) for ART patients in the Okongo District, Namibia.
- d) To describe the patient and health workers' perspectives on implementing the C-BART program in Okongo, Namibia.

1.7 Description of the Study Setting

The setting of this study was the Okongo Health District in the Ohangwena Region in Namibia. Okongo is one of the three health districts in Ohangwena. The catchment population of the

Okongo District is 25,600 [73]. The district has one (1) district hospital, three (3) primary healthcare clinics and 18 C-BART sites. By the end of 2016, there were 22 056 PLHIV (>15 years) in the Ohangwena region, and 16,314 were receiving ART [27]. The study focused on patients receiving ART at C-BART sites and the Okongo district hospital, facility based ART clinic.

1.8 Description of the Study Phases

The study was carried out in four phases, as presented in Figure 2 and described below:

- The initial phase, **Phase I**, focused on a scoping review of the literature on community-based ART service delivery models implemented in sub-Saharan Africa and published from 2006 to 2018. The review focused on mechanisms that make these models work, the actors and key outcomes reported as detailed in Chapter 2, and it informed the retrospective cohort and the qualitative studies.
- Second, **Phase II (A)** focused on a retrospective cohort study of adult patients receiving ART in the Okongo District from 1 January 2007 to 31 November 2017. The analysis focused on patients' characteristics, personal and clinical, as well as retention in care, viral load suppression and survival, as detailed in Chapter 3.
- **Phase II (B)** was a validation study to assess the completeness and accuracy of the electronic patient monitoring system (ePMS) for antiretroviral therapy. Ten percent (10%) of ART records of patients seen at the Okongo ART Clinic and C-BARTs and included in the cohort study were extracted from ePMS at the central-national level by using patients' unique ART numbers and validated them against the patients' care booklets at facility level. The validation study sample was drawn from records extracted from e-PMS national level database for the retrospective cohort study. The validation process focused on a few selected indicators and informed the retrospective cohort study as detailed in Chapter 3 and Chapter 4.
- **Phase III** was a descriptive qualitative study to assess patients and healthcare workers' perspectives of the implementation of the C-BART program in the Okongo District. Understanding the patients' and HCWs' perspectives helped to understand the program outcomes as detailed in Chapter 5.

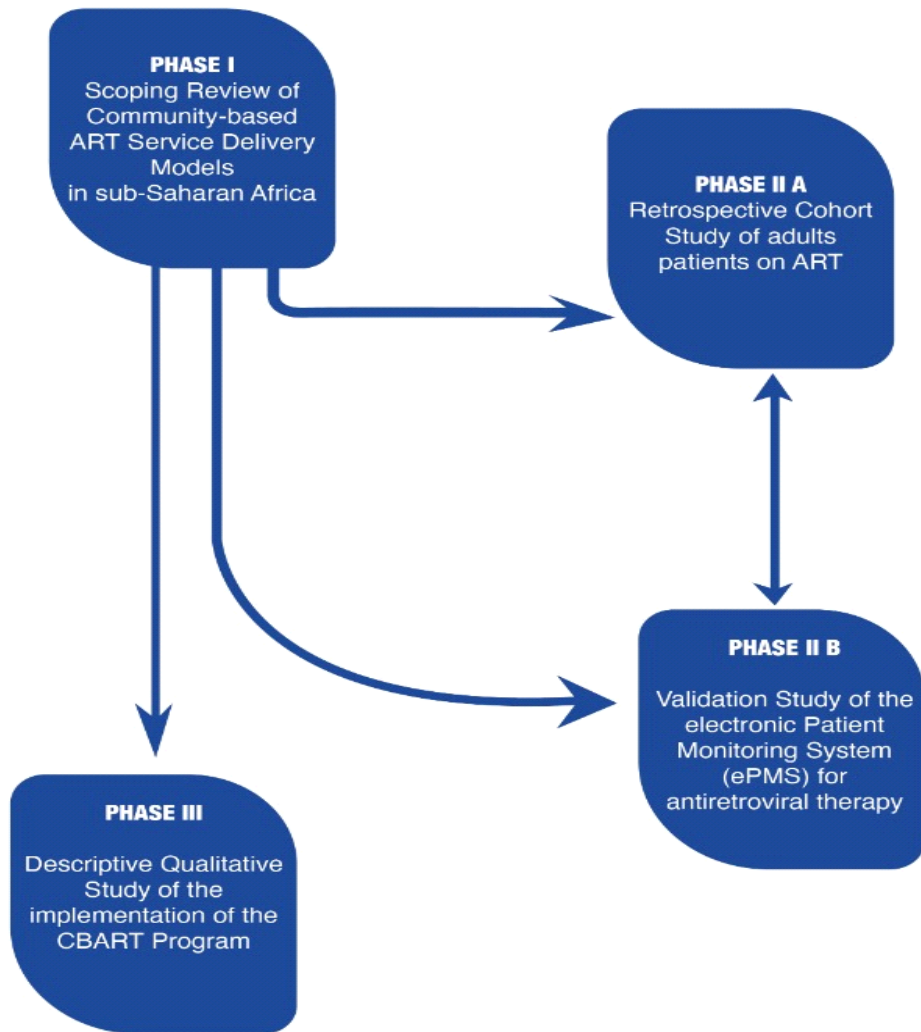


Figure 1: Study Phases

A detailed overview of the entire doctoral study is presented in Figure 2.

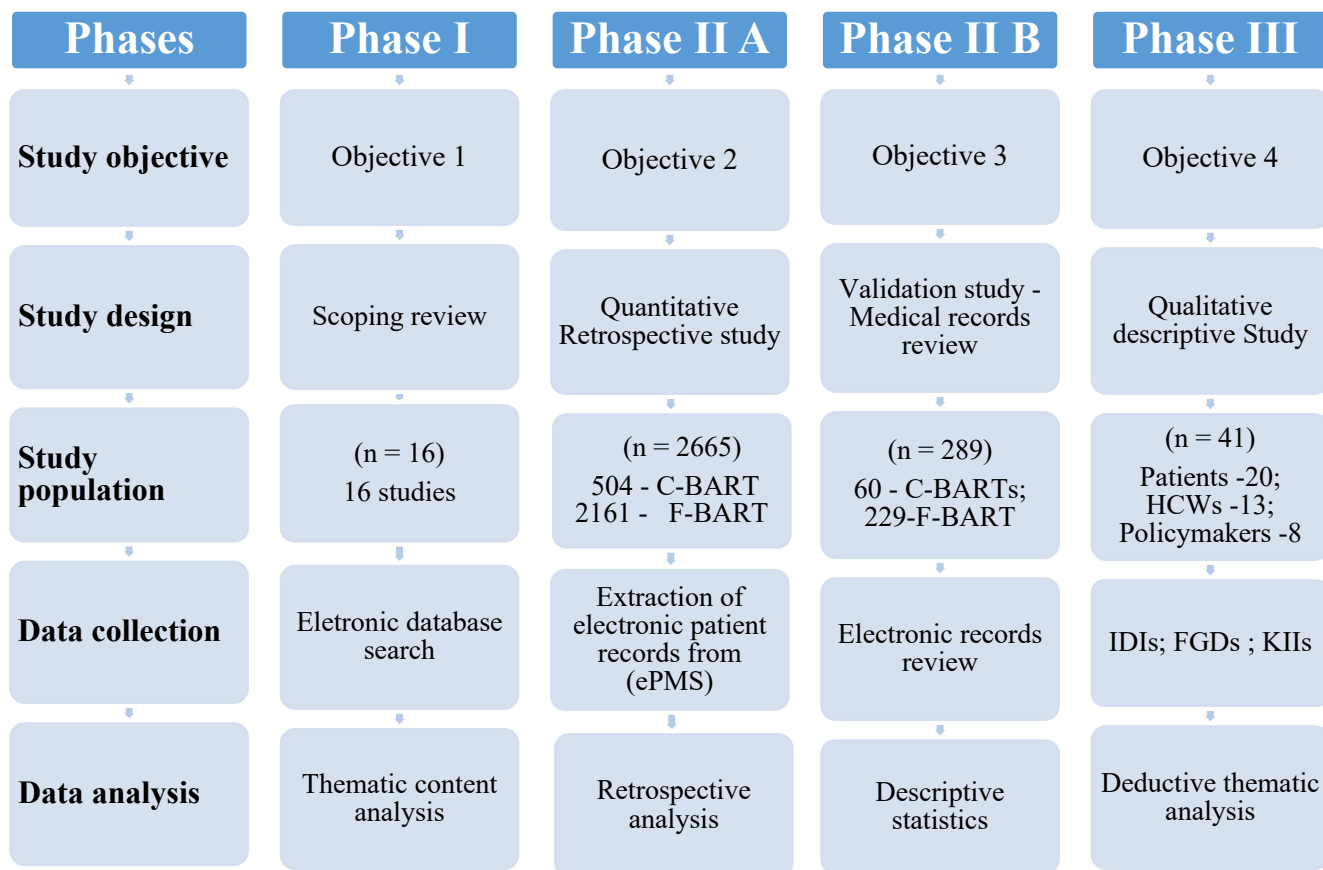


Figure 2: Overview of the doctoral study

1.9 Thesis Outline

The thesis is organised in six chapters.

Chapter 1: Introduction. The first chapter presents the introduction and background to the study, including the HIV/AIDS situation in Namibia and globally, and the definitions of key terms. The chapter also presents an overview to community-based ART models and key outcomes of interest among HIV-infected patients on ART.

Chapter 2: Scoping review of community-based antiretroviral therapy delivery models in sub-Saharan Africa from 2006 to 2018: Mechanisms and Outcomes. The second chapter goes into the results of the scoping review of literature on community-based ART in sub-Saharan Africa for the period from 2006 to 2018, which is the period encompassing the study period. The aim of the scoping review was to map evidence on the models of community-based ART delivery in Sub-saharan Africa. The scoping review was done instead of a literature review, with a focus on community-based ART delivery models, interventions, context, actors, and mechanisms that make the model work and the outcomes.

Data was collected through database searches for articles published in English, during the above period. The evidence was analysed through logical narrative synthesis, showing causal links between concepts and themes.

Chapter 3: *Quantitative Cohort Study.* The third chapter presents the results of the retrospective cohort analysis of adult ART patients from the Okongo Hospital facility-based ART (F-BART) and community-based ART sites (C-BARTs). The sociodemographic and clinical characteristics of the patient are described in this chapter. The key outcomes analysed were adherence to ART, retention in care, viral suppression, and survival.

Chapter 4: *Validation of the completeness and accuracy of the electronic Patient Management System (ePMS) for ART.* This chapter entails the results of the validation study, which assessed the completeness and accuracy of the data from the electronic Patient Management System (ePMS). A sample of 10% of patient records was drawn from the dataset extracted from ePMS at the national level which was generated for the retrospective cohort study and validated against a paper-based Patient Care Booklet (PCB) at the facility level. Hence, it was imperative to ascertain the degree of completeness and accuracy of data from this system.

Chapter 5: *Qualitative study of patient and health workers' perspectives on implementing the C-BART program in Okongo.* The fifth chapter presents the results of the qualitative study describing the C-BART patient and healthcare providers' perceptions of C-BART and the perspectives of policymakers.

Chapter 6: *Discussion, Recommendations and Conclusions.* This chapter discusses the findings from all study phases, the factors contributing to adherence, retention in care, viral suppression, and survival of patients on ART. It also discusses the C-BART models, benefits, opportunities, and challenges. The completeness, accuracy, and validity of using electronic databases for the research study are also discussed. The chapter also presents conclusions drawn and recommendations for improvement, both for patient care to achieve greater outcomes, and also the strategies that are necessary to improve data quality. In addition, the chapter presents recommendations for improving public healthcare practices and for future studies and concludes on the entire study's findings.

CHAPTER 2

SCOPING REVIEW

Scoping review of community-based antiretroviral therapy delivery models in sub-Saharan Africa from 2006 to 2018: Mechanisms and Outcomes

2.1 Introduction

An estimated 50% of the world's people living with HIV, translating to 19 million, and more than half of those receiving antiretroviral therapy (ART) (9 million) are living in sub-Saharan Africa [74]. In an endeavour to achieve epidemic control, UNAIDS recommends that countries ought to identify 90% of PLHIV, initiate 90% of those identified on sustained ART, and obtain HIV viral load suppression among 90% of those on ART. Furthermore, sustained, consistently high-level rates of adherence to ART and retention in care are required to ensure patients achieve viral suppression. However, the sharp increase in ART culminated in health facilities being overcrowded, patients experiencing long waiting times, high patient loads and reduced time spent by healthcare workers with patients newly initiated ART, inter alia. These barriers make it challenging to manage large cohorts of HIV patients using the current facility-based care models [24], [75].

In addition, numerous rural communities in sub-Saharan Africa are disproportionately and adversely affected and have a high HIV burden. Long distances to the nearest clinic, lack of transport, and childcare responsibilities, among other factors, are barriers to patients accessing health facilities for ART services [49], [76]. In such settings, ART programs that are predominantly facility-based do not adequately support patients to attain the desired levels of retention in care, adherence and virological suppression. Consequently, in sub-Saharan Africa, up to one-third (33.3%) of patients are lost to follow-up within two years of initiating ART [37]. This can be ascribed to individual patients' challenges, such as the distance to the healthcare facility providing ART services, the cost of transport to the clinic, and family and work responsibilities, including child-rearing and other family commitments and these affect individual patients' ability to adhere to scheduled clinic visits [37]. Long waiting times at clinics due to overcrowded facilities, the presence of stigma and discrimination, and the lack of social support from family and friends are part and parcel of the health system's challenges that derail patients' retention in care [37].

Cognisant of the above, there is thus a need to develop retention strategies that involve out-of-facility models for ART delivery that would bring services closer to patients' homes [34],

reduce out-of-pocket transport expenditure to visit the clinic for ART refills, and shorten waiting time during the ART refill encounter [24], [37], [38]. Community-based ART delivery models have shown improved adherence to treatment and retention in care, viral load suppression, reduced loss to follow-up (LTFU) and HIV-related mortality. In addition, it is commendable to have ART refills closer to the patient's home as this addresses some individual patients' challenges, i.e. waiting time and expenditure related to transport to the clinic for ART refill [34].

2.2 Community-based Antiretroviral Therapy Delivery Models

The WHO recommends differentiated care models for stable patients to improve retention in care and adherence to treatment[17]. Community-based ART delivery (C-BART) is one such care model offered to stable patients on ART. The name 'differentiated care' is derived from the fact that not all patients require the same type, frequency, and intensity of care, but care must be patient-centred to address the needs of the individuals[17]. In other words, a patient is said to be stable if they have been on ART for a certain period, for example, a minimum of 12 months; is virally suppressed; has no opportunistic infections or concurrent illness; is not pregnant or breastfeeding; and appears to have a recovered immune system[17], [35].

Recently published studies[29], [35]reviewed community-based ART models, including ART groups, adherence clubs, and community-based ART distribution points – “Poste de distribution Communautaire” (PODI)[77]. In connotation to the above, Bärninghausen et al.[77] conducted a systematic review to assess the effectiveness of various adherence interventions. One recommended structural intervention to improve adherence includes delivering ARVs at community-based centres.

In the same token, a synthetic review by Wouters et al.[33] reviewed community-supported ART models, focusing on models that implemented task-shifting to community lay workers for adherence support. Furthermore, Nachega et al 2016[24] conducted a systematic review with a meta-analysis of the community-based ART models in LMICs. They searched four electronic databases focusing on Randomised Controlled Trials and Comparative Cohort studies done in LMICs. The study looked at the comparability of outcomes (ART adherence, virological suppression, retention and all-cause mortality) from community-based to facility-based interventions. The findings of community-based models were comparable to facility-based care. In support of the above, Mukumbang et al. (2017)[47] reviewed theories that potentially make patients adhere to ART in group-based ART models. The Intervention-Context-Actor-Mechanism-Outcomes heuristic-analysis tool[47] was found useful to apply as

a framework for this scoping review. The ICAMO provides a systematic approach to dissecting evidence from community-based ART models for an increased understanding.

In the current review, community-based ART delivery (C-BART) is defined as a differentiated care model in which ARVs are delivered to the patient's home[34]or a place in the community other than a conventional health facility. C-BART interventions are offered at patients' homes or other places in the community, such as community or municipal halls, churches, schools, PLHIV network establishments or sites,[78]ART distribution points, other ART groups; and adherence clubs settings in the community[24], [34], [35].

Objective of the study:

The scoping review aims to map the evidence and describe the types of community-based antiretroviral therapy (C-BART) delivery models for HIV-infected adults (> 15 years) in sub-Saharan Africa that deliver ART at patients' homes or a place in the community other than primary healthcare facility. The study mapped and described the evidence generated, including intervention type, population, context, and key patient outcomes measured through narrative synthesis. The objectives of the study were :

- To identify community-based ART delivery models implemented in Sub-saharan Africa
- To describe the focus of identified models, package of services, patient outcomes measured, and benefits
- To map evidence into a logic model framework of how C-BART improves patients outcomes.

2.3 Methods

A scoping review was conducted based on the Joanna Briggs Institute's scoping review guidance[79] and Arksey and O'Malley's 5-stage methodological framework approach to scoping review[80]. These stages include 1) identifying a research question, 2) identifying relevant studies, 3) study selection, 4) extracting and charting of data, and 5) collating, summarising and reporting results[80]. This was an iterative process; hence, the researchers moved from one stage to another, not necessarily in sequential order, but in accordance with the need for a comprehensive understanding of concepts and definitions as they emerged.

2.4 Problem Identification

Quite a few C-BART delivery models have been implemented in many countries in sub-Saharan Africa. Previous reviews reported on program and patient outcomes (effects) of C-BART modalities. However, against the above hindsight, it is also prudent and of paramount importance to review the delivery models, intervention types, contexts, and mechanisms that contributed to their successful implementation and outcomes achieved in the various C-BART programs in sub-Saharan Africa. To the best of our knowledge, there has been no scoping review of community-based models that deliver ARVs to adult HIV-infected patients in their homes or places in their communities in sub-Saharan Africa that holistically reviewed each of those models by looking at the intervention, the context of implementation, to whom the actors are providing services, the mechanism that makes it work, or the outcomes.

2.5 Literature Search

2.5.1 Identification and selection of studies

Initially, a relevant search strategy was developed to identify all potential studies. A combination of keywords and Medical Subject heading (MeSH) terms related to community-based ART delivery models and Boolean operators “or” were used to search the electronic databases. An electronic search of selected electronic databases, including Medline (PubMed), Embase, Global Health, PsycINFO, CINAHL and PubMed Central, was conducted using these search terms: “(Community* ADJ2 ART) OR (community active antiretroviral therapy) OR (Community HAART) OR C-BART” AND “Africa South of the Sahara” OR sub-Sahara* OR (Angola OR Benin OR Botswana OR Burkina Faso OR Burundi OR Cameroon OR Cape Verde OR Central African Republic OR Chad OR Comoros OR Congo OR Cote d'Ivoire OR Djibouti OR Equatorial Guinea OR Eritrea OR Ethiopia OR Gabon OR The Gambia OR Ghana OR Guinea OR Guinea-Bissau OR Kenya OR Lesotho OR Liberia OR Madagascar OR Malawi OR Mali OR Mauritania OR Mauritius OR Mozambique OR Namibia OR Niger OR Nigeria OR Reunion OR Rwanda OR (Sao Tome ADJ2 Principe) OR Senegal OR Seychelles OR Sierra Leone OR Somalia OR South Africa OR Sudan OR Swaziland OR Tanzania OR Togo OR Uganda OR Western Sahara OR Zambia OR Zimbabwe).

Second, a search for additional articles through reference lists of identified studies and systematic reviews of community-based ART programs was judiciously done. More so, experts (Simon Agolory, Graham Mutandi, & Ferdinand Mukumbang) in ART adult treatment and Community-based ART delivery models were also consulted to determine if there are additional publications that are relevant to the study but were excluded based on their knowlwegde . The yield of additional searches is presented under results section.

Two authors (NS & BVW) screened titles and abstracts of articles identified from the literature searches to assess the relevance of each article following items applicable to scoping reviews from the Preferred Reporting Items for Systematic reviews and Meta-analysis protocols (PRISMA) and principles[81]. Full texts for potentially eligible articles were downloaded for review, and for articles that were found eligible, data that answered the review questions was extracted.

Furthermore, two reviewers NS and BVW shared a list of studies obtained through a search for eligibility. The disagreements between reviewers on the eligibility and relevance of the studies were resolved through discussions between the two reviewers. All the articles included were uploaded to Mendeley's reference manager. The extracted variables were author(s), year of publication, the study's title, type of the study, geographic setting (country), description of sample and sample size, packages of services, providers, and patient outcomes measured.

2.5.2 Study's inclusion criteria

The Population, Concept, and Context (PCC) guided screening studies' eligibility for inclusion in the scoping review. Studies were eligible for inclusion if they were primary studies published in English that reported on:

- a) *Population*: C-BART delivery models for HIV infected Adults (>15 years),
- b) *Concept*: For this review, C-BART delivery models refer to ART delivery at patients' homes and or community level other than a primary healthcare facility that reported on HIV
- c) *Context*: Conducted in sub-Saharan Africa and published from 1 January 2006 through 31 December 2018

2.5.3 Exclusion criteria

We excluded all studies in which the community-based intervention does not include ART delivery to patients' homes or places in the community. There was no consideration or reference for studies that did not report on adults, were not published in English, were not primary studies, were not from sub-Saharan Africa, or were published outside the stated period of 2006 to 2018. The search was confined to articles published in English because the student is monolingual, in addition, time and resources couldn't allow for translation of articles written in languages other than English.

2.6 Data Collection

A pre-designed form was used to extract data under the following headings: the author (s), year of publication, the title of the study, type of the study, geographic setting (country), and target population served. Furthermore, the package of services, patients' outcomes measured, and benefits of each community-based ART model to the patients and healthcare providers were also captured. This is in line with methods used in previous studies[79], [82]. Data from the charting form is presented in Tables 4 and 5. Data from additional studies reviewed after manuscript reviewers' comments to broaden the scope of studies on community-based models published in 2017 and 2018 followed the abovementioned process.

2.7 Data Analysis

A narrative synthesis approach was used for data analysis, as in the study by Popay et al. (2006)[83]. This implies that no new theory was developed during this study. Alternatively, a theory developed by Mukumbang et al.[47], the Intervention-Context-Actors-Mechanism-Outcomes (ICAMO) configuration, was found relevant and applied to this study[47].

For preliminary synthesis, extracted data were tabulated in Tables 4 and 5 to identify patterns in data[83] Narrative synthesis allows the mapping of evidence by bringing together findings on a particular topic from studies reviewed[83]. In this study, tabulated data provided a clear presentation of data and a systematic presentation of results. The framework for narrative synthesis includes, though was not limited to, developing a theory, a preliminary synthesis of included studies, exploring relationships in the data and assessing the robustness of the synthesis.

2.7.1 Identifying a framework for applying the narrative synthesis

The study's data was analysed based on the Intervention-Context-Actors-Mechanism-Outcomes (ICAMO) configurations for the group-based ART model[47]. The ICAMO was identified as an appropriate framework to systematically analyse data from the scoping review, as presented in Figure 3 below.

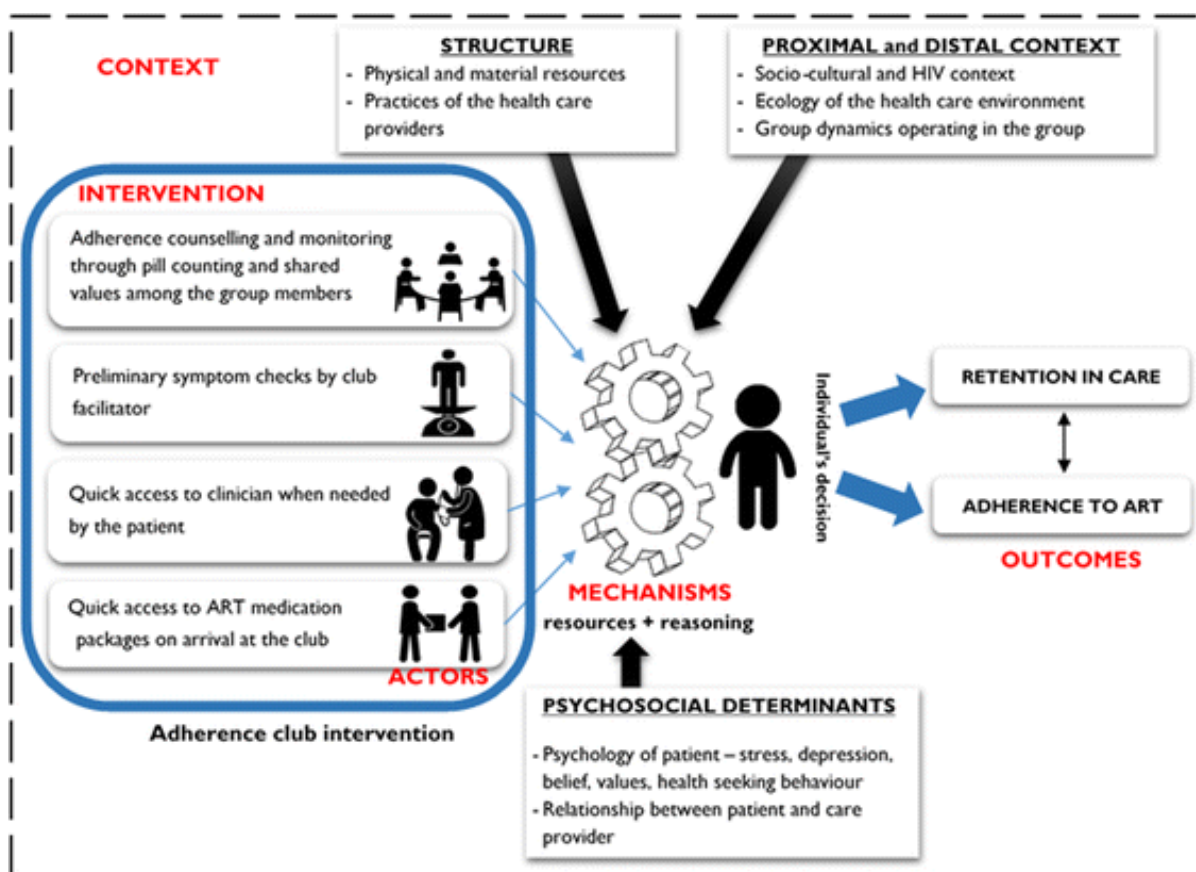


Figure 3: The ICAMO Configuration

(Source: Mukumbang et al., 2017)[47]

The ICAMO configurations outline several components of the group-based ART models and how they interact with the desired outcome:

- The *intervention* modalities are components of the interventions and package of services that make up the intervention and are tailored towards the client's needs (Client-centred).
- The *context (contextual factors)* includes socioeconomic and human resources (staff dynamics), physical space, and cultural and environmental factors that influence intervention, as the figure above shows.
- The *actors* in each intervention or model should be identified, as well as their roles. These actors may include the patients, peers, healthcare providers, other community volunteers, and the community to a greater extent.

d) The *mechanisms* are more significant determinants of interactions between the intervention providers and recipients and how recipients conceive the intervention. It was chronicled that mechanisms include motivation, trust, engagement, buy-in, and self-efficacy. The fifth and final is *outcomes*. Each intervention is designed with an outcome in mind, for example,, adherence to treatment, retention in care, and so forth. Finally, the actors involved in the package of services are tailored towards achieving the desired outcomes[47]. These data are presented in Table 5.

2.8 Results

2.8.1 Study selection and characteristics of included studies

The initial search focused on studies published from 2006 to 2016. The database searches returned 2586 records, while searches from references, bibliography, and recommendations by experts yielded 12 records. Additional searches recommended by reviewers to broaden the scope to studies published in 2017 and 2018 were conducted from 19 March to 13 April 2019. The same process was followed, and additional database searches returned 189 records and one (1) study from a bibliography check, totalling to 190 additional articles. After a review of titles and abstracts for studies from all the two searched, 1941 duplicates from across databases were eliminated. A total of 847 records remained after duplicates were removed. With further screening of the title and abstracts, 711 records were excluded. With further reading of the full-text article, 120 articles were excluded with reasons.

After all the above reviews, eleven (11) articles remained from the original search for studies published from 2006 -2016, and an additional five (5) articles from studies published from 2017-2018 were added to the scoping review, bringing the total number of articles reviewed to sixteen (16).

Most studies excluded after the further screening were about community-based HIV ART services, but they did not include actual distribution of ART or ART refills at the community level other than health facilities, and some described community adherence support through community health workers or volunteers – but the patient still collected ART from a health facility.

This process is outlined in the study selection diagram in Figure 4

A total of 16 full-text articles were retained for data abstraction and included in the analysis. Table 4 delves into the characteristics of the included studies. These studies were conducted in Uganda (6), South Africa (3), Mozambique (3), Kenya (2), and Tanzania (1) and Nigeria (1).

More than half of the studies were conducted between 2014 and 2016. The most frequently used study design was a retrospective cohort study (n = 9), followed by five randomised controlled trials (n=5), one unspecified observational study (n=1) and one non-randomised trial (n=1).

