Evaluation of Community-based Anti-retroviral Therapy (CoART) Program in Nigeria

Collaborating Institutions:

Ministry of Health, Nigeria – National Action Committee on AIDS (NACA) and National AIDS & STI Control Program (NASCP), University of Maryland School of Medicine (UMB), PEPFAR Program Implementing Partners in Nigeria and USG PEPFAR AGENCIES (CDC, USAID, & DOD)

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Contents

Abbreviations

µL	microliter
AIDS	acquired immunodeficiency syndrome
ALT	alanine aminotransferase
ART	antiretroviral treatment
ARV	antiretroviral drug
CDC	Centers for Disease Control and Prevention
CGH	Center for Global Health
CoART	Community ART
CPT	Cotrimoxazole Preventive Treatment
DGHT	Division of Global HIV/AIDS and TB
FMOH	Federal Ministry of Health
HIV	human immunodeficiency virus
IRB	Institutional Review Board
LTFU	Lost to follow up
LGA	Local Government Area
mL	milliliter
NACA	National Agency for the Control of AIDS
NAHSS	Nigerian Alliance for Health Systems Strengthening
NASCP	National AIDS and STI Control Programmes
PEPFAR	President's Emergency Plan for AIDS Relief
PI	principal investigator
PLHIV	people living with HIV
PMTCT	prevention of mother-to-child transmission (of HIV)
TB	tuberculosis
U.S.	United States
U.S.G.	United States Government
VL	viral load
WHO	World Health Organization
APIN	AIDS Prevention Initiative in Nigeria
CCFN	Catholic Caritas Foundation of Nigeria
CIHP	Center for Integrated Health Program
CITI	Collaborative Institutional Training Initiative
EMR	Electronic Medical Record
FHI360	Family Health International 360

GON	Government of Nigeria
HCTB	HIV Care and Treatment Branch
HTS	HIV Testing Services
ID	Identification
IDEA	Implementation Dissemination Evaluation Alliance
IHV	Institute of Human Virology
IHVN	Institute of Human Virology, Nigeria
IP	Implementing Partner
MGIC	Maryland Global Initiatives Corporation
NHREC	National Health Research Ethics Committee
POC	Point of Contact
RNA	Ribonucleic Acid
STI	Sexually Transmitted Infection
UMB	University of Maryland, Baltimore
UNAIDS	Joint United Nations Programme on HIV and AIDS
USAID	United States Agency for International Development

Principal Investigators (PIs)

Investigators profiles and roles

Sunday Aboje MD (**Co-PI)**: Dr. Aboje heads the National AIDS and STI Control Programmes (NASCP) division of the Nigerian Federal Ministry of Health (FMOH). His office implements the Nigerian health sector response to HIV and sexually-transmitted infections (STI), develops national health sector Monitoring and Evaluation tools for HIV and STIs, coordinates national surveys on HIV and STIs and has oversight on the activities of organizations and facilities providing HIV services in Nigeria. His office currently works with the Epidemiology and Prevention Division of the Institute of Human Virology (IHV), University of Maryland School of Medicine in the implementation of the Nigerian Alliance for Health Systems Strengthening (NAHSS) which *evaluates* the quality of HIV care provided by health facilities in Nigeria. In this evaluation, Dr. Aboje will be responsible for maintaining the overall operations of the study conduct and activities; he will lead the implementing partner working group, the Implementation Dissemination Evaluation Alliance (IDEA) and maintain regular communications with the PEPFAR implementing partners for the Test and Start program in Nigeria and ensure proper compliance with the protocol and the Government of Nigeria (GoN) strategic plan for HIV/AIDS in the implementation of the Test and Start evaluation. Contacts: cell: 234 8033038090; email: saboje@yahoo.com)

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Other co-investigators and collaborators (Table 1 below) support study implementation and data collection at the study sites. They will provide technical oversight and ensure adherence to protocol. They will ensure that patients and health care providers participating in the study as well providers helping with implementation at the sites are adequately informed about the protocol and their duties and functions. They will also participate in the analyses, interpretation, and reporting of de-identified data. Please note that CDC staff will not be involved in data collection or have access to identifiable patient information.

Conflict of Interest Statement: The study team members whose names are listed on this page and page 6 below certify that they have no affiliations with or involvement in any organization or entity with financial interest in this study.

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Protocol Summary

Title	Evaluation of Community-based Antiretroviral Therapy (CoART) Program in Nigeria
Purpose	To evaluate community-based ART program performance in achieving the short-term goals of improving HIV treatment uptake and maintenance within the community essential for long-term attainment of UNAIDS 90-90-90 goals
Study Design	Mixed design. Involves cross-sectional and retrospective cohort collections of qualitative (interviews) and quantitative (chart review) data.
Study population	Mixed population of program managers (point of contact for partners implementing CoART), health care providers, and patients enrolled in the community-based ART program for a minimum of 6 months.
Study Duration	12 months. Estimated start date for data collection is June 25, 2017.
Study Sites	The study will be conducted in communities in 26 local government authorities (LGAs) where CoART is currently implemented.
Sample size	A minimum of 155 persons will be interviewed directly in obtaining qualitative data while medical charts of at least 4,323 HIV-positive patients enrolled in CoART for 12 months will be reviewed.

Background

One in every ten people living with human immunodeficiency virus (HIV) (PLHIV) in the world lives in Nigeria [1] with an estimated 3.2 million persons living with the disease and a population of 170 million people [2]. Nigeria and 14 other countries accounted for 75% of the 2.1 million new infections in 2013; it is among the six nations facing the triple threat of high HIV burden, low antiretroviral treatment (ART) coverage, and little or no decline in new HIV infections [2].

To increase access to treatment and coverage, the Government of Nigeria (GON), with support from the United States (U.S.) President's Emergency Plan for AIDS Relief (PEPFAR) and Global Fund is scaling up ART services. At the end of 2015, Nigeria had over 1,078 facilities providing ART services, and over 853,992 PLHIV initiated on ART [3]. Despite the scaling-up, ART coverage in Nigeria has remained at 21%, lower than that of other countries in sub-Saharan Africa [4].

There is evidence that promoting more testing for HIV and immediate treatment of individuals found HIV positive, could lead to effective epidemic control at reduced ART costs in the long term [5]. A large, international, randomized control study involving HIV-infected, ART-naïve adults with CD4+ counts of more than 500 cells/μL, reported that the immediate initiation of ART was more beneficial compared to treatment initiation after the CD4+ cell count declined to less than 350 cells/μL [6]. Beneficial effects of immediate ART were observed in both serious acquired immunodeficiency syndrome (AIDS)-related and serious non-AIDS-related events -]. Furthermore, there was no apparent increase in the rate of adverse effects in individuals immediately initiating ART [6].

The beneficial gains of immediate initiation of ART led to the review of previous eligibility criteria based on CD4 cell count and clinical staging. In addition, baseline laboratory tests, such as electrolytes, urea and creatinine levels, alanine transaminase, aspartate transaminase and haemoglobin were also required. These tests were repeated at least once every six months for patients on ART. In September 2015, the World Health Organization (WHO) strongly recommended the initiation of ART at any CD4 cell count for adults >19 years old, pregnant women, adolescents 10 to 19 years old, and infants [6]. Based on this, CD4 cell counts as well as other baseline laboratory tests are no longer required for ART initiation. . Early initiation of ART will increase the number of HIV-positive patients receiving treatment, lead to better clinical outcomes, suppress VL and reduce transmission of infection and change the course of the HIV epidemic 7]. If fully implemented, this will expand access to HIV treatment and could support the achievement of the Joint United Nations Programme on HIV/AIDS (UNAIDS) 90-90-90 goal by 2020, averting over 21 million HIV-related deaths and 28 million new HIV infections by 2030 [6].

Some barriers to accessing treatment include long distances to ART-providing health facilities, competing social priorities such as work, use of health facilities only when obviously sick, and poor health seeking behaviour. Some barriers to retention in treatment are long patient waiting times in the hospital/clinics, lack of confidence in the benefits of ART, competing alternative treatment providers, high hospital staff burden, poor attitude of health care providers, as well as some cultural beliefs [7-10].

To help Nigeria overcome these barriers and improve ART uptake, the PEPFAR HIV program in Nigeria has proposed community-based ART (CoART) models. This alternative to the conventional facility-based ART model is expected to expand access to free treatment and improve quality clinical care. The CoART model also has the potential to decongest the facilities in which ART is provided allowing health care provider time to be focused on patients with more complex disease progression and/or comorbidities who need it [11, 12]. CoART models can be patient-driven, e.g., through the use of community ART groups (CAGs) for distribution and ART monitoring of adherence [13, 14] or health-facility-driven, e.g., appointment spacing for clinical and drug refill visits [15]. Patients' context (stable on treatment), task shifting to lay volunteers and the associated regulatory requirements are some important factors to consider in developing models for community service delivery [16-18]. CoART models used in different settings in sub-Saharan Africa demonstrated significant benefits directly to the patients, the health systems, and the community [19-21]. CoART program services were recently introduced in Nigeria as pilot programs in priority LGAs. This protocol evaluates the implementation and treatment outcomes of the various CoART models currently employed in high-burden communities where improving access to ART services has the potential of impacting HIV epidemic control.

Stakeholders

Stakeholders involved with this evaluation include the FMoH Division of HIV/AIDS, the National Agency for the Control of AIDS (NACA), US Centers for Disease Control and Prevention (CDC), University of Maryland School of Medicine and **the following** CDC and United States Agency for International Development (USAID) PEPFAR program implementing partners (IPs): Institute of Human Virology, Nigeria (IHVN), Catholic Caritas Foundation of Nigeria (CCFN), Center for Integrated Health Program (CIHP), AIDS Prevention Initiative in Nigeria (APIN), and Family Health International 360 (FHI 360).

Evaluation Question

The broad question: Are the models for CoART service delivery implemented in Nigeria effective and with quality treatment outcomes?

Specific questions

1. Process (formative) evaluation-service delivery and utilization

a) How differentiated are the delivery models and what community structures support service delivery?

b) What are the proportions of HIV-positive clients enrolled in the different services delivery models for CoART?

c) In the view of program managers and health care providers what are the barriers and facilitators to sustainable CoART delivery in Nigeria?
d) How satisfied are HIV-positive clients with the CoART program?

2. Outcome evaluation-ART outcomes

e) What proportions of HIV patients achieved viral suppression, optimal adherence, and retention in care; also lost to follow up or died, 12 months after enrolment in the CoART program?

Purpose

To evaluate community-based ART program performance in achieving the short term goals of improving HIV treatment, uptake, and maintenance within the community essential for long-term attainment of UNAIDS 90-90-90 goals, as well as secondary end points of mortality and lost to follow up.

Objectives

Process evaluation

- To assess CoART models' unique approaches to differentiated ART service delivery within the community
- To identify task-shifting community structures supporting models and range of services provided
- To assess patient satisfaction with the CoART program services
- To identify barriers to and facilitators for (programmatic or otherwise) sustainable CoART service delivery
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Outcome evaluation

- To measure treatment uptake at community level following CoART introduction

- To measure CoART treatment outcomes of patients' retention in care, drug adherence and pattern, and VL suppression

CoART program Implementation-overview

CoART program in Nigeria is implemented by CDC and USAID PEPFAR program IPs: IHVN, CCFN, CIHP, APIN, and FHI 360. This pilot program allows multiple differentiated models of ART care to be tested in select high-burden priority LGAs engaging patients at various stages of the clinical care continuum. Some of the models engage patients into the care continuum at HIV testing and diagnosis stage to initiate, retain, stabilize (achieve viral suppression) and maintain them on ART while others recruit patients at the end-stage of the continuum who are already stabilized on ART at the facility level and devolve them to community structures for maintenance in the HIV treatment cascade of care.

Models recruiting patients at diagnosis either 1) create demand for ART through community HIV counselling and testing (HTS), initiate the newly identified HIV positives and stabilize them on ART within the community or 2) create demand for ART through community HTS, initiate the newly-identified HIV positives and stabilize them on ART at the facility, then devolve them back to the community for treatment maintenance. 3) The third model recruit stable ART patients from facilities providing ART services and devolve them to community structures for drug refill and treatment maintenance. Secondary and tertiary health centres serve as hub facilities for community structures supporting the different models. Data collected from the community are regularly archived at the supervising hub facilities. At the hub, facilities data are coded separately with a different prefix for CoART patients' unique identification. Medical records for the program domiciled at the hub facilities are labelled in ways that distinguish community-based from facility-based ART data. From January to November of 2016, 6499 HIV-positive patients were enrolled in the CoART program from 26 high burden LGAs in Nigeria.

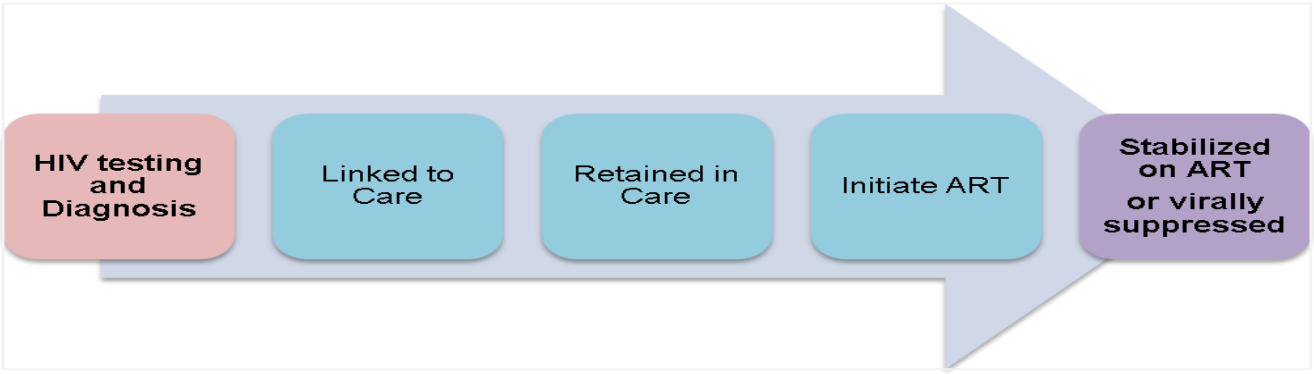

Figure 1. Points of enrolment into CoART (light red and purple boxes) along the spectrum of engagement in the clinical care

Methods

Study Design

A mixed design that involves cross-sectional obtainment of information from program managers, interviews with patients and health care providers, and retrospective cohort analyses of patients' medical records will be employed. Data for the retrospective analysis will be sourced from electronic and paper-based records of patient registers, medical charts, pharmacy records, laboratory records, and referral registers. This evaluation will be conducted from June to December, 2017.

Study sites

Nigeria has 36 states with an administrative capital called the Federal Capital Territory (Figure 2) [20]. HIV prevalence estimates in the 36 states ranging from 0.6% to 15.2% with a median of 3.4% [21]. The states in Nigeria are divided into smaller administrative units (LGAs) and there are 774 LGAs. Of those, 32 were prioritised for HIV epidemic control, where new treatment strategies are tested before they are considered for scale-up across the country. The 32 prioritized high burden, high prevalence LGAs are:Logo, Oshongo, Gwer West, Tarka, Buruku, Katsina ala, and Konshisha in Benue state; Abuja Muncipal, Bwari, and Karu in FCT-Abuja; Nassarawa, Lafiya, Obi, and Doma in Nassarawa state; and Alimosho, Ifako-Ijaiye, Ikeja Agege, Ajeromi, Apapa, Surulere, and Mushin in Lagos State; Calabar municipal and Calabar south in Cross rivers state; Oron, Ikot Ekpene, Uyo, Uruan, and Okobo In Akwa Ibom state; Eleme, Obio-Akpor, and Port Harcourt in Rivers state will serve as the study site.

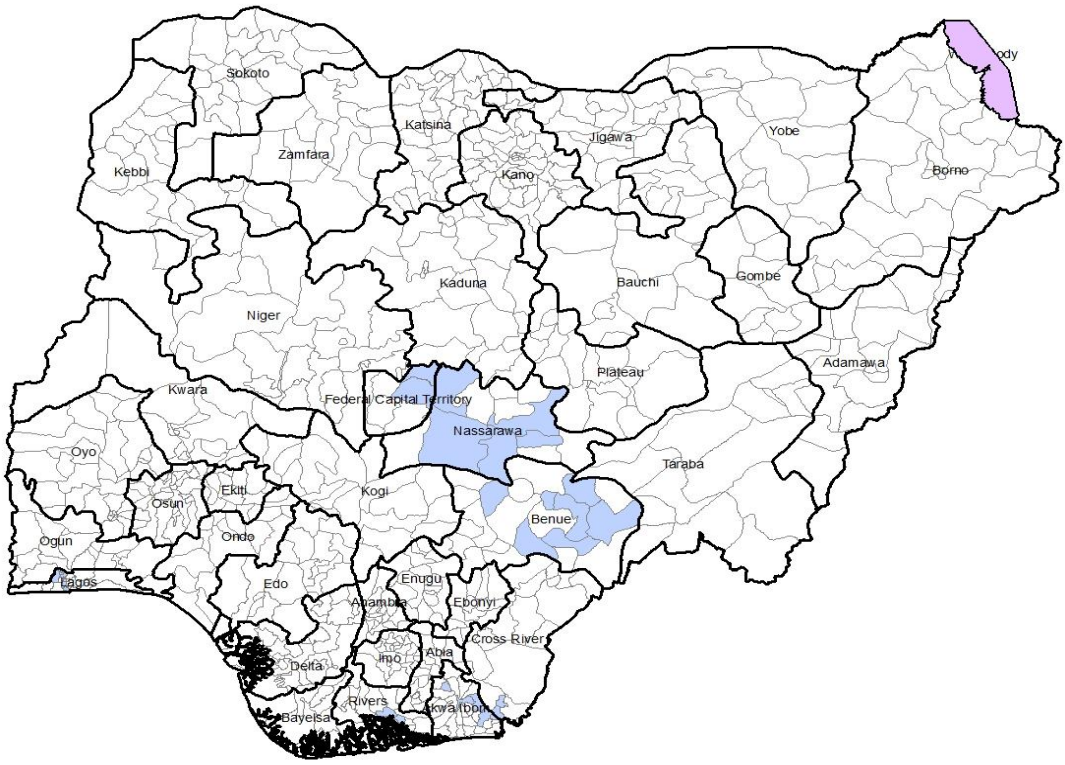

Figure 2: Map of Nigeria with areas highlighted in blue representing scale-up LGAs for epidemic control (32 LGAs)

Standard of care for HIV treatment (Test and Start) at the sites

To help Nigeria achieve HIV epidemic control, the Honorouble Minister of Health approved implementation of the Test and Start treatment approach across the 32 high burden LGAs. The program implementation started in October, 2015 and written approval of the Health Minister was conveyed in March of 2016. The PEPFAR program working in partnerhip with the Global Fund are currenly conducting pilot runs in the 26 high HIV-burden LGAs to assess feasibility and nation-wide scalability of the programThe . Newly identified HIV-positive patients and pre-ART (known HIV positive but ART naïve) patients are first offered a counselling session on the day of enrolment in HIV care, and a 2nd session one week later ("week 1"), in line with the revised National Integrated Guidelines that requires all HIV-positive adults and adolescents to be initiated on ART regardless of clinical or immunologic status, if the patient had a good understanding of HIV and the importance of life-long adherence to medication, ART could be initiated at week 1. Otherwise, a third counselling session is be planned and the patient is initiated on ART at week 2. As part of routine care, patients would be provided cotrimoxazole prophylactic therapy (CPT) if the patient is symptomatic for opportunistic infections or has a baseline CD4<350cells/µL, and isoniazid prophylactic therapy (after routine symptom screening to exclude tuberculosis (TB)).