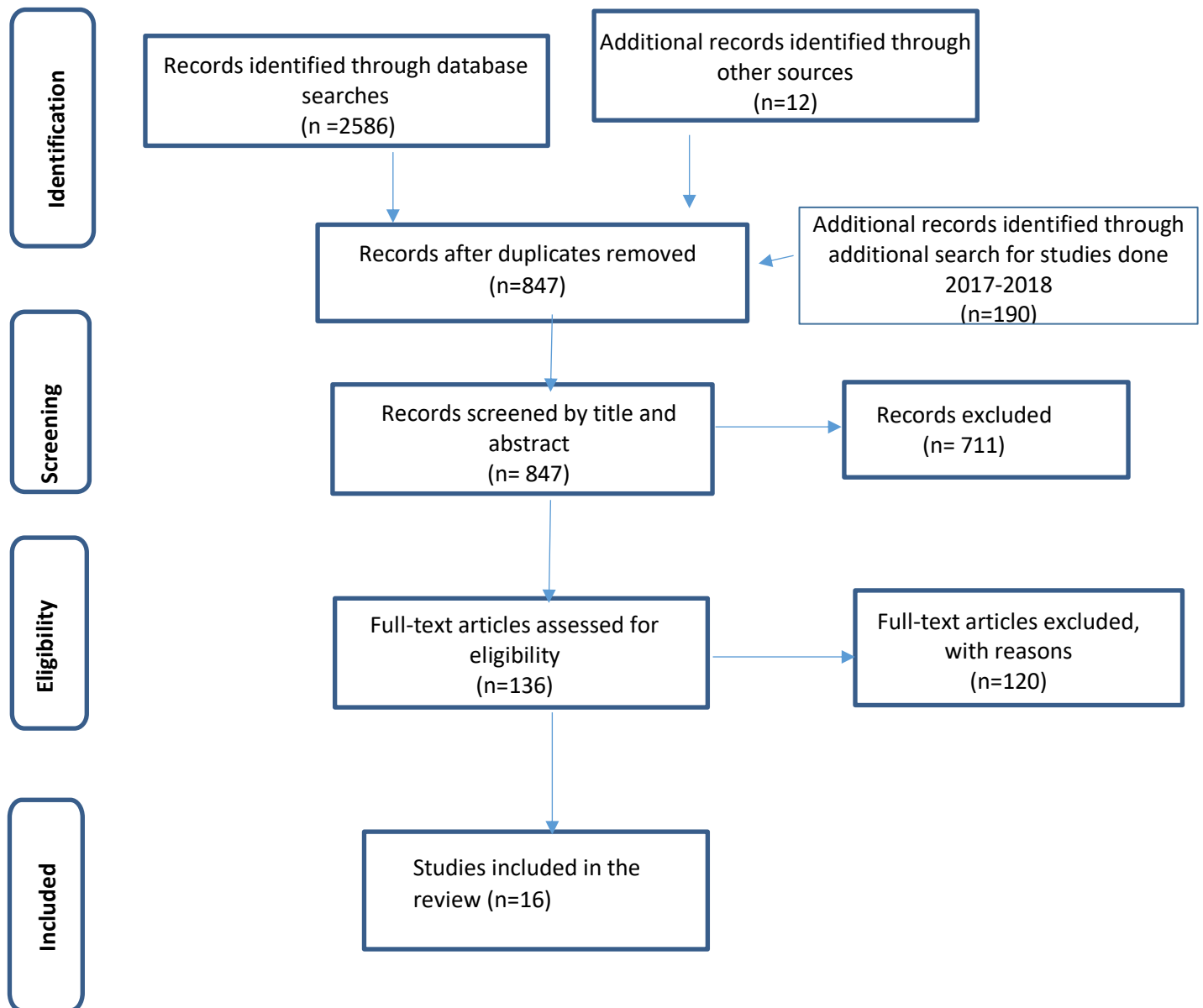


Figure 4: Flow of studies selection as per PRISMA guid

Table 4: Characteristics of included studies

Author (Year)	Study Location	Study Period	Study Design	Intervention Type	Intervention Description	Description of the Sample (S), and Sample Size (SS),
Geldsetzer et al. 2018 [20]	Dar es Salaam, Tanzania	March 01, 2016 - Oct 27, 2017	Non-inferiority Cluster Randomised Trial	Community Delivery of Antiretroviral drugs	Community (at home) delivery of Antiretroviral Therapy (ART) by Home Based Carers (HBCs) HBCs visit patient at home or at another point in the community deliver a supply of ARV monthly or 2-monthly	Clinically stable patients on ART; ≥ 18 years; taken ARV for at least 6 months; CD4 count >350 cells/ μ l; or Suppressed VL <1000 copies/mL at 6 or more months (S) N = 2172 (SS)
Avong et al. 2018 [6]	Abuja, Nigeria	Feb 25, 2016 –May 31, 2017	Descriptive Study	Community Pharmacy Model	Integrating Community Pharmacies (CPs) into community-based antiretroviral therapy (CART) Referrals from public facilities to CPs; Dispense first line and Cotrimoxazole prophylaxis; 2-3 monthly	Adult Patients stable on ART more than or equal to 6 months; Suppressed Viral Load below 20copies/ml; willing to participate through a written consent; on First line regimen (Tenofovir 300mg/Lamivudine 300mg/Efavirenz 600mg or Zidovudine 300mg/Lamivudine150mg/Nevirapine200mg) (S) N = 295(SS)
Myer et al. 2017 [37]	Cape Town, South Africa	February – September 2015	Cohort Study	Community-based Postpartum 'adherence Clubs'	Postpartum Adherence Clubs (ACs), has 20-30 patients; meets 2-4 monthly; meet in a community venue; women are referred immediately postpartum	18 years and older; breastfeeding at enrolment; documented Suppressed viral load; no comorbidity; intent to live in Cape Town through 12 months postpartum(S) Initiated ART in the recent pregnancy N = 129(SS)
Tsondai et al. 2017 [62]	Cape Town, South Africa	January 2011 – Dec 2014	Retrospective Observational Cohort Study	Adherence Clubs (ACs)	Antiretroviral Therapy Adherence Clubs are a group model for a stable patient on ART	Stable patients on ART >15 years; on ART >12 months; with two consecutive VL <400 copies/ml; no condition require frequent clinic consultation (S) N = 3216 (SS)
Decroo et al. 2017 [12]	Tete Province, Mozambique	August 23, 2008 –April 2012	Retrospective Cohort Study	Community ART Groups (CAGs)	Community ART refill Groups (CAGs) meet monthly; maximum of 6 members per group; Monthly Refill	The patient must be at least 15 years old to join Stable on Treatment; have been on ART for at least 6 months (S) N = 2406(SS)
Jobarteh et al. 2016 [30]	Central province, Tete, Mozambique	2004- April 2014	Matched retrospective Cohort Study	Community ART Groups	Community Adherence and Support Groups (CASG). Groups of up to 6 patients; Patient self-managed	Adults ≥ 15 years at ART initiation; started ART during 2004-2014; CD4 >200 cell/ μ l; >6 month on ART (S). N = 5475 (SS)
Khabala et al. (2015) [32]	Kibera, Kenya	August 2013 - August 2014	Retrospective, descriptive study	Adherence Clubs	Medication Adherence Clubs (MACs) A multi-disease novel model for HIV, Diabetes and Hypertensive stable patients medications delivered at the community level	HIV patients ≥ 25 years old; >1 year on ARVs, CD4 > 200 cell/ μ l, previous viral load was undetectable and not in WHO Stage 3 or 4; No active disease (S) N = 1432 (SS)
Grimrud et al (2015) [22]	Cape Town, South Africa	June 2012-December 2013	Observational Cohort	Adherence Clubs	Community-based adherence clubs (CACs) Clubs have 25-30 patients met every 2 week	Stable ART patient; voluntary down referred to CACs; on same ART regimen for >12 months; two consecutive viral load undetectable (<400 copies/ml); no other medical conditions requiring frequent clinical visits (S) N = 2133 (SS)
Okoboi et al. (2015) [47]	Jinja, Uganda	November 01, 2012 –May 31, 2013	Retrospective cohort study	Community Drug Distribution Points	Community-Drug Distribution Point (CDDP) Patients in small groups of 20-50, Distribution is done at a place in the community; monitored by a trained lay counselor (social worker; or Teachers); met every 2-3 months	Clinically Stable ART patients; >18 years; 6 months on ART; disclosed HIV status to friend or relative; have consented to participate (S) N = 1335 (SS)

Woodd et al. (2014) [68]	Jinja, Kenya	February 2005—January 2009	Cluster-randomized trial	Home-based ART delivery	Home-based HIV- Model ART Drugs delivered at patients' home by trained field officers every month	Adults >18 years; Patient newly initiated ART CD4 cell count < 200cells/ μ l; WHO stage III or IV (S) N = 1453 (SS)
Kipp et al. (2011) [33]	Rwini, Uganda	Not reported	non-randomized cohort	Home-based ART delivery	Rural Community-based ART Program (C-BART) ART delivery at home every month by trained volunteers	Stable ART patient; Received ART at in community-based ART (S) N = 185 (SS)
Decroo et al. (2011) [14]	Tete province, Mozambique	February 2008 – May 2010	Retrospective cohort study	Community ART Groups	Community ART Group Model (CAG) PLHIV ¹ members of CAGs collect and distribute ART every month; consultation every 6 months	Stable patients on ART for 6 months; CD4 \geq 200 Median age 36 years at enrollment (S) N = 1384 (SS)
Selke et al. 2010 [58]	Western Kenya	March 2006 –April 2008	Prospective Community Randomized Controlled Clinical Trials	Home-based ART delivery	Community Care Coordinators (CCCs), Good role Model ART patients; deliver ART at home; conduct in-home pill count	HIV infected adults 18 years and older; Clinically stable on ART for 3 months; no adherence issues; have a household member who was aware of their HIV status; not pregnant; not WHO stage 3 or 4 (S) N = 96 (SS)
Jaffar et al. 2009 [29]	Jinja, Uganda	Feb 15, 2005 – Jan 31, 2009	Cluster-randomized equivalence Trial	Home-based ART delivery	Home-Based HIV Care Model, Home visit every month; deliver ART Monitor drug toxicity using a checklist; by a Trained Field Officer	TASO patients >18 years; Started ART first time; Subsistence farmer; Lived 100km ² of TASO branch (S) N = 1453 (SS)
Chang et al. (2009) [11]	Kampala, Uganda	October 1, 2003 -April 1, 2006	Retrospective cohort study	Community Drug Distribution Point	Reach Out Mbuya (ROM) Parish HIV/AIDS Initiative ART provided at the Church; Nurse and peer PLHIV assigned 10 -15 patients to follow	Adults patients >18 years ; CD4 count <250; WHO stage 3 &4 Initiated ART Oct 2003 – July 31, 2004 (S) N= 360 (SS)
Weidle et al. (2006) [66]	Tororo & Busia, Uganda	July 2003- June 30, 2005	Randomized monitoring Trial	Home-based ART delivery	Home-based AIDS Care program Weekly ART delivery to the patients' home; Checklist used to screen for signs and symptoms	ART Patients 18 years and older; Naïve and started ART between July 2003 – May 2004 ; Subsistence farmer; Lived 100km ² of TASO branch (S) N = 987

¹PRISMA refers to the Preferred Reporting Items for Systematic Review and Meta-analysis[81]

2.8.2 Description of identified C-BART models

Six studies reported home-based ART delivery models that deliver ART to the patients' homes[76], [84]–[88]. In addition, two reported ART delivered at distribution points in the community other than the patient's home or health facility[75]; three were about ART delivered to small community-based groups[37], [40], [41]; one reported ART delivery at community pharmacies[89]and lastly, there were four studies about models that delivered ART to adherence clubs[30], [42], [90], [91].

The ICAMO configuration was used to analyse these models in detail, as presented in Table 2.2. Hence, the following sections will look into the details of their interventions, the context of implementation, the actors who provided the services, the mechanisms in which intervention works and the outcomes.

2.8.3 Interventions

Different countries implemented different community-based delivery models, depending on their contexts and needs. However, there are some similarities in terms of the eligibility criteria (description of the sample) for the down-referral of patients to community-based ART delivery programs, packages of services and outcomes measured as presented in Tables 3 and 4. Patients should be stable and eligible for a down-referral to a community-based ART delivery program. According to the information system in Africa (2009), down-referral connotes a mechanism of decentralising care by referring stable patients on ART from high-level to low-level care facilities. In this study, a low level refers to the patients' homes and other community places besides primary healthcare facilities.

*A **stable patient** on ART refers to: "those who have received ART for at least one year and have no adverse drug reactions that required regular monitoring, no current illness or pregnancy, are not currently breastfeeding and have a good understanding of lifelong adherence and evidence of treatment success (i.e. two consecutive viral load measurements below 1000 copies/ml. In the absence of viral load monitoring, rising CD4 cell counts or CD4 count above 200 cells/mm³" WHO (2016).*

Most studies used eligibility criteria for the down-referral of patients to community-based ART delivery models that were in line with the WHO's definition above for a stable patient, as outlined in Table 4. Although there are similarities noted, that did not completely remove the uniqueness of each model, for example, the population served, the provider of care in that

model, the location where the distribution or ART refill happens, other services offered as part of the package and the frequency of visits as outlined in Table 5. Most studies included in the scoping review describe the population serviced by community-based ART delivery services in terms of geographic location as rural communities, those that are distant from health facilities or living in slums[30], [37], [40], [49], [75], [76], [84], [86], [89], [90]. Some studies further described the population in terms of socioeconomic status and education as poor or low socioeconomic status and no formal education or less than secondary education, and subsistence farmers [30], [37], [40], [49], [75], [76], [84], [86], [87], [89], [90]. Self-employed urban dwellers highly utilised the community pharmacies model[89]. Age wise, the studies mainly included adults 18 years and above, and participants were predominantly women[30], [37], [40], [49], [75], [76], [84]–[87], [90]. A study by Myer et al. (2017) enrolled postpartum women in the community adherence club system immediately post-partum[92].

2.8.4 Context (C) – Structure, HIV context, distance, socio-cultural and group dynamics

This review, by nature, only included studies that have a component of the actual delivery of ART to the patient's home or another place in the community. All these models were implemented in a different context (urban/ rural; some new ART program/matured ART program), driven by different needs and variations in resource availability[29], [30], [37], [40], [41], [42], [49], [75], [76], [85], [86], [87], [88], [89], [90], [91], [92]. Physical places for C-BARTs identified from the review included patients' homes, churches, municipal centres, workplaces, private, individual or community pharmacies or other venues in the community belonging to the Community AIDS Organisation, for example,, TASO. More women were accessing services at most community-based sites than men; over half of the patients seen through community-based ART models were women[30], [37], [40], [49], [75], [76], [85], [86], [87], [88], [91]. Some models were implemented in rural, poor communities and among subsistence farmers. Most ART groups and clubs were self-forming and ranged from 2 to 50 patients per group or club. These models shifted the burden of patient care from healthcare workers to peer patients and volunteers. However, the clinical staff trained and supervised volunteers to maintain program quality[86], [91].

2.8.5 Actors (A) – Providers of services

Most community-based ART delivery is done by people living with HIV as individuals or as treatment supporters, buddies to patients who are family members, neighbours or friends[30], [37], [88]. Patients deliver some through the PLHIV networks that recruit them as volunteers

and give them a stipend or other non-monetary incentives[75], [76], [85], [88] and only one study used pharmacists to dispense ART to patients at community pharmacies[90]. Various terminologies are used to describe these volunteers, based on their role, but the core principle applied to involve them is “community participation and empowerment”. Terminologies used to describe lay actors include, among others, field officers, home based carers (HBCs),

Community volunteers, expert patients, peer health workers, medicine companions, counsellors, buddies, and community care coordinators [CCCs] are cited as actors[30], [37], [40], [49], [75], [76], [85], [86], [87], [88], [89], [91]. Studies reviewed focused on adult patients on ART and revealed that, at minimum, patients were 18 years old, with the median age ranging from 18 to 37 years. In addition, patients were predominantly female (58% and above)[30], [37], [40], [49], [75], [76], [85], [86], [87], [88], [91]. One study focused on postpartum women[92].

2.8.6 Mechanics (M) – Resources and reasoning

It was unveiled that patients who disclosed their HIV status to a member(s) of the household were likely to adhere to and be retained in home-based or community-based ART delivery programs, experience social support, and reduced experience with stigma[30], [49], [75]. In addition, community-based organisations (CBOs) and community health cadres provide a robust social network, which becomes a favourable context for C-BARTs[49], [86]. To substantiate the above, it was unearthed that CBOs have the infrastructure and human capacity in the community, and the community self-identifies with them, which enhances effective collaboration[49], [86]. A participatory approach to the community entry process and community consultation are mechanisms that heighten the program’s success. Community ART delivery programs that engage patients themselves, as peers and community leaders as gatekeepers in the design, implementation, and monitoring of programs have also been shown to be successful [30], [49], [75], [88]. This approach proliferates program success by addressing the social norms and values of understanding the community entry process. The engagement of patients and leaders in the entire process strengthens the relationship between the community and self-identifies with the intervention[30], [37], [40]. Therefore, approaches that consult with the patients and their leaders and engage them will likely be successful and sustained. Community-based models that support self-forming and self-selected small groups of up to 25-30 patients with those closest to them or who can relate to them are ideal in the African setting where communities are self-forming with no cohesion. This links to the value of health and

well-being as a community problem rather than an individual problem [75], [93]. This reduces stigma as the whole community is affected and considers it their problem.

2.8.7 Outcomes (O) – Patient outcomes

Studies reviewed had key patient treatment outcomes measured: adherence to treatment, retention in care, LTFU, virological suppression as well as deaths. Most studies report improved adherence to treatment, retention in care and viral load suppression or levels that are as good as outcomes observed among patients seen at facility level or superior[30], [37], [40], [42], [49], [75], [76], [85], [86], [87], [88], [89], [90], [91], [94], [95]

The time point for measuring these outcomes by different programs depended on the program's resources and maturity. Some programs measured outcomes as early as 3 months, others 6, 12, 24 and up to 36 months. Some studies followed the routine program schedule for outcome measurement by collecting specimens routinely as part of the service delivery, and others collected the specimens at baseline and the end of the study, because they were not offered routinely. In some instances, the quality of routine program data was poor and could not be used, so retesting was done during the evaluation. Apart from the above patient outcomes, eleven (11) studies reported how community-based ART delivery models reduced the cost of transport, reduced the burden of frequent clinical consultation and less time spent at the facility, improved health-related quality of life[30], [37], [40], [41], [42], [49], [85], [89], [90], [91], [92]. About 6% (83) of patients enrolled in community ART groups in Mozambique and transferred back to the facility, three (3) had poor adherence. Over ninety per cent (90%) of patients who remained in community groups were retained in care, 0.2% (2) were lost to follow-up, and 2% (30) died[37]. The risk of attrition was higher among young patients less than 25 years old[42] and postpartum women[89], [92], and viral rebound increased with the duration of ART and younger patients[42].

Clinical characteristics at the time of down-referral (referring patients from facility-based care to community-based) C-BARTs are critical. A prospective community-based ART cohort study by Lawn et al. in Cape Town, South Africa, experienced high mortality of up to 66% among pre-treatment patients down-referred to community-based ART[94] Mortality has also been experienced among patients down referred who had advanced HIV disease with WHO stage 3 and 4 or CD4 cell count below 200, acute infections or illness and Tuberculosis. Some patients also died due to immune reconstitution syndrome. Some down-referred postpartum women (15%) never attended adherence clubs, and 11% of those who attended were never

retained[92]. Hence, the authors recommended to down-refer patients who are clinically stable, not pregnant, do not have any active diseases or conditions, and are stable on ART for >6 months[96]. Therefore, the concept of using PLHIV as providers of community-based ART delivery enhances the interaction or interconnections with patients as patients relate to the providers as colleagues[30], [37], [41], [42].

Table 5: Identification of recurrent themes across the selected studies based on the ICAMO configurations

Study	Intervention	Context	Actors	Mechanism	Outcomes
Geldsetzer et al. 2018 [20]	Community Delivery of Antiretroviral drugs <ul style="list-style-type: none"> Clusters randomized to community ART delivery A Home-Based Carer visited the patient at home or at another meeting point in the community Provide ART adherence Counseling; education on family planning, basic nutrition, and prevention of onward transmission Pill count and ARVs 	Randomized Clusters <ul style="list-style-type: none"> Trained Home Based Carer visit the patient for the duration of the study Most urbanized municipalities HBCs exist as lay workers in Tanzania’s Public Health System Home visits for HIV patient every 1-3months is a routine for HBCs 	<ul style="list-style-type: none"> Stable Patients Home-Based Carer (Lay Workers) Facility-based Nurse (Community outreach Nurse) HBCs were trained 	<ul style="list-style-type: none"> Existence of HBCs as lay workers in the Tanzania Public Health System Routine Home visits for HIV patient every 1-3months Supervision by a facility-based Nurse 	<p>83.1% of the patients were very satisfied with the intervention</p> <p>Only 9.7% of patient were filing virologically in the intervention arm compared to 10.9% in the control arm.</p> <p>18.9% were LTFU in the intervention arm compared to 13.6% in the control arm. However, decongesting the facilities and reduced expenditure was not realized with this model</p>
Avong et al. 2018 [6]	Community Pharmacies Model <ul style="list-style-type: none"> Trained Medical Doctors and Pharmacists Referral system- from public facilities to Community pharmacies; Patient provide written consent ART prescription is written by the Physician and ART Refill at Community Pharmacy. Provided counselling; provided Cotrimoxazole prophylaxis Pharmacovigilance services: monitor adherence and Report adverse events 3 months refill 	<ul style="list-style-type: none"> Urban dwellers, civil servants Rural, farmers 42.8% of participants were self-employed Designated HIV service priority Areas - High HIV burden 	<ul style="list-style-type: none"> Stable Patients Medical Doctors Pharmacists 	<ul style="list-style-type: none"> Using points of service in patients own community where patient go first to seek services, e.g Community pharmacy is the strength that makes this model work. The patient remained linked to a health facility and referred back when needed Readily available; Temperature controlled drug store and pharmacists on site 	<p>Gradual decongestion of the facility created more space at the facility;</p> <p>Prescription refill was excellent (100%);</p> <p>Retention in care was high (99.3%)</p> <p>Only one patient out of 295 was lost to follow-up</p>
Myer et al. 2017 [37]	Community-based Postpartum ‘adherence Clubs’ <ul style="list-style-type: none"> Differentiated care for postpartum women who initiated ART during pregnancy Enrolment of Postpartum women to the adherence Club system 2-4 monthly ART refill Weighed; short symptom screening; ART Counselling group education; a treatment buddy can pick ARVs on behalf of the patient 	<ul style="list-style-type: none"> Low income Former African-Township Community Health Centre High antenatal HIV prevalence and coverage Integrated ANC & PMTCT Better educated; Employed 	<ul style="list-style-type: none"> Postpartum women Nurse-midwives Study Counsellors 	<ul style="list-style-type: none"> Location and proximity to the club; acceptability of services; short visits; family member or friend goes to the same club; peer support; few appointments a year; Proximity to “well-baby” clinical services for infants 	<p>Women enrolled in the club 10 days postpartum; a quarter of the women who chose ACs were not retained; 15% never attend the club; a further 12% was not retained in the club after the first meeting;</p> <p>20% of women choose clubs because they were located further from home than PHC clinic; increase VL overtime, but VL at 6 months in adherence clubs was comparable to facility-based</p>

	<ul style="list-style-type: none"> The patient is referred for MCH and infant follow-up services 				<p>Sending postpartum women in mix adherence clubs of the general adult patient may not be ideal; MCH focus ACs with integrated MCH services for mothers and infants may be ideal</p>
Tsondai et al. 2017 [62]	<p>Adherence Clubs (ACs)</p> <ul style="list-style-type: none"> A group model for stable patients 25-30 patients; Prepacked ART supply; brief symptom screening; annual clinical consultation by a clinician in the facility Buddy can pick ARVs at alternate club meeting; Patients referred back if ill-health is identified; ACs facilitated by a lay counsellor 	<ul style="list-style-type: none"> Self-forming group Pre-packed ARVs Urban setting After scale-up of the model Assessment from 10% of the eligible ACs population in the district Predominantly female 	<ul style="list-style-type: none"> Stable patient on ART >12months Lay counsellor Clinicians at facility 	<ul style="list-style-type: none"> Self-forming Can send a buddy to collect ART Proximity 	<p>70% were female; cross-sectional retention of 93.1% using linked databases; cumulative LTFU was 2.6%; Death 0.1%;</p> <p>Cumulative retention was 95.2% at 12 months and 89.3% at 24 months and 82.1% after 36 months; Viral load was 95.7% at 16 months and 94.1% at 28 months after joining ACs.</p> <p>Risk of viral rebound was high among patients who have been on ART for a longer duration or sending a buddy to collect their ART reduces the risk of viral rebound</p>
Decroo et al. 2017 [12]	<p>Community ART Groups (CAGs)</p> <ul style="list-style-type: none"> Peer groups; member takes a turn to collect ART monthly; ART refill; Group meet in Community; discuss member health and treatment status; Use group monitoring card; monthly pill count; 	<ul style="list-style-type: none"> Predominantly female 70.3% Predominantly rural ART decentralise in peripheral facilities Limited infrastructure Shortage of medical staff Lack of regulation to implement task-shifting to lay health cadres 	<ul style="list-style-type: none"> Stable patient on ART; join CAGs after have been on ART for >6 months; Support from Clinician/Nurse Counsellor at the facility Medical Doctor 	<ul style="list-style-type: none"> Social Network of CAGs in the community; Family networks; Members share the cost of transport; fast-tracked at the facility for refill; periodic meeting with Counsellor; the group knows immediately when a member missed a visit or travelling out of town 	<p>12% died or were LTFU</p> <p>Retention in care was great for the patient in CAGs, 12 months retention was 90.8% and 86.0% at 24 months; risk of attrition was higher among the young less than 25 years and males compared to the older age 30-39 years categories and the females.</p>
Jobarteh et al. 2016 [30]	<p>Community ART Support Groups</p> <ul style="list-style-type: none"> A delegated group representative pick up ART monthly and have their six monthly Clinical consultations and blood drawn for CD4 Count Pill Count; filling of screening questionnaire done during a group meeting 	<ul style="list-style-type: none"> Self-forming groups Member rotates to pick up ART Urban and rural Patients with no formal education were very likely to join CASG 	<ul style="list-style-type: none"> Stable patients Group has up to six members Clinician-based at the facility 	<ul style="list-style-type: none"> Ownership (Inherently confers responsibility to patients) Support (members experience difficulty taking ARVs are counselled by other patients) 	<p>Predominantly female (74%); Retention in the CASG was 91.4% compared to 82.9% in an-CASG; Lost to follow-up was 7.2% in CASG and 15.9% in an-CASG; There was no significant difference in mortality; improved adherence; Reduce the number of routine facility visits reduced financial constraints; Accurate reporting of mortality in CASG; Low financial investment.</p>

<p>Khabala et al. (2015) [32]</p>	<p>Medication Adherence Clubs</p> <ul style="list-style-type: none"> ▪ Patient meets quarterly ▪ Brief health discussion and received ART ▪ Receive prepacked ART ▪ Annual visit and review by Clinical Officer 	<ul style="list-style-type: none"> ▪ Informal settlements ▪ Urban environment ▪ Care shifted from overburdened clinics to peers ▪ Predominantly female 	<ul style="list-style-type: none"> ▪ Nurse-facilitated ▪ Mixed groups of 25-35 stable patients ▪ Clinical Officers 	<ul style="list-style-type: none"> ▪ Peers Support ▪ Patient involvement ▪ Multi-disease care program- hypertension and Diabetic ▪ Patients satisfaction ▪ The offering of free medications 	<p>Patients in the community-based cohort were more likely to achieve Viral Load suppression than the hospital-based; Quality of life significantly increased; Overall excellent adherence; Low Lost to follow rate 3,5% of patient were lost to follow-up; Reduce the burden of regular clinic follow-ups; Flexible care delivery for the patient; better cost-effectiveness per patient treated.</p>
<p>Grimsrud et al. (2015) [22]</p>	<p>Community ART Adherence Clubs</p> <ul style="list-style-type: none"> ▪ Pre-Packed ART delivered by CHWs ▪ Club met every two months ▪ Group Counselling, session; brief symptoms screening at each CAC meeting and distribution of ART ▪ Safe Conception ▪ Weight monitoring for all patients ▪ Annual facility visit for phlebotomy ▪ Four monthly blood was drawn at CACs • 	<ul style="list-style-type: none"> ▪ Offered at the municipal community centres ▪ Lived within 3 km radius of the Community Health Centre <ul style="list-style-type: none"> • ART pre-packed at the central pharmacy • Unemployed, predominantly female 	<ul style="list-style-type: none"> ▪ Stable ART Patients in groups of 25-30 ▪ Community Health Workers ▪ Buddy or Treatment supporters 	<ul style="list-style-type: none"> ▪ Support system (Patient nominated treatment supporter or “buddy”) ▪ Patient-centred approach (patient who was late for CACs had five days of grace period to get their ART <ul style="list-style-type: none"> • Proximity (ART delivered at CACs meeting) 	<p>Patient receive ART within their community; ART can be collected by treatment buddy</p> <p>Decongest health facilities</p> <p>Improved time to viral suppression; High level of retention and VL suppression; Patient in the community-based cohort were more likely to achieve Viral o Load suppression than the hospital-based; Quality of life significantly increased; Overall excellent adherence; better cost-effectiveness per patient treated. Low Lost to follow rate 3,5% of patient were lost to follow-up</p>
<p>Okoboi et al. (2015) [47]</p>	<p>Community ART distribution points</p> <ul style="list-style-type: none"> ▪ ART refill and review by TASO Lay Counsellors ▪ Six monthly reviews by the TASO clinical Staff ▪ Patient nominate one expert patient to monitor all patient in the group 	<ul style="list-style-type: none"> ▪ Rural, resources limited setting ▪ Distance (patients in the radius of 75 Km) ▪ Clients mostly have some primary education ▪ The patient disclosed HIV serostatus to friend or relatives ▪ Near to TASO 	<ul style="list-style-type: none"> ▪ Stable patients in small groups of 20-50 ▪ Counsellors ▪ TASO Clinical Staff ▪ Expert Patients 	<ul style="list-style-type: none"> ▪ Client-centred program ▪ Careful design and scale of ART in TASO ▪ Patient involvement (Patient identify a place where they will be seen in the community) 	<p>Mitigated time and cost constraints related to transport to the ART site;</p> <p>For a patient on first-line therapy, there was very low of virologic failure; mortality rates were low compared to other studies in Africa</p> <p>Retention was 69% after 5 years; only 9% were Lost to follow up; 93% had Viral Load <1000 copies/mL of which 87% were VLs <50 copies/mL; Those with Virologic failure were most likely to be younger than those without. ART regimen and year of ART initiation were significantly associated with mortality.</p>

Woodd et al. (2014) [68]	<p>Home-based care vs Clinic-based care</p> <ul style="list-style-type: none"> The patient visited monthly in their home by trained lay-workers Patient assessed clinically and ART delivered in their home Adherence Support 	<ul style="list-style-type: none"> TASO, the largest provider of ART No incentives given to patients or staff- it is part of routine care Well function facility based Care with Doctors and Nurses Reliable drug supply 	<ul style="list-style-type: none"> Patient starting ART Trained Lay workers supervised by Clinical based staff Clinicians 	<ul style="list-style-type: none"> Support - Home visits Proximity (ART delivered at Home) Personalized HIV adherence to Patients on ART in their home by lay- counsellor improve adherence 	<p>Survival outcomes similar to those of clinic-based; Low mortality</p> <p>The majority were female, a phenomenon common in African ART program,</p> <p>High mortality noted during the pre-treatment among patients waiting to complete 3-4 sessions of adherence counselling; deaths in the Home-based care arms were Tuberculosis related while the deaths in the facility-based arm were nutrition related.</p> <p>There was no difference in mortality between those who received Home-based care vs facility-based</p>
Kipp et al. (2011) [33]	<p>Rural Community-Based ART Program</p> <ul style="list-style-type: none"> Volunteers deliver ART to assigned patients monthly Monitoring adherence A weekly visit to the patient 	<ul style="list-style-type: none"> Long distance (50 km away from the hospital) Rural Community Less resource input Unpaid Volunteers, non-cash incentives- training and supervision 	<ul style="list-style-type: none"> PLWHIV on ART Clinical Officers Lay Community volunteers 	<ul style="list-style-type: none"> unpaid volunteers recognized by the community Healthcare worker support volunteers Proximity 	<p>Increased quality of life measure by Health-related quality of life (HRQL); excellent adherence</p> <p>Model is cost-effective per patient successfully treated</p> <p>Reported significant increase in Health-Related Quality of life; Cost-effectiveness per patient successfully treated; Women benefited more from Community-based ART; More patient in community-based was likely to achieve viral suppression.</p>
Decroo et al. (2011) [14]	<p>Community ART Groups (CAGs)</p> <ul style="list-style-type: none"> Members collect and distribute ART in the community Adherence support and treatment outcome monitoring Group Counselling and educational session 	<ul style="list-style-type: none"> Guideline - 1 clinical visit every 6 months Predominantly rural population Guaranteed supply of ART and prophylaxis for opportunistic infection Transport for CD4 count sample Self-forming groups of up to 6 patients 	<ul style="list-style-type: none"> Clinical stable patient Group leader selected amongst the patients 	<ul style="list-style-type: none"> Highly acceptable (CAGs is designed together with patients) The greater responsibility of taking care of their own health CAGs encouraged building and reinforcing social networks and peer support 	<p>The reduced financial and economic social cost associated with transport; patient took greater responsibility for their own health; Decongested health facility; 4- fold workload reduction in consultation of the patient in CAGs</p> <p>About 6% (83) transferred back to facility- 3 due to poor adherence; of the remaining 97.5% were retained in care; 0.2% were lost to follow-up; 2% died. Reported Workload reduction; reduction in the number of consultations</p>

Selke et al 2010 [58]	<p>Task-shifting of ART from Healthcare workers to Patient living with HIV- as Community Care Coordinator (CCC)</p> <ul style="list-style-type: none"> ▪ CCCs assigned patient in Sub-locations ▪ Provide adherence, food security, domestics violence information ▪ Symptoms reviews; monthly home assessments ▪ Transport the patient to a facility for urgent evaluation 	<ul style="list-style-type: none"> ▪ PLWHAs – Community Care Coordinator with secondary education ▪ Predominantly female patients ▪ Resource-limited setting ▪ An electronic decision support tool 	<ul style="list-style-type: none"> ▪ Stable Patients on ART ▪ Community Care Coordinators ▪ Clinical Officers at the facility 	<ul style="list-style-type: none"> ▪ Good role modelling and mentoring by CCC as PLWHAs ▪ Psychosocial support 	<p>Task-shifting ART care to lay CCs reduced clinical visits;</p> <p>CCC identify psychosocial issues, for example, food security; alcohol; Significantly few clinic visits; median CD4 count, percentage Viral Load detectable was not significantly different from the intervention and control group. Self-reported adherence to medication was high in both groups.</p>
Jaffar et al. 2009 [29]	<p>Home-based HIV Care</p> <ul style="list-style-type: none"> ▪ Transferred care from the clinic to lay workers visiting the patient home ▪ One-on-one and group information regular counselling and adherence support ▪ ART delivery at Patients home ▪ Free voucher for HIV testing of family members 	<ul style="list-style-type: none"> ▪ Rural, semi-urban Poor population ▪ Low Cash Income ▪ Subsistence farmers ▪ Few formal works ▪ Eligibility to start ART at WHO Stage II or IV; CD4-cell count <200 cells per μL 	<ul style="list-style-type: none"> ▪ HIV infected patients ▪ Trained field officers-degree/Diploma holders ▪ TASO Staff ▪ Counsellors ▪ Nurses trained in ART ▪ Newly qualified Medical Officers 	<ul style="list-style-type: none"> ▪ Transport to delivery ART to patient home ▪ Personalized support delivered by the same individual ▪ Use of lay workers who are easily accessible and trained at a low cost ▪ Home visits 	<p>Reduce the burden of regular clinic follow-ups;</p> <p>Flexible care delivery for the patient; Low LTFU</p> <p>Reduced burden of the cost of access incurred by the patient</p> <p>In the first year, 11% both in the home-based and facility care died; 1% receiving home-care. Lost to follow-up was 1% from Home-based care and 2 % from those received Facility care.</p> <p>There 16% of patients with virologic failure from Home care and 17% from facility-based care. The mortality rate was similar.</p> <p>So, Home-based care was as effective as facility-based care</p>
Chang et al. (2009) [11]	<p>Reach Out Mbuya (ROM) Parish HIV/AIDS Initiative;</p> <ul style="list-style-type: none"> ▪ ART provided at the Church ▪ Peer PLHIV assigned 10 -15 patients to follow ▪ ART refill; food aid; lab; clinic review; microfinancing; school fees; ▪ Home visits ▪ Clinical assessment and adherence 	<ul style="list-style-type: none"> ▪ Structural barriers ▪ Transport cost issues ▪ Low socioeconomic status/poverty ▪ Predominantly Displaced populations; urban slum ▪ Perceived stigmatization by attending clinics often ▪ Health Worker force crisis ▪ Intensive efforts are taken to address adherence 	<ul style="list-style-type: none"> ▪ Stable Patients ▪ Peers PLHIV ▪ Nurses 	<ul style="list-style-type: none"> ▪ Reach out is a Faith-based organization - extensive community relationships; promote buy-in ▪ Family and community function as a unit (Personal, family, and community-integrated ART delivery) 	<p>Reduced stigma;</p> <p>the microfinancing Address structural barrier to ART uptake and adherence; respond to Health Workforce crisis;</p> <p>After 2 years on treatment, 72% of patients at community were retained; 86% virologic suppressed VL <400 copies/mL; median increase in CD4 count of 197 cell/mm². Survival was 84% and 82% at one and two years respectively.</p>

Weidle et al. (2006) [66]	<p>Home-based AIDS care programme</p> <ul style="list-style-type: none"> ▪ Structure individual and a group session on HIV prevention, care, and treatment, expected side effects ▪ Home visit before treatment start ▪ Home delivered ART; weekly pillboxes ▪ Adherence support ▪ CD4 count and viral load monitoring done quarterly ▪ Medicine companion 	<ul style="list-style-type: none"> ▪ Rural areas, small villages, substance farmers, Poverty, with no access to basic municipal service ▪ Low literacy 	<ul style="list-style-type: none"> ▪ Clients of TASO ▪ TASO Counsellors ▪ TASO Field Officers ▪ Medicine companion 	<ul style="list-style-type: none"> ▪ Counsellors were trained in building rapport ▪ Treatment simplified, clear, precise instruction ▪ (Use of pictorial forms; ▪ The patient only get weekly pillboxes) ▪ Support and client centeredness (medicine companion; family; home visit) 	<p>Excellent retention and adherence; removed external economic constraints to retention; addressed barriers to adherence; excellent virologic response. Quarterly Pill Count Adherence (PCA) was at 99% and Medication Possession Ratio (MPR) was 98-99% Viral Load Suppression of 98% and 96% was achieved among patient during the second and fourth quarter respectively.</p>
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2.9 Discussion

This scoping review presented several community-based ART delivery models that indicate encouraging results in improving patients' adherence to treatment, retention in care and virological suppression for stable adult patients on ART. In some cases, the patients' outcomes at community-based ART delivery are as good as those at facility care[30], [40], [41], [42], [49], [85], [86], [88], [89], [90], [91], [92]. However, in one study, community-based ART delivery outcomes are inferior to facility-based outcomes[86]. The impact of community-based ART on mortality varies, while in some studies, low mortality rates have been reported[31] In another study, no difference was observed in death rates between community-based ART delivery and facility-based care[40]. Evidence of long-term outcomes beyond five years is limited, which is crucial to inform sustainability.