ART Initiation for newly-enrolled HIV-positive patients and current pre-ART patients

- Week 0 = the first visit to the ART clinic for newly-diagnosed patients or first visit back to the clinic of current pre-ART patients. The attending medical doctor/health worker would do the following:
    - Take a detailed clinical (including TB symptoms) and social history, and conduct a complete physical examination,
    - Identity, whether the patient is newly diagnosed as HIV positive or, is currently a pre-ART patient
    - Document the clinical or social eligibility criteria for ART, as they apply to the patient, e.g.,
        - Patient eligible for ART based on Test and Start protocol
        - Any WHO clinical stage 3 or 4 condition
        - Active TB
        - HIV-positive client in an HIV-discordant relationship
        - HIV-positive client in an HIV-concordant relationship and planning to conceive a child
        - CD4 result, if available
    - Perform all pre-ART laboratory tests on date of enrolment in care (first visit) for all patients if not already done (for some pre-ART patients some results may already be available)
        - CD4 (cryptococcal antigen test should be done if CD4<100cells/µL), Hepatitis B surface antigen hemoglobin concentration, creatinine, and urine dipstick (if applicable)
    - Provide first counselling session
    - Give an appointment for the 2nd visit in one week, and invite client to bring a treatment supporter
    - Encourage client to bring partner(s) and children (if applicable) for HIV testing if not already HIV+ and on treatment

- Week 1 (2nd visit)
    - Review results of blood tests (if available).
        - Calculate creatinine clearance (if applicable)
        - Determine appropriate antiretroviral drug (ARV) regimen
        - Determine need for (CPT) and prescribe, if required.
    - Provide second counselling session, ideally with treatment supporter.
    - If the patient is ready to start ART, clinician ensures that client understands information regarding HIV and treatment plan, and initiates ART on that day
    - Pharmacist/Pharmacy assistant provides routine adherence support counselling before dispensing ARVs
    - Enter further relevant information in the patient care booklet during visit
    - If laboratory results not yet available, give appointment for 3rd visit in one week

- Week 2 (3rd visit)
    - If not yet initiated on ART, review results of baseline blood tests, as above
        - Calculate creatinine clearance (if applicable)
        - Determine appropriate ARV regimen
        - Determine need for CPT and prescribe if necessary
    - Enter relevant information and classification of patient as mentioned above in the patient care booklet
    - Provide third counselling session
    - If the patient is ready to start ART, ensure that client understands information regarding HIV and treatment plan, and initiates ART on that day
    - Pharmacist/Pharmacy assistant provides routine adherence support counselling before dispensing ARVs

Patient follow-up and care after ART Initiation

- Standard follow-up at two weeks, eight weeks, and three months for all patients initiating ART including an emphasis on adherence
- Complete the patient care booklet at each visit

Technical Support to implementing staff

The staff at the pilot implementation sites will receive ongoing technical assistance through various means.

- Training:
  Implementing staff would receive an initial one-and-a-half-day training on the implementation of HIV Test and Start. The training would touch on the implementation details of the pilot, the basics of HIV testing and counselling, patient referral and linkage to care, initiation of treatment, and patient follow-up. Training on ART guidelines would not form part of this training.
- Distance consultations

Clinical mentors in the regions and at the national level would continue providing technical support through distance consultation and training throughout and beyond the pilot.

- Site level mentoring visits
  As part of their scheduled visits to the sites, clinical mentors will provide hands-on trainings and other mentoring support to the staff implementing the project. Health care providers at facilities that might not have clinical mentors attached to them would continue receiving technical support from a distance.

Study population

This study will involve CoART program managers, health providers and HIV-positive patients.

Inclusion criteria-participant

- CoART program managers must have spent at least 6 months implementing a given CoART model to be eligible to respond to questions on the model's implementation
- Health care providers must have spent at least 6 months providing CoART services to participate in cross-sectional interviews on the CoART program
- Patients must be 16 years or older and received CoART services for at least 6 months at the time of enrolment to participate in patient satisfaction interviews.
- Patients must be 16 years or older with a minimum of 12 months follow-up period since enrolment into care and have available medical records at the time of the study for recruitment into the retrospective cohort review of records. We will document missing charts and charts with missing data.

Exclusion criteria-participant

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- HIV-positive woman pregnant at the time of ART commencement

Inclusion criteria-model

- Process evaluation: model must be implemented for at least 6 months at the time of the evaluation
- Outcome evaluation: model must be implemented for at least 6 months at the time of the evaluation

Sample Size Considerations

Qualitative interviews:

The IP's program manager (point of contact person) involved with CoART model implementation will be invited to provide information on the CoART model implemented by his/her employee organization. For each model, a minimum of 15 health care providers and 15 patients receiving CoART services per model across all implementation sites will be selected using simple random sampling and invited to participate in qualitative interviews to share their

perspectives on the program and satisfaction with services. The recommended range of key informants for qualitative interview is between 15-35 persons [24]. We opted for 15 because of the time allotted and resources available. At the time of the protocol submission, the implementations of these models were in their infancy and less numbers accrued in the program.

Quantitative analyses (retrospective review of records): Available literature within Nigeria and elsewhere in the sub Saharan Africa show the rate of attrition, adherence and virologic failure among patients initiated on ART and followed up for at least 12 months to range between 14-20% [25, 26] ; 11-15% [27, 28] and 17-19% [29, 30 respectively. For the purpose of this evaluation we assume conservative attrition rates from ART, sub-optimal adherence rates (defined as less than 95% adherence to pharmacy refill appointments during the review period), and viral failure rates at 25%. We thus expect 75% of the patients enrolled to be alive and on treatment (retained in care) and achieve optimal adherence and achieve viral suppression 12 months after CoART initiation.

In calculating the sample size for estimating the proportion of HIV-positive patients enrolled in CoART that may be retained in care or achieve optimal adherence or achieve viral suppression, we used a 95% confidence interval with the aim of accuracy within 2.5% of the true proportions. Our conservative estimates of the proportions with successful retention, adherence, and viral suppression based on the literature were 75% (above). With a 95% confidence interval, a success rate of 75% and a 2.5% margin of error (precision of 0.025), the minimum number of HIV-positive patients required to evaluate the endpoints of interest using precision method and online calculator:http://epitools.ausvet.com.au/content.php?page=1Proportion&Proportion=0.75&Conf=0.95&Precision=0.025&Population=10000 is 1153. This sample size is the conservative number required in the worst case scenario in which the outcomes of interest were at lowest levels comparable to other places in the Sub-Saharan Africa. In the best case scenario (90% or higher), this number will be less than 800. However, given that some of the models have recruited less number of patients, prevalence estimates will be drawn from the total number of patients recruited in a given model. In that case, the precision of the estimate will depend on the number recruited and levels of the end points measured.

Since not all patients approached accepted to receive HIV services in the community and to correct for selection of patients successfully enrolled in CoART, but have missing medical charts at the time of data abstraction we made some assumptions to estimate the sample sizes required to evaluate models based on their implementation strategy or approach. According to UNAIDS, HIV prevalence estimates in Nigeria among adults 15-49 years was 3.1% in 2015 [31]. In addition, we make the following assumptions:

- 90% of the HIV positives identified through community HTS will be successfully enrolled in CoART
- 60% of the stable facility-based patients approached for devolution to the community will agree to enrol in CoART
- 20% of patients selected for medical records review will have missing charts

Table 1: Approach and minimum sample size requirement for outcome evaluation of community ART

	Model approach	Strategy	# HIV+ without missing charts	# HIV+ adjusting for 20% missing charts	# HIV+ HTS identified or ART stable (90 or 60%)	# to screen via community HTS (3.1% prevalence)	LGA	Implement-ing Partner
1	Community-based HIV	HIV Continuum of Care Services fully					Benue state – Logo,	CCFN;

	continuum of care delivery	provided within the community HTS – Community Linkage – Community ART initiation – Community Treatment support - Community	1153	1441	1601	**51,649**	Gwer West	
2	Integration of community structure into facility hub-spoke clusters for treatment support	Enrol and devolved stable facility-based patients to community structures for drug refill and treatment maintenance HTS – Not applicable Linkage – Not applicable ART initiation – Facility Treatment support – Facility and community for stable patients	1153	1441	**2,402**		Lagos – Alimosho, Ifako-Ijaye, Ikeja, Mushin, Apapa, Surulere, Ajeromi, Agege FCT - AMAC, Bwari; Akwa-Ibom – Oron, Uyo, Ikot-Ekpene; Rivers – Port Harcourt, Obio Akpor; Cross Rivers: - Calabar South, Calabar Municipal;	APIN; IHVN; FHI360;

Recruitment strategy

IP's CoART program managers will be invited to complete an instrument with itemized questions regarding program implementation, model structures and uniqueness, and data generated. The eligible health care providers will be selected using simple random sampling (SRS) for IP models that have more than the required sample size of 15 and all health care providers that consent to an interview will be interviewed in IP models with less than 15 eligible health care providers. A systematic sampling with an option of replacement will be employed to select patients that are eligible to participate in the interview.

The health care providers providing ART services at community structures will be approached by our trained interviewers through the program manager. The program manager is responsible for coordinating interviewers' activity at the site including access to data and program staff. The interviewers will request the site manager to inform the program staff that their participation in any interview is absolutely voluntary. They are at liberty to decline without any loss of benefit or privilege. Following this introduction, the interviewers will then approach the program staff to find out if they are interested in the study and would like to learn more about it. Those who indicated willingness to participate will be requested to provide informed consent. They will be invited to read the informed consent or have the interviewer read it to them. Patients will be approached in a similar way through their care providers.

Medical records for chart reviews will be selected by SRS from a sample frame of eligible patients. If the number of eligible charts to be abstracted is small, all the charts that are found to be eligible will be abstracted. Selection of medical records for chart review will be done through a sampling frame of eligible (>= 16 years followed up for 6 months). We will use line listing of eligible individuals enrolled in the program as sample frame and use SRS to select a sample for review. Models with less number of patients enrolled for CoART than the sample size will have all available folders abstracted. The availability of medical records for the selected IDs will be confirmed by the program lead of the service providing organization. The electronic records archived at the relevant hub facilities will then located for abstraction.

Data Collection

*Cross-sectional data***:** data on CoART model will be collected from program managers with the aid of the tool in Appendix B. Variables of interest include program start date (model implementation start date), priority LGAs involved, primary structures (patent medicine stores, community pharmacies, primary health facilities, etc.) and hub facilities, differentiated care type (model specific approach to treatment and care for the enrolees), numbers enrolled and spectrum of engagement in HIV continuum of care, visits and drug refill frequencies, and administrative and logistical barriers to the model program implementation. The Patient Satisfaction Survey (Appendix C) will collect information on patient's general perspective of CoART service delivery including ability to access needed services, referrals, quality of provider-client interaction, and convenience (place, time, and cost) Health care providers interviews will include questions on human resource capacity for CoART implementation, task shifting, providers satisfaction, support services, referrals and tracking of referrals, identified barriers and facilitators for effective program implementation (Appendix D)

Longitudinal data abstraction: The contract research organization's (the University of Maryland, Baltimore (UMB), Maryland Global Initiative Corporation (MGIC) staff are trained in data abstraction, survey interviews, and human subject protection with hands-on experience in confidentiality protection in handling clinical and health data. Implementation of the CoART program started at different calendar times by the different IPs. **Data will be abstracted in batches as participants engaged by the CoART models complete the 12 months observation period. Models implemented for less than 12 months by March 31, 2018 will not be considered for patients' records abstraction. Models must have accrued the minimum sample of subject based on their strategy or approach for program implementation by March 31, 2018.** The UMB MGIC team of abstractors will work with the IPs point-of-contact (POC) for this evaluation and the program lead to develop sample frames of eligible patients to select IDs with available medical records. The program managers will facilitate records retrieval and access to relevant electronic and paper registers.

The UMB MGIC team of abstractors are familiar with the various electronic medical records (EMR) platforms used by the different IPs and are currently abstracting data from EMR platforms for evaluating a similar program. Data

elements of interest not captured in the EMRs would be manually abstracted from patients' medical records (paper records) and hard copies of clinic registers. Data de-identification and abstraction begin with the selection of IDs and medical records or charts of eligible patients. IDs with missing charts will be replaced. A laptop with a data collection application will be used for data collection. This device is GSM data (3G)-enabled, with 512 MB of random access memory and 8 GB of internal storage memory. It is also global positioning system-compatible and has WiFi 802.11b/g/n capacity.

De-identification and Study Identification: Data entered into the abstraction form on the laptop will not include patient's name, phone number, fax numbers, email or physical addresses, health insurance number, biometric identifier, or photographic images if any. Enrolment ID will be generated and assigned during abstraction. It includes a prefix 3-digit model code, patient's hospital record number, and a 2-digit abstractor's code. e.g., 113667702 identifies patient with CoART medical record number 6677 enrolled in model 113 by data abstractor number 02. Patients' hospital record number was included as part of the enrolment ID to allow re-tracing of patients charts if required to correct errors, missing data, or data lost in the process of capturing data into the central server. Access to identifiable information is regarded as engagement in research. Persons engaged in research will be required to have relevant IRB or ethics committee approvals and must have signed the confidentiality agreement form. The same method of data collection using a laptop will be used to collect qualitative data through interviews of key informants.

*Data elements for abstraction***:** The breadth of information to be abstracted from patients' medical records is provided in the CoART Data Abstraction Tool (Appendix E). Below is a summary of data elements of interest for abstraction.

Outcomes and Dates: *Retention in care*: patient still alive and on CoART. We will record the date of the most recent clinical visit to the health care provider or medications pickups. Death during CoART and date of death, lost to follow up (LTFU) during CoART (No clinical visit or medication refill for the last 90 days from date of missed appointment.), transfer to another CoART or back to facility-based ART with documentation of the date of transfer, and voluntary stoppage of ART or for reasons indicated in the medical chart (health care provider must indicate that he/she is aware that the patient will not be returning for further CoART care) and date of stopping the ART will be recorded. Where applicable, we will record reasons for ART interruption, and cause of death?

Adherence: Due to concerns that self-reported measure of adherence to ART is prone to recall bias and exaggerations that could positively skew outcome [32] we intend to use drug prescription refill records to measure adherence to ART. Use of pharmacy refill data in measuring adherence to HIV treatment in large programs has been reported with success [33, 34] . We will look at the patterns of treatment interruption including missed appointments, voluntary stoppage of medication, and structured discontinuation of ARVs due to adverse events.

VL suppression: We will collect data on VL measurements at, 6, and 12 months to determine the proportion of patients achieving viral suppression below the limit of detection at 6 and 12 months after ART initiation.

General outcome data: Demographic--date of birth (month and year only), age at enrolment into the CoART program, gender; village, town, or LGA of residence at CoART initiation; marital status, educational level reached at the time of enrolment, employment status at the date of enrolment; HIV testing services- date of first HIV diagnosis; support services and referrals-adherence counselling and other variables of interests including weight, haemoglobin, CD4 count, clinical stage, co-trimoxazole prescription, ART regimen and changes, adverse events, and opportunistic infections.

Review of registers: *Referral records* will be reviewed to track referrals that were not captured in the client records leading to erroneous classification of such clients as LTFU. Data in the referral registers may help to re-classify some patients initially thought to be LTFU after medical record review as either dead, stopped ART, or transferred out. *Laboratory records*-If CD4 counts, haemoglobin levels, or VL are missing from the charts, the laboratory register where all the results are recorded will be reviewed in an attempt to complete as much of the data abstraction form as possible. Pharmacy records will be reviewed for each ID with available medical record to appointment dates with drug pickups dates to identify missed appointments or LTFUs.

Data Management Plan

Data collection and handling: A laptop with data collection application will be used for the collection of patient data and information obtained through interviews. Trained study staff will de-identify and abstract patient-level data at the facility level, obtain consent and administer questionnaires to the health care providers. Data completeness and accuracy will be checked as the data are entered into the abstraction form on the device by automated checks set up and enforced at the outset.

Data transfer and capture: Data on the laptops are transferred into the central server at the UMB MGIC office. Data will be transferred from the laptops to the central server on daily bases during data collection and abstraction. The connection between the client devices (Laptops) and the central server is protected using SSL (Secure Sockets Layer) encryption to ensure that intercepted data packets cannot be decrypted without the encoding key, making it difficult to access patient information. The central server is located in the UMB Nigeria data centre which is protect with an access controls and other industry standard physical and network security features and process. The data is entered on the collection devices and synced to the central server daily once the data entry is completed.Access to the device is limited by user credentials (passwords). The application allows data to be stored only on one central database. Data stays on the device temporarily when Internet service is disrupted and synced with the resumption of internet service. Data are encrypted as files are transferred between application and the database. Unauthorized access is further prevented by auto time-out after 5 minutes of inactivity. The data manager monitor's data transfer and upload on the desktop and central server. The manager checks data elements from each site to ensure accuracy and completeness and keep custody of the data.

Data storage and back up: Hard copies of consent forms and survey instruments will be kept in locked cabinets at the UMB MGIC office, and in secured UMB Nigeria server for electronic data. All electronic data are stored in Microsoft Excel format with a data dictionary that describes each data element. Collected data will be backed up on external data storage devices secured in a fire-proof cabinet. The lead investigator and study staff will have access to the data through user name and passwords controlled by the data manager. The data collection application store all collected survey data on the device's removable memory card and backs it up on the device's internal memory. That way, if a device fails, data can be recovered from the memory card and vice-versa. In the event of accidental loss or theft of a collection device before data are uploaded on the central server or MGIC office computers, data abstraction and collection at the affected site(s) will be repeated. After the study, written data will be stored in a secured warehouse used by the UMB MGIC and can be made available on a week's notice. Electronic data will be stored on UMB MGIC secured servers for the entire duration of the project and 3 years after the project ends while ensuring instant availability. Written paper forms are destroyed after 3 years of storage through onsite shredding and secured destruction of shredded materials.

Data integrity and security: Data entry will be monitored at the collection sites and reviewed weekly by the Implementation Dissemination Evaluation Alliance (IDEA) at the UMB MGIC central database. Automated error checks will be set at the outset to identify data entry errors (e.g., data collection dates incompatible with the study period, outlier values, etc.). Each abstractor's data entry will be randomly and independently reviewed to look for errors or inconsistencies. We will set acceptable transcription error rates at 1% per week. If an abstractor exceeds that level on any given week, the total of their data entry for that week is reviewed. Consistent error rate above the acceptable level will require review of error patterns by the IDEA group to determine if it is the result of improper training, wrong assumptions, a problem with the data entry form itself or some other issue. Corrective action will then be taken and the data entry errors monitored more aggressively. Access to the data on the device and on the program computers (central server) will require two levels of individual passwords, one at the user account level and one at the database level. Knowledge of the account password will be limited to each account holder and the database password will be limited to the data manager and the team lead investigator. Both passwords will be changed every 3 months. Digital databases and archives are protected from security breaches through encryption while data losses by redundancy of the system. Data shared in this study will not contain enrolment IDs.

Table 2: Data Handling and Management-UMB MGIC Team Members Roles

Data Abstraction	Supervision (IDEA)	Data Management	Data Analyses
Akipu E.	Collins I. (CIHP)	Emeka M. Akipu E Ramat Ibrahim	Gumel A.
Samuel D	Moses K (IHVN)		Kristen S.
Anukam O	Bolanle B. (APIN)		Charurat M.