It was observed that proper screening of patients and timing before down-referring to community-based ART is of utmost importance to ensure the down-referred patients benefit from the intervention without compromising their health. High mortality (66%) was noted among pre-treatment clients down referred to C-BART, as well as those with advanced disease (CD4<200 and WHO 3 or 4[94]). Although community-based ART delivery models reviewed comply with the WHO's recommendations and guidelines of down-referring patients who are stable on ART[19], i.e., they have been on ART for 6 months, have a suppressed viral load, they are WHO stage 1 or 2, and they are showing immunological recovery; CD4 count >200 cells/mL and no condition or illness that require frequent clinic visit. High mortality was noted during the pre-treatment among patients waiting to complete 3-4 sessions of adherence counselling; deaths in the home-based care arms were TB related, while the deaths in the facility-based arm were nutrition-related.

The description of the sample in Table 1 complies with the WHO's recommendations to down-refer patients who are stable on ART; however, new evidence from recent studies showed comparable retention and viral suppression rates even among patients down-referred 6 months after initiating ART[41], [89], [90]. In addition, most models included adults, except pregnant women. Findings from a study that enrolled postpartum women in adherence clubs suggest that immediate down-referring of breastfeeding women and their infants to general adult community-based models post-partum poses a risk of attrition if not carefully adapted[92].

By the same token, the engagement of the beneficiaries of the intervention (the patients), community leaders, community-based organisations, networks of people living with HIV and

members of the communities are key to successful implementation. Expert patients and volunteers from the community have been cited as providers of community-based ART delivery in several interventions. The community is the custodian of the context and facilitates mechanics that make community-based individual and group-based ART delivery interventions work[47]. Hence, community participation and engagement are vital principles that play a significant role in improved patient outcomes, expansion, and sustainability of the community-based ART delivery model[79]. The work of Mukumbang et al., cited above, concurs with the approach by Chambers et al. that recommended the interpretation of study results in the context of study participants, an approach known as the decolonising knowledge approach[93]. In this case, there is a need to understand the dynamics and functions of a community, units such as a family, and the roles of different community members in an African setting. The decolonising knowledge approach recommends researchers explore, synthesise and interpret the realities of how and why interventions such as community-based ART work in an Afrocentric culture where the practices of interdependence, togetherness, and the spirit of ‘Ubuntu’, is that of helping and supporting each other; an individual sickness is a family problem and of the community as a unit[93]. Hence, this context and mechanics facilitated the effects and sustainability of the community-based ART delivery model. Therefore, the ICAMO configuration used as a framework for analysing data in this scoping review meets these recommendations by looking at the context and mechanisms that produce the desired outcomes.

2.9.1 Logic mapping of evidence from reviewed C-BART models

A narrative synthesis was used for the logical mapping of evidence, as presented in Figure 5. The logic mapping shows casual links between concepts and themes[84], [97] and provides a big picture of factors that facilitated desirable outcomes for patients in the community-based ART program[97]. Figure 5 illustrates the context (situation) under which community-based delivery models were designed (inputs), implemented (activities) and contributed (outputs) to patients’ outcomes (adherence to treatment, retention in care and viral suppression).

2.9.2 Logic model framework

A logic model is a graphic presentation of concepts and how they relate to each other towards producing the desired outcome[98]. The components of the logic model indicate inputs, activities/processes, outputs and outcomes – referring to short-term, medium-term and long-term outcomes or impacts[98], [99]. This study focused on patient-level outcomes. Therefore, the main input assumption is the HIV-infected adult patients’ sociodemographic and clinic characteristics initiated on ART. In this retrospective cohort study, the logic model developed during the scoping review of C-BART models in sub-Saharan Africa is used as an

“intervention logic” of the ART program outcomes. There was no theoretical framework developed during the C-BART program’s planning and inception in Okongo District. However, from the literature review, concepts and outcomes emerged, as well as the logic of how these variables relate to each other in community and facility-based ART programs to produce the observed outcomes. Therefore, this study uses a logic model framework to show the relationship and association between patients’ characteristics, clinical characteristics, outputs and outcomes. In this study, the logic model framework was used as a *“goodness of fit”* to test the observed outcomes in relation to what is documented in literature to demonstrate the effects of the C-BART program in Okongo. However, it was used not necessarily as a gold standard evaluation framework. Logic mapping of themes and concepts for understanding how and why community based-ART delivery models work in improving adherence to treatment, retention in care and viral load suppression are presented in Figure 5.

SITUATION	INPUTS	ACTIVITIES	OUTPUTS	OUTCOME
<p>What were the issues?</p> <p>An increasing number of patients on ART; some live in the rural areas far from ART facilities; with limited transport, low income; others live in high populations density urban dwellings; former township with high HIV prevalence leading to a high volume of PLHIV at public health facilities in the midst of healthcare workers crisis/shortage leading to overcrowded facilities, long waiting time and overburden HCWs; Frequent health facilities visits are costly to the patients.</p>	<p>What resources were invested or readily available?</p> <ul style="list-style-type: none"> • Patients' home; churches (in-kind contribution) • Community pharmacies • A stable supply of ARVs • Stationaries; checklists • Time • Training • Transport • HIV testing vouchers • Buddies • Treatment supporters • Companions • Lay counsellors • Community health workers • Healthcare providers • Expert patients • Field officers • Bicycles • Money (salary; other incentives) 	<p>What was done?</p> <ul style="list-style-type: none"> • Pre-packed ART refill delivered at patients home or picked by a group/club representative • Up referral to facility/clinical officers • Facility consultation visits (at 6 to 12 months) – blood for VL and CD4 count • Home-visits for patients (at 1 week – monthly) • Adherence counselling and support • Pill Count; Weight monitoring • Use a brief checklist to assess the patient for signs & symptoms; adverse events & toxicities • Safe conception counselling & Family planning education • Nutrition education • Prevention education on on-ward transmission of HIV • Patient group/clubs meet (weekly, monthly or quarterly) for educational sessions • Monitor treatment outcomes ; Pharmacovigilance for adverse events • Provide free testing for family 	<p>What were the Immediate and medium-term changes?</p> <ul style="list-style-type: none"> • Reduce the burden of regular clinic & follow-ups; • Flexible care delivery for patients • Reduced burden of the cost of access incurred by the patient • Reduced stigma • Removed external economic constraints to retention • Patient satisfied with models; acceptable • Task-shifting ART care to lay, counsellors and patients, themselves • Decongested health facility • Reduced patient waiting time in queues; • Workload reduction in consultation of the patient • Mitigated time and cost constraints related to transport to an ART site • Accurate reporting of mortality • Low financial investment • Improved time to viral suppression • Improved efficiencies and effectiveness of community-level lay cadre • High levels of prescription refill <p>Medium-term change</p> <ul style="list-style-type: none"> • Improved Adherence to ART • Low LTFU • Improved Health-related Quality of Life 	<p>What were the long-term changes?</p> <ul style="list-style-type: none"> • Improved/maintained Retention in care • Improved/maintained Viral load suppression • Improved Survival
<p>Context/Assumptions:</p> <ul style="list-style-type: none"> • <u>Stable ART patients ≥15 years</u> ; Self-forming small patients groups/clubs (up to 50); Mostly in rural settings far away from the facilities- <u>distance</u> • <u>Support</u> from Lay counsellors; treatment supporters or companions; ability to refer the patient back to the facility if there are issues • Patient with limited education and low income (subsistence farmers); self-employed • Reliable drug supply - <u>Pre-packed ARVs</u>; community pharmacies with <u>drug storage in the community</u> <p>Access to routine viral load monitoring</p>		<p>Mechanism/Assumptions:</p> <ul style="list-style-type: none"> • Models inherently confer responsibility to patients increasing - <u>ownership</u> • Members experience difficulty taking ARVs are counselled by other patients – <u>Peer support</u> • <u>Groups know immediately when a patient missed a follow-up</u> – Social network; Family networks • Patients in their own communities with members from the same community- <u>Reduced language and cultural barriers</u> • A patient nominated treatment supporter or “buddy” –<u>support system</u> • Patients satisfaction; offering of free medications – <u>access policy</u> ART offered in patient homes/church/municipal hall/community centres – <u>Proximity</u>; Care personalized to patient/patient given a grace period to collect ARV at community setting – <u>Patient-centred approach</u> 		

Figure 5: A Logic Model Framework for evaluation of patient outcomes for Okongo Community-based ART delivery (C-BARTs) Program

This review demonstrated variations and uniqueness of community-based ART delivery models implemented in sub-Saharan Africa, the context, and the populations for which they were implemented. The involvement of People Living with HIV (PLHIV) networks, patients, family members and community volunteers, people who know the context as actors in the design of the community-based ART delivery models program, implementation, monitoring and evaluations are mechanics that enhance program quality and the quality of life of people living with HIV in sub-Saharan Africa. The findings from the studies reviewed suggest key patient treatment outcomes measured are adherence to treatment, retention in care, LTFU, virological suppression, and death. Furthermore, organising patients in small manageable groups of 20 to 50, both self-formed and self-managed groups, and/or using lay-trained counsellors is beneficial. Future studies will add value to evaluate program and patient outcomes in self-management groups beyond 2 to 5 years to inform the sustainability of community-based ART delivery programs. The application of decolonising knowing processes and approaches was explored further for critical reflection, dialogue, knowledge synthesis, and knowledge discovery, while applying a community-based research framework to assess and document community-based ART interventions and research in African settings. Appreciative inquiry and knowledge discovery were crucial to documenting the contribution of communities' practices and cultural values to the implementation and patient outcomes at community-based ART delivery programs. Evidence from the scoping review demonstrated optimal patient outcomes at 6 months, 12 months, and 24 months, but waning beyond two years. Special populations, such as postpartum women and young adults under 25 should be evaluated carefully for readiness and other potential needs and risks before enrolment in community-based models. Using observational cohort study designs to evaluate community-based models allowed researchers to observe participants receiving interventions in a natural setting with minimal controlled conditions.

2.10 Strengths and Limitations of the Review

Applying the ICAMO configuration to the narrative synthesis allowed us to analyse data extracted from the studies systematically and meaningfully. Consultation with information specialists allowed a broad search for studies screened for eligibility and included in the study. This scoping review and study selection were made, based on Arkey and O'Malley's 2015 framework, namely identification of research questions for this scoping review, identification

of relevant studies, selection of the relevant studies using the pre-defined eligibility criteria; extraction and data charting, collating, summarising and reporting of results[81]. Hence, the studies reviewed to meet the definition of community-based ART delivery models that have a component of actual ARV delivery to the patients' homes or community settings other than a healthcare facility. Therefore, it may have excluded other models that support other patient ART outcomes. This review excluded grey literature and non-primary studies, studies published in languages other than English, studies evaluating children under 15 years of age, and the studies were limited to sub-Saharan Africa. The limited period of publications from 2006 to 2018 may have excluded other studies published before or after the stated period. In addition, the limitation of using a scoping review of studies published from sub-Saharan Africa may have presented an unrealistic perspective of the impact of community-based ART as an intervention, because community interactions and social networks are naturally occurring in most African settings.

CHAPTER 3

QUANTITATIVE STUDY

Retention, Adherence, and Viral Suppression among Adults in the Okongo Community-based and Facility-based Antiretroviral Therapy Programs in Namibia, 2007-2017

3.1 Overview of the Study

The aim of the retrospective cohort study was to describe and compare treatment outcomes (adherence, retention, viral suppression and survival) among HIV infected adult patients seen at the Community-based ART sites (C-BARTs) and F-BART in Okongo District, Namibia.

The objectives were:

- a) To describe sociodemographic and clinical characteristics of adult HIV infected patients receiving ART at C-BARTs and F-BARTs in the Okongo District.
- b) To describe adherence, retention, viral suppression and survival at 6,12,24,36 months after initiating ART at C-BARTs and F-BART
- c) To determine predisposing factors for adherence for HIV-infected adults on ART at C-BARTs and F-BARTs.
- d) To determine risk factors for retention in care for HIV-infected adults on ART at C-BARTs and F-BARTs.
- e) To determine risk factors for virological suppression for HIV-infected adults on ART at C-BARTs and F-BARTs.

3.2 Methods

3.2.1 Study design

A retrospective cohort analysis of all patients on ART in the Okongo Districts who were down-referred from health facilities to one of 18 Community-Based ART delivery (C-BART) sites for the continuation of HIV care and patients who remained at Okongo Hospital facility-based ART was conducted.

3.2.2 Study population

The study population for the retrospective cohort study was HIV-infected patients who met the inclusion criteria indicated below.

Inclusion criteria

The population for the study comprised adult HIV-infected patients (>15 years) initiated on ART from 01 January 2007 to 31 July 2017. For C-BART patients who were down-referred to C-BART latest by 31 July 2017, allowing a >3 months duration in C-BART care as of 30 November 2017, the date of data abstraction were included in the study. In addition, adult patients who ever received ART at the Okongo District Hospital during the same period and were not down-referred to C-BART were also included in the study.

Exclusion criteria

Patients recorded as C-BART patients in ePMS but with missing down-referral dates in ePMS and those who transferred out or were lost to follow-up (LTFU) before the down-referral date to C-BART were excluded from C-BART cohort.

3.3 Sample Size and Procedures

The study included all HIV infected adults enrolled on ART at the Okongo District Hospital from 01 January 2007 to 31 July 2017, including those down-referred to any of the 18 C-BART sites. Data was extracted by 31 November 2017 to ensure patients had a minimum follow-up of 3 months of care in C-BART before analysis. Data for C-BART and F-BART patients was extracted from the Okongo ePMS database hosted at the Ministry of Health and Social Services at national level and submitted monthly from the Okongo District Hospital ART. All patients down-referred to C-BART sites are already assigned a C-BART site name under the outreach field in the ePMS. This is done at the facility level before the database is sent to the national level for reporting. The outreach field in ePMS was then used to extract records of patients seen at C-BART sites. Records of all patients who remained in the facility and were not assigned a C-BART site name in ePMS were extracted for the F-BART analysis. A sample of 2665 (504 C-BART and 2161 F-BART) patient records extracted from ePMS formed the basis for the sample included in this retrospective cohort analysis. The detailed sample selection is presented in results, section.

3.4 Data Collection Methods

Patients' sociodemographic characteristics, clinical characteristics and ART-related data was extracted from the central electronic Patient Management System (ePMS) database. The ePMS

captures routinely collected patient data from the F-BART and C-BART sites paper-based HIV Patient Care Booklet (PCB). Patient variables collected for each eligible patient were: date of HIV diagnosis; date of enrolment to care; date of ART initiation; date of all follow-up visits from initiation up to 60 months; date of the latest visit; ART status at last visit for each time point, i.e. alive and on ART (retained in care). Patient Transfer Out (TO) during ART and date of transferred out; stopped ART; date stopped and reasons for stopping; if died, date of death; if lost-to-follow-up, date of loss to follow-up were also collected. Viral load data was collected, including the date of the viral load result and viral load value to indicate virological suppression.

In the case of missing viral load data, viral load values abstracted from the Medical Technology (MEDTECH), the electronic patient laboratory information system was used. ART dispensing, regimens and patients' adherence data was also generated from the ePMS and complemented with data from the Electronic Dispensing Tool (EDT). These included all regimen changes and reasons, all regimen substitutions and reasons, dates of ARV pick up, the number of days in the interval, adherence to ART code, and pill count records. All data collected from ePMS, EDT and MEDTECH electronic databases was entered into a composite Microsoft Office Excel 2013 study database.

3.5 Data Analysis

Data entered into a composite study Microsoft Office Excel 2013 database was exported to a Statistical Software package (Stata Corporation, College Station, TX, USA) for statistical analyses. Okongo C-BART and F-BART stratified analyses.

3.5.1 Patient demographic and clinical characteristics

Descriptive statistics were used to summarise patients' demographic and clinical characteristics for the cohorts of C-BART and F-BART patients. The demographic characteristics included sex, age categories based on age at ART initiation, and marital status. Clinical characteristics included the year of ART initiation, the years of ART initiation were grouped in cohorts based on the criteria for ART initiation as per the guideline. For 2007-2010, the eligibility criteria was CD4 200 cells/ μ L; 2011-2014 was 350 cells/ μ L ; 2015-2016 was 500 cells/ μ L; and from

2017 was “test and start”, hence these were considered to be similar cohort based on ART initiation criteria.

WHO clinical stage and CD4 at ART initiation, and duration on ART from ART initiation to outcome event. We stratified these characteristics by C-BART and F-BART. For the patients at C-BARTs, we also analysed the duration on ART before down-referral to C-BART and the duration from down-referral to C-BART to the outcome event. In addition, CD4 count trends over time were analysed from baseline, 6, 12, 24, 36, 48, and 60 months stratified by F-BART and C-BART. All Outcomes were stratified by C-BART and F-BART sites.

Chi-square tests were performed to test the null hypothesis of no association between the ART delivery model, demographic and clinical characteristics and to determine if the observed differences in demographic and clinical characteristics between the F-BART and C-BART patient cohorts were statistically significant at a p-value less than 0.05.

3.5.2 Retention

We measured retention in ART care for cohorts of C-BART and F-BART patients followed longitudinally from the ART start date until 30 November 2017. This approach allows for assessment of retention in care for patients in C-BARTs and F-BART from the ART start date at time “zero” for both groups to the end point.

Patients were categorised into cohorts based on retention in care, defined as the number of months a patient was in care from the ART start date until the date of an outcome event. The primary outcome events of interest were: alive and on ART at the end of the study, Lost-to-follow-up (LTFU), or death. We have analysed ART stopped and transferred out (TO). Patients were categorised into cohorts (3, 6, 12, 24, 36, 48 and 60 months) based on retention in care, defined as the number of months a patient was in care from the date of ART start until the date of an outcome event. A patient outcome event was included in a given cohort if the time from the ART start date to the outcome event was at least as long as the time defined by the cohort.

The outcome events were either the end of the study period or the date of death, ART stopped, loss to follow-up, or transfer out of the health district. Cohorts were classified into 3, 6, 12, 24, 36, 48, and 60 months, as displayed in Table 6 below. For each retention cohort, retention was defined as the number of patients alive and retained on ART at the F-BART or C-BART site at the end of the retention cohort period, divided by the number of C-BART and F-BART

patients who were initiated on ART and were expected to be alive and on ART at the end of the retention cohort period. Patients who were transferred out were included.

The Namibian ART Guidelines of 2016 categorised patients as lost to follow-up (LTFU) if they interrupted care by missing a clinic appointment or ART refill pick-up for 90 days or more consecutive days after the scheduled appointment[27]. Therefore, 90 days were added to the duration of ART for C-BART and F-BART patients after the scheduled visit date before they were considered LTFU or not retained in care.

In equal measure, retention in ART care was measured from the date of ART initiation until the date of an outcome: 1) date died, 2) date of loss to follow-up (LTFU), 3) date transferred out (TO) and 4) date of the end of the follow-up period[98]. This study’s end period was 60 months, or 31 November 2017[101].

Table 6: Retention cohort definitions

Retention Cohort	Number of days after ART start date for C-BART and F-BART patients
3 months	91 days
6 months	182 days
12 months	364 days
24 months	728 days
36 months	1, 092 days
48 months	1, 456 days
60 months	1, 820 days

3.5.3 Adherence

We analysed adherence to ART for C-BART and F-BART patients by taking the average adherence score across pharmacy visits during the 12 months before data extraction from ePMS, which was 30 November 2017. This ensured that the most frequently reported adherence score was used, given the limited recording of the adherence scores in ePMS. A patient’s pharmacy visit adherence score is an average medicine adherence score for all ARV medicines. It is calculated from information collected during the patient’s pharmacy visit. The numerator consists of (Previous pill count + Quantity of pills dispensed) – Current pill count. The denominator is the number of Pills per day prescribed multiplied by the days since the last visit[101].

3.5.4 Viral suppression

Viral suppression was analysed by looking at the number of F-BART and C-BART patients alive and on ART as of the data extraction date, which was 30 November 2017. Viral suppression was defined as a viral load result of <1000 copies/ml or “TND”, standing for Target Not Detected[27], and total viral suppression was defined as a viral load result of <400 copies/ml. The latest viral load for each patient was included in the analysis for each cohort. Time to viral suppression after ART initiation was also analysed.

Chi-square tests were performed to test the null hypothesis of no association between the ART delivery model, viral suppression at <1000 and <400, and to determine if the observed difference in viral suppressions between the F-BART and C-BART patient cohorts were statistically significant at a p-value less than 0.05.

3.5.5 Survival

Demographic and clinical characteristics of F-BART and C-BART patients who died during the period covered by the study were analysed. This included deaths among F-BART or C-BART patients irrespective of place of death, as long as it had been reported in ePMS. Some deaths were already reported in ePMS at the beginning of the study. However, additional deaths were identified during data validation. All PCBs for deceased patients were removed from the filing cabinets and kept separately. Hence, during the process of retrieving PCBs for the data validation study, we could not locate some of the PCBs, and then discovered that the PCBs were in the facility but kept separately. All PCBs for the deceased were retrieved, and the date of death was entered into the ePMS database.

The cumulative probability of retention in care at 6, 12, 24, 36, 48, and 60 months was analysed stratified by C-BART and F-BART and plotted using the Kaplan-Meier curve. The Kaplan-Meier survival curves were used to show the time-to-event, i.e., death, lost-to-follow and attrition, by sex, age, WHO clinical stage and CD4 at ART initiation, stratified by C-BART and F-BART. Patients were classified as dead based on the date of death recorded in ePMS. Attrition was defined as patients who died or LTFU by the end of the study in a given cohort [44], [102]; stratified by C-BART and F-BART.

Covariate analyses were conducted to assess if patients' sociodemographic characteristics such as age and sex, clinical characteristics such as CD4 cell count and WHO stage at baseline, first ART regimen, influenced death or LTFU. ART entry points for patients and switching ART regimens were dropped from the analysis due to the high number of missing data for these two variables.

3.6 Ethics Considerations

Ethical approvals were sought and granted by the University of the Western Cape Biomedical Research and Ethics Committee and the Namibian Ministry of Health and Social Services Research Review Committee (Appendices A and B). Approval was sought and granted to extend the study endpoint from 2015 to 2017. This retrospective cohort study used routinely collected data from the electronic Patient Management System. Hence, there was no interaction with patients, and informed consent was not required. The dataset extracted from ePMS was de-identified of personal identifying information by the Ministry after linkage before being

handed over for analysis. Study IDs were allocated to each unique C-BART and F-BART record.

3.7 Results

A total of 504 records from the C-BART and 2161 from F-BART cohorts were included. The final sample of C-BART and F-BART included in the analysis is 2665. An initial total of 534 records were extracted for C-BART patients. Thirty patients were excluded because it was confirmed during data verification that their down-referral date to C-BART occurred after 31 July 2017. The initial number of all patients on ART at Okongo District Hospital Facility-based ART were 2301. However, 140 were children under 15 years old. Hence, they were excluded from the analysis. There were 2161 adult patients who remained in the sample and were analysed for this study. A detailed sample selection for C-BART and F-BART patients is presented in Figures 6 and 7 below.

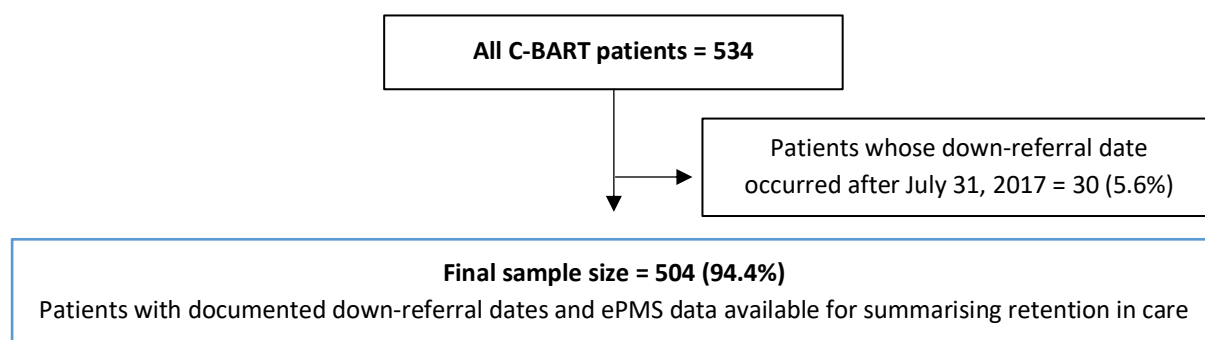


Figure 6: Selection of patients for the evaluation: C-BART

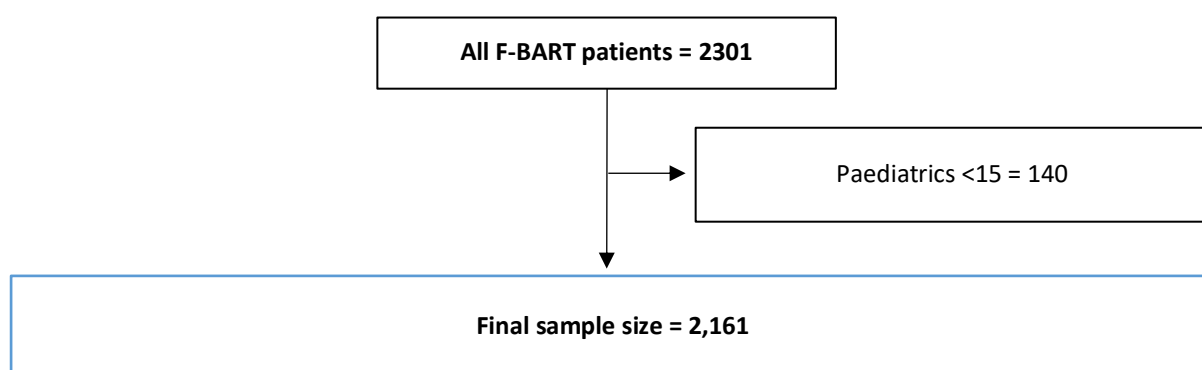


Figure 7: Selection of patients for the evaluation: F-BART

3.7.1 Patients' demographic characteristics at ART start

Data from 504 C-BART and 2161 records of F-BART adult patients who met the eligibility criteria were abstracted and included in the cohort analysis. Table 3.1 summarises the demographic and clinical characteristics of patients. Of the C-BART and F-BART records abstracted, 40.4% are males and 59.6% are females. The median age at the start of ART was 38 (Interquartile range [IQR]: 32-45) years for C-BART and 29 (24-36) years for F-BART. Many patients (67.9%) were single/separated or widowed. A total (89%) of patients initiated ART between 2007 and 2014. For the patient in C-BART, the median duration on ART before down-referral to a C-BART site was 81 (Interquartile range [IQR]: 51-102) months.

3.7.2 Baseline clinical characteristics

Most patients started ART at WHO Stage 1 or 2, at 89.2% and 86.3% for C-BART and F-BART, respectively. The median CD4 count at ART initiation among the C-BART cohort was 200 (Interquartile range [IQR]:140-314) cells/mm³ and 214 (143-328) cells/mm³ among the F-BART.

3.7.3 Down-referral timing

The median time on ART before down-referral was 31 months. However, 4% of patients were down-referral to C-BART before 3 months on ART, 9.2% were on ART 6 months or less, and 20.7% were down-referred before 12 months. The majority of patients (79.3%) were on ART for 12 months or more and considered stable before down-referred to C-BART.

Table 7: Demographic and clinical characteristics of adult patients in C-BART and F-BART care at Antiretroviral initiation in Okongo district in Namibia, 2007–2017

Characteristic	All patients N=2,665	C-BART N=504	F-BART N=2,161	<i>P-value*</i>
Overall N	n (%) 2,665	n (%) 504	n (%) 2,161	
Sex				
Female	1,610 (59.5%)	294 (58.3%)	1,316 (60.9%)	0.29
Male	1,055 (40.4%)	210 (41.7%)	845 (39.1%)	
Age - years^a, at ART initiation				
15–24 years	654 (17.4%)	29 (5.8%)	625 (29.0%)	0.00

Characteristic	All patients N=2,665	C-BART N=504	F-BART N=2,161	<i>P-value*</i>
25–34 years	1,079 (37.1%)	159 (31.6%)	920 (42.6%)	
35–44 years	587 (28.4%)	194 (38.5%)	393 (18.2%)	
45+ years	343 (17.2%)	122 (24.2%)	221 (10.2%)	
Median age (IQR), years	67 (28-41)	38 (32–45)	29 (24-36)	
Marital Status				
Single/separated	1,639 (61.5%)	260 (51.6%)	1,379 (63.8%)	0.00
Married/cohabitating	787 (29.5%)	184 (36.5%)	603 (27.9%)	
Widowed	29 (1.1%)	6 (1.2%)	23 (1.1%)	
Unknown	210 (7.9%)	54 (10.7%)	156 (7.2%)	
Year of ART initiation				
2007–2010	1,048 (42.1%)	235 (46.6%)	813 (37.6%)	0.00
2011–2014	1,126 (42.9%)	221 (43.8%)	905 (41.9%)	
2015–2016	370 (12.2%)	48 (9.5%)	322 (14.9%)	
2017	121 (5.6%)	0	121 (5.6%)	
WHO clinical stage at ART initiation				
1 or 2	2,277 (86.8%)	444 (89.2%)	1,833 (86.3%)	0.17
3 or 4	346 (13.2%)	54 (10.8%)	292 (13.7%)	
Unknown	42 (1.6%)	6 (1.2%)	36 (1.7%)	
CD4 count (cells/μL) at ART initiation				
< 100	250 (9.4%)	67 (13.8%)	183 (8.5%)	0.00
100-200	829 (31.3%)	177 (36.4%)	652 (30.2%)	
201-350	894 (33.8%)	166 (34.2%)	728 (33.7%)	
351-500	318 (12.0%)	49 (10.1%)	269 (12.4%)	
>500	356 (13.4%)	27 (5.6%)	329 (15.2%)	
Unknown	18 (0.7%)	18 (3.6%)	0	
Sample size	2467 (99.3)	486 (96.4%)	2161 (100%)	
Median CD4 count (IQR)	207 (142-321)	200 (140–314)	214 (143-328)	
Duration on ART from ART initiation to outcome event^b				
≤ 3 months	182 (6.9%)	1 (0.2%)	181 (8.4%)	0.00
4–6 months	110 (4.1%)	0	110 (5.1%)	
7–11 months	140 (5.3%)	1 (0.2%)	139 (6.5%)	
1–2 years	572 (21.6%)	63 (12.5%)	509 (23.7%)	
3–4 years	520 (19.6%)	83 (16.5%)	437 (20.3%)	
5–6 years	496 (18.7%)	147 (29.2%)	349 (16.2%)	
7–8 years	357 (13.5%)	101 (20.0%)	256 (11.9%)	

Characteristic	All patients N=2,665	C-BART N=504	F-BART N=2,161	<i>P-value*</i>
9–10 years	275 (10.4%)	108 (21.4%)	167 (7.8%)	
Unknown	13 (0.5%)	0	13 (0.6%)	
Median (IQR), months	122 (34-91)	81 (51-102)	41 (16-79)	
Duration on ART from ART initiation to down-referral^c				
≤ 3 months	20 (4.0%)	20 (4.0%)		
4–6 months	26 (5.2%)	26 (5.2%)		
7–11 months	58 (11.5%)	58 (11.5%)		
1–2 years	180 (35.7%)	180 (35.7%)		
3–4 years	99 (19.6%)	99 (19.6%)		
5–6 years	71 (14.1%)	71 (14.1%)		
7–8 years	30 (6.0%)	30 (6.0%)		
9–10 years	20 (4.0%)	20 (4.0%)		
Median (IQR), months	31 (14-57)	31 (14-57)		
Duration on ART from down-referral to outcome event^d				
≤ 3 months	3 (0.6%)	3 (0.6%)		
4–6 months	62 (12.3%)	62 (12.3%)		
7–11 months	80 (15.9%)	80 (15.9%)		
1–2 years	156 (31.0%)	156 (31.0%)		
3–4 years	75 (14.9%)	75 (14.9%)		
5–6 years	73 (14.5%)	73 (14.5%)		
7–8 years	38 (7.5%)	38 (7.5%)		
9–10 years	17 (3.4%)	17 (3.4%)		
Median (IQR), months	28 (10-61%)	28 (10-61%)		

^a Age at the time of ART initiation

^b Time from the date of ART initiation to the date of a patient's outcome event (died, LTFU, stopped ART, or transferred out of the health district) or the end of the study period (November 30, 2017) if the patient was alive and on ART on that date.

^c Time from the date of ART initiation to the date of down-referral to C-BART.

^d Time from the date of down-referral to C-BART to the date of a patient's outcome event (died, LTFU, stopped ART, or transferred out of the health district) or the end of the study period (November 30, 2017) if the patient was alive and on ART on that date.

* Test of *t* the null hypothesis that there is no association between the mode of ART delivery, demographic and clinical characteristics. The null hypothesis is rejected for a *p*-value less than 0.05, the significant value -0.05

3.7.4 Retention in care

At 3-6 months after ART start date, patients were more likely to be retained in at 95.1% and 90.7% compared 87.0% and 86.1% in C-BART, respectively. However, patients were more

likely to be retained in C-BART at 48-60 months at 80.0% and 81.0% in C-BART compared to 65.9% and 61.6% in F-BART. The results are presented in the table below.

Table 8: Retention in Care among all adults (≥ 15 years old) from ART start date by model of care, C-BART and F-BART in Okongo district in Namibia, 2007–2017

Retention cohort ^a	Number of patients followed (% retained) ^b			P-value*
	All patients n (%)	C-BART n (%)	F-BART n (%)	
3 months	2464/634 (93.5%)	438/504 (87.0%)	2,026/2,130 (95.1%)	<0.01
6 months	2303/2,563 (90.0%)	401/466 (86.1.0%)	1,902/2,097 (90.7%)	<0.01
12 months	2042/2,400 (85.0%)	310/371 (83.6.0%)	1,732/2,029 (85.4%)	0.37
24 months	1,716/2,190 (78.3%)	251/307 (82.0%)	1,465/1,883 (77.8%)	0.12
36 months	1,410/1,928 (73.1%)	182/228 (80.0%)	1,228/1,700 (72.2%)	0.02
48 months	1,090/1,608 (67.7%)	161/199 (80.0%)	929/1,409 (65.9%)	<0.01
60 months	906/1,424 (63.6%)	121/149 (81.0%)	785/1,275 (61.6%)	<0.01

^a A retention cohort is a group of patients whose follow-up time from the date of ART start (for C-BART and F-BART) to the date of outcome event is as long as the follow-up time specified.

^b The percentage retained is the number of patients alive and on ART at the follow-up time specified, divided by the number of patients followed at least this long before their outcome event (died, LTFU, stopped ART, or transferred out of the health district, or alive and on ART at the end of the study).

*Test of the null hypothesis that there is no association between the mode of ART delivery and retention in care for cohorts. The null hypothesis is rejected for p-value less than 0.05, the significant value -0.05

The retention in care above was analysed based on the retention for each cohort. Cohorts are based on months of ART after initiation for both C-BARTs and F-BART. All p-values are calculated using chi-square tests.

By design, all patients initiate ART at the facility and continue care in C-BART. The results of the retention care above might have included the time patients were still in F-BART and not down-referred. This prompted us to do additional analysis for retention in C-BART, by only looking at the cohorts from *date down-referred to C-BART* to the end of the study or outcome event. Several studies have used this approach. The results are presented in the table below.

Table 9 Retention in Care among all adults (≥ 15 years old) by model of care, C-BART (after down referral) and F-BART in Okongo district in Namibia, 2007–2017

Retention cohort ^a	Number of patients followed (% retained) ^b			P-value
	All patients n (%)	C-BART n (%)	F-BART n (%)	
3 months	2,528/2,634 (96.0%)	502/504 (99.6%)	2,026/2,130 (95.1%)	0.00
6 months	2,359/2,563 (92.0%)	457/466 (98.1%)	1,902/2,097 (90.7%)	
12 months	2,091/2,400 (87.1%)	359/371 (96.8%)	1,732/2,029 (85.4%)	
24 months	1,750/2,190 (79.9%)	285/307 (92.8%)	1,465/1,883 (77.8%)	
36 months	1,431/1,928 (74.2%)	203/228 (89.0%)	1,228/1,700 (72.2%)	
48 months	1,103/1,608 (68.6%)	174/199 (87.4%)	929/1,409 (65.9%)	
60 months	913/1,424 (64.1%)	128/149 (85.9%)	785/1,275 (61.6%)	

^a A retention cohort is a group of patients whose follow-up time from the date of down-referral (for C-BART) or date of ART start (for F-BART) to the date of outcome event is as long as the follow-up time specified.

^b The percentage retained is the number of patients alive and on ART at the follow-up time specified, divided by the number of patients followed at least this long before their outcome event (died, LTFU, stopped ART, or transferred out of the health district, or alive and on ART at the end of the study).

*P-value less than 0.05

At 12 months, 96.8% of patients in C-BART and 85.4% in F-BART were retained in care from the ART start date, respectively. At the same time, the percentage retained in care at 60 months was 85.9% for C-BART and 61.6% for F-BART, respectively. C-BART cohorts were more likely to be retained at all time points than F-BART.

3.7.5 Adherence to ART

The results showed that 83.8% of patients in C-BART care achieved optimal adherence by Namibian Standards ($\geq 75\%$) compared to 56.2% among F-BART. Similarly, 50.4% of patients in C-BART care achieved adherence of $\geq 95\%$ compared to 35.9% among F-BART. Overall, there was limited documentation of adherence assessment. Adherence data was available for 640 patients (24%).

The above results must be interpreted with caution, considering that 79.3% of patients down-referred to C-BART have been on ART for 12 months or more before down-referral to C-BART. Secondly, adherence to ART was also a criterion for remaining in C-BART. Therefore, it is very likely that patients who started ART but are not adherent to ART remain in F-BART.

Table 10: Adherence to ART among adult (≥ 15 years) C-BART and F-BART patients in Okongo district in Namibia, 2007-2017 (n = 640)

Variable	All patients n = 640	C-BART n = 359	F-BART n = 281	
Score category	n (%)	n (%)	n (%)	P-value*
$\geq 95\%$	282 (44.1%)	181 (50.4%)	101 (35.9%)	0.00
80%–94%	141 (22.0%)	90 (25.1%)	51 (18.1%)	
< 80%	217 (33.9%)	88 (24.5%)	129 (45.9%)	
Median adherence score (%) (IQR)	81% (52-100%)	95% (80-99%)	67% (23-100%)	
Adherence by Namibia standard definition	n (%)	n (%)	n (%)	P-value
Good adherence ($\geq 75\%$)	459 (70%)	301 (83.8 %)	158 (56.2%)	0.00
Poor adherence (< 75%)	181 (30%)	58 (16.2%)	123 (43.8%)	

**Test of the null hypothesis that there is no association between the mode of ART delivery and adherence to ART for C-BART and F-BART cohorts. The null hypothesis is rejected for p-value less than 0.05, the significant value -0.05*

All p-values are calculated using chi-square tests. The p-value is less than 0.05, the null hypothesis is accepted, that there is no association between the mode of ART delivery and adherence to ART, the observed difference is not significant.

3.7.6 Viral suppression

Table 10 below shows the number and percentage of F-BART and C-BART patients with viral suppression <1000 copies/ml per retention cohort. Patients in C-BART are more likely to achieve VS <1000 (95.7%) than F-BART patients (89.1%). For the 60-month retention cohort, VS was 89.4% in C-BART compared to 76.3% among patients who remain in F-BART.

Table 11: Viral Suppression (<1000 copies/ml) at least 3 months after down-referral to C-BART and after starting ART at facilities, among patients retained in HIV care in Okongo district in Namibia, 2007–2017, by retention time point

Retention Cohort	All Patients		C-BART		F-BART		P-value*
	Total ^a	% VS	Total ^a	%VS	Total ^b	% VS	
Overall	968/1028	94.1%	488/489	99.8%	480/539	89.1%	0.00
3 months	1011/1028	98.3%	488/489	99.8%	523/539	97.0%	0.000
6 months	960/985	97.5%	444/451	98.4%	516/534	96.6%	0.071
12 months	840/870	96.6%	349/358	97.5%	491/512	95.9%	0.207
24 months	720/769	93.6%	279/295	94.6%	441/474	93.0%	0.396
36 months	580/652	90.0%	201/218	92.2%	379/434	87.3%	0.061
48 months	463/553	83.7%	172/191	90.0%	291/362	80.4%	0.003
60 months	377/471	80.0%	126/142	88.7%	251/329	76.3%	0.002

^a Number of patients with viral suppression (<1000 copies/ml) / number of retained patients with available results on a viral load test conducted at least 3 months on ART after down-referral to C-BART and closest to the data abstraction date (November 30, 2017).

^b Number of patients with viral suppression (<1000 copies/ml) / number of retained patients with available results on a viral load test conducted at least 3 months after starting ART at health facilities and closest to the data abstraction date (November 30, 2017).

*Test of the null hypothesis that there is no association between the mode of ART delivery and viral suppression among patients retained in care for cohorts. The null hypothesis is rejected for p-value less than 0.05, the significant value -0.05

Viral suppression data is analysed based on retention at each cohort. cohorts are based on months on ART after ART initiation for C-BARTs and F-BART by VL. All p-values are calculated using chi-square tests.

Table 11 below shows total viral suppression for various cohorts of patients in F-BART and C-BART. Notably, 88.9% of patients with VS data were totally suppressed with <400 copies/ml. Overall, patients in C-BART were more likely to be totally suppressed compared to patients in F-BART.

Table 12: Viral Suppression (<400 copies/ml) at least 3 months after down-referral to C-BART among patients retained in HIV care in the Okongo District in Namibia, 2007–2017, by retention time point

Retention Cohort	All Patients		C-BART		F-BART		p-value*
	Total	% VS	Total ^a	%VS	Total ^b	% VS	
Overall	922/1028	89.7%	458/489	93.7%	464/539	86.1%	0.001
3 months	1011/1028	98.3%	488/489	99.8%	523/539	97.0%	0.001
6 months	960/985	97.5%	444/451	98.4%	516/534	96.6%	0.071
12 months	840/870	96.6%	349/358	97.5%	491/512	95.9%	0.207
24 months	720/769	93.6%	279/295	94.6%	441/474	93.0%	0.396
36 months	580/652	89.0%	201/218	92.2%	379/434	87.3%	0.061
48 months	463/553	83.7%	172/191	90.1%	291/362	80.4%	0.003
60 months	377/471	79.7%	126/142	87.5%	251/329	76.3%	0.005

^a Number of patients with viral suppression (<400 copies/ml) / number of retained patients with available results on a viral load test conducted at least 3 months after down-referral to C-BART and closest to the data abstraction date (November 30, 2017).

^b Number of patients with viral suppression (<400 copies/ml) / number of retained patients with available results on a viral load test conducted at least 3 months after starting ART at health facilities (F-BART) and closest to the data abstraction date (November 30, 2017).

Test of the null hypothesis that there is no association between viral load for each retention and the mode of ART delivery. The null hypothesis is rejected for p-value less than 0.05, the significant value -0.05

Viral suppression data is analysed based on retention at each cohort. cohorts are based on months on ART after ART initiation for C-BARTs and F-BART by VL. All p-values are calculated using chi-square tests.

3.7.7 Summary of outcomes in cohorts (C-BART and F-BART)

Table 11 summarises the outcomes in the total cohorts for C-BART and F-BART patients. The percentage of patients alive and on ART was higher among C-BART (86.9%) than among F-BART patients (51.1%). Lost to follow-up and deaths were lower in C-BART than in F-BART. More patients transferred out of F-BART than C-BART, which is anticipated since patients down-referred from F-BART to C-BART. The low retention in F-BART should be interpreted with caution. Some patients self-transfer to C-BARTs from F-BART, without requesting for transfer-out from the F-BART, also known as “silent transfers”, and this will appear as if they are lost to follow-up, contributing further to low retention and high lost-to-follow-up in F-BART.

Table 13: Outcome in total cohort by end of the study period, by C-BART AND F-BART , 2007-2017

Outcomes	Total (n = 2665)	C-BART (n = 504)	F-BART (n = 2161)
Alive and on ART	1,542 (57.9%)	438 (86.9%)	1,104 (51.1%)
Lost to follow-up	301 (11.3%)	13 (2.6%)	288 (13.3%)
Died	139 (5.2%)	24 (4.3%)	115 (5.3%)
Transferred out	674 (25.3%)	29 (5.8%)	645 (29.8%)
Stopped ART	9 (0.3%)	0 (0%)	9 (0.4%)
Total	2665	504	2161

Figure 10 shows the Kaplan-Meier survival estimates for lost to follow-up among adult patients in C-BART and F-BART in the Okongo District. Most patients remained in care longer in C-BART and F-BART, while 4.3% of patients in C-BART were lost to follow-up compared to 13.3% in F-BART. The duration of ART only showed a significantly increased risk for LTFU after 60 months.

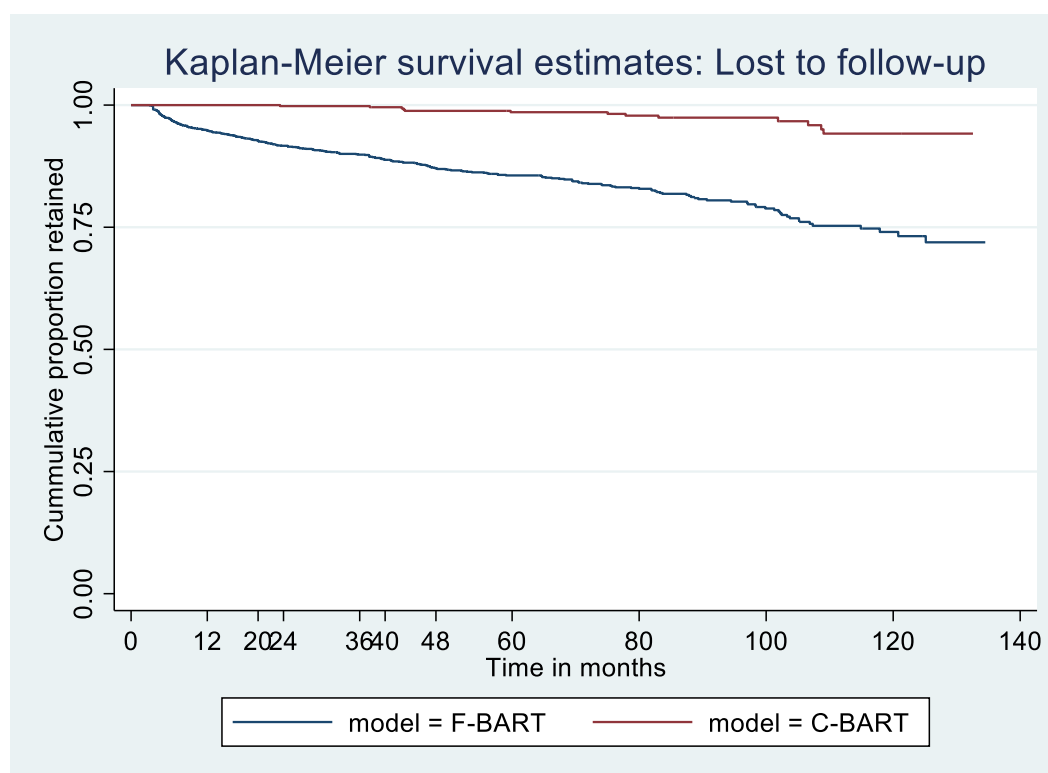


Figure 8: Kaplan-Meier survival estimates for loss to follow-up among adult patients in C-BART and F-BART in the Okongo District

Overall, 8% of patients in C-BART and F-BART were LTFU by the end of the study period. However, patients in F-BART were more likely to be LTFU (13.3%) than those in C-BART care (2.6%).

Figure 11 shows the cumulative attrition of patients from C-BART and F-BART by gender. Although the attrition is slightly higher among males than females, the difference was not statistically significant ($P < 0.005$).

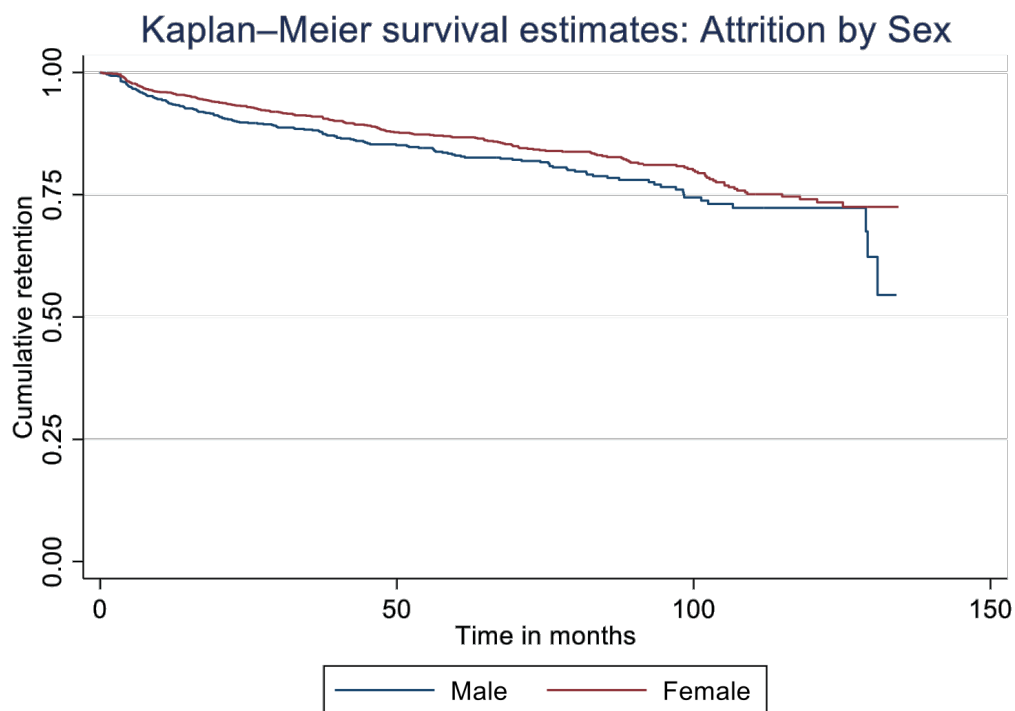


Figure 9: Cumulative attrition in C-BART and F-BART by sex

Figure 12 shows attrition by age group. The attrition was low for all age groups for over 60 months on ART. However, the young age group had slightly higher attrition after 60 months on ART, though not statistically significant ($P < 0.05$).

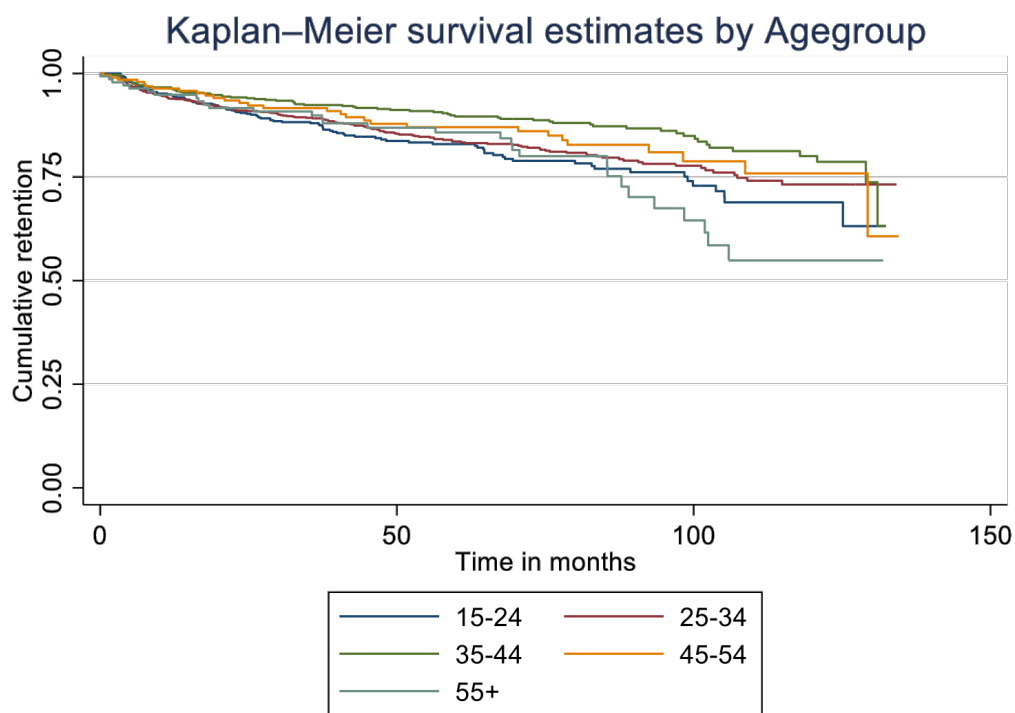


Figure 10: Attrition in C-BART and F-BART by age group

Discussion

The cohort study included a total number of 2665 patients, comprising 2161 patients from the Okongo facility-based ART and 504 from C-BART sites in the Okongo District, Ohangwena Region. Okongo was the first health district in Namibia to formalise a community-based ART delivery program in 2007. The number of C-BART sites and patients seen at C-BART increased over the years. Patients’ outcomes have improved over the years. By 2017, Okongo had 18 C-BART sites providing ART services.

Data for patients seen at F-BART were included in the study to assess if the outcomes seen at C-BART were as good as those seen at F-BART. No direct comparison was made because patients were not matched between the C-BART and F-BART models.

In this study, most patients (70.3%) were down-referred to C-BART after 12 months, which aligns with the WHO’s recommended timing for down-referral to C-BART. However, 20.7% were down-referred before 12 months on ART. In fact, 4% were down-referred before they were on ART for 3 months, and 9.2% were on ART for 5 months or less. A study by Auld et al. (2015) reported that 7% of patients were referred to a community-based ART model before

3 months and 17% between 3 and 6 months[100]. At the same time, a study[41] indicated that patients were referred to a community-based care after being on ART for a median of 8.3 months. Therefore, the timing of the down-referral to C-BART in Namibia is within an acceptable range, considering the WHO's recommendations and findings from Auld et al.'s study[104].

Over 50% of patients seen in C-BART are females. This is a collaboration with general services utilisation in Namibia, recording that more women are likely to seek health services than men. Similarly, women are disproportionately more affected by HIV than men; hence, more women are on ART than men. Therefore, it is no surprise that there are more females than males in C-BART. There was no statistically significant difference in age and marital status of patients in C-BART and F-BART.

This study revealed the ongoing challenge of using traditional or “manual” methods of measuring adherence among patients on ART, such as pill count; hence, adherence assessment documentation was only available for 24% of patients. Since the roll-out of viral load monitoring as an ultimate measure of treatment success, the significance of using adherence measures such as pill count and clinic appointments has reduced, and HCWs rarely complete this information. The result has shown high adherence in C-BART, with 83.8% of patients achieving $\geq 75\%$ and 50.4% achieving $\geq 95\%$. These results are supported by the findings presented in the qualitative study, which indicates that adherence assessment is empathised in C-BART care, and patients are aware that if they do not adhere to treatment and clinic appointments, they will be up-referred to the hospital for follow-up, which will be an additional transport cost for them. These adherence scores were higher than the findings of a study reported by Wakibi et al. 2011[23], whereby up to 72% of patients were non-adherent when different adherence assessment measures were used. The reasons reported for non-adherence were “being busy” and forgetfulness. Gender, age and marital status did not predict adherence[23].

Retention in care was high among patients in C-BART, 85.9% at 60 months compared to 61.6% in F-BART, while at 12 months, retention was 96.8% in C-BART and 85.4% among F-BART patients. These retention rates are similar to those reported by various studies[30], [40], [41], [88]. This indicates the effectiveness of the C-BART model in retaining patients. However, improving records of patients up-referred to C-BART would be informative. One anticipated that non-retention patients are up-referred to F-BART, which may have influenced these findings. A study by Decroo et al. (2017)[41] identified factors such as reduced waiting time,

reduced healthcare related transport costs, enhanced information sharing among patients from the same community and peer support as some of the factors that promote good retention[41]. Long waiting time is reported to be associated with high attrition among patients on ART[88]. Overall, 91.8% of patients in C-BART and F-BART were virally suppressed, and 88.9% were totally suppressed. Total suppression (<400 copies/ml) for C-BART patients was 99.1% at 12 months and 89.4% at 60 months, compared to 95.9% and 76.3%, respectively, for F-BART patients.

Based on the outcome in the cohort, by the end of the study period, 86.9% of patients in C-BART were alive and on ART compared to 51.1% in F-BART. In addition, there were 24 deaths in C-BART (4.3%) and 115 (5.3%) in F-BART. As indicated previously, these statistics must be integrated with caution because all patients diagnosed with TB are up-referred and may die while at the facility. As a practice, patients who are sick are up-referred for frequent review and management at the hospital. Hence, the number of deaths in the facility may be inflated because of this factor.

In conclusion, the results of this study show the feasibility and effectiveness of using a community-based model for the delivery of ART services in the rural setting. Therefore, C-BART is a promising model to expand access and increase the utilisation of ART services at the community level. It has demonstrated continuity of care at the community level and that services can be rendered effectively through task-shifting and task-sharing.

Recommendations

Based on the findings of this study, it is important to strengthen data management and quality. There seems to be less utility for adherence score data, suggestive of the fact that it is high time to cease the collection of adherence score-based pill counting, as it seems to be just an administrative exercise. Instead, other innovative electronic measures such as medication electronic cap monitoring (MEM) should be considered, which send data when the medicine container is opened, or the use of new innovative diagnostics such as urine tests, which measure the presence of ARVs in urine. In addition, investing in viral load monitoring must be the gold standard and effective, because it is given virally suppressed clients who are adherent. For efficient use of electronic data, e-health must be expedited to ensure the use of a unique identifier across multiple systems. The result shows that the treatment outcomes are as good or

better in C-BART retention, viral suppression and survival as in F-BART. Hence, C-BART is an effective model of ART service delivery at the community level.

Limitation and Conclusion

The nature of the retrospective observation cohort studies utilising routinely collected data on events that have already taken place with no conditioning or control, one cannot control for confounders.

Patients at C-BART and F-BART might have been different in the case where some patients might have been kept at F-BART due to poor adherence, frequent treatment interruption, or other risk factors disqualifying them from being down-referred to C-BART. The data used were extracted from the patients' electronic system, and some data elements were less complete, such as adherence scores, and viral load date and results. Additionally, data on patients' residence and distance from health facility was not available; therefore, the impact of distance from facility of C-BART site could not be explored. However, given the overall good outcomes of the ART program in Namibia, we anticipate no significant differences.

CHAPTER 4

VALIDATION STUDY

Assessment of Completeness and Accuracy of the electronic Patient Management System (ePMS) for Antiretroviral Therapy

4.1 Overview of the Study

Longitudinal data from electronic systems are increasingly used for medical research and observational studies[102][103]. However, some studies have raised issues regarding the quality of data from electronic systems[104][105]. Among the data issues identified were data incompleteness[106], data quality inconsistency and inaccuracy[107], poor documentation of services provided and erroneous reporting[104], [108], [109]; these are key issues affecting the quality of data from electronic systems. Convincingly, using data extracted from an electronic system can save time and money[110]. Namibia, for example, established a longitudinal electronic patient monitoring system in 2014, and by the end of 2017, over 150,000 patients on ART were entered into the electronic database. Therefore, it is essential to assess the completeness and accuracy of data in electronic databases for use in studies[110]. Findings from validation studies that focus on data quality, including completeness and accuracy[111], [112]can inform program managers and researchers to determine if available electronic medical records can be used for effective patient management and planning research[112].

This chapter presents the results on the assessment (validation) of the completeness and accuracy of data from the Namibia ART program electronic Patient Management System (ePMS) database compared with the facility's paper-based record, the Patient Care Booklet (PCB), as the standard reference. The PCB records patient encounters at each visit for ART services at the facility-based ART (F-BART) and the community-based ART (C-BART). Patients present to the ART sites with their health passports. The patients' unique ART numbers are written on the health passport. Staff at the ART sites collect these patient health passports to search for the patient care booklets, which are stored at the health facilities. Patients' consultation information is entered into the PCBs; minimum information is recorded in the health passport. The validation study focused on the completeness and accuracy of the ePMS, compared to the PCB, the source document. Clinicians complete the PCB during the patient's visit at the ART clinic or C-BART. A data entry clerk will then take the PCB after

the patient has been seen and transcribe the information documented during the visit into the ePMS.

This study assessed Namibia's antiretroviral program electronic data completeness and data accuracy by reviewing records of patients on ART seen between 01 January 2007 and 30 July 2017 at facility-based ART (F-BART) and community-based ART (C-BART) in the Okongo District compared to paper-based records in the PCB.

4.2 Methods

4.2.1 Study setting

The study was conducted in the Okongo District (one of the three health districts in the Ohangwena region) to inform the quality and usability of data extracted from the ePMS for program evaluation. The focus sites for the assessment were the Okongo District Hospital facility-based ART (F-BART) and the community-based sites in the Okongo District. The Okongo District was the first health district to implement the C-BART in Namibia. The study was nested in the C-BART program evaluation[113]. Therefore, two other clinics from the Okongo District, Ekoka and Omboloka, included in the initial study protocol, were excluded from the actual data collection because they were not part of the main C-BART evaluation.

The validation study was conducted to determine the completeness and accuracy of electronic data extracted from the ePMS for program evaluation. The ePMS captures data from the PCB at the facility level. Hence, the PCB is the standard reference patient data-capturing tool. At the national level, ePMS databases from all sites are merged into one for reporting. Therefore, data for a particular patient can be retrieved, even if the patient was seen at or unofficially transferred to a different health facility. A new PCB is opened for a patient transferred from another health facility. However, newly opened PCBs may be incomplete because patients do not move with the PCBs from one facility to another.

4.2.2 Study design

We conducted a retrospective medical records review of patients' records from the ePMS by selecting a random sample of patients' records for patients seen at C-BART and F-BART.

We then extracted data on selected variables from records of patients seen at C-BART and F-BART between 01 January 2007 and 30 July 2017 (study period). The study period was

adjusted from 01 October 2014 to 31 October 2016 to fit the study period for the main evaluation as stated above. The assessment was done between June/July 2018. We assessed the data completeness and accuracy of selected variables across ePMS and PCB. The PCB was considered the primary source document. Table 12 below shows 10 selected data elements assessed in this study.

Table 14: Data elements (variables) assessed for completeness and accuracy in ePMS and the paper-based PCB

Variable	Definition	Assessed in:	
		ePMS	PCB
Unique ART ID	Patient assigned 12-digits unique ART identification number assigned at enrolment into care	x	X
Sex	Sex (gender) recorded	x	X
Date of birth	Date of birth recorded	x	X
Date enrolled in care	Date patient enrolled in HIV care recorded	x	X
Date ART started	Date patient has started ART recorded	x	X
Date of the last visit	Date of last clinical visit recorded	x	X
Latest ART regimen	The latest ART regimen recorded	x	X
Next visit date	Date of the next clinical visit recorded	x	X
Last VL date	Date last viral load was taken		
Last viral load	Value of last VL, both numeric or nominal scale (TND; <20; <40) recorded	x	X

4.2.3 Study population and sampling

4.2.3.1 Sampling criteria

The study applied a Lot of Quality Assessment Sampling design (LQAS) to assess the completeness and accuracy of the electronic patient management system (ePMS). The LQAS was first used in the manufacturing industry to inspect lots to ensure that lots with many defective items are rejected, based on predetermined critical values[114], [115]. In this study, we first applied stratified sampling to generate lists of records of patients seen at F-BART and all 18 C-BART sites as non-overlapping strata. The F-BART (Okongo District Hospital) was considered as one lot, and all 18 C-BART sites as another lot. We then randomly selected records from each lot to form the final sample. Selected patient records with data elements of

interest were extracted from the central level ePMS database, exported into an Excel spreadsheet, and checked against the paper-based PCBs at the site level[114], [115].

LQAS does not require a large sample; a minimum of 10% of the population under study should be sufficient. This study included a sample of 10% of the total records from each lot. The sample was calculated based on the number of patients initiated on ART as per Table 15. The LQAS method uses a binary method to test the null hypothesis and only rejects the null hypothesis if there is overwhelming evidence. The LQAS design that rejects a null hypothesis is the preferred approach to using LQAS worldwide[115]; this study used the LQAS method to test the null hypothesis about the accuracy and completeness of C-BART and F-BART ePMS data. The responses are **binary**, indicating whether C-BART and F-BART ePMS are **incomplete**, **complete**, **inaccurate**, or **accurate**. The WHO recommends an acceptable threshold for electronic data accuracy and completeness of 80%[116]. Hence, this recommended 80% was set as the acceptable threshold level of completeness and accuracy for accepting a lot in this study, as per the LQAS principles. Therefore, for this study, the null hypothesis (Ho) was that data in C-BART and F-BART ePMS are incomplete and inaccurate; the significance level was set at 0.05. The alternative hypothesis (Ha) was that C-BART and F-BART ePMS data are complete and accurate. This study design was inspired by the work of Rhoda et al.[115] to apply a process of LQAS design that constructs a protective null hypothesis. A protective null hypothesis can protect the population in case of a malady[115]; in this case, the malady would be a false assurance of data quality, the assumption that the data is complete and accurate when it is not.

4.2.3.2 Study population

This study used a sample of routinely collected data for HIV-infected adult (>15 years) patients ever initiated ART between 2007 and 2017 in the Okongo District, Namibia. First, the Okongo District Hospital and 18 C-BART sites were included in the study. These facilities were stratified into two strata and considered "lots". The Okongo District Hospital (F-BART) was regarded as one lot, and all 18 C-BART sites were considered another. Second, a random sample was selected depending on the total number of adult patient records (>15 years) who initiated ART between 01 January 2007 to 31 July 2017 at each site. Therefore, based on the

LQAS, C-BART and F-BART are “lots”, and a sample of records was sampled from each lot[117].

4.2.3.3 Sample size

We first generated data of patients on ART at the Okongo Hospital from the “ePMS card first”. The card first is the record in ePMS that captures all information about each patient’s first visit and the last ART regimen and status. A total of 2302 patient records from the “ePMS Adult Card first” were generated. Next, we reviewed the data from the card follow-up window to compare whether all patient records under the card first list appeared on the card follow-up. The card follow-up is the record in ePMS that captures all information about each patient’s follow-up visit. There were 2518 records for adult card follow-up from ePMS; 222 had no card first records and were excluded.