Henrietta	Olanrewaju O. (CCFN)	Gumel A.	
Ramat I	Oluwasanmi Adedokun (FHI360)		

Analyses plan

Data collected for this evaluation will be analyzed according to the evaluation type and objectives outlined at the beginning of this protocol. Data obtained from key informants will be examined as the interviews are conducted to identify better and easier ways to elicit and interpret patient or health provider response that best describe their perspectives on the barriers and facilitators of the CoART program with questions content preserved

Qualitative content analysis will be used to analyze the data to obtain a description of respondent perspectives of the program. An inductive approach will be used to derive from the research question and directly from the data collected. The codes will be arranged in tentative categories based on similarities and differences. These tentative categories will be discussed and reviewed at a data analysis review meeting until they are agreed upon and encoded into final categories. The final categories derived from the data will then be arranged into themes that address the evaluation objectives and highlight patient or health providers' perspective on successes and barriers of the program. Reasons for program success may provide insight on good treatment outcomes deduced from the quantitative data while information on important barriers may explain possible reason for program failure. Analyst will look for repetitive trends and similarities and differences between trends in participants' responses. They will also assess relationships between trends and how these relationships provide additional information to the findings from the quantitative data.

For the outcome evaluation, the measures of interest are along the HIV continuum of care cascade- VL suppression, retention in care and optimal adherence over 12 month following CoART initiation. We define the outcomes as follows:

Retention in care: defined as continuous engagement of patients who are alive and on therapy 12 months after CoART initiation. Patients who are documented to have transferred out of each program model will be excluded from the analysis. We will document patients who died or were LTFU, or stopped ART indefinitely (all patients who discontinued treatment by 12 month after CoART initiation.

Optimal adherence to ART: defined as the extent to which a patient picks up the prescribed pharmacy refills of ART regimen as demanded by the health care provider. With 90% as the threshold for optimal adherence.

Viral suppression: Functional suppression--HIV-1 ribonucleic acid (RNA) below 1000 copies/ml (WHO). Absolute suppression- defined as HIV-1 RNA load below the limit of detection of the most sensitive assay available in Nigeria

Statistical analysis software (SAS) version 9.2 will be used for the analysis. Data will be examined for missing values, outliers, and normality using histograms and normal plots. Data will first be explored in univariate analyses to generate descriptive statistics and then examine correlates of retention, optimal adherence and virial suppression in which odds ratios and 95% confidence intervals will be reported. We will compare baseline characteristics between patients in different models and identify potential confounders. The Chi-square test or Fisher's exact test will be used in assessing the significance of associations between the categorical groups. T-Test will be used to evaluate difference in the means between groups. A P-value of 0.05 or less will be considered statistically significant.

Changes in the outcome over time will be computed with 95% confidence intervals and graphic displays of the pattern in time series plots. We will describe uptake of ART and spectrum of engagement in the treatment continuum of care by graphical display of numbers and proportions to show the different models contributions to the treatment uptake in the CoART program and relative contributions to the benchmark epidemic control goals of 90-90-90. We will compare models with similar approaches of engagement on treatment uptakes, viral suppression, retention in care, and adherence. We will examine time to viral suppression for models that recruit patients via HTS and initiate

them on ART. We will examine trend and compare slopes in the mean VL or CD4, retention, and adherence over time with the individual CoART models as different treatment groups.

Standard survival analysis methods will be used for the analyses of secondary endpoint of mortality. Survival time will be measured as the time from the date of CoART initiation to either the date of death or date of censoring (1 month after CoART initiation). Kaplan-Meier graphs and cumulative survival probabilities will be computed. Multivariate Cox proportional hazard models will be used to estimate relative risks (hazards ratios) associated with the different CoART models while adjusting for potential confounding variables, e.g., age, gender, comorbidities, etc. Cox models assume that the effect of covariates is constant over time (proportional hazards assumption). We will test this assumption using graphical and formal methods as proposed by Therneau and Grambsch.[35.

Monitoring of study planning and implementation

Data Quality Assurance

The protocol will engage the services of the UMB office in Nigeria, MGIC for the implementation of this study. Staff from this office with guidance and supervision from the Division of Epidemiology and Prevention, IHVN, UMB School of Medicine will collect, manage, and analyze data for this study. The study implementation team is led by Manhattan Charurat, the Division Head, Epidemiology and Prevention, IHVN, UMB School of Medicine. For best quality assurance with improved adherence to protocol, data completeness and accuracy, a stakeholders' committee (IP working group) will be created to supervise the study implementation.

IP Working Group; IDEA

Data for abstraction in this study will be sourced from electronic and paper medical records at the selected sites supported by the PEPFAR program IPs in Nigeria. Through the IDEA working group, each IP will contribute a POC person who will represent the IP and monitor adherence to protocol and implementation at the IP's supported sites. The IDEA group will supervise data abstractors training, site activity during data abstraction and transfer to UMB MGIC. This working group will have representatives of CDC, USAID, PEPFAR, and the FMOH Division of HIV/AIDS. The IDEA group will supervise data collection and meet monthly to review implementation and proper solutions to challenges encountered. The representatives of CDC and FMOH will however not be involved in the data collection supervision.

Training

Data abstractors and the supervising IDEA group will be trained on the survey objectives and their roles in the survey, as well as the need for good quality data. The abstractors and data managers who are trained with hands-on experience on data collection, capturing, storage and human subject protection will be required to take refresher Collaborative Institutional Training Initiative (CITI) training on confidentiality and human subject protection. They will receive internal two days of training on data security from the IMD's School of Medicine. Supervisors will undergo a four-day, central-level training. The IDEA group members will be required to take the CITI training on human subject protection.

Field supervision

During the data abstraction, the IDEA group members supervising data collection at the sites will supervise abstractors' handling of chart selection, maintaining confidential records, ID coding, entry into the laptop and review of abstracted data immediately after the abstraction to ensure identified mistakes and missing information are corrected, and identifiable information for exclusion are excluded before the client folder is returned or electoronic record closed. We shall facilitate multiple peer review of abstraction process among data abstractors to serve as additional quality assurance for completeness and accuracy.

Training of Abstractors

Before beginning data collection, all data abstractors will undergo a 3-5-day training on the protocol, forms, and study procedures. UMB MGIC in collaboration with CDC and FMOH will conduct the required training for data abstractors. During training, the importance of data de-identification and maintenance of confidentiality for patients whose charts are reviewed will be emphasized.

Also, as part of the training, UMB MGIC team will pilot the medical chart review and data abstraction at three health facilities in LGAs that are not part of the survey to ensure that the instruments are appropriate and that all team members are given consistent directions. We will also pilot the data entry process, including generating key tables illustrating patients' clinical and social demographic factors, rates of LTFU, mortality, and retention as well as rates of virologic failure by duration on ART. We will use data generated from piloting data abstraction instruments to pilot the data entry process. The instruments and the data entry process will be revised, as necessary, before the main study data collection process starts.

Ethical concerns

Patients and health care providers participating in this interview will be made to understand the procedures, benefits, risks and that their participation is entirely voluntary and they are at liberty to decline without loss of benefit or privilege. A waiver of documentation of informed consent will be requested from the relevant ethic committees as required by U.S Code of Federal Regulation (CFR 46.117) which states that an ethic committee may waive the requirement for the investigator to obtain signed consent from some or all subjects if it finds that the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

Risks of accidental disclosure of HIV status

The greatest risk is accidental disclosure of HIV status. This involves patients interviewed in the cross-sectional surveys and those whose medical records will be abstracted for the longitudinal analysis. To minimize this risk, interviews will be conducted in a secure and private location in a closed room in strict privacy and confidentiality where routine HIV and adherence counselling are offered to the patients as part of the CoART care package. Data collected for the survey will not include patients' names. Medical records data will be de-identified at the source as the data are abstracted. Data will be recorded using codes and will be kept in secure databases. Access to the computerize database is password protected. Access to all code keys will be limited.

Potential Benefits

Participants: Participants in this study are accessing ART through the various CoART models, barriers to ART access that may relate to program, health provider, or even patients themselves could be identified through these interviews. If found these barriers will be discussed with the health providers, program implementers, and the sponsor to provide actionable information for improvement.
Society: The proposed research may have important benefits to society. It offers us the opportunity to appraise the outreach capabilities and impact of the differentiated CoART models with potential for scalability of service delivery that improves adherence and prevent spread of HIV (treatment as prevention) within the community.

Privacy – Assurance and Protection

All key investigators and members of the study team will be trained in responsible conduct in research and privacy protection and will be required to obtain online certification/training on the protection of human subjects. Confidentiality will be maintained throughout the duration of the study. Clinical and study information about individual participants will remain confidential and all study documents (informed consents, log books, etc.) will be locked in secure cabinets to which only study personnel will have access. Friends, journalists, health officials, and any other category of persons outside the research team will not have access to any of the data produced as part of this study. Participants' confidentiality shall be maintained through the use of codes and identifiers. Documents linking names to data will be locked in a secure cabinet with access by key study personnel only.

Confidentiality

The research data will be linked to individual participants and will be de-identified. However, mechanisms will be put in place to ensure confidentiality. Study staff will be required to sign a written agree (appendix H) to ensure confidentiality of the health protected information they accessed in this study. All study documentation will be kept under lock and key at the study sites. Electronic data will be stored under password-protected database accessible by restricted number of study personnel. To secure the data, the information with linkage and personal identifiers will be kept under lock and key and separate from the other study documentations at the study sites. No study

documents will be left on desks or in any public place at any time. Privacy of the study subjects will be protected and confidentiality maintained at all times. Study forms will be entered into a password-protected database by a data manager and data assistant. Both data managers and data assistants will be trained on the Protection of human subjects in research. No personal identifiers such as names or addresses will be entered into the database. Should the data need to be shared electronically, the database will be encrypted and password protected. Only de-identified information will be sent and used for data analyses.