From the remaining 2296 records, we randomly selected 230 records, which we rounded off to get the 10% sample of the remaining records (Table 13). We used the same process to select a sample for the C-BART sites randomly. For C-BART, 616 records were generated from the card first and matched card follow-up. Therefore, 10% of 616, equivalent to 61 records, were included in the study. The final sample of 291 records, including 230 from the Okongo Hospital ART (F-BART) and 61 from the C-BART sites, were included. The samples used in the validation study (Phase II B) were from records in the retrospective cohort study (Phase II A).

Table 15: Sample size per lot

Lot No.	Site Name	Site Type	# of Adult Pts initiated ART and with a follow up visit 2007-2017	Sample size
1	Okongo	District Hospital (F-BART)	2296	230
2	Okongo	C-BART sites (C-BART)	616	61
			Total Samples	291

4.3 Data collection and management

The study included ten (10) variables related to patients' sociodemographics, clinical characteristics, and ART status. These data elements of interest were collected from all C-BART and F-BART records. Each data variable collected was entered into an Excel spreadsheet. To assess completeness and accuracy, data elements extracted from the ePMS and PCB included unique patient ART ID (Unique ART ID); sex (gender); date of birth; date enrolled into HIV care; date ART started; date of the last visit; latest ART regimen; next visit date; last viral load date and last viral load (results). In addition, a list of randomly selected records of adult patients-initiated ART from 01 January 2007 to 31 July 2017 at the Okongo District was generated from the central level ePMS consisting of the data elements above. The generated lists of records for the Okongo F-BART and C-BART sites were exported and saved in Microsoft Excel 2013, irrespective of the latest ART status. Every *n*th record was selected from each lot as per the sample size in Table 13. The list of records generated from ePMS was used to locate the PCBs at the facility for review. Data collected from PCB were entered into the same Excel spreadsheet, which was exported from ePMS to form a composite validation database for analysis.

4.4 Data Analysis

For analysis, data entered into Microsoft Office Excel 2013 formed a composite validation database with C-BART and F-BART data elements of interest. The Excel database was exported to the Statistical Software package (Stata Corporation, College Station, TX, USA) for statistical analyses. Descriptive statistics were used to calculate the frequencies for the data recorded on each of the ten (10) selected data elements for validation. Data on selected variables was analysed for completeness and accuracy, stratified by F-BART and C-BART.

We used descriptive statistics to calculate the frequencies of data recorded for each variable to determine the accuracy and completeness of each variable. We analysed the proportion of matched variables between the ePMS and PCB for C-BART and F-BART records. Completeness for all variables in a lot was analysed by looking at the proportion of data elements of interest recorded in the central ePMS. All proportions were presented as a percentage. Rhonda et al.[115]recommend pre-selection of the proportion threshold of interest for use in testing the null hypothesis (2010).

For this study, we chose the WHO's data quality threshold of 80%[116]. This threshold formed the basis of the null hypothesis we constructed. A lot was rejected as incomplete or inaccurate if it was less than 80% complete and accurate.

The counts of data elements complete and accurate from C-BART ePMS records were combined to calculate the aggregated proportions for completeness of C-BART ePMS. The same steps were repeated for F-BART ePMS and for finding the aggregated proportion of accuracy for C-BART and F-BART ePMS. This approach is recommended because the denominator for data completeness and accuracy of each data element may vary[115]. A one-tailed Z-score test was used to test the null hypothesis[118]; and to statistically inform conclusions on the completeness and accuracy of C-BART and F-BART ePMS.

4.4.1 Demographic and clinical characteristics of the sample

Age and sex were key demographic characteristics collected as key variables of interest for this validation study. In addition, clinical characteristics such as the date ART started were used to compute the patients' duration on ART. Similarly, the latest ART regimen was used to classify and describe the sample by the latest ART regimen, using the "backbone" ART regimen. Lastly, the viral load results were reported as ≥ 1000 and < 1000 copies per ml.

4.4.2 Assessment of data completeness

Data completeness assessment was based on the completeness of each data element extracted from the ePMS database. ePMS data completeness is the extent to which the data elements of interest are completed or filled out in the ePMS from the source document, the PCB[119]. The hypothesised acceptable level of data completeness was set at 80%.

- **In step 1**, we assessed the extent to which each of the ten (10) data elements was completed in the C-BART ePMS records by determining the number of complete data elements.
- **Step 2**: We then determined the percentage of records complete, generated by dividing number of complete data elements from all records by the total number of data elements of interest from all records, multiplied by 100%.
- **In Step 3**: We repeated all steps above to assess the completeness of the F-BART ePMS records.

- **In Step 4:** To determine the overall level of ePMS completeness for the two “lots” the C-BART and F-BART, we calculated proportions completeness for C-BART and F-BART ePMS records.
- **Step 5:** We tested the null hypothesis for C-BART and F-BART ePMS completeness, as outlined in sections below. The hypothesised acceptable level of data completeness was set at 80%.

4.4.3 Assessment of data accuracy

Data accuracy was assessed by comparing if the data element in ePMS matched the data element in the PCB. Data accuracy is the extent to which recorded data value in ePMS reflects the data value from the source document or the actual value[110][119]. In this study, accuracy is defined as the extent to which the data variables recorded in central level ePMS match or replicate the actual data variables in the paper-based HIV PCB. The PCB is the standard reference tool for data capturing of patient encounters in the ART clinic/setting. Hence, the ePMS should reflect what is in the PCB. However, limitations such as transcription error may also contribute to the non-matching of variables captured in the ePMS. The acceptable proportion threshold level of data accuracy was set at 80%.

- **Step 1:** We assessed the extent to which each of the 10 data elements was replicated accurately in the C-BART ePMS record as recorded in the PCB by determining the number of accurate data elements. Missing and incomplete data elements were excluded from the analysis for accuracy. Hence, the denominator only included completed variables.
- **Step 2:** We then determined the percentage of accurate records generated by dividing the number of accurate data elements for each variable in ePMS by the total number of data elements of interest reported completed, multiplied by 100%.
- **Step 3:** We repeated all steps above to assess the accuracy of the F-BART ePMS records.
- **Step 4:** To determine the overall level of ePMS accuracy for the two "lots", the C-BART and F-BART, we calculated proportions accuracy for C-BART and F-BART ePMS records.

- **Step 5:** We then tested the null hypothesis for C-BART and F-BART ePMS accuracy as outlined in sections below. The hypothesised acceptable level of data accuracy was set at 80%.

4.4.4 Testing the null hypothesis

We used a one-tailed Z-test to test the null hypothesis. The completeness and accuracy of C-BART and F-BART ePMS were assessed, based on the WHO's threshold of 80% as an acceptable level of completeness and accuracy. The sample size for C-BART was (n = 60) and F-BART (n = 229).

4.4.4.1 C-BART and F-BART ePMS completeness

In step 1, we defined the null and alternative hypotheses. The null hypothesis states that the true proportion of data in the central ePMS for a patient seen at C-BART and F-BART is incomplete (<80%). The alternative hypothesis states that the true proportion of data in the central ePMS for patients seen at C-BART and F-BART is complete ($\geq 80\%$). The hypotheses are expressed below:

$H_0: \hat{p} < 0.8$ (the null hypothesis is that data is incomplete)

$H_a: \hat{p} \geq 0.8$ (the alternative hypothesis is that data is complete)

In step 2: To determine the significance level, the study used a 5% significance level.

In Step 3: We calculated the Z-test statistic for completeness as presented by the expression below:

$$Z = \frac{\hat{p} - p}{\sqrt{pq/n}}, \text{ where } q = 1 - p$$

In the above steps, “**p**” represents the sample proportion of data completeness, whereas “**P**” represents the hypothesised data completeness proportion under the null hypothesis (10 variables) of interest, were tested individually to determine the completeness records (elements) in each variable. For C-BART, there were 10 variables from EPMS for 60 records, giving a total of 600 elements, which were tested within their individual variables. In addition,

F-BART also consisted of 10 variables from ePMS with 229 records (elements) each. The latter added up to 2290 elements, which were tested within their individual variables for completeness. Therefore, each variable under C-BART (n = 60) and each variable under F-BART (n = 229) were analysed.

In Step 4: The null hypotheses were rejected if the p-value for each variable in the C-BART ePMS and F-BART ePMS was less than or equal to the significant value 0.05.

4.4.4.2 C-BART and F-BART ePMS accuracy

In step 1, we defined the null and alternative hypotheses. The null hypothesis was that the proportion of data in the central ePMS for a patient seen at C-BART and F-BART is inaccurate. The alternative hypothesis was that the proportion of data in the central ePMS for patients seen at C-BART and F-BART is accurate. The hypotheses are expressed below:

$$H_0: \hat{p} < 0.8 \text{ (the data is inaccurate)}$$

$$H_a: \hat{p} \geq 0.8 \text{ (the data is accurate)}$$

In step 2: To determine the level of significance, the study used a 5% (0.05) significance level.

In Step 3: We calculated the Z-test statistic for accuracy as presented by the expression:

$$Z = \frac{\hat{p} - p}{\sqrt{pq/n}}, \text{ where } q = 1 - p$$

In the above steps, “**p**” represents the sample proportion of data accurate, whereas “**P**” represents the hypothesised data accuracy proportion under the null hypothesis. A total of 10 variables of interest were tested individually to determine each variable's accuracy (elements). C-BART has 10 variables with 60 records (elements) each. The latter totalled 600 elements, which were tested within their individual variables. In addition, F-BART also consisted of 10 variables with 229 records (elements) each. The latter totalled 2290 elements, which were tested within their individual variables for accuracy. Therefore, for each variable under C-BART (n = 60) and each variable under F-BART (n = 229)

In Step 4: The null hypotheses were rejected if the p-value for each variable in the C-BART ePMS and F-BART ePMS was less than or equal to the significant value, 0.05.

4.5 Ethics Considerations

Permission was sought and granted to access selected variables from the National ePMS databases hosted at the national level, the Response and Monitoring and Evaluation (RME) subdivision, Directorate of Special program, Ministry of Health and Social Services. We worked with the data manager assigned from the subdivision to extract data on selected variables from ePMS in the researcher's presence. Since the database contains patients' names, the randomly generated list was de-identified by removing all names. The unique patient ID was kept, allowing identification of PCB at the facility level for assessment and comparison. The regional director and district supervisor were informed about the data validation study. The district supervisor and staff at the ART clinic were given the background to ensure they understood the study's purpose and data collection methods.

4.6 Results

A total of 291 unique patient records were extracted from the ePMS database at the national level, consisting of 61 C-BART and 230 F-BART records. Two (2) PCBs, one (1) from C-BART and one (1) from F-BART, were not found at the facility and were thus excluded from the analysis.

The generated list was de-identified by removing patients' names. We then located the patient care booklets at the Okongo Hospital ART clinic using the unique patient ART IDs as identifiers for the C-BART and F-BART PCBs. All PCBs are kept (filed) in lockable steel cabinets at the Okongo Hospital ART clinic. The PCBs were reviewed and entered into an Excel sheet with data already generated from the ePMS (validation study database).

4.6.1 Demographic and clinical characteristics of the sample

The median age of patients included in the study was 31 years (IQR 24-37). The table below shows that 55% of patient records sampled at C-BART were females, compared to 69% at F-BART. Similarly, 45% of patient records sampled at C-BART were male, while at F-BART, 31%. Most patients have been on treatment for 5 years or more (63%). In addition, overall, most patients (72%) were on a Tenofovir-based regimen, which is the preferred base.

Table 16: Demographic and clinical characteristics of adult patients seen at C-BART and F-BART included in the validation study (n=298*)

	Overall n = 289 n (%)	C-BART n = 60 n (%)	F-BART n = 229 n (%)
Age, Median, years (IQR)	31 [24-37]	29 [23-35]	32 [26-38]
Sex			
Male	98 (33.9)	27 (45.0)	71 (31.0)
Female	191 (66.1)	33 (55.0)	158 (69.0)
Duration on ART**			
< 4 months	27 (9.3)	3 (5)	24 (10.5)
4-6 months	1 (0.4)	0 (0)	1 (0.4)
7-11 months	8 (2.8)	1 (1.7)	7 (3.1)
1-2 years	45 (15.6)	14 (23.3)	31 (13.5)
3-4 years	26 (9)	9 (15)	17 (7.4)
5-6 years	35 (12.1)	12 (20.0)	23 (10.0)
7-8 years	39 (13.5)	9 (15.0)	95 (41.5)
9-10 years	104 (36.0)	9 (15.0)	95 (41.5)
Unknown	4 (1.4)	3 (5.0)	1 (0.4)
Latest ART Regimen			
Abacavir (ABC)-based regimen	4 (1.4)	1 (1.7)	3 (1.3)
Zidovudine (AZT)-based regimen	58 (20.1)	9 (15.0)	49 (21.4)
Didanosine (D4T)-based regimen	19 (6.6)	0 (0.0)	19 (8.3)
Tenofovir (TDF)-based regimen	208 (72.0)	50 (83.3)	158 (69.0)
Latest Viral Load			
≤ 1000 copies/ml	191 (66.1)	34 (56.7)	157 (68.6)
>1000 copies/ml	25 (8.7)	4 (6.7)	21 (9.2)
Unknown	73 (25.3)	22 (36.7)	51 (22.3)

*Two PBCs were not found at the site during the validation exercise, hence excluded from the study.

**Duration on ART is the number of months from the date started ART to the last visit date.

4.6.2 Data completeness

We retrieved the PCBs by matching C-BART and F-BART records generated from ePMS with the PCB at the facility by unique ART ID. Ninety-nine, 99% (n = 289) of 291 records with unique ART ID matched between the ePMS and PCB, meaning the PCB was found at the facility level and allowed for validation of selected data elements. The non-matching records included two (n = 2;1%) records in the ePMS dataset, whose PCBs were not found at the facility, one (1) C-BART and F-BART record each. The files might have been misplaced, particularly for C-BART PCBs that are filed according to C-BART sites and not sequential unique ART IDs, making it difficult to trace the files.

4.6.2.1 Proportion of data completeness

For the analysis, a variable was considered completed if a value was entered on that specific data element field in ePMS. For completeness, we did not compare ePMS and PCB record entries to determine whether a data element was entered accurately or not, as long as it was filled in. The denominator for analysing completeness was (n = 289). The two (2) PCBs, which could not be found at the facility during the validation process, were excluded from the denominator.

Table 17: Completeness of ePMS records of adult patients seen at C-BART and F-BART included in the validation study compared to the PCBs: Okongo Hospital, 2007-2017 (n=298*)

	Overall n = 289 n (%)	C-BART n = 60 n (%)	F-BART n = 229 n (%)
Unique ART ID			
Completed	289 (100.0)	60 (100.0)	229 (100.0)
Not completed	0 (0.0)	0 (0.0)	0 (0.0)
Sex			
Completed	289 (100.0)	60 (100.0)	229 (100)
Not Completed	0 (0.0)	0 (0.0)	0 (0.0)
Male, completed	97 (100.0)	27 (100.0)	71 (100.0)
Not completed	0 (0.0)	0 (0.0)	0 (0.0)
Female, completed	192 (100.0)	33 (100.0)	158 (69)
Not completed	0 (0.0)	0 (0.0)	0 (0)
Date of birth			
Completed	289 (100.0)	60 (100.0)	229 (100.0)
Not completed	0 (0.0)	0 (0.0)	0 (0.0)
Date enrolled in care			
Completed	289 (100.0)	60 (100.0)	229 (100.0)
Not completed	0 (0.0)	0 (0.0)	0 (0.0)
Date ART Started			
Completed	289 (100.0)	60 (100.0)	229 (100.0)
Not completed	0 (0.0)	0 (0.0)	0 (0.0)
Date of the last visit			
Completed	285 (98.6)	56 (93.3)	229 (100.0)
Not completed	4 (1.4)	4 (6.7)	0 (0.0)
Latest ART regimen			
Completed	289 (100.0)	60 (100.0)	229 (100.0)
Not completed	0 (0.0)	0 (0.0)	0 (0.0)
Next visit date			
Completed	268 (92.7)	41 (68.3)	227 (99.1)
Not completed	21 (7.3)	19 (31.6)	2 (0.9)
Last VL date			

Completed	217 (75.0)	38 (63.3)	179 (78.2)
Not completed	72 (25.0)	22 (36.7)	50 (21.8)
Last Viral Load			
Completed	216 (74.7)	38 (63.3)	178 (77.7)
Not completed	73 (25.3)	22 (36.7)	51 (22.3)

*The initial sample extracted from ePMS contained 291 records; however, 2 PCBs were not found at the facility during the validation process, and hence, excluded, the final sample size was (n = 289).

Table 18: Summary of complete ePMS data elements by C-BART and F-BART

Variables	C-BART (n=60)			F-BART (n=229)			All ART Model (n=289)		
	n complete	% complete	P-value ^a	N complete	% complete	P-value ^a	N complete	% complete	P-value ^c
Unique ART ID	60/60	100	0.01	229/229	100	<0.01	289/289	100	<0.01
Sex	60/60	100	0.01	229/229	100	<0.01	289/289	100	<0.01
Date of birth	60/60	100	0.01	229/299	100	<0.01	289/289	100	<0.01
Date Enrolled in Care	60/60	100	0.01	229/229	100	<0.01	289/289	100	<0.01
Date ART Started	60/60	100	0.01	229/229	100	<0.01	289/289	100	<0.01
Date of the last visit	56/60	93	0.04	229/229	100	<0.01	289/289	100	<0.01
Latest ART Regimen	60/60	100	0.01	229/229	100	<0.01	229/229	100	<0.01
Next Visit Date	41/60	68.3	0.98	227/229	99.1	<0.01	229/229	100	<0.01
Last VL date	38/60	63.3	0.99	179/229	78.7	0.75	229/229	100	<0.01
Last Viral Load	38/60	63.3	0.99	178/229	77.7	0.80	229/229	100	<0.01

Total missing Values	67/600	11.17%		103/2290	4.50%	-
Total values completed	533/600	88.83%		2187/2290	95.50%	-
Total Number of Elements	600	100.0%		2290/2290	100.0%	-

^aTest of the null hypothesis that the proportion complete is less than 80%. p-value=>0.05

^bTest of the null hypothesis that this is no difference in completeness between C-BART and F-BART, p-value=>0.05.

Table 16 shows that only three variables of the 10 variables tested in the C-BARTs have a p-value greater than the significant value of 0.05; thus, the null hypothesis is rejected.

Therefore, there is statistical significance to conclude that the proportion of completeness is greater than 80% in C-BART. Similarly, Table 16 illustrates that the two variables, last VL date and last VL results, have a p-value greater than 0.05 significance level; therefore, the null hypothesis is retained and concludes that the proportion of completeness in the latter two variables is less than 80%

Based on the table above, the total C-BART data elements for all 10 data elements combined were (n = 600), and 533 were completed. Whereas, for F-BART, the total data elements (variables) of interest were (n = 2290), and 2189 were completed. Most of the data elements (sex, date of birth, date started ART, date of the last visit, and latest ART regimen show a statistically significant completion greater than 80% in both C-BART and F-BART. However, the last viral load data and last viral load results elements show a statistically significant result in completion for F-BART data, and C-BART data.

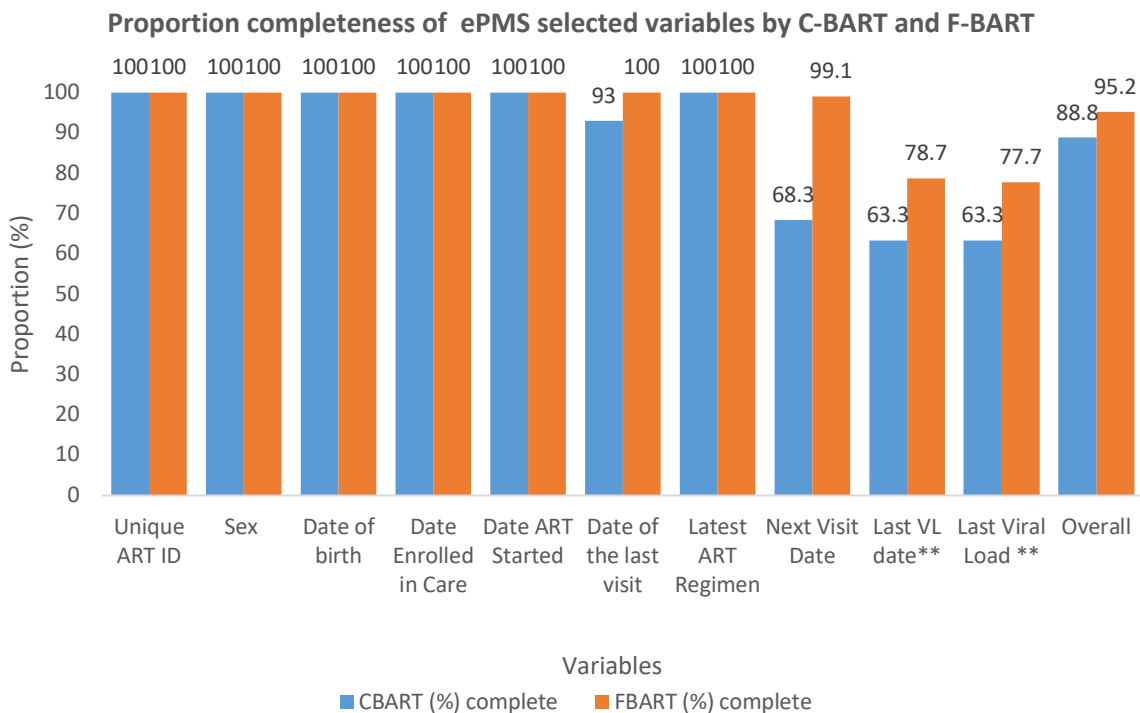


Figure 11: Proportion completeness of ePMS selected variables by C-BART and F-BART

The proportion of completeness for data elements for all 10 variables combined was calculated to determine the overall proportion completeness of C-BART and F-BART ePMS as “lots” of interest.

$$\text{Proportion C – BART ePMS Complete (p)} = \frac{\text{Number of complete data elements}}{\text{Total number of data elements of interest}} = \frac{533 \times 100}{600} = 88.83\%$$

The proportion of C-BART ePMS data completeness is 88.83%

$$\text{Proportion F – BART ePMS Complete (p)} = \frac{\text{Number of complete data elements}}{\text{Total number of data elements of interest}} = \frac{2187 \times 100}{2290} = 95.50\%$$

The proportion of F-BART ePMS data completeness is 95.50%

4.6.3 Data accuracy

4.6.3.1 Proportion of data accuracy

The denominator for each variable is the number of records reported as completed in ePMS in Table 15 above. This varies from variable to variable. A variable recorded in ePMS is considered accurate if the value of that variable in ePMS is replicated/matches the value of the variable for the same record in the PCB.

Table 19: Accuracy of completed ePMS records of adult patients seen at C-BART and F-BART included in the validation study compared to data in PCBs: Okongo Hospital, 2007-2017 (n=289, unless the variable was not 100% completed in Table 16)

Variables	Overall n =289 n (%)	C-BART n = 60 n (%)	F-BART n = 229 n (%)
Unique ART ID			
Accurate	289 (100.0)	60 (100.0)	229 (100.0)
Not accurate	0 (0.0)	0 (0.0)	0 (0.0)
Sex (n = 286*)			
Missing	3 (1)	3 (5)	0 (0)
Female (n = 189*)			
-			
Accurate	189 (100.0)	31 (100.0)	158 (100.0)
Not accurate	0 (0.0)	0 (0.0)	0 (0.0)
Missing	2	2	0
Male (n = 97*)			
Accurate	97 (100)	26 (100.0)	71 (100.0)
Not accurate	0 (0.0)	0 (0.0)	0 (0.0)
Missing	1	1	0
Date of birth (n = 275*)			
Accurate	275 (100.0)	46 (95.8)	229 (100.0)
Not accurate	0 (0)	2 (4.2)	0 (0.0)
Missing	14	12	0
Date enrolled in care (n = 280*)			
Accurate	289 (96.9)	51 (100.0)	229 (100.0)
Not accurate	0 (0)	0 (0.0)	0 (0.0)
Missing	0	9	0
Date ART Started (n = 287*)			
Accurate	287 (100.0)	58 (100.0)	229 (100.0)
Not accurate	0 (0)	0 (0.0)	0 (0.0)
Missing	2	2	0

Date of the last visit (n = 286*)			
Accurate	286 (100.0)	57 (100.0)	229 (100.0)
Not accurate	0 (0)	0 (0.0)	0 (0.0)
Missing	3	3	0
Latest ART regimen (n = 289)			
Accurate	289 (100)	60 (100)	229 (100)
Not accurate	0 (0.0)	0 (0.0)	0 (0.0)
Missing	0	0	0
Next visit date (n = 267*)			
Accurate	266 (99.6)	40 (100.0)	226 (99.6)
Not accurate	1 (0.4)	0 (0.0)	1 (0.4)
Missing	22	20	2
Last Viral Load date (n = 228*)			
Accurate	213 (93.5)	38 (100.0)	175 (92.1)
Not accurate	15 (6.5)	0 (0.0)	15 (7.9)
Missing	73	22	51
Last Viral Load result (n = 228*)			
Accurate	215 (94.3)	38 (100.0)	177 (93.2)
Not accurate	13 (5.7)	0 (0.0)	13 (6.8)
Missing	73	22	51

*Missing refers to data elements not completed in PCB. Hence, comparison for accuracy is not possible for those records. The number indicated under missing data includes using non-standardised values for viral load date and results, "N/A" as recorded in ePMS and PCB instead of a date or value.

Accuracy assessment is based on the number of records with variables of interest completed. Therefore, the denominators for each variable assessed for accuracy vary based on the number of records assessed and reported as completed for each variable per the summary table below.

Data accuracy is the extent to which recorded data value in ePMS reflects the data value from the source document or the actual value[110], [119]. This study defines accuracy as the extent to which the data variables recorded in central level ePMS match/replicate the actual data variables in the paper-based HIV PCB.

Table 20: Summary of ePMS data elements accurately entered into ePMS as recorded in the PCB by C-BART and F-BART

Variables	C-BART			F-BART			All ART Model (n=289)		
	n accurate ^a	% accurate	P-value ^b	n accurate ^a	% accurate	P-value ^b	n accurate	% accurate	P-value ^c
Unique ART ID	60/60	100.0	<0.01	229/229	100.0	<0.01	289/289	100.0%	<0.01
Sex	57/57	100.0	<0.01	229/229	100.0	<0.01	286/286	100.0%	<0.01
Date of birth	46/48	95.8	<0.01	229/229	100.0	<0.01	275/277	99.3%	0.02
Date Enrolled in Care	51/51	100.0	<0.01	229/229	100.0	<0.01	280/280	100.0%	<0.01
Date ART Started	58/58	100.0	<0.01	229/229	100.0	<0.01	287/287	100.0%	<0.01
Date of the last visit	57/57	100.0	<0.01	229/229	100.0	<0.01	286/286	100.0%	<0.01
Latest ART Regimen	60/60	100.0	<0.01	229/229	100.0	<0.01	289/289	100.0%	<0.01
Next Visit Date	40/40	100.0	0.08	226/227	99.6	<0.01	268/269	99.6%	0.69
Last VL date	38/38	100.0	<0.01	175/190	92.1	0.01	213/228	93.4%	0.07
Last Viral Load	38/38	100.0	<0.0010	177/190	93.2	<0.0001	215/228	94.3%	0.09

^aNumber of data elements assessed for accuracy is based on the number of data elements replicated in ePMS from the PCB as the source document. Only data elements with the data element completed in PCB and ePMS were included in the denominator in C-BART and F-BART.

^bTest of the null hypothesis that the proportion accurate is less than 80%. $p\text{-value} > 0.05$

^cTest of the null hypothesis that this is no difference in accuracy between C-BART and F-BART, $P\text{-value} > 0.05$

Total element inaccurate	2/507	0.4%		29	1.3%	
Total element accurate	505/507	99.6%		2181	98.7%	
Total expected element	507			2210		

It is illustrated in Table 18 above that C-BART has about 3 variables with inaccurate information, while F-BART has only two such variables. It can also be seen that all p-values in both C-BART and F-BART have less than a 0.05 significance value; thus the null hypothesis is rejected. Therefore, there is a statistical significance to conclude that the proportion of accurateness is greater than 80% in both C-BART and F-BART.

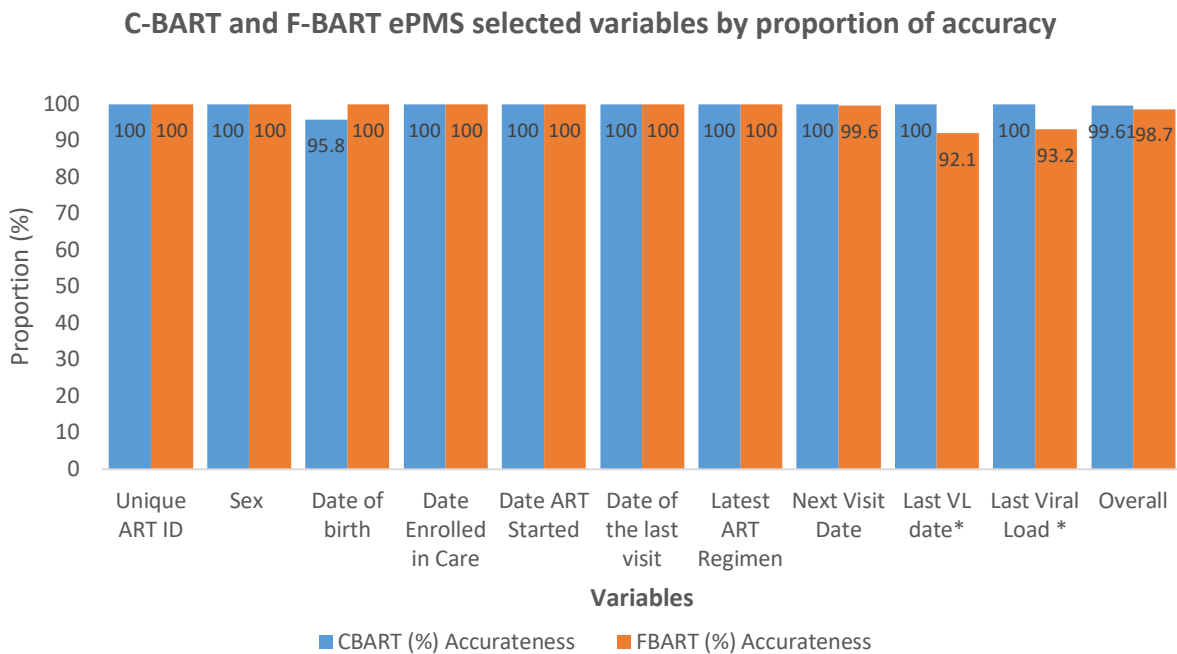


Figure 12: Proportion accuracy of ePMS selected variables, by C-BART and F-BART

The proportion of accuracy for data elements of interest was calculated to determine the overall accuracy of C-BART and F-BART ePMS as "lots" of interest.

$$\begin{aligned} \text{Proportion F – BART ePMS accurate (p)} &= \frac{\text{Number of data elements replicated accurately between ePMS and PCB}}{\text{Total number of data elements of interest being correlated}} \\ &= \frac{505 \times 100}{507} = 99.61\% \end{aligned}$$

The proportion of C-BART ePMS data accurate is 99.61%

$$\begin{aligned} \text{Proportion F – BART ePMS accurate (p)} &= \frac{\text{Number of data elements replicated accurately between ePMS and PCB}}{\text{Total number of data elements of interest being correlated}} \\ &= \frac{2181 \times 100}{2210} = 98.96\% \end{aligned}$$

The proportion of accurate F-BART ePMS data is 98.96%.

4.7 Discussion

This study assessed the completeness and accuracy of data in the electronic ePMS for patients on ART seen at C-BART and F-BART in the Okongo District.

The proportion of data completeness of ePMS data for C-BART patients' records was found to be acceptably higher than 80% (88.83%) and for F-BART patients' records at 95.2%. Similarly, the proportion of data accuracy of ePMS for C-BART and F-BART patient records was high at 98.96% and 99.61%, respectively. The proportions of completeness and accuracy surpass the WHO's threshold for an acceptable level of completeness and accuracy, i.e. 80%.

Previous studies focusing on the completeness and accuracy of electronic data for ART reported a level of completeness and accuracy in the same range. For example, a study conducted at a large public-sector outpatient HIV clinic in Mozambique assessed the completeness, accuracy and reliability of data elements of interest from the electronic system compared to paper-based records. Completeness was 72% at enrolment, but it declined to 65% at follow-up visits, and accuracy was 95% and 84% at the follow-up visits, respectively[110]. A similar pattern with declining data completeness and accuracy of data elements from first visits compared to follow-up visits was also observed in a study in HIV clinics in Zambia[120]. In addition, a South African study assessed the completeness and accuracy of electronic data from an HIV clinic compared to laboratory surveillance data for VL and CD4. Data completeness was reported to be 83.9%, and only 0.3% of data were inaccurate[121].

According to the null hypothesis testing results in sections 4.4.4.1 and 4.4.4.2, we can infer that data completeness and accuracy in C-BART and F-BART ePMS met the WHO's acceptable data quality standard threshold of 80% and above. The findings reject the null hypothesis that C-BART and F-BART ePMS are incomplete and inaccurate. Therefore, we accept the alternative hypothesis that ePMS data for patients seen at C-BART and F-BART are complete and accurate. Although there were variations in completeness and accuracy for some data elements, the study found no statistically significant differences in completeness and accuracy between the lots, i.e. C-BART and F-BART ePMS. Therefore, we conclude that C-BART and F-BART ePMS are complete and accurate for use in evaluation studies.

The application of null hypothesis testing methods and results demonstrated the usability of LQAS to assess the completeness and accuracy of routinely collected ART data at C-BART and F-BART, which were considered as “lots”. Therefore, as quality assurance, we conclude that the data extracted from the ePMS and used in the retrospective cohort presented under Chapter 5 of this study is acceptably complete and accurate.

Prior studies that assessed the completeness and accuracy of electronic records emphasised the importance of data in electronic medical records, health information systems and electronic data systems; and suggested the usability of data extracted from electronic patient systems for cost-effective research and evaluation studies. However, the quality of data dimensions, such as completeness and accuracy, remains challenging. A study was conducted in Malawi to assess the completeness and accuracy of the prevention of mother-to-child transmission of HIV. Some data systems are reported to produce incomplete, inaccurate or inconsistent data, which compromises efforts to improve the quality of services. Complete and accurate data is needed for decision-making to improve programs, health services delivery, patient care and outcomes[110], [112], [118], [122]–[124]: [125].

One interesting finding from this study is the high data accuracy (100%) level for viral load date, viral load result and next visit date for C-BART and F-BART ePMS records. The results clearly demonstrate that completed data elements are transcribed accurately from source documents into ePMS. We learned during data collection that viral load (collection) date and results are transcribed from an individually printed result report generated from the MEDITECH systems, so there might be limited HCWs transcription errors. However, while the accuracy of capturing data is good, completeness of the next visit date for C-BART patients is low (68.3%), as are the last viral load date and viral load result (63.3%). These indicators are also somewhat low in F-BART at 78.7% and 77.7%, respectively. Therefore, the percentage completed for each data element above falls below the WHO’s standard threshold of 80%. These findings of low level of completeness of the above data element can be explained by the known challenges of non-real-time, manual data capturing of patient data into electronic data systems due to non-interoperability between various data systems used for the same patient, such as laboratory, pharmaceutical and patient care data systems. Given the limitation of possible overstated accuracy for these three data elements, the results need to be interpreted cautiously. Lack of real-time data capturing during the patients’ visits and lack of data quality prompts increases the chance of data incompleteness and inaccuracy[122].

In reviewing the literature, no data was found on studies assessing the completeness and accuracy of the ePMS for ART, explicitly using an LQAS method and comparing the completeness and accuracy of data in ePMS among patients seen at C-BART compared to F-BART. Most studies compared completeness and accuracy between HIV or ART electronic systems and paper-based records, but not between the facility and community-based care electronic records. On that account, the findings in this study are positive and reassuring to know that even the quality of electronic data of patients seen in community-based models is acceptably complete and accurate and can confidently be used in studies.

The above findings are significant and valuable to inform practice and further research. One implication of this study is that quality electronic data capturing can also be done effectively in C-BART models. Second, improving data capturing and completeness for viral load results and leveraging them to a high level, given that viral suppression is the ultimate goal for treatment success, is key.

Of equal importance, the findings revealed low completeness of the next visit date at C-BART (68.3%) compared to F-BART (99.1%). The implications of not having the patients' next visit dates completed or inaccurate may appear to be incorrectly reported as non-retained or retained, affecting final patient outcome analyses, tracing those lost to follow-up, and bringing them back in care. Similarly, resources and time can be wasted, while tracing patients who are incorrectly reported as non-retained. Despite the lack of complete documentation of the next visit date in ePMS, it does not necessarily translate into patients missing their follow-up visits, because C-BART are visited on fixed outreach scheduled dates, which are announced through the radio, schools and other community platforms, including reminders by the community health workers. Since patients are synchronised into one cohort, most, if not all, visit the site when the outreach team is visiting. The Okongo District implemented a data quality improvement project, based on immediate feedback given during data collection to improve the completeness and accuracy of ePMS data.

Despite these promising results, further research should be undertaken to holistically assess human health, i.e., HCWs and patients, health delivery and data systems-related factors contributing to data incompleteness and inaccuracy to inform further interventions. LQAS can be applied easily for binomial hypothesis tests for small samples from multiple districts or groups[115]. Hence, the use of LQAS in studies assessing data completeness and accuracy should be further explored as it presents opportunities to statistically test for the overall proportion of small samples and binary outcomes. This refers to incompleteness or inaccurate

OR complete or accurate for a sample from a dataset in comparison to hypothesised proportions, or acceptable standards or thresholds. As extraction of routinely collected data available in electronic data systems is becoming increasingly used in research, this approach will aid researchers in extracting a 10% sample of data to determine if the level of completeness and accuracy achieved makes the “lot” or dataset suitable for use in a comprehensive study.

4.8 Limitations

The validation study was nested on a C-BART evaluation. The C-BART evaluation sample was large enough, but not representative of all ART sites in Namibia. It was limited to the Okongo Health District and cannot be generalised to all of Namibia's districts. The Okongo District was the first to implement community-based ART services; hence, there might have been data issues emanating from limited guidance at the start of C-BART services and the self-referrals of patients from F-BART to C-BART and vice versa. The picture may look completely different in other districts. Additionally, there was limited use of electronic data capturing systems and a shortage of data clerks for data capturing in the early years of C-BART implementation, which may have contributed to incomplete data capturing.

The National ART Guidelines paper is updated regularly, and changes in VL monitoring interval, VS level, and reporting style may vary yearly. In addition, the use of non-standardised entries for viral load result values was observed both in ePMS and PCB, ranging from "TND", "Target Not Detected", "N/A", "0", "20", "40", "<40" and other numeric figures, this might have led to transcription errors between ePMS and PCB.

The assessment for data accuracy was based on data elements completed as stated in the method and data analysis sections, excluding missing data or data that was completed but used non-standardised values. In particular, the analysis of accuracy for a viral load test date, viral load results and next visit date had limitations due to the low proportion of completion for these data elements. As indicated in the result section, next visit date was completed for 68.3% of records at C-BART, while the viral load date and viral load results were completed in 63.3% and 77.7% of records at C-BART and F-BART, respectively. However, accuracy ranged from 92.1 to 100% for all three data elements. Therefore, the reported percentage accuracy for these data elements could be overstated due to methodological limitations.

In quantitative studies, small samples make it challenging to draw convincing conclusions about a phenomenon, as the sample may not be powered enough. In this study, the Z-test was used to address this phenomenon. However, we had no reason to doubt that there was a considerable variation in data distribution between data in C-BART and F-BART.

Finally, the main limitation with the LQAS was that a sample has to be drawn from each lot, which could be costly if there are many lots. The proportion threshold must be set during the study design, which can be challenging for studies of rare phenomena. The strata must be

homogeneous; hence, one must sample from each lot by listing all unique records for that strata to compute proportion estimates, and this is what we have done in this study.

4.9 Recommendations

This study found that the C-BART and F-BART ePMS data achieved acceptable completeness and accuracy levels by the WHO's standards. Hence, all lots, C-BART and F-BART ePMS, are acceptable for use in evaluation studies. However, when we assessed completeness for individual variables, viral load test date and viral load, the results were below 80%. The goal of ART is to achieve viral suppression (VS). Hence, there is a need to address completeness and standardise the recording of VS data in the PCB and ePMS as received from the laboratory. We recommend using additional paper-based tools, such as the facility attendance register, MEDITECH laboratory database, and patient health passports to update viral load in PCBs and, subsequently, the ePMS. In addition, we recommend using barcodes with unique patients' ART IDs for VL specimens to be captured in MEDITECH. The interoperability and linkage of MEDITECH and ePMS laboratory results modules should also be prioritised for automated VL transcription from MEDITECH to ePMS to prevent transcription errors. This may require in-service training, Data Quality Audits (DQA) and Continuous Quality Improvement (CQI). Data quality assessments, supervision and related interventions can improve data completeness, accuracy, and program quality[122]; [65]

We have also observed variations in the completeness of variables, with ePMS being relatively more complete than PCBs for some data elements. For example, some patients' viral load results were in ePMS, but had not been entered in the PCB, although PCBs are the primary source. It was explained that for some patient visits at the C-BART and F-BART sites, the PCBs are not retrieved, but HCWs use a patient health passport instead. As a result, the data clerk will capture information from the patient's health passport into ePMS, without updating the PCBs. Hence, we recommend prioritising completing the appropriate sections of the PCBs and transcribing from PCBs to ePMS instead of using the health passport to update ePMS. In this regard, developing standard operating procedures (SOPs) will help improve viral load data quality.

4.10 Conclusion

Using routinely collected data for program evaluation studies and clinical research is cost-effective and timely, mainly where electronic databases with longitudinal cohorts' data are available. The high level of completeness and accuracy of C-BART and F-BART ePMS above 80% makes it a promising source of primary data for studies. Improving data quality by ensuring data completeness and accuracy is important to enhance confidence in using such data in studies.

The MOHSS should consider mandatory in-built quick data quality checks into electronic data capturing platforms for quality assurance. Continuous quality improvement and mentorship in data management and use are key. Documentation of all data elements must be strengthened in C-BART models, and data quality validation and audits should be prioritised.

Using multiple data systems has proven challenging; hence, the need to expedite the roll-out of the e-health strategy and automation of data sharing between multiple data systems to address fragmentation, improve data quality, and achieve efficiencies. The e-health strategy aims to introduce one electronic medical record for each patient, which will be used at all service delivery points in Namibia. The e-health strategy is premised on using unique identifiers and has modules that will capture every patient's encounter with the health system for all services. The e-health system will be interoperable with MEDITECH for improved access to patient laboratory data[126].

CHAPTER 5

QUALITATIVE STUDY

Patients, Healthcare Workers and Policymakers' Perspective of Context, Implementation and Effectiveness of the C-BART Program in the Okongo District

5.1 Overview of the Study

The previous chapters described and analysed the determinants of adherence to ART, retention in care and virological suppression among adult patients in the Okongo C-BART program, in-depth. It became imperative to present the patient outcomes as well as to describe, discuss and deduce comprehensive conclusions on the implementation and effects of the C-BART model.

The essence of this chapter is to present the results of a qualitative study that described the context, implementation and effectiveness of the C-BART program and sites in the Okongo District in Namibia. Reporting qualitative research that often studies complex issues which health care workers encounter, could be very challenging. Hence, Tong et al developed a 32-item checklist to guide researchers with reporting qualitative research known as the Consolidated Criteria for Reporting Qualitative Research (COREQ) (Tong et al, 349:2007). This chapter aligns with the COREQ to ensure complete and transparent reporting. Through a descriptive exploratory approach, this inquiry focused on patients, HCWs and health managers' perspectives on how the C-BART idea was conceived, its acceptability and site utilisation, service adequacy, barriers, facilitators and recommendations for program and site improvement.

The aim of this qualitative study was to describe the context, perspectives, and implementation of the adult C-BART program in the Okongo District and the barriers and facilitators.

The objectives of the qualitative study were:

- a) To describe the evolution and implementation of the C-BART program
- b) To explore barriers to the implementation and success of the C-BART program
- c) To describe facilitators to implementation and success of the C-BART program.

5.2 Study Design

A descriptive qualitative study was conducted to explore patients' and healthcare workers' perspectives of C-BART. This study also garnered individual perspective of the C-BART program implementation.

The qualitative methodology was a design of choice to address the aims stipulated above, as it provided opportunities to gather in-depth information from those utilising and/or those providing services at the C-BART sites to understand the acceptability, utilisation of services, barriers, the facilitators to using C-BART sites, and successes and challenges experienced, as well as the recommendations for improvements. This design further allowed collections of in-depth information about experiences with C-BART by using open-ended questions and the flexibility to probe deeper[127]. The face-to-face encounters capacitated the researchers to observe social cues such as changes in voice, intonation, or body languages[128].

5.3 Study population and sampling

For the qualitative component, three groups of participants were included in the study: patients receiving services at C-BART sites, healthcare workers, and health manager participants who have been involved in the C-BART conception of the idea, planning, implementation, and service delivery. The purposive or convenient sampling method was used to select five (5) out of 18 C-BARTs sites. The C-BART outreach schedule was used to select the 5 C-BART sites. The number of C-BART sites included was dependent on available resources. However, a combination of criteria was used to ensure a wide range of sites were included. These criteria ranged from the number of patients at C-BART sites, distance to the district hospital and years in existence. This ensured the inclusion of C-BART sites with high volume and low volume of patients, which are far and near to the district hospital in terms of distance.

5.4 Data Collection

Three methods of data collection were employed, namely, in-depth interviews (IDIs) with patients, focus group discussions (FGDs) with HCWs and key informant interviews (KIIs) with health manager participants. The data collection took place from August to December 2017.

5.4.1 Patient in-depth interviews

The patient interviews were conducted with HIV-infected adults (18 years and older) who received ART at five (5) of the 18 C-BART sites in the Okongo District, as described in the preceding section. A sample of twenty (20) patients were recruited for interviews – four (4) from each of the five selected C-BART sites. C-BART site selection is described in detail under section 5.4.4 below.

The in-depth patient interviews explored patients' satisfaction with and quality of services provided at the C-BART sites. Focus was also placed on the benefits of accessing services at C-BART, issues related to stigma, challenges affecting adherence and retention in C-BART and successes. Interviews with patients also explored what can be done to improve services provided at C-BARTs. These interviews with patients were conducted in the local Oshiwambo language, and they were audiotaped, transcribed and translated in English using Microsoft Word.

5.4.2 Healthcare workers focus group discussions

Two focus group discussions of 13 HCWs were conducted, with six (6) and seven (7) participants in FGD 1 and FGD 2, respectively. Each FGD was conducted with HCWs from the Okongo District ART team who provided services at C-BART sites for at least three visits in the last 12 months. These included nurses, health assistants (previously known as community counsellors), health extension workers (HEWs), a government Ministry of Health community health worker cadre based at the community level, pharmacists and pharmacist assistants, and data clerks. The FGDs were facilitated by the researcher using an FDG guide described in method section. The FGDs focused on understanding the context, perspective and implementation of CBARTs from the HCWs perspective. Topics covered during FGDs with HCWs included the role of HCWs in setting up C-BARTs, HCWs' preparation and training to work at C-BART sites, the perspective of which patients are utilising C-BART sites, the perspective of community and patients attitudes toward C-BARTs, challenges and recommendations to improve utilisation and care at C-BARTs.

5.4.3 Health managers

Relevant health managers and policymakers were interviewed to explain the conception of the C-BART idea and implementation process. These were health managers at district, regional and national levels. Key informants were selected based on a priori theoretical qualifications, namely, their role, position, status, possession of knowledge and personal attributes that made them suitable informants for a specific inquiry. A total of eight key informants knowledgeable of the C-BART model/program evolution and implementation were interviewed.

5.4.4 Site selection

The 18 C-BART sites were “clustered”, from which a sample of five sites was selected. This clustering of C-BART sites was purposefully selected to meet predetermined criteria. The inclusion criteria were that a site should have been providing C-BART services for > 6 months; and a mix of sites with high to low volume patient volume, traditional and conventional structures, with variable distances from main ART sites, and year of the establishment were selected. In addition, a site should have a scheduled C-BART visit date during the study period. This enabled patient interviews during routine scheduled visits to a C-BART site. Further details are described in the method sections in Chapter 5.

5.5 Data analysis

Data from interviews and FGDs were reviewed during the process of being transcribed from the audio recordings. Audio recordings of the interviews and FGDs were simultaneously transcribed and translated into English, using Microsoft Word. These findings were coded in a qualitative software program, MAXqda, based on the study’s objectives and findings. Thematic Analysis was Data reduction and summary tables with the main findings were created after the coding process. Further details are described in the method sections.

5.6 Ethics Considerations

In addition to the ethics approval for this study obtained from the University of the Western Cape Biomedical Research Ethics Committee and the Namibia Ministry of Health and Social Services Research Review Committee, informed consent was obtained from all participants for

the qualitative study. All patients' interviews were kept confidential. The study thoroughly explained in the language that the patients understood by using lay terms. Patients were informed that participation was voluntary. Hence, study identities were assigned to participants. This research project involved making *audiotapes*; all the interview recordings, transcripts and field notes were kept in a lockable cabinet during and after the study was completed. The transcripts and field notes' soft copies were kept on a password-protected computer. All study materials, including audio recordings, will be destroyed after five years as per the Ministry of Health and Social Services' records retention policy.

5.7 Results

5.7.1 Description of participants characteristics

Healthcare worker participants

Table 21 presents characteristics of Healthcare Workers who participated in the FGDs. A total of 13 HCWs participated in the two FGDs (n = 13); the mean age of HCWs was 34.8 years. Eight (8) healthcare workers had high school/secondary education, and five (5) had university qualifications. The majority had been working less than five years in their current positions (8). The various cadres of HCWs who participated in the study included nurses, health assistants, data clerks and pharmacist assistants. Sixty-nine (69%) were female and 31% were male.

Table 21: Line list of Health Care Worker participants (n=13)

Participant number	Gender*	Age	Education Level**	Length of time served in the positions (Years)	Number of times worked at the C-BART
O-H-1-01	2	38	3	6 Years, 9 months	120
O-H-1-02	2	36	4	10 months	30
O-H-1-03	2	31	2	4 Years, 10 months	35
O-H-1-04	1	30	4	10 months	40
O-H-1-05	2	37	2	3 Years, 9 months	320
O-H-1-06	2	43	3	7 Years, 9 months	357
O-H-1-07	1	30	4	3 Years, 9 months	250
O-H-2-01	1	34	2	2 Years, 4 months	58
O-H-2-02	2	31	4	6 Years	204
O-H-2-03	2	38	2	11 Years, 7 months	420
O-H-2-04	2	27	4	1 Years, 1 months	9
O-H-2-05	2	38	3	6 Years	106
O-H-2-06	1	34	3	6 months	4

*Gender: 1=Male; 2=Female

**Level of education: 2=Secondary; 3=High School; 4=University

Patient participants

A total of 20 patients were interviewed, four from each of the selected C-BART sites. Nine participants were male and 11 were female; the ages ranged from 30 to 67 years (median 48 years). The inclusion criteria allowed patients from the age of 18 years to take part in the study. Eleven (11) of the patient participants were married, 1 divorced and 2 widowed. Six (6) had not attended school, most had received some primary education (12 out of 20) and none had completed secondary school education. Most patients had been on ART for a long time, over 10 years (11); six had been on ART between 7-10 years and the rest of the patients had been on ART for a period up to 6 years. Patients were identified using assigned anonymous numbers, e.g.O-C-01, referring to Okongo C-BART patient number 1, and so forth. Numbers from 11 to 50 were assigned to participants in Eenhana district. For the gender, “2” represent female and “1” Males. Education and marital status categories are explained below Table 22.

Table 22: Line list of patient participants' characteristics (N=20)

Participant	Gender*	Age	Marital Status**	Education Level***	How long on ART?	How many times patient accessed C-BART?
O-C-01	2	42	2	1	10yrs	12
O-C-02	2	55	1	1	11yrs	7
O-C-03	2	55	5	2	12yrs	12
O-C-04	1	45	1	2	4yrs 4 months	13
O-C-05	1	42	1	2	10yrs	13
O-C-06	2	52	1	4	5yrs	9
O-C-07	2	36	2	2	11yrs	30
O-C-08	1	50	2	2	20yrs	10
O-C-09	2	52	1	2	17yrs	18
O-C-10	1	40	6	1	10yrs 5 months	5
O-C-51	1	58	1	2	9yrs	15
O-C-52	1	41	1	3	17yrs	27
O-C-53	2	56	5	3	7 yrs	9
O-C-54	1	47	1	2	11yrs	4
O-C-55	1	66	1	1	14yrs	4
O-C-56	2	61	5	1	9yrs 8 months	4
O-C-57	2	42	1	3	17yrs	2
O-C-59	2	67	4	1	20yrs	10
O-C-60	2	33	1	4	7yrs	2
O-C-61	1	30	6	2	1yr 1 month	2

*Gender: 1= Male; 2= Female

**Marital Status : 1=Married; 2=Never married; 3= Separated; 4=Divorced; 5=Widowed; 6=Living with partner

***Education level: 1=No school; 2=Some primary; 3=Completed primary; 4=Some secondary; 5=Completed secondary; 6=Some tertiary

Demographic characteristics of key informants

The district, regional and national level HCW managers, policymakers and stakeholders who were at the inception of the C-BART program participated in the key informant interviews to provide their knowledge and experience with implementation of the C-BART program. A total

of 8 key informants, knowledgeable of the C-BART model/program evolution and implementation, were interviewed.

5.7.2 C-BART program implementation themes

The evaluation of the Okongo C-BART context and implementation drew five main themes; historical context, perspectives towards C-BART sites, C-BART site utilisation, service providers' experiences and recommendations for C-BART sites. The table below is an extract of the themes and sub-themes.

Table 23: Okongo C-BART evaluation themes and subthemes

THEME 1: HISTORICAL CONTEXT
1.1 The conception of the C-BART
1.2 Preparations and community engagement
1.3 Role of stakeholders
THEME 2: PERSPECTIVES TOWARD C-BART SITES
2.1 Patient and community perspectives about C-BART sites
2.2 Adequacy and satisfaction with services
2.3 Benefits of C-BART
THEME 3: C-BART SITE UTILISATION BARRIERS & FACILITATORS
3.1 Barriers to using C-BART sites
3.2 Facilitators to using C-BART sites
THEME 4: SERVICE PROVIDERS' PERSPECTIVES
4.1 Readiness to implement C-BART
4.2 HCW concerns and challenges
THEME 5: RECOMMENDATIONS FOR C-BART SITES
5.1 Guidelines and standard operating procedures
5.2 Managing information
5.3 Expansion of C-BART services
5.4 C-BART site location and infrastructure
5.5 Training and capacity-building
5.6 Integration of services at C-BART sites

5.7.3 The Okongo C-BART historical context

Conception of C-BART in Okongo

The idea to establish the C-BART program and sites in the Okongo district was conceived by HCWs at Okongo's main ART clinic after noting poor adherence among patients and patients complaining of long distances and transportation challenges as their reasons for poor adherence and missing clinic appointments. In addition, HCWs stated how they observed the crowdedness of the ART clinic. Due to transport challenges, when patients from the same village got transport (4x4 vehicles), patients were travelling and arriving at the clinic in groups. Although travelling in groups reduced the transport costs, it introduced a bottleneck in patient flow at the clinic, causing congested ART clinics and long waiting times. However, patients were reported to be coming from afar and needed to go back with the same transport that brought them to the hospital, which was not always possible. Pursuant to that, some patients had to spend nights at the district hospital's outpatient department (OPD), while waiting to travel back home the following day. The statement below confirms this observation.

The idea was that there were a lot of patients just accumulating at the district site, and now we wanted to change them to the clinics. But a lot of patients were still travelling over long distances from some places to the clinic or from places to the district. Now, we have decided that a lot of patients are seen on the same day, so let's divide them and go to their villages instead. Let's set up a site and talk to the village headman for approval. Then, once they agreed, then we said, let's start a C-BART site at this village. (District Informatn, O-P-02, Female, 31-40 years)

HCWs also noticed that it was challenging for some patients who had not fully recovered and were a bit weak, to adhere to clinic appointments due to the long distances to get to the facility. It was also established that patients would still come to the hospital for their follow-ups, which shows that they were committed to their care, though they would come a few days later after their scheduled appointments.

When we were giving the results of the patients, we realised that our patients are suffering a lot. Because of the distance, the hospital is the only one in the district, and the people are coming from far. Others are coming even 100 kilometers to the

hospital, but those people are walking, sleeping in between there, just in order to reach the hospital. (District Informant, O-P-03, Female, 50+ years)

In sync with the above, HCWs brainstormed and agreed to take ART services to the community, closer to where the people live. The development also sought to reduce the number of patients who travel to the district hospital for services to ease the overwhelming burden caused by large groups of patients arriving at the facility and reduce the burden of transport cost, travel time, and related cost stress on patients; and subsequently, improve adherence to ART.

Preparations and community engagement

HCWs at the site level were not only advocating the C-BART idea, but they were also very involved in preparations and implementation, as espoused by informants at district, regional, and national levels. More so, managers considered this as a bottom-up approach intervention. They regarded it as an initiative by the community and presented to management and leadership for endorsement, and not vice versa. Therefore, their efforts were considered to be true community-initiated interventions. The response below gives testament to the above.

Not many officers were involved directly in terms of rolling out this process, which is something which was unique, because this was driven from the bottom up rather than from the top down. (National Informant, N-P-07, Female, 31-40 years)

Extensive consultations with various stakeholders were held before the C-BART program was launched. HCWs who were at the helm of managing C-BART received input from various experienced program managers attached to the MoHSS and from partners such as CDC field officers for guidance on the successful implementation of C-BART. The Okongo District Coordinating Committee was initially consulted for transportation needs and availed the outreach vehicle for use by both the PHC and C-BART outreach services. The Ministry of Health's Directorate of Special Programs at the national level mobilised resources, and through the CDC, a 4x4 vehicle was procured specifically to cater for C-BART service. The regional management team provided input in village selection to equitably distribute the services based on the number of clients in surrounding villages, "village clusters", as the HCWs on site analysed.

However, the community, patients, family members, their traditional leaders and significant others were the biggest drivers of the initiative and had the greatest level of involvement by providing input regarding the community's needs and what they were prepared to contribute. Village headmen gave approval and official land ownership certificates for land to organised groups of PLHIV. This type of ownership allowed for the land to be allocated free of charge, as it is allocated to non-profit welfare community groups. The community, mostly PLHIV set up the initial C-BART sites at selected locations, but other community members also helped by clearing out land and building the traditional structures such as "Huts", which served as a consultation room for C-BART services. The response below buttresses the above position.

The first thing we did after the c'mmun'ty meeting with the headmen was to see where we could establish those points [C-BART sites]. First of all, people were informed because the idea also came from the community. 'We can put up a shelter, even a small room, where you can bring us the services.' But first, we started just under a tree, and then the community started to put up their own shelters, those traditional ones, so that if there is rain when you bring the services, you can be inside there. (Regional Informant: O-P-02, Female, 31-40 years)

One informant discussed how, in most cases, members contributed their own money to establish physical structures or make improvements on existing sites. The response was as follows:

When we started, we started seeing them under the tree, then during the rainy season ... we felt we should create a shelter. [Community members] are the ones who even cleaned the place, build the shelter, some of them donated or contributed NAD\$10 or NAD\$5 to buy the iron sheet. So, they are the ones who started everything. [Our role] was just to come, sit and provide the service. (Regional Informant, O-P-03, Female, 31-40 years)

Although there is no training curriculum for C-BART services and none of the HCWs attended formal training in preparation for the provision of services at C-BART sites, HCWs did all they could to provide the service of good quality as provided at the main ART site and taught each other as they discharged the services. When new HCWs come on board, they are oriented by

experienced colleagues, and that is the only training they receive to prepare them to provide C-BART services. This is borne witness by the remark below:

When you are new in the place, especially when I came first, my older colleagues were telling me how to run the whole program ... when you go in the field ... actually just like orientation as to how to run the program when you go in the field. We received a training about how to put the information on a patient care booklet and entering it in the ePMS system (HCWs). ... pharmacist assistants ... we received some training on the mobile dispensing tool and how to use them on outreach. (HCW, O-H-1-05, Female, 37 years)

The MoHSS pharmaceutical services, through support from donors, availed mobile electronic dispensing devices as quoted above. ARV dispensing data for patients on ART can be downloaded on this device and can be updated at the point of dispensing- spot-on at the C-BART site. The size of a camera, this device can be carried to the C-BART site for data entry and upon return, it is docked on the main computer, which hosts the main district EDT database to transfer the data and update the patient ART refill and regimen information for each C-BART visit.

Drawing up a C-BART site visit schedule was another helpful preparation, as it allowed for planning and distributing resources, including humans, vehicles and related resources. The district used this schedule of a visit to C-BART sites to pre-allocate a vehicle the previous day so that the team could depart on time from the district to the C-BART site and for the team at the ART clinic to equally plan for the rotation of HCWs to the C-BART. Furthermore, community members were a driving force in establishing C-BART services. These included patients and community-based volunteers. By way of an extension, the volunteers were an arm of the HCWs in sensitising and mobilising the community and their patients to participate in establishing C-BART and using services. Having community members at the forefront encouraged participation in the program and created a great sense of ownership. This was recognised as the cornerstone of C-BART implementation.

Stakeholders and their role in C-BART implementation

Key district-level staff members involved from the start of the program included nurses from the ART clinic who were at the forefront of consultations with various stakeholders and sensitising patients and community leaders in the setting up of C-BARTs. A pharmacist or pharmacist assistant accompanied the team in the field to manage the mobile electronic dispensing tool, and data clerks worked with nurses in establishing the reporting system by ensuring that data from the C-BART visits were captured on the electronic patient monitoring system (ePMS).

Health assistants and health extension workers also assisted in community sensitisation, providing health education, adherence counselling, HIV disclosure for children, viral load monitoring education, and triaging patients' health passports for consultation, ART refill, and blood investigations. At most C-BART sites, there were expert patients who voluntarily offered their service to render assistance, especially in informing other patients about the availability of the C-BART services, identifying patients from their community who have missed appointments and reminding patients who could not read about their next appointment dates. All in all, staff members laid much of the groundwork for the program's design and implementation. Nurses, in particular, acted as the core component in establishing the program and the service delivery.

Regional and national levels took on the more administrative roles, including resource allocation and program authorisation. The regional management team approved the district level to promote further decentralisation of ART to the community level. The Red Cross also assisted the MOHSS by providing additional HCWs (volunteers) to help mobilise community members.

In the same token, the national level gave final approval for medication to be taken from the facility into the C-BART sites after consulting with pharmacists. They also mobilised more resources for logistical support, such as 4x4 vehicles and provided facility equipment, including chairs and desks. The senior medical officer promoted the program and reported its impact to the senior Ministry of Health and Social Services officials. Occasionally, the senior medical officer or chief clinical mentor performed monitoring visits to the C-BART sites and mobilised donors to support this initiative. In furtherance, developmental partners, such as the CDC, provided support to address human resources for health gaps and transportation by

providing a 4x4 vehicle that is utilised by the team from the main ART site to conduct outreach service to the C-BART sites in addition to technical guidance, and program monitoring through site monitoring visits.

5.7.4 Perspectives towards C-BART Sites

Patients and Community perspectives

C-BART site establishments were generally well-received and had high community ownership. Patient participants narrated how, in organised groups, they approached traditional leaders to allocate them land for C-BART sites. They chose the site's location, cleared and prepared the site for construction, contributed materials and constructed the structure they are using for C-BART services. The sites are easily accessible to most patients, although there are still some patients who do not have C-BART sites in their community and have to travel to the neighbouring village to access services; but still, these sites are not as far as the distance they used to travel to the hospital and they do not require them to get transport. Although they could still walk for two hours to get to the C-BART sites, this is negligible compared to what they went through before to get to the main hospital for their follow-up appointments. Equally, the C-BART sites are highly accepted in the community by the patients, family members or the wider community. The service at C-BART sites is easily accessible, and the HCWs apply a 'first come, first serve' approach in providing services. The above was observed from the response given below:

It Is easy because we usually put our health passport cards in order, depending on who came early, and who came last. The first person gets helped first and the last will be assisted last. It is also easy because the HCWS also are fast and help us really well. (Patient, O-C-05, Male, 42 years).

Community leaders welcomed the establishment of C-BART sites in their community wholeheartedly. Proudly, they could allocate land for C-BART services and enable their people to receive services in their own community. Community leaders appreciate the C-BART sites because they now see the health of their people improving a lot. In addition, for most communities that were given prefabricated containers, the C-BART sites are considered as community development in those villages.

However, there are also some community members who are unhappy that on some days the sites only see ART patients and do not carry treatment to see other patients with other health ailments and conditions.

Adequacy and satisfaction with services provided at C-BART sites

In general, it appeared that patients were satisfied with the services provided by C-BART sites. The same HCWs who provide service at the main ART site are the ones who provide services at the C-BART sites. At C-BART sites, clinical consultations, ARV refill and adherence assessment by pill count, a collection of blood specimens for CD4, viral load, and other appropriate, adherence to counselling, and HIV disclosure for children are done. Pill counts were observed as follows:

HCWs always count the number of tabs they put in our ART containers and how many were left. (Patient, O-C-04, Male, 45 years)

HCWs also provide health education on selected topics, for example, positive living with HIV, nutrition, prevention of alcohol abuse, family planning, HIV disclosure, sanitation and water hygiene, and they provide water purifying tablets. To substantiate the above, one patient had this to say:

I can see this is a good thing because the healthcare workers always give us great information that helps us stay alive. I can see that I stay healthy ... that is a good thing. We also get information through health extension workers (HEW) who walk around the village. (Patient, O-C-07, Female, 37 years)

Primary healthcare service is provided at most C-BART sites. However, not all C-BART sites provide these services on the same days. For sites where these services are combined on the same day, HCWs are different. This is evident from the statement below:

This community site is divided into two parts: there are those that bring ART and there are those who bring primary healthcare. (HCW, O-H-2-01-, Female, 34 years)

Some female patients indicated how they are missing out on some services such as cervical cancer screening and access to all family planning methods, because they are not provided at C-BART. Other patients wished to have access to be examined for STIs at C-BART sites, or get their treatment for diabetes and hypertension as well at the same time. However, HCWs indicated that it is difficult to administer injections and conduct cervical cancer screenings and physical examinations at some C-BART sites due to limited privacy and the lack of examination beds.