The final protocol will be submitted to the NHREC in Nigeria, UMD IRB and the CDC for review and approval before the implementation phase starts.

Resources

In addition to the high-profile team of investigators with tested expertise and skills in HIV program evaluation, this study will involve a team consisting of stakeholders, study staff, program managers with complementary skills in data collection, analyses and human subject protection. The timeline (p 26) and expected outcomes show sufficient resource of time for the planning and implementation of this evaluation.

Budget

The budget and the budget justification for this activity are part of a larger cooperative agreement between UMB and CDC for the SHIELD grant. However the total cost of the CoART evaluation is estimated at $335,000.

Evaluator Qualification and Independence

As provided earlier in the investigators profile, the lead investigators are program and implementation research experts. Dr. Sunday Aboje, a trained MD, heads the National AIDS and STI Control Programmes (NASCP) division of FMOH with oversight function on organizations and facilities providing HIV services in Nigeria. Dr. Charurat, on the other hand, is Professor and Director of the Epidemiology and Prevention Division, IHV, UMB School of Medicine involved with PEPFAR program implementation, monitoring, and evaluation since 2005. The two lead investigators are currently leading the implementation of a similar but larger evaluation study for in the implementation of the Nigerian Alliance for Health Systems Strengthening (NAHSS) which evaluates the quality of HIV care provided by health facilities in Nigeria. None of the lead investigators work for the sponsor, the CDC. The investigators declare a lack of any conflict of interests on their parts, the program, or both. They did not contribute to the design of the CoART program or models and neither the investigators nor the CDC, staff are responsible for the program or models implementation and successes. However, representatives of the service-providing organizations will be included in the implementation and outcome dissemination working group that will ensure balanced, honest, and unbiased collection of data, analyses, and timely reporting of findings that are independently interpreted. This group of stakeholders will provide oversight to ensure the quality of the outcomes and whether they meet the PEPFAR standards evaluation requirements.

Reporting Standard

The findings will be reported in conformity with the CDC and PEPFAR standard of reporting evaluation studies. The content will consist of background, rationale, evaluation questions, methods, and analyses. In addition, limitations and recommendations that are actionable in achieving the short and long-term goals of improving HIV treatment uptake and attainment of UNAIDS 90-90-90 will be offered.

Data Ownership and Results Dissemination

The database will be co-owned by the Nigerian FMOH and UMB. After data entry, data collection forms will be stored in a locked cabinet at the UMB MGIC office in Abuja. Data from the study will be released to stakeholders after approval by the NHREC, FMOH. Results dissemination will be guided by the stakeholders; at the conclusion of the evaluation, the evaluation implementing partner working group will work with FMOH, CDC and other relevant stakeholders to assess the findings and evolve a joint framework for interpretation and information dissemination tailored towards service delivery that match the unique goals of Test and Start program in Nigeria. We will explore effective mechanisms for information sharing across target audiences (policy or decision makers, program implementers and PLHIV in Nigeria). The new knowledge created will be shared in interactive group discussions, newsletters, conferences and seminars, and will be published in reputable peer-reviewed journals. The final

evaluation report will be produced in alignment with the PEPFAR Evaluation Standards of Practice requirements and posted (in English) on a publicly accessible website within 90 days of clearance.

Study timeline

Activity/Calender Time	2017									
	3	4	5	6	7	8	9	10	11	12
Stakeholders engagement and IDEA formation										
Protocol development and endorsement by stakeholders										
Ethics review of protocol by NHREC										
Ethics review of protocol by UMD-IRB										
Protocol review and approval by CDC, ADS										
Training of data abstractors and IDEA										
Establish program start dates by the different IPs										
Pilot test data abstraction and collection tools										
Develop implementation plan with IDEA										
Conduct data abstraction and interviews										
Clean and analyze data										
Discuss results with stakeholders										
Interpret findings										
Present findings in scientific meetings and publish										

Appendix A. Informed Consent

STUDY CONSENT FORM

Community HIV Treatment Program Evaluation in Nigeria

Study No.: HP-000---

Principal Investigators:

- **Sunday Aboje, MD; saboje@yahoo.com; +234 8033038090**
- **Manhattan Charurat, PhD; mcharurat@ihv.umaryland.edu; +1 4107061948**

You are invited to participate in this study because you are a patient receiving HIV drugs through the community treatment program, or you are a HIV heath care provider. Please take time to review or listen to this consent as it is being read to you and ask any questions you may have of the study staff. Taking part in this study is voluntary. You may take time to make your decision about taking part and may discuss it with your colleagues before you make your decision. This consent form may contain words that you do not understand. Please ask the study staff to explain any words or information that you do not clearly understand. This study is carried out by the University of Maryland and is paid for by the centres of Disease Control and Prevention (CDC) in the United States of America.

PURPOSE OF STUDY

HIV is a leading cause of illness and death in Nigeria. The success of HIV treatment with drugs or antiretroviral treatment (ART) in reducing HIV-associated illness, death, and transmission of new infections has provided hope for ending the HIV epidemic. Different treatment approaches are now being introduced to speed up the effort of ending the HIV epidemic. The purpose of our study is to find out the perspectives of patients and health care providers on community approaches to HIV drug delivery, what works well, and what needs improvement. You are invited take part in this study because you are a patient receiving HIV drugs through a community treatment program or are an HIV health care provider. About 75 patients and 75 HIV health care providers are needed to take part in this study.

PROCEDURES

If you take part in this study, you will be asked to take part in an interview. The interview will last for about 20 minutes. You will be asked to respond to questions concerning the treatment services you receive in this program or the services you provide to the patients.

POTENTIAL RISKS/DISCOMFORTS

Some of the questions may make you feel uncomfortable. You are free to skip a question and continue with the rest of the interview. You may choose to discontinue the interview at any point during the interview. Your name and the information you provide will not be linked. The information you provided will be protected in a secure place. Access to the information will be minimized and limited to study staff. The information collected from the health care providers will not be shared with your supervisors.

POTENTIAL BENEFITS

You may or may not benefit by taking part in this study. We hope the information obtained from this study will be useful in strengthening the ART service delivery to cover more people and reduce HIV transmission in the community.

ALTERNATIVES TO TAKING PART

Your alternative is to not take part. If you choose not to take part, the services you receive in this program will not be affected. If you work for this program, your work as HIV health care provider will not be affected.

COSTS TO PARTICIPANTS
It will not cost you anything to take part in this study other than your time.

PAYMENT TO PARTICIPANTS
You will not receive any payment for taking part in this study

CONFIDENTIALITY AND ACCESS TO RECORDS
Efforts will be made to protect your personal information and your responses to the interview questions. A study code will be used instead of your name to identify the information you provide. Any responses included in the final report will be kept anonymous. We cannot promise complete confidentiality. However, the information you provide will not be linked to your name. Organizations that may inspect the information you provided include the institutional review board or ethics committee, the CDC and the Federal Ministry of Health. The data from this study may be published. However, you will not be identified by name. Everyone using study information will work to keep your personal information confidential. Your personal information will not be given out unless required by law.

RIGHT TO WITHDRAW
Your taking part in this study is voluntary. You do not have to take part in this evaluation. You are free to withdraw your consent at any time. Refusal to take part or stopping taking part in the study will involve no penalty nor will it affect the services you receive. If you are a health care provider, it will not affect your job in anyway. You will receive all the benefits you are entitled to. If you decide to stop taking part, or if you have questions, concerns, or complaints related to the study, please contact the investigator, Dr. Sunday Aboje at 08033038090.

TERMINATION FROM STUDY
The person in charge of the study or the sponsor can withdraw you from the study without your approval. We will notify you if this happens. You will have a chance to ask questions.

If you have concerns, or believe you have been harmed by taking part in this research study, please feel free to contact NHREC. The staff at NHREC are responsible for protecting the rights of people taking part in research studies. You may contact thenthrough this number 08063190328

Signing this consent form indicates that you have read this consent form (or have had it read to you) and you understand that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study. You will receive a copy of this signed consent.
.
If you agree to take part in this study, please sign your name below.

_____
Participant's Signature/ Thumb print

Date:_____

_____
Investigator or Designee Obtaining Consent Signature

Date:_____

Appendix B. Model Assessment Tool

Community ART (CoART) Model Description and Implementation Information Tool

1.**0 Implementing Partner Organization** Choose an item. **1.1 Date**Click here to enter a date.

1.2 Program manager name: **1.3 Program starts Date** Click here to enter a date.

1.4 Model Name:

1.5 Select an implementation strategy that applies to your model

Community HIV counselling and testing (HTS), initiate newly identified HIV positives and stabilize them on ART within the community	☐
Community HTS, initiate newly identified HIV positives and stabilize on facility-based ART then devolve to community for treatment maintenance	☐
Enroll and devolved stable facility-based patients to community structures for drug refill and treatment maintenance	☐

1.6 List the priority LGAs where this community ART model is currently implemented

1.7 What community structures (e.g., community ART group, patent medicine vendors support the model implementation?

1.8 What health facilities (e.g., secondary, tertiary facilities etc.) support the community structures above?

1.9 Using a summary table(s), please provide the following information (numbers to date) disaggregated by community structures and their supporting health facilities. (Write N/A to the data element that does not apply to your model)

- Tested for HIV
- Found positive for HIV
- HIV+ linked to facility
- Enrolled on ART
- Stabilized in the facility
- Devolved back to the community
- HIV+ on ART at Hub facility
- Devolved to 'Spoke' community structure
- Drug refill frequency

2.0 If your model devolves stable ART patients from facility to community structures, please define stability in the context of your model and other criteria for devolution.

2.1 Describe the frequency for the following activities as applicable to your CoART model

- Clinical visits
- HIV testing services
- Linkage to ART services
- Baseline assessment
- Adherence counseling
- Sample collection
- Referral to hub facility
- Drug refill
- Documentation of new enrollees

2.2 Please describe the cadre of staff or community volunteers that deliver each of the above services and provide information on where, when, and how these services are provided

2.3 Describe how CoART data are coded and archived at the hub facilities that distinguish facility from CoART program data.

2.4 Please provide your perspectives on the followings:

a) Barriers to the implementation and uptake of CoART service utilization

b) Barriers to the sustainability of CoART program

c) Facilitators of the CoART program

Appendix C. Patient Satisfaction Interview

Community-based Antiretroviral Therapy (ART) Evaluation

Enrolment ID_ _ _ _ _ **Sex: M☐ F☐ Date**Click here to enter a date.

	Question	Response
1.	How old are you?	
2.	When did you start receiving HIV medications in this program?	
3.	How often do you receive the medications?	
4.	Tell me about problems that make it hard for you to receive care in this program.	
5.	What changes could you suggest that would make this program better?	
6.	How comfortable are you with the Health service providers in this program?	
7.	Can you tell me how you feel about the manners of l the service providers toward you?	
8.	Can you speak freely with them about your concerns? (Yes/No) Can you give reasons for your response?	
9.	Do you receive answers to your questions in ways you feel your questions are adequately answered? (Yes/No) Can you give reasons for your response?	

10. Do you feel your privacy is adequately protected in this program? (Yes/No) Can you give reasons for your response?	
11. Do you pay for medical care in this program? How much do you pay? (Yes/No) If yes how much do you pay?	
12. How much time (in minutes, hours) do you spend between the time you arrive at the hospital and the time you are attended to by a health service provider?	
13. Can you tell me the average length of time your health care provider spends with you during a visit?	
14. Do you get referrals for tests and other services?	

Appendix D. Health Care Provider Interview

Interview of ART Focal Persons for Community ART (CoART) Program

Enrolment ID__ __ __ __

We are conducting this interview to gather information on human resource capacity for CoART implementation, task shifting, worker's satisfaction, support services, referrals and tracking of referrals, identified barriers and facilitators for effective program implementation. Your taking part in this study is voluntary and you are free to withdraw your consent at any time. This is an anonymous interview and we will not be collecting any information that can be used to identify you. All reports or publication from this study will use aggregate information only. The responses and opinion you provide will not be linked to you in any way.

01. Participant's Age in Years__ __ **02. Sex: M** ☐ **F** ☐

03. CoART model name _____ **04. Interview Date** Click here to enter a date.

05. Community, Priority LGA_____ _____

06. Time in months you spent providing CoART services < 6 months ☐ **(if yes. STOP. Thank the respondent for his or her time >= 6 months** ☐

07. Which of the following describes your CoART model strategy and approach?

a) Community HIV counselling and testing (HTS), initiate newly identified HIV positives and stabilize them on ART within the community ☐

b) Community HTS, initiate newly-identified HIV positives and stabilize on facility-based ART, then devolve to community for treatment maintenance ☐

c) Enrol and devolve stable facility-based patients to community structures for drug refill and treatment maintenance ☐

08. How many health care providers provide community services in your team?

09. Tell me about their levels of education and training for community ART care.

10. How often do you refer patients to hub facilities for expert care or routine tests?

11. How do you track referrals to ensure they are not lost to follow-up?

12. Do you screen HIV-positive patients for TB? (Yes/No)

13. If a patient is diagnosed for TB, where do they receive TB medications?

14. How do TB negative positives access isoniazid prophylactic therapy (IPT) against TB?

15. Do you provide HIV-infected patients with co-trimoxazole prophylaxis? (Yes/No

16. Which of the following activities or services are provided by your model and which health care staff provides them (indicate N/A for activity that does not apply to your model)

- ☐**HIV testing services**
- ☐**Linkage to ART services**
- ☐**Baseline assessment**
- ☐**Adherence counseling**
- ☐**Sample collection**
- ☐**Referral to hub facility**
- ☐**Drug refill**
- ☐**Documentation of newly enrolled**

17. Please provide your perspectives on the following:

a) Barriers to the implementation and uptake of CoART services

b) Barriers to the sustainability of CoART program

c) Facilitators of the CoART program

Appendix E. CoART Data Abstraction Tool

Community ART Evaluation Data Abstraction Tool

Enrolment ID: __ __ __ __ __ __ __ __ **-- Community and LGA:** _____ _____

Abstractor's ID: __ __ **Date of Abstraction:** Click here to enter a date.

A. SUBJECT DEMOGRAPHY	
1. Sex:	☐ **Male** ☐ **Female**
2. Date of Birth:	D D **/** M M **/** Y Y (cannot be missing)
3a. Age at last birthday:	D ____**Years** (cannot be missing)
3b. Date of enrolment	D **/** M M **/** Y Y
4a. Marital status of patient at the time of enrolment in ART program:	☐ **Single** ☐ **Married** ☐ **Divorced** ☐ **Widowed** ☐ **Other, specify:** _____ ☐ **Missing**
4b. Village, town, or city of residence at enrolment	
5. Partner/spouse HIV status:	☐ **HIV positive** ☐ **HIV negative** ☐ **Missing/Unknown** ☐ **Don't know**
6. Patient education level at time of enrolment in ART program:	☐ **None** ☐ **Primary school** ☐ **Secondary school** ☐ **Post-Secondary** ☐ **University** ☐ **Other, specify:** _____ ☐ **Missing**
7. Patient employment status at the time of enrolment in the CoART program:	☐ **Employed** ☐ **No, not currently employed** ☐ **Missing**

8. Was patient pregnant at time of enrolment in the CoART program?	☐ **Yes** ☐ **No** ☐ **N/A** ☐ **Missing**
9. Did patient start ART at a facility BEFORE transferring to the community?	☐ **No** *(skip to question 12)* ☐**Yes,** **if yes: *date of transfer in:*** ____/_____/_____ ☐ **Missing**
10. If patient is a "**transfer in**", from facility enter the dates of HIV ART initiation at the facility *(if available)*.	**ART Initiation:** D D **/** M M **/** Y Y ☐ **Missing**
11. Name of the ART regimen initiated at the facility?	_____/_____/_____☐ **Missing**
B. CLINICAL INFORMATION	
12. Date first confirmed HIV positive:	D D **/** M M **/** Y Y ☐ **Missing**
13. Patient height:	_____ **Meters** ☐ **Missing**
14. Patient weight at start of CoART:	_____ **kg** **BMI**_____ ☐ **Missing**
15. Date initiated into CoART program:	D D **/** M M **/** Y Y (cannot be missing)
16. Baseline CD4+ cell count at initiation of CoART:	_____ **cells/µL** ***Date of test:*** D D **/** M M **/** Y Y ☐ **Missing**
17. WHO clinical stage at start of CoART:	☐ **Stage I** ☐ **Stage II** ☐ **Stage III** ☐ **Stage IV** ☐ **Missing**
18. Functional status at start of CoART:	☐ **Working** ☐ **Ambulatory** ☐ **Bedridden**

	☐ **Missing**	
19. TB status at start of CoART:	☐ **No sign of TB** ☐ **On INH prophylaxis** ☐ **Presumed TB** ☐ **Prior history of TB treatment** ☐ **On TB treatment** ☐ **Missing**	
20. For patient on INH prophylaxis, was the patient on INH at last visit?	☐ **Yes** ☐ **No** ☐ **Missing**	
21. Opportunistic infections during CoART treatment and dates of diagnosis (dx): *(check all that apply)*	☐ **Chronic diarrhoea** ☐ **Tuberculosis (pulm/extrapulm)** ☐ **PCP** ☐ **Cryptococcosis** ☐ **Kaposi sarcoma** ☐ **Herpes zoster** ☐ **Vaginal thrush** ☐ **Herpes simplex** ☐ **Other, specify:** ☐ **No documented OIs**	***date of dx,*** D **/** M M **/** Y Y ***date of dx,*** D D **/** M M **/** Y Y ***date of dx,*** D D **/** M M **/** Y Y ***date of dx,*** D D **/** M M **/** Y Y ***date of dx,*** D D **/** M M **/** Y Y ***date of dx,*** D D **/** M M **/** Y Y ***date of dx,*** D D **/** M M **/** Y Y ***date of dx,*** D D **/** M M **/** Y Y ***date of dx,*** D D **/** M M **/** Y Y
22. History of sexually-transmitted infections before CoART initiation:	☐ **Gonorrhoea** ☐ **Chlamydia** ☐ **Syphilis** ☐ **Herpes** ☐ **Other (s), specify**_____ ☐ **No history of sexually-transmitted infection**	

23. History of other chronic illnesses e.g., diabetes, kidney disease, etc.:	☐ **Yes** ☐ **No** ☐ **Missing** **If yes, please specify: 1. _____2.__ _____3. _____**
24. Was patient on cotrimoxazole (CTX) at start of CoART?	☐ **Yes** ☐ **No** ☐ **Missing**
25. Was patient on cotrimoxazole (CTX) at last visit?	☐ **Yes** ☐ **No** ☐ **Missing**

C. CoART REGIMEN

26. If a drug is changed in a regimen (substitution) or if the whole regimen is changed (switch), give date of the change, old and new regimens, and reason(s) for change. Use the below list to pick the reason (s) for change:

1 = Toxicity **2 = Pregnancy** **3 = Suspicion of pregnancy** **4 = Active TB**

5 = New medicine available **6 = Break in supply of a drug** **7 = Other, please specify**

If documentation shows no regimen changes, tick here: ☐ **NO REGIMEN CHANGES**

Date of change	**Old Regimen**	**New Regimen**	**Reason(s) for change**	**(Enter appropriate number)** 1c. TDF-3TC-NVP 1d. TDF-3TC-EFV
D D / M M / Y Y				
D D / M M / Y Y				
D D / M M / Y Y				
D D / M M / Y Y				