Benefits of C-BART

As described above, the C-BART sites have increased HIV awareness and support in the community, but the main benefit was the increased adherence for HIV positive patients. The main reason for increased adherence was that patients perceived or experienced fewer barriers preventing them from accessing their medication, so they missed fewer appointments. The response to support that is as follows:

Because like I mentioned, we used to suffer... I used to walk long distances, we used to get sun burnt and almost die of hunger, we used to walk at night time in the dark, making sure to arrive early at the hospital, so you can be first in line, but now that we have a C-BART site, everything is made easier. (Patient, O-C-02, Female, 42 years)

Interactions at the C-BART sites also provided opportunities for a community-based volunteer to develop a patient-volunteer relationship, conduct home visits and decrease loss to follow-up. The HEWs and other community members also played an important role in decreasing the number of people missing ART pickup by collecting the ART from the C-BART site when the patients were not able to attend. Although this practice was not preferred, it was allowed from time to time if there were no other alternatives. HEWs were also able to create relationships with patients and do house checks if patients missed appointments or stopped taking their medication, which resulted in a decrease in loss to follow-up. In line with this, one participant revealed:

So even now that we walk among the houses, patients are open to telling us that they are HIV positive and we encourage them and tell them never ever to stop taking their ARVs. Because sometimes, they collect their medicine and when I came to

their houses, I found out that they did not take their medicine, so I tell my clients to take medicine until it is finished. (HCW, O-H-1-05, Female, 37 years)

More-so, the C-BART site also presented an opportunity for patients to meet and interact with others, strengthening their sense of community and belonging. A response supporting the above position is captured as follows:

I like everything done here at the C-BART site because HCWs unite us with other patients who do not attend the support group, but on the day of outreach, we use to be happy here, together. (Patient, O-C-10, Male, 40 years)

The increased adherence also caused decreased viral loads, leading to secondary benefits, including increased strength and energy and decreased levels of stress. These changes have increased patients' confidence and allowed them to experience a better quality of life, leading to them succeeding at duties that they could not balance before, such as taking care of livestock. An HCW testified below:

Now the viral loads are even suppressed because of these C-BART sites, I can see the adherence improved, viral load very much improved even the people now have peace, they are very joyful and their lives have just generally improved. (HCW, O-H-2-02, Female, 31 years)

Most patients receiving services at C-BART sites are not employed, and they borrow money from relatives, friends, and neighbours to go for follow-up treatment. Since patients no longer pay for transport to go to the hospital, they no longer have to borrow money and use the little they have to support their families and buy food. This is apparent from the response below:

It is very nice and easy because we do not pay anything here. We do not pay for transport and we do not buy food to eat while waiting because we can just eat at our houses before we come as it is very near. (Patient, O-C-55, Male, 66 years)

Health education provided at C-BART sites also benefits other community members. Patients received health education information from the C-BART site and from HEWs. Some information was specifically directed towards their treatment, but they also received general

health and wellness advice as well. This advice included proper use of toilets, hand washing, and the importance of boiling water for consumption. In many communities, these teachings were also shared with the general public, so that water and sanitation hygiene guidance could benefit the entire population.

5.7.5 C-BART Utilisation, Facilitators and Barriers

Barriers to implementation and using the C-BART sites

Several challenges to C-BART implementation came up during the evaluation. The table below presents healthcare workers, health system and patient-related factors that hinder or are barriers to the successful implementation and usage of C-BART sites.

Table 24: Barriers to using C-BART sites

Barrier level	Barriers
Healthcare system and healthcare providers related	<ul style="list-style-type: none"> • Inconsistency in arrival time/waiting time • Inconsistent scheduling/change in scheduled visit day without prior notification • Inadequate infrastructure, working pace and vital equipment; lack of privacy • Transportation • Stock-outs of some regimens and subsequent up-referral • Limited service integration
Patients and community related	<ul style="list-style-type: none"> • Personal preference • Stigma from others and self-perceived stigma • Literacy level • Living in a distant community away from the C-BART sites • Proximity of a C-BART site to a school or shebeens; or using an existing school; office for C-BART services

Healthcare system and HCWs related barriers

It was noted that the lack of formal C-BART training for providers and staff members is one of the perceived barriers. There was no formal training provided to HCWs, but rather a form of orientation and on-the-job shadowing of experienced staff by new incoming staff. Any training regarding ART was based on or gained from previous experience and any national guidelines, which did not include implementation guidance for C-BART. There might have been variations in care standards due to the fact that HCWs are not trained, using a standardised C-BART training curriculum in the absence of SOPs. This was articulated as follows:

We provided an in-service training on how to manage patients on ART, and it's just like a training of roster or checklist of things you need to prepare when you go on outreach and what services to be provided at the site ... or the flow of patients and what to do. But not much training happened on C-BART. (District Informant , O-P-03, Female, 50+ years)

Sourcing and obtaining transport to take the HCWs to the C-BART sites is another barrier. Finding transportation was difficult, and also at times, the available vehicle was a single cab that could only take the driver and one HCWs. This limited the numbers of HCWs who could provide services at a C-BART site due to limited space in the available vehicles.

In some situations, the available vehicle is assigned for multiple tasks in a day, which delayed the departure of the outreach team and their arrival at C-BART sites. The lag in securing transportation also indirectly complicated the specimen arrival time at the local laboratory and processing. The statement below supports that:

If you go late on an outreach to the C-BART, and that day is a day for collecting blood, you won't collect blood because by the time you arrive back to the main ART site, if the C-BART was 70 kilometers [away], then by the time you arrive back (from the C-BART), it's a bit too late to take the (blood) specimens to the lab ... and the lab has to take the specimens too because some specimens are not being processed at the district lab. (National Informant, N-P-07, Female, 31-40 years)

The waiting time and an inconsistent schedule are some of the main challenges stated by patients trying to access the C-BART sites, ascribed to the inconsistency of HCW arrival times, which created a variety of barriers for different people. Patients arriving at the site early in the morning were exposed to longer waiting times in not-so-comfortable conditions and to arguments over the queues, as most of the sites did not have adequate seating. A HCW and patient testified to that effect as follows:

The only thing I have heard of them complaining about is apparently that the healthcare workers don't come on time. You know the community site is nearby and everybody ... when they wake up, they have a responsibility to pick their ART at the community sites. They come at 8am and the healthcare workers will only come at 11am. (HCW, O-H-2-02, Female, 31 years)

There is actually an issue with time because sometimes they come nice and early at 8am and the others they come to 12, like today. So in cases where they come at 12 and we came early in the morning and some people come from far, they leave home even earlier, so they are never free and attentive anymore because by the time the HCWs get here they are hungry and angry, so that is actually just the challenge with time. (Patient, O-C-52, Male, 41 years)

Some patients who arrived early chose to leave their health passports at the C-BART site, then passed the waiting time at local bars and returned to the site drunk, which caused disruptions due to their behaviour. This made it difficult for the drunk patients to understand their ART instructions properly, but it also annoyed the HCWs and made it more difficult for patients who did not drink to receive their ART. This was confirmed in the statement below:

Some patients came here under the influence of alcohol ... that is why sometimes, we may see things are not right because they are misbehaving in front of our HCWs, these are the things I don't like because HCWs will say we are all drunkards, and for those who don't drink alcohol, we get ashamed. (Patient, O-C-55, Male, 66 years)

Inadequate infrastructure was identified by many patients from multiple sites as the direct cause of many challenges. The first challenge was a lack of privacy, and in some sites, passers-by

could identify patients on the streets as ART patients. Patients did not have separate rooms at many sites to discuss sensitive matters with HCWs or conduct physical examinations. Instead of private consultation rooms, some sites were forced to use a distant tree as their designated privacy spot. This privacy deficit meant that some patients would not be truthful about their ailments, while others simply did not use the sites. The situation above is captured in the response below:

There is no proper place to talk with healthcare workers about our illness, the open tree is not appropriate enough, we find it hard to discuss some of our sicknesses with healthcare workers. (Patient, O-C-56, Female, 61 years)

The lack of infrastructure also exposed patients to the elements, which forced them to wait for longer periods in sometimes extreme and harsh of conditions, such as excessive heat or torrential rains with no proper shelter, shade or seating. Snakes and scorpions had also been seen in the C-BART sites, as well as droppings from larger animals that passed through the sites when they were not occupied. These unsanitary and unsafe conditions put patients at risk and were not appropriate for dispensing medications or drawing blood. Patients with HIV may also be weak, and waiting hours in extreme weather conditions with inappropriate seating is very dangerous. This was expressed as follows:

We have spoken of the infrastructure that is also affecting the patients, we have spoken of the rain ... if the rain comes during the rainy season. We will run into the car, but, them ... they can't fit. Even if you want to accommodate them, they cannot fit. (HCW, O-H-2-03, Female, 38 years)

In the early stages of C-BART implementation, the absence of a C-BART register hindered tracking of which patients are referred to a C-BART site and when. There were no specific codes for the C-BART site used in the ePMS system, nor were there separate registers only for patients seen at C-BART. One participant said that:

There was not any specific electronic monitoring system designed for the community. There was no separate reporting system ... Because when we are reporting, we were reporting as one report, Okongo Hospital report. So, that's why we were having difficulties seeing how the C-BARTs are progressing because you

cannot separate ... we don't do separate reports. It's only in 2014, 2015 we created a separate register. (Regional Informant, R-P-01, Male, 50+ years)

Some patients had also experienced stock outages, which prevented them from receiving their medications. Sometimes, if patients arrived later in the day, the HCWs told them that the medications were finished and they had to go to the hospital to get their medication. The main reason for stock outages was due to the fluctuation in the number of patients at sites. Patients from other sites or facilities who were in the area during the visit were allowed to get ARV refills at the C-BART sites as 'patients in transit'. They could not be denied treatment. One participant remarked that;

The stock-out is not necessarily that we don't have medication in our stock. Number one is because we do not know how many patients are on this regimen when it comes to the site where we go for outreach. (HCW, O-H-2-06 , Male, 34 years)

Patients and community-related barriers

It was identified that living in a distant community, far away from the C-BART sites, posed a challenge, as patients who live far away arrive later in the day. If patients arrived late, they still received their ART. However, some of them missed the health education component of the visit. In some cases, HCWs would only attend to patients who were present at the site before their arrival and would not wait for patients arriving in the afternoon. The patients who would arrive late then could be told to continue to the main site to collect their medication there instead. This is evidenced by the response below:

If you came late and you find other patients done with their health passports, then, in this case, you just have to go to the main hospital. (Patient, O-C-09, Female, 52 years)

Stigma and perceived stigma are high among young people. HCWs and patients have observed that young people rarely use the C-BART sites for ART services. Even those on treatment prefer going to the hospital or a different C-BART outside their community. They prefer to access services in communities away from their own community members who know them. This observation was expressed by at least three patients below:

They are afraid of bad words from others, maybe that's what forces them to go that far. (Patient, O-C-51, Male, 58 years)

I cannot say much about this because my aim to come here is just to get my medicine and go back home, but at the meeting places (referring to bars), the ones that I heard people talking are only young people when they meet with other young people elsewhere. They are saying we are picking 'omahakashalaomwoonde' (referring to the rattling sounds of certain seed pods that make a sound similar to the one made by ARVs in the containers when you shake them). They are saying we are picking them (laughs). That's what keeps young people uncomfortable and some decide to leave the place and start receiving ART elsewhere, very far. People do not know where you are, but it does not matter. (Patient, O-C_54,, Male, 47 Years)

The thing I do not like about thi" com'unity site is that now I am the last person here; when I am going to pass by the bars, the people there will start gossiping about me, saying I am taking ARVs. (Patient, O-C_55, Male, 66 years)

Some patients do not use C-BART sites for personal preference reasons. There are patients who still prefer to go to the main site instead of using C-BART sites, especially those who want to access other services offered in town, which are not available in the village, for example, go to the hospital and go shopping or to the bank thereafter. This participant revealed the following:

... so when I go to the main hospital, I discuss my privacy with the doctor in the consulting room. (Patient, O-C-56, Female, 61 years)

Patients do not prefer to use schools, offices, and churches as C-BART sites. They have a limited sense of 'belonging' and 'ownership'. The revelations below point to this assertion:

We are not free, because this place belongs to the church, it is not our place. (Patient, O-C-57, Female, 42 years)

The thoughts we have is to talk to the headman to have our own place for us to move out of the church's place and find a place by these trees (pointing some trees behind us). So that we clean it and have our separate place and move out of the church's place. (Patient, O-C-59, Female, 67 years)

I have taken note of times when people do not show up and then it makes you wonder why they didn't come, but just to learn that it is probably because they do not want to be seen around the school premises. (Patient, O-C-60, Female, 33 year)

Patients are concerned that there is limited privacy for physical examinations when they have STIs-related complaints, and some are uncomfortable discussing other private matters at C-BARTs. They still have access to these C-BART sites, but must go to the main site for such conditions and issues. One patient confirmed that:

For now, I might have something that I need to discuss with HCWs, but I can't say it because people are so close, maybe I have a problem with my private parts, I cannot remove my dress because this consulting room is not good, it is too open. (Patient, O-C-61, Male, 30 years)

Facilitators to implementation and using the C-BART Sites

Certain factors seem to support the use of the C-BART sites. The table below presents healthcare workers, health system and patient-related factors that facilitate implementing and using C-BART sites.

Table 25: Facilitators to using C-BART sites

Level	Facilitator
Healthcare system and providers related	<ul style="list-style-type: none"> • Proximity • Ease access • Consistent C-BART schedule • Provision of prefabricated container • Quality of services provided at C-BART • Health education and adherence counselling • Presence of HEWs, a community volunteer cadre

Patients and community related	<ul style="list-style-type: none"> • Less stigma • Open and free about HIV status • Self-motivation • Disclosure of HIV status • Community acceptance of C-BART • Supportive environment • Pride of C-BART ownership • Supporting tradition leadership
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Healthcare system and HCWs related facilitators

It was established that HCWs’ strong and consistent outreach efforts helped to keep the program sustained. As time progressed, any initial doubts were resolved, and HCWs chose to prioritise the needs of the community rather than focusing on uncertainties and potential challenges. Overall, HCWs were highly motivated because they were dedicated to seeing a change in the main ART centres and a change in patients’ adherence. They took pride in their work and were committed to the care model they helped establish. The statement below summed it up:

We were feeling very happy because when we were working in the C-BARTs, the overcrowding in the facilities was no longer there. Because of that time, you could see 120 people per day or 80 people per day, but now only 40 or 50 per day. (District Informant, O-P-02, Female, 31-40 years)

HCWs had to deal with difficult weather conditions; yet, they did not allow this type of challenging work environment to deter their motivation. This was supported by a participant who said the following:

They didn’t have a problem; they felt proud. Even if it’s raining, they feel like they have to do it. We had to succeed at this. They had to be careful to make sure the medication did not get rained on or anything. Then, the patients had to be there and be rained on, they didn’t have any problem. When it stops raining, then they have to continue with their work. (District Informant, O-P-03, Female, 50+ Years)

In equal measure, the introduction of government HEWs cadre in the community has also significantly linked patients to C-BART services. Although they were not originally a part of the program design, they have become a necessary component in helping to prevent loss to follow-up and providing patient support. They assist in providing health education not only to the patients, but also to other members of the community. They are also involved in adherence counselling and they provide HIV testing. As the program expands, their role is necessary in sustaining an impactful service delivery. This is revealed in the following:

Health extension workers at the sites do not only target HIV people. They are also targeting every individual in the community with any problem. They give adherence counselling, they do HIV testing, and they also give first aid to someone who has simple things [simple health problems]. By working like that, they are able to identify patients who maybe miss follow-ups. When they come across a health passport, they check it. If they found out that they, this patient, has missed the follow-up, they have to give adherence counselling and give the importance of getting medications and also refer that patient to the health facility. (Regional Informant, R-P-01, Male, 50+ Years)

In addition, providing a vehicle to support the C-BART program, folders, chairs and tables, and additional HCWs boosted the morale of the HCWs to look forward to providing services at the community level.

Patients-related and community-related facilitators

It was noted that a shift in the community's attitude was beneficial to program implementation. Once the program staff communicated information about the C-BART services and how this could help their community, public support increased so much that individual community members, irrespective of whether they were ART patients or not, insisted on being part of the C-BART site-building process.

The shortened distance greatly influenced the patients' ability to attend C-BART sites and adhere to medication. Due to the proximity and ease of access, patients missed fewer visits and improved adherence.

Patients were also stronger because they no longer had to walk long distances in harsh weather conditions and could spend their transport money on food. One participant confirmed this in the following words.

It is because the community site is nearby, and I no longer feel the pain of walking long distances like previously when I had to walk from morning hours until late hours ... nowadays, I can easily come here without getting tired. (Patient, O-C-02, Female, 42 Years)

As mentioned earlier, the community's acceptance of the site and supportive environment also created a situation where patients experienced less stigma and felt far more open and free about their status. In some cases, this pride of ownership surrounding C-BART sites was directly related to improvements being made to the site, such as receiving a pre-fabricated container. It can be noted below:

This stigma ended when we received the prefabricated container; that's when the community realised that the HIV patients are bringing good changes because the villagers were told that we receive this container because HIV patients are adhering to their ART. (HCW, O-H-1-07, Male, 30 years)

It was also found that this decreased stigma, while openness created an environment where patients felt encouraged to attend the C-BART site because they saw other community members attending and knew that they were not the only ones infected with the virus. This is evident from the statement below:

It also now brought self-motivation; yeah, people that come receive their ART at the C-BART sites are very confident, and they are not shy anymore. Everywhere they go they testify that they are fine now ... they carry their pills with them without fearing to be seen. (HCW, O-H-2-02, Female, 31 years)

In the same vein, it was established that another motivating factor for adherence was that patients valued the C-BART site and stated that they received better service compared to the main site. Patients built a strong relationship with the healthcare providers and felt that the C-

BART sites ran efficiently, especially when the HCWs treated the patients with respect. Patients did not want to lose this strong relationship, and they feared being sent back to the main site. This served as another motivator for adherence, as patients with a weak viral load must receive services at the facility. Many patients preferred the close, easily accessible C-BART sites, and patients knew that decreased adherence and increased viral loads would lead to them being sent back to the hospital to receive ART, as testified below.

And they find out that you don't adhere, they won't let you go receive your ART at the community sites. That makes people adhere to the medication because everybody wants to receive at the community sites. (Patient, O-C-55, Male, 66 years)

5.7.6 Service providers' perspectives

Readiness to implement C-BART

It appeared that the C-BART program was positively received by patients, communities, HCWs, and managers. HCWs were ready to extend their services to patients at the community level. This is evident in the fact that they gave up their own comfort of working inside a building to reach out to their patients at the community level. HCWs understood well that the C-BART sites would improve service access and alleviate the travel burden on patients.

Over time, the benefits of the C-BART program were increasingly becoming visible to community members, encouraging more patients to seek the services at the C-BART site. Patients were satisfied with the services, and this is reflected in a response to that effect:

From the beginning, the response was good, but I would say when they started, they had few patients, but I think through word of mouth and the fact the patients have seen that the others are saving money, they are spending money to travel. They have seen that others are taking the same medications, which they are taking, they have seen that others are doing quite well, and I think that's what encourages patients to join. (National Informant, N-P-07, Female, 31-40 years)

However, in as much as managers and HCWs reported the majority of community members accepting the program, some have also acknowledged that some patients preferred to go to the district hospital for fear of being seen by their community members receiving ART within the community. This is testified by the stance taken below:

There are some individuals ... but it is not that they are not given the opportunity, because the opportunity is given to everybody and ... there are those who are given but they do not qualify. Yeah, because maybe (cough) poor adherence of the high viral load, yeah. And there are those who chose that even if they qualify, even if they are stable, they choose not to go there, they do not want to be seen by fellow community members, so they choose to come ... even if it is long distances. (HCWs O-H-1-02, Female, 38).

Those feelings of uneasiness did not last long, as community members started to see the benefits of C-BART sites and this improved their understanding of how the program would also benefit them.

Another informant recalled how some community leaders were hesitant and not convinced the PLHIV would live longer, to utilise the C-BART sites being set up in their communities. PLHIV in their community looked weak and frail, and that gave them no hope that they would survive longer and be able to use the C-BART sites. The lack of hope was believed to come from a lack of understanding that patients can be treated, achieve viral suppression and live normal lives. This informant confided that:

The community leaders who were hesitant did not understand. Their main concerns were only that 'Those people', referring to 'PLHIV in their community', they are dying, they will die (anyway) and anytime. Who will you 'HCWs' come to consult because they will die any day?' (District Informant O-P-03, Female, 50+ years)

HCW concerns and challenges

Some HCWs who were in doubt about the C-BART program were concerned about its feasibility and sustainability in the long run.

There were some nurses who did not support the idea. They were saying 'How can we go to do outreach in the forest?' (District informant, O-P-03, Female, 50+years)

According to one manager's perception, concerns among some nurses who were not as supportive of implementing the C-BART program included harsher working conditions, exhaustive and long drives on the sandy roads or providing services from makeshift structures. Arriving in the evening was typical because of the distance, so staff would work late, with no food or water being available. At the national level, KIIs revealed that pharmacists initially had concerns with environmental needs for medications, drug management, dispensation, and accountability. However, after explaining the process, they were on board to contribute. While it was highly acceptable to HCWs who have been at the conception of the idea and at the helm of implementation, it was accepted with mixed feelings for new incoming HCWs, who were not prepared to work in the community. This was elaborated as follows:

It wasn't easy that I applied for a job and hired for a post at the district hospital. But finding myself doing outreach in the community, I had no choice because all HCWs in the district ART clinic were on a rotation schedule to provide services at C-BART sites. (HCWs, O-H-1-04, Male, 30 years)

However, those 'hard feelings' faded with time, and seeing the benefits and impact on patients' health outcomes, and HCWs' increase in job satisfaction then motivated HCWs. This was expressed in the following words:

You know ... eventually, you wake every morning and set your goals, you have the desire of helping someone, you really know tomorrow is an outreach day, so you prepare for the day, go there and once you get to the site, the people (patients) have already gathered just waiting for you and that is a good thing, you just deliver your work, so I am satisfied. (HCWs, O-H-1-06, Female, 43 years)

5.7.7 Recommendations for C-BART sites

Guidelines and standard operating procedures

With respect to the above responses and a nuanced background, the development of standard operating procedures (SOPs) was found to be of utmost importance. As a way to improve C-BART sites, participants recommended developing SOPs, which should include details regarding who is eligible for services and should be consistent with national policy. Eligibility should be granted to those with more stable conditions. Since one of the goals is to help promote adherence, the C-BART program should prioritise services to those managing their HIV better in order to prevent disruptions in treatment. Participants noted that without the presence of an official SOP, the program could be susceptible to variations in care. This is clear from the statement made below:

In terms of the services offered, one of the things I think need to be looked at is also again standardising because of ... one of the issues, which has been a bit unclear in terms of who is eligible for the C-BART sites. Ideally, if you are looking at the national policy, it should be ideally somebody who is actually stable, right? Otherwise, unstable patients will still need to be seen at the main clinics because their needs are more and must be constantly monitored very closely. The C-BART model, given that it goes infrequently into the community ... may not be the best model. But in terms of just ensuring that the standard is very clear ... in terms of who is eligible because I think they ... there is a mix of some of those ... and with new patients, for example, can be initiated at the C-BART sites or should that be restricted to the patients that are stable. (National Informant, N-P-07, Female, 31-40 years)

In this regard, it was also noted that standardising the package of service offered at the C-BART sites may be beneficial. To do this, a consultation with a pharmacist about which medications are suitable for dispensing in the C-BART environments may also increase appropriateness. This is evident from the statement below:

The services, some of them are already in the pipeline and already implemented; they also incorporate other services like ANC to be provided at the C-BART. I think

some of the things that started were then stopped. (Regional Informant, R-P-01, Male, 50+years)

In addition, it is important to develop a consistent annual schedule for C-BART site visits integrated with PHC and other relevant services. This is evident from the following response;

An annual schedule or annual work plan is really helpful because the staff would know exactly when to visit the site. Even the patients themselves would know when they expect the C-BART team to come. (Regional informant, R-P-01, Male, 50+years)

However, the guidelines within the SOP should be somewhat flexible so that the program can adapt to a community's cultural context and needs as deemed necessary. This is apparent from the observation made below:

There is a need for standard operating procedures. Recently, Namibia has added C-BART as a strategy in the national ART guideline. But there is a need for standard operating procedures to ensure that wherever C-BART is implemented in the region, the staff follow the SOP. They might differ a little bit to adapt to the local context, but the key elements and components should be the same. We are hoping that if this could be done, it would really help other regions, which are expanding, to understand what the components are that need to be in place and to make sure that the quality of care is not compromised. (National level informant, N-P-08, Female, 30 years)

Managing information

In an interview with a participant at the national level, it was recommended to establish a standardised M&E system that tracks adherence. Although some type of systems may be in place already, different sites may use different approaches. In order to collect complete and cohesive data across all sites, one type of system should be in place to ensure better records.

One of the improvements is trying to make sure that the M&E system is standardised across what's happening in the district. Because you find some variations, you talk to people in Okongo ART, and C-BART, you find some differences, but the model is the same. And you see some gaps in what information you can capture easily without necessarily digging into records and trying to link the data. I think the improvement has to be how to actually make sure that we have a standard SOP for how data is actually captured at the main site and what data is captured during visits, and how the dispensing records are actually managed. So that we don't lose any important patient data in that process and will always continue to have a very good understanding of how the outcomes for the patients are. (National Informant, N-P-10, Female, 41-50 years)

Expansion of C-BART services

In many communities, patients would like to see their C-BART space expanded and enhanced in various ways to make it more accessible to the community. Suggestions for doing this included making the site open on additional days of the week and always having a nurse or HEW on duty.

Participants also wanted to see the site introduce more services so that other community members could use the site for hypertension, diabetes, PHC, immunisations, cervical cancer screening and antenatal care. In many communities, participants wanted to have a fully functional clinic, and they hoped that these small additions would eventually lead to the building of a clinic.

They want the clinic to be built here, they also talked about many different health services that need to be provided at the site to ensure that when a community member is not feeling well, she or he will just come and get the treatment here. For example, school kids to be able to access the health services at the site once they are not feeling well. Apparently, the site should be for all the community members and not only for HIV infected people. (Patient, O-C-55, Male, 66 years)

Participants also felt that the C-BART sites should be providing more support for HIV patients than just their ART. Patients should be provided with food and vitamins to

ensure they can take their medications correctly and build the strength they need to live a long, fulfilled life. The responses below supported this observation:

Making gardens for cabbages and tomatoes, so that after harvesting, they will divide and sell the rest, for example, if they sell 50 cabbages and keep the money for in case ... if one of them is not feeling well and do not have money to go to the hospital, they will use their money. (HCW, O-H-1-02, Female, 36 years)

Some patients also felt that the C-BART site could be used to provide them with social or financial support as well, by helping patients find employment or other social benefits that they may have been eligible for. (HCW, O-H-1=05, Female, 37 years)

Let me think, I think us HIV patients need to be taken care of at least with employment or other benefits because most of us ... we are just at home with no income. (Patient, O-C-54, Male, 47 years)

C-BART site location and infrastructure

All study participants discussed a need for improvements in infrastructure at their C-BART site as this will also enhance patients' privacy there. A closer scrutiny of the responses revealed recurring complaints about the lack of privacy. Against that backdrop, participants suggested that structures must be erected to ensure that patients could be examined in private, so that patients waiting for ART could not be easily detected by passers-by. Participants also complained about a lack of shelter from the extreme heat and rains, again suggesting that structures should be erected to deal with this. While some participants suggested moving into other government buildings, such as PHC sites, others suggested that traditional huts or even zinc structures would suffice. However, the 'holy grail' of C-BART sites was the pre-fabricated containers, which most sites hoped to receive. Their sentiments are as follows:

We were told that we will be given a pre-fabricated container, but now we heard that they are finished. So we need a container or at least just zinc sheets or just a roof for shade so that even during rainy season patients can be there so they do not get rained on. (HCW, O-H-1-07, Male, 30 years)

In sync with these requests, infrastructure improvements were also suggested so that HCWs could store drugs, files and other sterile or temperature-controlled supplies on site. This was suggested as a way to avoid stock outages and get HCWs to arrive at the C-BART sites earlier because they would save time if they did not have to prepare, pack and load up every time at the main site. To this end, transportation for HCWs to the C-BART sites for service delivery needs to be improved. HCWs reported needing better or larger vehicles to transport them and their supplies to and from C-BART sites. HCWs stated that they did not have vehicles dedicated specifically to the C-BART sites, and the current ones were not equipped to carry appropriate supplies or drive on the rough sand roads in the rural communities. The only available vehicles were not even equipped to transport enough healthcare providers to the site, and HCWs would like this to change. To qualify the above, one participant posited that:

*Okay, at least two transport, two vehicles and a team should consist of a doctor if it is possible, a doctor, two nurses, two pharmacists or just two people from the pharmacy, health assistants, the counselor for the adherence and for the kids.
(HCW, O-H-2-12, Female, 38 years)*

Informed of the above observations, it was recommended that the location of C-BART sites must be established away from shebeens. There must be enough patients for a site to qualify as a new C-BART site and for HCWs to recommend at least 20-40 patients for a site to be considered for C-BART sites. C-BART sites must be clearly identifiable through signage and should have good roads leading to them. New sites are needed because some patients are still travelling for long distances and many hours to get to the current C-BART sites. The position above is confirmed below:

We ask patients who want to have community sites in their community to list their names at the facility and if they come up with about 40 names, then it is an indication that the community ... ART is needed in that community. (HCW, O-H-2-13, Male, 34 years)

Likewise, the location of sites in the community should be strategic, and the sites should not be placed in busy areas near schools or churches, as some patients did not want to be seen by other community members. Sites should also not be next to shebeens/bars, as drunk patrons

have been known to stigmatise patients, and some patients will go drink while waiting for the HCWs, which in turn impedes HCWs' ability to provide services.

Training and capacity-building

It was also revealed that most HCWs stated that they had not received any specific training regarding C-BART sites, and would like to see the program include this, as well as protocols for working in rural communities. Others stated that they wanted training on using equipment, such as EDT mobile pharmaceutical systems and training on new standard operating procedures for patient tracing who are lost to follow-up. Many of them also suggested more specialised training, such as gender-tailored or specific counselling, as well as how to deal with patients under the influence of alcohol.

To this end, some of the HEWs had specific training requests, such as training on malaria, or counselling and disclosure, but for many of them, their training needs were much simpler. Many of them stated that they had not received enough general training surrounding HIV and ART, and would like to learn more. This was evident from the statement below:

We need training on how patients have to take and handle ARVs, we also need training on how to assist an HIV patient on how they should take care of themselves, for now, we only say the little we read from books that [we were] given at hospitals because we haven't received such training. Even food, what types of food patients need to eat and how to eat or how to rest, we really need these training. (HCW, O-H-1-04, Male, 30 years)

Integration of services at C-BART sites

In the same vein, an integration of C-BART services with PHC and other relevant services is provided at C-BART sites. In fact, most C-BART sites are reported to have been PHC outreach points for years before they start providing ART services. At some C-BART sites, services are rendered the same day. However, at some C-BART sites, PHC and ART outreach teams have different schedules and visit dates to C-BART sites. Hence, if a patient needs PHC services and ART, they have to visit the site on different dates. This is challenging for patients and patients want to see PHC and ART services fully integrated and provided on the same day.

In connection to the above, HCWs felt that the provision of individualised health education to patients was hindered by a lack of promotional material, and they also felt that there was not enough time to speak with all of the patients during their C-BART site visits. Healthcare professionals also suggested that they introduce a multi-disciplinary approach to health education, incorporate HCWs, HEWs, headmen and expert patients. There were also suggestions to use media to bring HIV into the spotlight to help raise awareness and decrease stigma about the topic. A common narrative of the recommendations above was in agreement with the response given below:

I think there is a need for programs to educate them, a program on TV, radio just to provide information to HIV positive people to use the established community ART sites. It should be shown on televisions or radios because I think it might encourage people to start utilising community sites, I think people are willing to utilise those community sites, but they are just shy. (HCW, O-H-1-01, Female, 38 years)

It was observed that patients are eager to know what their laboratory results for CD4 and Viral Load show. They prefer to have individually tailored health education at C-BART sites, then group health education; and individualised health education as given at the main hospital. It was noted by the following:

They should also teach us or tell us about the results after blood testing, as I have said most people do not know how to read ... I never attended school. For example, I am just given my file, but I do not know where the doctor used to read or to see what is happening to my CD4 count, I just want to add that they need to teach us or tell us individually, but not as a group. HCW need to tell us like 'Your CD4 was at this level, now it drops or increased to this level. (Patient, O-C-53, Female, 56 years)

5.8 Summary of Findings

This chapter presented the results of the patients, HCWs and key informants' perspectives of the C-BART implementation in the Okongo District. The concept of the C-BART program and

sites in the Okongo District was a bottom-up approach. Identifiably, the idea was conceived by HCWs at Okongo's main ART clinic after observing poor adherence among patients, patients complaining of long distances and transportation challenges, and patients missing clinic appointments. The intervention was initiated to reduce the burden of transport, travel and related cost stress on patients, the congestion at the ART clinic and subsequently improve adherence to ART. They divided patients according to their village, sought the approval of headmen and once agreed, HCWs started to provide ART services to the communities. The district, regional, and national levels and stakeholders provide support for implementation.

C-BART sites seem to be of particular benefit in rural communities that are distant from the hospital and indeed all C-BART sites used in this study were rural. Patients and community members showed general appreciation of the C-BART model as they no longer had to travel long, costly distances. While C-BART sites were open to all PLHIV, most employed patients seemed to prefer and had the means to travel to health facilities. Hence most clients seen at the C-BART sites are unemployed, have low education or are uneducated. Some young people, both male and female, shy away from accessing services at C-BART sites due to social stigma, with fear of being seen by parents, neighbours, grandparents, and suitors. It is also imperative to realise that some patients go to C-BARTs that are outside their own communities, where they are not known because some community members stigmatise C-BART sites.

It was further discovered that HCWs providing services at the C-BART site only received training on ART and orientation from peers on how to provide services at C-BART sites and there was no specific training for differentiated service delivery or C-BART. There were no SOPs or training curriculum explicitly for C-BART implementation. Despite this, HCWs were happy to provide services to patients in the community as it reduces the burden of ART care on patients. Although it was difficult in the beginning, most HCWs now appreciated and were satisfied with their effort, seeing how patients' adherence and quality of life improved.