D D / M M / Y Y				1e. TDF-FTC-NVP
D D / M M / Y Y				1f. TDF-FTC-EFV
D D / M M / Y Y				1g. AZT-3TC-NVP
D D / M M / Y Y				1h. AZT-3TC-EFV
D D / M M / Y Y				1j AZT-FTC-NVP
D D / M M / Y Y				1k. AZT-FTC-EFV
D D / M M / Y Y				
D D / M M / Y Y				2a. ABC-ddI-SQV/r
D D / M M / Y Y				2b. TDF-ddI-IDV/r
D D / M M / Y Y				2c. TDF-3TC-LPV/r
D D / M M / Y Y				2d. TDF-3TC-IDV/r
D D / M M / Y Y				2e. TDF-3TC-SQV/r
D D / M M / Y Y				2f. TDF-FTC-LVP/r
D D / M M / Y Y				2g. TDF-FTC-IDV/r
D D / M M / Y Y				2h. TDF-FTC-SQV/r
D D / M M / Y Y				2i. TDF-3TC-ATV/r
D D / M M / Y Y				2j. TDF-FTC-ATV/r
D D / M M / Y Y				2k. AZT-TDF-3TC-LVP/r
D D / M M / Y Y				2l. AZT-TDF-3TC
D D / M M / Y Y				2m. AZT-FTC-TDF-LVP/r
D D / M M / Y Y				2n. AZT-3TC-ATV/r
D D / M M / Y Y				2o. AZT-FTC-ATV/r
D D / M M / Y Y				3a. Other, specify: / /
D D / M M / Y Y				_____
D D / M M / Y Y				
D D / M M / Y Y				
D D / M M / Y Y				

D. CoART INTERRUPTIONS AND ADVERSE EVENTS	
27. Any history of stopping CoART use?	☐ **If yes, enter 1st stop date:** D D / M M / Y Y ☐ **If yes, enter 1st restart date:** D D / M M / Y Y ☐ **If stopped a 2nd time, enter 2nd stop date:** D D / M M / Y Y ☐ **If stopped a 2nd time, enter 2nd start date:** D D / M M / Y Y ☐ **If stopped a 3rd time, enter 3rd stop date:** D D / M M / Y Y ☐ **If stopped a 3rd time, enter 3rd start date:** D D / M M / Y Y ☐ **No – No history of stopping ART use**
28. If patient **stopped CoART**, what was the reason?	☐ **Developed active TB** D D / M M / Y Y ☐ **Drug toxicity/intolerance** D D / M M / Y Y ☐ **IRIS** D D / M M / Y Y ☐ **Other, _____** D D / M M / Y Y ☐ **Unknown** ☐ **LTFU**
29. Any documented adverse events to ART under the CoART program?	☐ **Yes** ☐ **No** ***If Yes, check all that apply*:** ☐ **Severe rash** ☐ **IRIS** ☐ **Anaemia** ☐ **Hepatitis** ☐ **Neuropathy** ☐ **Renal Impairment** ☐ **Other, specify:_____**

E. FOLLOW UP STATUS

30. List the dates of **ALL** scheduled and actual clinic visits and enter weights, follow-up status for each prior visit.

For follow-up status use the following codes: **1 = On treatment** **2 = Dead** **3 = Stopped CoART**

4 = Lost to follow-up **5 = Transferred out** **6 = Restarted CoART** **7 = Other, specify_____**

8 = Missing			
Scheduled date	**Actual Visit Date**	**Weight**	**Follow-up status**
D D / M M / Y Y	D D / M M / Y Y	___Kg ☐ Missing	
D D / M M / Y Y	D D / M M / Y Y	___Kg ☐ Missing	
D D / M M / Y Y	D D / M M / Y Y	___Kg ☐ Missing	
D D / M M / Y Y	D D / M M / Y Y	___Kg ☐ Missing	
D D / M M / Y Y	D D / M M / Y Y	___Kg ☐ Missing	
D D / M M / Y Y	D D / M M / Y Y	___Kg ☐ Missing	
D D / M M / Y Y	D D / M M / Y Y	___Kg ☐ Missing	
D D / M M / Y Y	D D / M M / Y Y	___Kg ☐ Missing	
D D / M M / Y Y	D D / M M / Y Y	___Kg ☐ Missing	
D D / M M / Y Y	D D / M M / Y Y	___Kg ☐ Missing	
D D / M M / Y Y	D D / M M / Y Y	___Kg ☐ Missing	
D D / M M / Y Y	D D / M M / Y Y	___Kg ☐ Missing	
D D / M M / Y Y	D D / M M / Y Y	___Kg ☐ Missing	
D D / M M / Y Y	D D / M M / Y Y	___Kg ☐ Missing	

F. COUNSELLING & SUPPORT SERVICES

Did patient receive any of the following?

31. Pre-CoART counselling	☐ **Yes, *No. of times*____** ☐ **No** ☐ **Missing**
32. Counselling at CoART initiation	☐ **Yes, *No. of times*____** ☐ **No** ☐ **Missing**
33. Any adherence counselling during follow-up	☐ **Yes, *No. of times*____** ☐ **No** ☐ **Missing**

G. PHARMACY REGISTER

34. List dates of **ALL** ART regime dispensed and the date of collection (use ARV codes from question 28), and number of days for which ART prescription is given (use the last page if more space is needed)

Date	Regimen	# days of prescription	Date	Regimen	# days of prescription
D D / M M / Y Y			D D / M M / Y Y		
D D / M M / Y Y			D D / M M / Y Y		
D D / M M / Y Y			D D / M M / Y Y		
D D / M M / Y Y			D D / M M / Y Y		
D D / M M / Y Y			D D / M M / Y Y		
D D / M M / Y Y			D D / M M / Y Y		
D D / M M / Y Y			D D / M M / Y Y		
D D / M M / Y Y			D D / M M / Y Y		
D D / M M / Y Y			D D / M M / Y Y		
D D / M M / Y Y			D D / M M / Y Y		

H. LABORATORY RESULTS

35. Please record the test dates and values of **ALL** CD4 **cells/µL** counts, viral loads (VL) **copies/mL**, hemoglobin (Hb) **g/dL** levels, alanine aminotransferase (ALT) **I/U/L**, and serum creatinine (Cr) □mol/L or mg)/dL (indicate the unit), for this patient.

Visit #	**CD4+ cell count (/µL)**	**Date**	**VL (copies/ mL)**	**Date**	**Hb (g/dL)**	**Date**	**ALT (IU/L)**	**Date**	**Cr (mol/L or mg/dL)**	**Date**
1		DD/MM/ YY		DD/MM/Y Y		DD/MM/ YY		DD/MM/YY		DD/MM/YY
2		DD/MM/ YY		DD/MM/Y Y		DD/MM/ YY		DD/MM/YY		DD/MM/YY
3		DD/MM/ YY		DD/MM/Y Y		DD/MM/ YY		DD/MM/YY		DD/MM/YY

4		DD/MM/YY		DD/MM/YY		DD/MM/YY		DD/MM/YY		DD/MM/YY
5		DD/MM/YY		DD/MM/YY		DD/MM/YY		DD/MM/YY		DD/MM/YY
6		DD/MM/YY		DD/MM/YY		DD/MM/YY		DD/MM/YY		DD/MM/YY
7		DD/MM/YY		DD/MM/YY		DD/MM/YY		DD/MM/YY		DD/MM/YY
8		DD/MM/YY		DD/MM/YY		DD/MM/YY		DD/MM/YY		DD/MM/YY
9		DD/MM/YY		DD/MM/YY		DD/MM/YY		DD/MM/YY		DD/MM/YY
10		DD/MM/YY		DD/MM/YY		DD/MM/YY		DD/MM/YY		DD/MM/YY
11		DD/MM/YY		DD/MM/YY		DD/MM/YY		DD/MM/YY		DD/MM/YY
12		DD/MM/YY		DD/MM/YY		DD/MM/YY		DD/MM/YY		DD/MM/YY

36. Hepatitis B status	☐ **Antibody positive** ☐ **Antigen positive** ☐ **Negative** ☐ **Unknown** ☐ **Missing**
37. Hepatitis C status	☐ **Positive** ☐ **Negative** ☐ **Unknown** ☐ **Missing** **Date of test:** D D / M M / Y Y
38. Date of last visit:	D D / M M / Y Y

39. Patient's outcome at the last visit?	☐ **Died, d*ate of death:*** D D / M M / Y Y ☐ **Alive, on CoART** ☐ **Transferred out, *date of transfer out:*** D D / M M / Y Y ☐ **Stopped CoART, *date of voluntarily stopping care:*** D D / M M / Y Y ☐ **Lost to follow up**

Appendix F: Confidentiality Agreement

CoART Data Confidentiality Agreement

I, _____ in my role as a/an ……., on the CoART, understand and agree to comply with each of the following requirements:

I will treat all information collected for this study as confidential prior, during, and after the study period. I will not use such information for any purposes other than for the work assigned to me during this study.

I will not discuss the study information of any study participant except only with those who are authorized to have access to such information.

I will relegate all questions asked of me that are not within my mandate to the necessary study team leader, study coordinator, supervisor and/or study investigators.

I will maintain all pertinent study data in a secured location at all times. I will also ensure that persons not involved in this study will not have access to study material.

I will report the loss of any study data/material or corruption of any computer files containing study data immediately to the team leader, study coordinator, supervisor, and/or study investigators.

If I use a computer to enter or store collected information, I will keep that information in password-protected electronic files only in a computer that has current virus protection software. I will not misuse any information security privileges that I may have access to by virtue of being in this study.

I will comply fully with any other data confidentiality procedures that I will be instructed to follow for this study.

I recognize that failure to adhere to this agreement may result in my termination from study.

Your signature below indicates that you understand and accept the above requirements.

NAME (PRINT NAME)	
SIGNATURE	
DESIGNATION	
DATE	

WITNESS NAME	
WITNESS SIGNATURE	
DESIGNATION	
DATE	

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