In the same token, the study found that the C-BART site is visited every 3rd or 4th month, depending on the schedule. Services provided at C-BART sites include ART medication pick up, blood tests, health education, adherence education and counselling, viral load testing, patient tracing, emotional support and motivation for patients, referral of patients to the main hospital, paediatric HIV disclosure, TB screening, physical examination, transfer or link of patients to other services such as primary healthcare. Additional services provided at the C-

BART site include height, weight and BMI measures. Cervical cancer screening and HIV testing services are not provided during the C-BART visit. Blood pressure monitoring is also not integrated into C-BART services. Based on the findings of this study, there is a need to expand primary health service delivery at the C-BART sites, or use C-BART sites as templates for expanding primary health care.

This evaluation demonstrates that C-BART benefits include, among other things, increased patient adherence to ART due to reduced barriers to adherence, a decrease in the burden of care on patients and their families, and improved community support for HIV-infected patients. Consequently, the proximity of service to the community led to a sharp increase in understanding of the disease and led to the formation of support groups. It also allowed the patients to pick up their ARVs quickly to go back home to do her house chores. Patients were allowed to collect ARVs for other patients so that they would not miss out on their treatment or they were collected by the HEWs. The study realised that C-BART allows patients to have someone pick up their medication when they cannot, which also motivates them. Patients are motivated not to miss an appointment or have an unsuppressed viral load, as it would risk them being sent back (up-referred) to the main hospital, hence their adherence to appointments.

Challenges of C-BART include inadequate infrastructure and the late arrival of HCWs and patients at C-BARTs as barriers to using C-BART sites. It was further noted that the occasional stock outage of some ARV regimens, personal preference, shyness, stigma and location of C-BART services were also barriers to utilising C-BART sites. However, despite these barriers, the patients claim to use C-BART sites because it has reduced the distance to services and cut travel-associated costs. Most, if not all, patients walk to the C-BART sites. The HCWs, the headmen, and other community leaders demonstrated support to continue utilising services.

In conclusion, patients were motivated to utilise C-BART, which was also conducive to peer support and overall positive experiences by patients while exerting minimal burden on health care facilities and staff. HCWs too had a generally positive experience despite inadequate preparation and challenges with implementation. More, however, needs to be done to integrate services at community level and meet the community expectations.

CHAPTER 6

DISCUSSION, RECOMMENDATIONS AND CONCLUSIONS

6.1 Introduction

The Okongo District established a community-based ART (C-BART) delivery program in 2007. Based on anecdotal evidence, even when the ART services were decentralised from the District Hospital to clinics, access remained a challenge to some patients that could be ascribed to long distances, the lack of and the cost of public transport. Hence, the C-BART program was introduced to improve access to ART for patients in rural settings. The evaluation of the Okongo CABRT program focuses on adult patients who initiated ART from 1 January 2007 to 31 July 2017 and were down-referred to any of the 18 C-BART sites. The aim of the C-BART program was to take ART services to patients who live in distant communities from the Okongo District Hospital. The current study aimed to evaluate and describe the effectiveness of the C-BART program.

6.2 Summary of Key Research Findings

6.2.1 Patients' demographic and clinical characteristics at ART start

Data for 2665 (504 C-BART and 2161 F-BART) adult patients were extracted and analysed for the retrospective cohort study. Patients down-referred to C-BART had similar demographics as patients in F-BART. Overall, 58.3% of C-BART patients analysed in the cohort study were males, and 60.9% of F-BART patients were females. For both the C-BART and F-BART, 50% of patients in C-BART and in F-BART were females. The finding is consistent with the result of Namibia's HIV impact assessment and national program data that shows that men are lagging behind in terms of testing and ART[5]. Therefore, men targeted testing for active case finding must be adopted. The median age at the start of ART was 38 (Interquartile range [IQR]: 32-45) years for C-BART and 29 (24-36) years for F-BART. A total of 81% of patients initiated ART between 2007 and 2014. For the patients in C-BART, the median duration on ART before down-referral to a C-BART site was 81 (IQR:51-102) months. Patients in C-BART and F-BART also had similar clinical characteristics. The majority of the patients started ART at WHO Stage 1 or 2: 88.1% for C-BART and 84.8% for F-BART,

respectively. The median CD4 count at ART initiation among the C-BART cohort was 200 (IQR:140-314) cells/mm³ and 214 (IQR: 143-328) cells/mm³ among the F-BART.

6.2.2 Adherence

Adherence to ART is crucial to achieve the desired treatment outcomes and reduce risks of virological failure and HIV drug resistance[28]. However, achieving accurate patients' adherence data is remains a challenge. Self-reported adherence, on-time pill pick up, and on-time clinic appointments, which are used as a proxy for adherence, are not 100% reliable, and none of them can validate that the patients take their treatment as prescribed. In this study, using the adherence standard of ($\geq 75\%$) adherence was reported to be high (83.8%) among C-BART patients compared to F-BART (56.2%). The results also showed that 50.4% of patients in C-BART care achieved adherence of $\geq 95\%$ compared to 35.9% among F-BART. These findings were supported by the qualitative results, in which patients and providers reported that patients in C-BARTs adhere to their treatment and appointments – because if they do not, they are up-referred to the hospital for close monitoring and monthly follow-up for adherence counselling, since the C-BART site is only visited once every 3 months. The observed high percentage of adherence among C-BART could be due to selection criteria for patients down-referred to C-BART. Hence, patient adherence is high so that they remain in C-BART care.

We have noticed limited documentation and missing values for adherence assessment, as only 24% of patients had adherence assessment documents, a factor attributed by the increased focus on viral load suppression as an ultimate measure of treatment success. Nevertheless, adherence to clinic appointments – an acceptable proxy to adherence – was high. The desirable level of adherence to clinic appointments should be 80% or more[28].

6.2.3 Retention in care

C-BART care was associated with high retention (96.8%) at 12 months, compared to 85.4% among patients seen at F-BART. Similarly, the percentage of patients retained in care at 60 months was 85.9% for C-BART and 61.6% for F-BART, respectively. C-BART cohorts were more likely to be retained at all time points compared to F-BART.

6.2.4 Viral suppression

The results of F-BART and C-BART cohort analyses have shown that patients in C-BART were more likely to achieve $VS \leq 1000$ (95.7%) compared to 89.1% among F-BART patients. For the 60-month retention cohort, VS was 89.4% in C-BART compared to 76.3% among patients who remain in F-BART. The above results support the purpose of taking ART services closer to where the people live to ensure improved retention and viral suppression. As described in the qualitative study results, patients who were not adhering to clinic appointments were transferred back to the facility for follow-up care. Patients did not prefer to be up-referred due to costs associated with transport to the hospital and time taken away from home and other commitments.

6.2.5 Survival

Overall, 139 patients (5.2%) had died; 24 (4.3%) among patients seen at C-BART and 115 (5.3%) for F-BART. These rates are lower than those reported in the study by Nachega et al. (2016), which reported an all-cause mortality of 9.3% among C-BART and 10.3% for F-BART, respectively[24]. However, these figures were higher than the 3% deaths overall reported in a study by Auld et al (2015)[101].

6.2.6 Completeness and accuracy of the electronic patient management system

The validation study assessed the completeness and accuracy of key variables reported in the National Antiretroviral electronic Patient Management System (ePMS) and extracts from the paper-based patient care booklets (PCB) at the Okongo District of the Ohangwena Region, both for records of patients seen at the F-BART and C-BART sites.

The most complete variables in ePMS are sex, date of birth, latest ART regimen, and date ART started. It was evident during this study that variables with in-built data quality checks in ePMS, such as sex, date of birth, latest ART regimen, date enrolled in HIV care, and date ART started, tend to be more complete than others. We also found variables missing in PCBs but complete in ePMS, especially for patients enrolled in ART care elsewhere before ART initiation.

The overall completeness of variables assessed in ePMS was 93.5%, and data missing for all variables in ePMS was 5.9%. Similarly, overall completeness for variables assessed in PCBs was 92.9%, and data missing for all variables in PCBs was 7.1%. The overall findings on completeness met the WHO's recommended data verification and recreating factor of not less than 90% or 110%. This means that data generated from the electronic data must be reproducible from the standard reference document and match 90%, or not to be over 110% accurate[116]. In this study, the results have shown missing VL data in ePMS and PCB for the date of the last viral load, which was missing in 26% (n = 75) of records and the viral load results value, which was missing in 25% (n = 74) of records as well. Missing data can compromise the quality of care[104]. In this case, recommends the expansion of verification to other sites[116]. For this study, the verification was limited to the Okongo District F-BART and C-BART being the study settings. However, recommendations for expanding verification to other sites are included in the recommendations section.

According to the national guidelines for ART, viral load for treatment monitoring is done at 6 months, 12 months, and then every 12 months. In case of suspected treatment failure, VL is repeated after three months of good adherence to treatment and once the possibility of the infection with an opportunistic infection is ruled out. An additional viral load is performed in case of virological failure[17]. Hence, it is expected that most of the patients whose records have been reviewed should have a viral load test done. Missing VL data may be an issue of viral load documentation from laboratory results' printouts into the PCB and ePMS. Poor documentation of services provided leads to incomplete and inaccurate reporting[109], in this case, both in ePMS and PCBs. During the onsite validation, we found many PCBs had printout(s) of VL results stapled in PCBs, but not recorded in the appropriate section. We also found some VL results filed in separate paper-based files, marked by the month specimens were taken. However, these are not the standard approaches to documenting patients' VL results. In addition, the use of several non-standardised entries for viral load result values varied both in ePMS and PCB, ranging from "TND", "Target Not Detected", "N/A", "0", "<20", "20" "<40", "40" might have led to transcription errors between ePMS and PCB. This validation study prompted a recommendation to the Okongo District to conduct site-level verification of key variables for all patients who had a follow-up visit after July 2018, especially for the date ART started, viral load date, and value using MEDITECH. The district was also advised to update the latest ART regimen using the pharmaceutical Electronic Dispensing Tool (EDT)

and patient-held health passports at any patient encounter with the health facility or C-BART site.

For this study, the completeness and accuracy of variables extracted from ePMS and PCB data were comparable. Hence, they have shown a substantial degree of completeness and accuracy above 80%. This indicates good data quality from the ePMS electronic database for research and evaluation purposes. However, additional verification and triangulation could be done for selected variables such as viral load results. As a short-term intervention, triangulation could be done by extracting viral load data from MEDITECH, the laboratory database. As a medium-term intervention and goal, data quality assurance should be routinised to address missing viral load data in EPMS, while the long-term goal is to roll out the Namibia e-Health Strategy[126] and other approaches to ensure interoperability of data systems to improve data completeness and accuracy further.

6.2.7 Perspectives of the C-BART Program Implementation

The conception of the C-BART program and sites in the Okongo District was a bottom-up approach. Identifiably, the idea was conceived by HCWs at Okongo main ART clinic after observing poor adherence among patients, patients complaining of having to travel long distances and transportation challenges, and patients missing clinic appointments. The intervention was initiated to reduce the burden of transport, travel and related cost stress on patients, the crowdedness of the ART clinic and subsequently, improve adherence to ART. They divided patients according to their village, sought the approval of headmen and once agreed, HCWs started to provide ART services to the communities. The district, regional and national levels and stakeholders provided support for the implementation.

It was confirmed that the C-BART sites are in rural communities that are distant from the hospital. In that regard, it was noted that patients and community members appreciated the C-BARTs as they no longer have to travel long distances and spend money on transport. The C-BART sites are accessible to all PLHIV. However, those employed prefer and have means to travel to the main site. Most clients seen at the C-BART sites are unemployed, have low education or are uneducated. Some young people, adult males and females, shy away from accessing services at C-BART sites for fear of being seen by parents, neighbours, grandparents, and suitors. It is also important to realise that some patients go to C-BART sites that are outside

their own communities, where they are not known because some community members stigmatise C-BART sites. It was further identified that HCWs providing services at the C-BART site received training on ART and orientation from peers on how to provide services at C-BART sites. However, there is no SOPs or training curriculum explicitly geared toward C-BART implementation. HCWs are happy to take services to patients in the community, and they reduce the burden of ART care on patients. Although it was difficult in the beginning, they now appreciated and were satisfied with their effort, seeing how patient adherence and quality of life improved for their patients.

The study discovered that the C-BART site is visited every 3rd or 4th month, depending on the schedule. Services provided at C-BART sites include ART medication pick up, blood test, health education, adherence education and counselling, viral load testing, patient tracing, emotional support and motivation for patients, referral of patients to the main hospital, paediatric HIV disclosure, TB screening, physical examination, the transfer or linking of patients to other services such as primary healthcare. Additional services provided at the C-BART site include height, weight and BMI measures. Cervical cancer screening and HIV testing services are not provided during the C-BART visit. Blood pressure monitoring is also not integrated into C-BART services.

The C-BART benefits include, among other things, increased patient adherence to ART due to reduced barriers to adherence, a decrease in the burden of care on patients and families and improved community support for HIV patients. Consequently, the proximity of service to the community led to a sharp increase in understanding of the disease and the formation of support groups. It also allowed the patients to pick up their ARVs quickly to go back home to their personal chores. Patients were allowed to collect ARVs for other patients so that they would not miss out on their treatment, or they were collected by the HEWs. Patients are motivated not to miss an appointment or have an unsuppressed viral load, as it would risk them being sent back (up-referred) to the main hospital; hence, they adhere to appointments at C-BART sites.

The study further highlighted the inadequate infrastructure and the late arrival of HCWs and patients at C-BART sites as barriers to using C-BART sites. It was further discovered that the occasional stock outage of some ARV regimens, personal preference, shyness, stigma and location of C-BART services are also barriers to utilising C-BART sites, although the patients claim to use C-BART sites because it has reduced the distance to services and cut travel-

associated costs. Most, if not all, patients walk to the C-BART sites. The HCWs, the headmen, and other community leaders encourage and help them continue utilising services. In that regard, patients are motivated when they see other patients utilising the sites. Having HEWs in their community who remind them of the scheduled visits is also a motivating factor. From the study, it was deduced that HCWs are reported to be friendly and have a positive attitude toward the patients.

However, it is important to note that the HCWs need electronic systems, ePMS and EDT, which facilitate patient management and pharmacy dispensing record keeping, facilitate the smooth flow of patients and document patient follow-up visits in a timely manner. Both, patients and HCWs, acknowledge arriving on time facilitated utilisation.

6.3 Conclusions

The study found that patients seen in C-BART were more likely to be retained and achieve viral suppression than patients in F-BART. C-BART was acceptable in the community and patients appreciated the benefits of C-BART sites, including reduced cost of transport and waiting time. Patients recommend improved infrastructure for privacy and to shield them from other natural elements such as rain and heat. The validation of data for completeness and accuracy showed a high degree of completeness and accuracy. However, documentation of viral load results in ePMS required improvement. In-built data quality prompts must be considered for key variables in ePMS. C-BART provides a promising model for sustained HIV response in resource-limited settings.

6.4 Recommendations

Based on the findings of this study, it is recommended that:

- a) Replicate the C-BART program in other districts
- b) Build the data quality prompts into ePMS
- c) Improve viral load results documentation in the PCBs and in the ePMS
- d) Improve infrastructure and privacy at C-BART sites
- e) Enhance utilisation of C-BART by men and youth

- f) Provide training and orientation to healthcare workers before deploying them to provide services at C-BART
- g) Consider adjusting the frequency of visits to C-BART sites to be in line with the frequency of follow-up for patients in F-BART
- h) Consider task-sharing for community healthcare workers to do HIV rapid testing; provide pre-pack for ART initiation and linkage to care; provide PrEP for HIV-negative partners of patients on ART and ART refill.

6.5 Significance of the Study

The study findings provided additional evidence confirming the effectiveness of C-BART as a differentiated service delivery model for patients on ART. For the Okongo C-BART, being on ART for over 12 months was not a strict eligibility criterion. The model demonstrated effectiveness in retaining patients in care for up to 60 months, suggestive of the model's usability for long-term chronic care. The model also demonstrated no inferior adherence, retention or viral suppression among patients in C-BART compared to patients seen in F-BART. Patients in C-BART were more likely to be retained and virally suppressed. The qualitative study's findings support the cohort analysis results in C-BART sites.

As presented in this study, the recommendation for C-BART sites and services will aid the Ministry of Health and Social Services in Namibia in addressing structural gaps to enhance the utilisation of C-BART. Viral suppression was not a prerequisite for down-referring patients to C-BART. Patients were down-referred based on their willingness to be seen at C-BART sites. Hence, the results should change the pre-conceived idea that the patient must have been on treatment for more than 12 months and shown viral suppression before being down-referred to C-BART. This study was important to evaluate and document the effectiveness of the C-BART program in the Okongo District, Namibia, and will help other districts replicate the program in their respective districts, and modify and attend to issues raised in this study as a barrier to utilising C-BART.

6.5.1 Significance and implications for future studies

We recommend future studies focus on interventions to facilitate increased utilisation of C-BART by men and youth. In addition, given the presence of CHWs at the community level, it may be high time to consider rapid HIV testing, PrEP for partners and ART refills by CHWs.

While we had wished to do further analyses on many other predictive factors to retention, adherence, viral suppression and survival, it was not possible at this time. Therefore, follow-up studies are recommended to statistically test if the survival curves were different between patients at F-BART and those at C-BART. In addition, Cox's proportional hazard can be done to predict patient-level and clinical characteristics associated with death or LTFU.

Similarly, future researches could look at time on ART to down-referral by age, sex and distance to clinic or ART initiation place. In addition, comparison and mirror analysis would be informative to compare and examine variability among patients initiated on ART in Okongo District and those that migrated from other facilities outside the district or region. One may also look at how distance to F-BART impact C-BART usage to determine whether there will be people who qualify to use C-BART, but opt to use F-BART and how this might impact the results.

6.5.2 Significance for public health and clinical practice

C-BART sites must be provided with proper structures for patients' privacy and to allow healthcare to conduct physical examinations when needed. C-BART fits well in Namibia's Ministry of Health and Social Services health system facility type, "Class E", the Community Health Post. Hence, the Ministry should consider converting C-BART sites' into Community Health Posts to provide comprehensive community-based health services. Documentation of VL in the ePMS is essential to ensure complete data for evaluation and research to save time and money.

C-BART sites are visited on a quarterly basis, but all patients in F-BART are only seen after every six months or annually. Therefore, it is worth exploring transitioning C-BART site visits to annual or bi-annual visits just as for the patients seen at the facility. This will reduce the cost of transporting mobile teams and save the patients time as well. However, assessment must be undertaken to determine individual patients' capacity to safely store large quantities of medications and ensure adequate stock at facility level to prevent stock-out.

Given the importance of treatment adherence, retention in care and improved treatment outcomes, this study will contribute to the policy directions for HIV management in Namibia and beyond.

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Annexure A: University of Western Cape Biomedical Research Ethics Committee Approval



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02 November 2017

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Ethics Reference Number: BM17/8/6

Project Title: Evaluation of community based antiretroviral therapy delivery program for adults in Okongo district, Namibia: 2007-2015.

Approval Period: 02 November 2017 – 02 November 2018


I hereby certify that the Biomedical Science Research Ethics Committee of the University of the Western Cape approved the scientific methodology and ethics of the above mentioned research project.

Any amendments, extension or other modifications to the protocol must be submitted to the Ethics Committee for approval.

Please remember to submit a progress report in good time for annual renewal.

The permission letter from the Namibian Health Ministry must be submitted for record-keeping.

The Committee must be informed of any serious adverse event and/or termination of the study.


Ms Patricia Josias
Research Ethics Committee Officer
University of the Western Cape

PROVISIONAL REC NUMBER -130416-050

**Annexure B: Namibia Ministry of Health and Social Services research Review Committee
Ethics Approval**



REPUBLIC OF NAMIBIA

Ministry of Health and Social Services

Private Bag 13198
Windhoek
Namibia

Ministerial Building
Harvey Street
Windhoek

Tel: 061 - 2032150
Fax: 061 - 222558
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OFFICE OF THE PERMANENT SECRETARY

Ref: 17/3/3 NS

Enquiries: Mr. J. Nghipangelwa

Date: 06 November 2017

Ms. Naemi N. Shoopala
University of the Western Cape
Private Bag X 17, Bellville 7535
South Africa

Dear Ms. Shoopala

Re: Evaluation of community based antiretroviral therapy delivery program for adults in Okongo district, Namibia; 2007-2015.

1. Reference is made to your application to conduct the above-mentioned study.
2. The proposal has been evaluated and found to have merit.
3. **Kindly be informed that permission to conduct the study has been granted under the following conditions:**
 - 3.1 The data to be collected must only be used for academic purposes;
 - 3.2 No other data should be collected other than the data stated in the proposal;
 - 3.3 Stipulated ethical considerations in the protocol related to the protection of Human Subjects' should be observed and adhered to, any violation thereof will lead to termination of the study at any stage;
 - 3.4 A quarterly report to be submitted to the Ministry's Research Unit;
 - 3.5 Preliminary findings to be submitted upon completion of the study;

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3.6 Final report to be submitted upon completion of the study;

3.7 Separate permission should be sought from the Ministry of Health and Social Services for the publication of the findings.

Yours sincerely,

Andreas Mwoombola (Dr.)
Permanent Secretary



"Your Health Our Concern"

Annexure C: Focus Group discussion guide for C-BART Healthcare Workers

Date of the FGD ___ / ___ / _____ (dd-mm-yyyy)

Site Number _____

Research Assistant
Number for leading FGD _____

Research Assistant
Number for note taking _____

FGD Number _____ Number of participants: ___ Start time ___ : ___

Introduction

Introduce the moderator and note-taker. Explain that we are here to learn about the healthcare provider's experience of providing services in the community based ART program and their perceptions of patients' attitudes towards the community based ART program. Explain that we want to learn from them so that we can better improve the HIV/AIDS program within and outside Namibia.

Assign participant numbers to be referred to throughout the FGD (give each person a piece of paper with their number on it). Explain that this helps protect their privacy and makes it easier for the note taker to capture what they said.

Overview of working in a community ART site

- 1) Please describe your different roles in supporting the community ART sites. It would be great to hear from each of the different groups (nurses, doctors, psychosocial counselors/health assistants, lab technicians, pharmacist assistants and pharmacists). *Please make sure that not too much time is spent on this question, in order to have enough time for the rest of the tool.*

Preparation/ Training to provide services in community site

- 2) Did you receive any additional training to provide services in the community sites? If yes, please describe. *Be sure to hear from the different types of HCWs.*
- 3) For any of your roles, do you think any additional training is necessary to be able to provide services in the community sites? If yes, what kind of training would help? Let us hear from all different group members, nurses, doctors, psychosocial counselors/health assistants, lab technicians, pharmacist assistants and pharmacists.

Patients utilizing community sites

- 4) Who are the general patients accessing the community site? (Probe to get a sense of if it is more men, women, pregnant ladies, adolescents, children, etc.)
- 5) Do you think that there are any community members who are not adequately accessing the community sites? If yes, please describe who, why they may not be accessing the community site and what can be done to attract these others to utilize the community sites.

- 6) For those who have been working the in the community ART program for more than two years, what changes have you seen with uptake of services from the community ART program since you started supporting it? (Probe- increased client flow, increase in different types of services requested, more community acceptance of the program, etc.)

HCWs perspectives: attitudes towards the community ART sites

- 7) Do you think the services currently provided at the community sites are sufficient? Why do you think so? Are there any other services that you think should be provided, if yes, please specify? (probe frequency of C-BART scheduling, range of services provided)
- 8) What impact do you think the community ART program has on individual's ability to adhere to ART?
- 9) Has providing services at the community sites had any impact on your own personal professional satisfaction as a service provider? If so please explain.
- 10) What do you think are some of the main successes of the community ART sites?
- 11) What do you think are some of the main challenges with the community ART sites?

Patient's perspective attitudes towards community ART sites

- 12) What are some of the challenges that you think patients experience when utilizing the community sites?
- 13) What helps the patients to utilize the community sites?
- 14) What are of the complaints that you have heard from patients about utilizing the community sites?
- 15) What are some of the things that patients have said they like about the community sites?

Challenges providing services in the community sites

- 16) As a healthcare provider working in the community ART sites, what are some of the challenges that you experience providing care in the community ART site? *Be sure to hear from each group.* (Probe- stock-outs, insufficient space to provide services, lack of privacy for patients, insufficient training/preparation to work in the communities, safety issues, schedule challenges, travel challenges, too much work, too rushed, etc.)
- 17) How can these challenges be addressed?

Recommendations to improve the community sites

- 18) How can the community ART sites be strengthened? What changes would you recommend? (Probe- services provided, set-up of the site, schedule of site visit, number of HCWs servicing

the community site, types of HCWs servicing the site, supplies, communication with community, etc.)

19) What changes have patients suggested?

20) For other sites thinking about starting community-based ART services; what would you say are the most important things to consider in setting up a successful program?

This is the end of our discussion. Thank you very much for your participation today!

End time: ____ : ____

Annexure D: Structured interview guide for C-BART patients

Participant number _____

Interviewer Name: _____

Site Number: ____ (pre-assigned number)

Visit date: ____ / ____ / ____ (dd-mm-yyyy) Start time: ____: ____

***INSTRUCTIONS:** This interview should only be started once informed consent has been obtained from the participant. Read all of the questions and all of the information that is in bold print aloud to the participant. Use the probes as needed if the participant looks uncertain or indicates that he/she is unsure what you mean. Interviewer instructions are in italic print—these are for your use and should not be read aloud.*

Thank you again for agreeing to participate in our study.

Demographic Information

A1. Gender

Male (1)
Female (2)

A2. Date of Birth _____ (If not known, Age: ____ (years) (age at last birthday))

A2. What is your marital status?

Married (1)
Never married (2)
Separate (3)
Divorced (4)
Widowed (5)
Living with partner (6)

A3. What is your level of education?

No school (1)
Some primary (2)
Completed primary (3)
Some secondary (4)
Completed secondary (5)
Some tertiary (6)
Completed tertiary (7)

A4. How long have you been on ART? _____ (months) _____ (years)

A5. How many times have you accessed the community site for ART? _____

A6. What other services do you access at this site?

- Pick up ART (1)
- Treat opportunistic infections (2)
- General exam (3)
- Test CD4 count (4)
- Test viral load (5)
- Treat TB (6)
- Nutrition assessment/support (7)
- Family planning (8)
- Screen for STIs (9)
- Screen for cervical cancer (10)
- Treat HIV associated complications (11)

A7. How do you normally get to the site? (Select one method only)

- Walk (1)
- Bicycle (2)
- Private car (3)
- Bus (4)
- Donkey cart (5)
- Other (6)
- Specify _____

A8. How long does it take you to reach this community site? ____ (minutes) ____ (hours)

A9. Has there been a time that you could not access ART at the community site and had to travel elsewhere for ART?

- No (0)
- Yes (1)

A10. Do you ever pick up ART for others?

- No (0)
- Yes (1)

Accessibility of the Community ART Program

- 1) How easy for you is it to access services at this community site? (Probe to understand if the location is easily accessible, if they receive enough notice that the healthcare team is visiting, if the hours that the community site is open are okay, etc.)
- 2) Once you arrive at the community site, how easy it is for to utilize services at this community site? (Probe- queuing, time to receive services, always receive the services they came for, issues with stock-outs, etc.)
- 3) What are the services that you utilize at this site? (Probe to learn about ALL services that they receive from this site including drugs, check-ups, counseling, support, etc.)

Barriers/ Facilitators to Utilizing Community ART Program

- 4) What are some of the challenges you face utilizing services at this community site? (Examples could include not having enough time to be seen by the doctor, lack of privacy, not receiving all the services needed, challenges with schedule of visits, needing more services that are offered at the community sites, etc.)
- 5) How have you solved any of these challenges?

- 6) Are there any financial costs for to use services at this site? (Probe- costs of transportation, bringing medical supplies, medication costs, taking time off work to come to the site, etc.)
- 7) What are some of the benefits of utilizing services at this community site? (Probe- easy to access, able to get multiple services done in one place, etc.)

HCWs providing Services

- 8) What do you think about the healthcare workers providing services at the community site? (Probe- Friendliness? Trust their advice? Feel that you receive the information and support you need?)

Effect of Community ART Sites on Adherence

- 9) How has the community sites affected your ability to adhere to ART? (Probe- if the community sites were not here, do you think it would affect your ability to adhere to ART?).
- 10) *Question for those who initiated ART before 2007-* How has the arrival of the community sites affected your ability to adhere to ART? (Probe to understand if adherence has strengthened with the arrival of the community sites or if it has stayed the same or weakened).

Personal perspectives towards Community Sites

- 11) What are some of the things that you like most about this community site? (Probe- convenience of location, ability to receive ART nearby, able to get services needed, etc.)
- 12) What are some of things that you don't like about this community site? (Probe- not enough services provided, no privacy, not enough time to receive services, location is inconvenient, no waiting space, etc.)
- 13) If you could improve the community sites, what changes would you make? (Probe- more services offered, more frequent visits, longer hours, more healthcare providers, more privacy, more frequent notice of upcoming visits, etc.)

Community Perspectives toward the Community ART Program

- 14) What is said in the community about these community sites? (Probe- messages from leaders, what elders say, what community members say, what the youth say, etc.)
- 15) Please tell me about any stigma associated with using the community site? (Probe- being seen utilizing site, stigma in the community towards the site, etc.)
- 16) Has stigma affected your use of the community site? If yes, please tell me how it has affected you.

Recommendations to Improve Program

17) What recommendations do you have to improve the community program? (This is very open, can be about the location of site, physical space in which services are provided, what services should be provided, attitudes toward healthcare workers, etc.)

This is the end of our interview. Thank you very much for taking the time to participate in this interview.

End time: ____ : ____

Annexure E: Interview Guide for Key Informant Interviews - Policymakers and Program Managers

Identification

Participant number _____ Site Number: ____ (*pre-assigned number*)

Interviewer Name: _____

Visit date: ____ / ____ / _____ (*dd-mm-yyyy*) Start time: ____ : ____

***INSTRUCTIONS:** This interview should only be started once informed consent has been obtained from the participant. Read all of the questions and all of the information that is in bold print aloud to the participant. Use the probes as needed if the participant looks uncertain or indicates that she is unsure what you mean. Interviewer instructions are in italic print—these are for your use and should not be read aloud.*

Thank you again for agreeing to participate in our study.

Demographic Information

Policymaker (1)
Program manager (2)

A1. Gender

Male (1)
Female (2)

A2. Age: >30
31-40
41-50
50+

A3. Confirm involvement with Okongo District

Yes No

A4. Place of employment (specify district, regional levels):

A5. Current title:

A6. How many years have you been a policymaker/ program manager?

_____ (years)

A.7 How were you involved in the creation of the C-BART? *(Select all that apply)*

Conception of idea (1)
Design of C-BART (2)
Planning of C-BART (3)
Implementation (4)
Reporting data (5)
Other (describe): _____

Conception of C-BART sites: POLICYMAKERS

- 1) Can you tell me how the idea of having community-based ART was conceived?

- 2) Who was involved in this process?

- 3) Was anyone else consulted? If so, who?

- 4) Who (which groups/stakeholders) initially supported the idea, and who (which groups) did not support the idea?
- 5) Why did these groups oppose the idea? What were their concerns?
- 6) For the groups that were supportive of the idea, what were their reasons for supporting the idea?
- 7) In the end, how did you gain support for the idea to at least be tested?
- 8) Who approved the idea to be implemented?
- 9) After getting support for the idea/concept, can you tell me how the idea was implemented?
- 10) At the national level, who was responsible to implement the program?

Design and planning of the C-BART program: POLCYMAKERS/PROGRAM MANAGERS:

- 11) Tell me about the process of designing, planning and implementing the program.
For example, who was consulted in its design and implementation? Where did the resources come from for the program, including the staffing? Who designed the reporting/M&E system? Was there any training involved? Who was trained and who provided the training?
- 12) What role did various interest groups and stakeholder play in the design and implementation of the program?
- 13) How were the local communities involved?
- 14) Please describe the current system of the C-BART sites.
Probe: Who are the different groups (such as HCWs, community leaders, etc.) involved in the C-BART sites? How is communication managed? Who is in charge of the program?
- 15) What were the initial community responses when the program was first implemented?
- 16) How has the arrival of the C-BART sites changed attitudes towards HIV in the community?

Probe to understand any effects of the C-BART sites (HIV discussed more openly, community more knowledgeable about HIV, development of support groups, development of additional services or program for people living with HIV.

17) How has the community attitude towards the C-BART sites changed over time?

18) How did the HCWs initially feel about working in the C-BART sites?

Probe: How has this attitude changed?

19) Please describe how the health extension workers (HEWs) work with the sites?

Probe: How do the HEWs communicate with the HCW teams at the C-BART sites? What is the role of the HEW in supporting the C-BART sites?

20) How do you think the presence of the C-BART sites has affected patient's adherence?

Probe: What has been said by HCWs providing the services? What has been said by community leaders? What data has the participant seen to indicate how adherence may be affected?

21) What have been some the challenges experienced implementing the C-BART sites?

Probe for the different types of challenges: financial, staffing, coordination, communication, logistics (like transportation), ownership, political, etc.). With this question be sure to clarify who was experiencing the challenge (community, HCW team, main ART site, etc.). Please take notes on this.

22) How have these challenges been resolved?

Probe- refer to your notes and ask about the solutions for each of the problems mentioned. If there was no solution, ask what possible solutions were considered and why they were not implemented.

23) Has the C-BART program affected the programs at the clinics and hospitals? If so, how have they been affected?

24) In your opinion, what can be done to strengthen the C-BART programs?

Probe for the different areas: staffing, coordination, scheduling, communication, physical sites, organization (such as transportation), services offered, costs, etc.

25) If this program was being implemented in another district, what are the three most valuable pieces of advice you would give a new district implementing community-based ART?

We have reached the end of our interview. Thank you for your time.