OUTCOME EVALUATION STUDY FOR ART "TEST AND START"

Nigeria multi-Center ART Study (NCAS)

Collaborating Institutions:

Ministry of Health, National AIDS & STI Control Program (NASCP), National Action Committee on AIDS (NACA), University of Maryland School of Medicine (UMD), PEPFAR program implementing partners in Nigeria and USG PEPFAR AGENCIES (CDC, USAID, & DOD)

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Acronyms and abbreviations

µL	microliter
AIDS	acquired immunodeficiency syndrome
ALT	alanine aminotransferase
APR	Annual Progress Report
ART	antiretroviral treatment
ARV	antiretroviral drug
CDC	Centers for Disease Control and Prevention
CGH	Centers for Global Health
CPT	Cotrimoxazole Preventive Treatment
CSPro	census and survey processing system
DGHT	Division of Global HIV/AIDS and TB
FMOH	Federal Ministry of Health
HCTB	HIV Care and Treatment Branch
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
PEPFAR	President’s Emergency Plan for AIDS Relief
PI	principal investigator
PITC	provider-initiated (HIV) testing and counselling
PLHIV	people living with HIV
PMTCT	prevention of mother-to-child transmission (of HIV)
PwP	Prevention with Positives

TB	tuberculosis
U.S.	United States
U.S.G	United States Government
VL	viral load
WHO	World Health Organization

Principal Investigators

Investigators profiles and roles

Sunday Aboje MD (**multiple PI**): Dr. Aboje heads the National AIDS and STI Control Programmes (NASCP) division of the Nigerian Federal Ministry of Health. His office implements the Nigerian health sector response to HIV and STI, develops national health sector Monitoring and Evaluation tools for HIV and STIs, coordinates national surveys on HIV and STIs and have 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 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 (IDEA) and maintains regular communications with the PEPFAR implementing partners for the test and start program in Nigeria and ensures proper compliance with the protocol and the 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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Gambo G. Aliyu, MD, PhD: coordinates protocol writing, obtainment of ethical approvals and study implementation. He will guide and supervise study conduct, data management and analyses. He will work with the stakeholders and the PIs to evolve a framework for data interpretation, presentation, dissemination and translation of new knowledge created.

Solomon Odafe, MD, MPH: provides technical oversight for protocol writing, study design and methods, study set up and conduct analysis of de-identified data, presentation and publication. Monitors implementation and human subjects related issues associated with the protocol and keeps CDC apprised of these issues as they arise. Provides input to CDC contracting officer related to progress toward satisfactory contract completion

Chukwuemeka Asadu, **MD, MPH:** coordinates day to day activities of the implementing partner working group (IDEA) in monitoring all aspects of the study conducts including access to ART facilities, data collection, management and analyses. Interacts directly with the PEPFAR implementing partners for the test and start program in Nigeria to ensure compliance with the protocol and updates NASCAP FMoH on the study progress and compliance relevant regulations.

Other co-investigators and collaborators (Table 1 below) support study implementation and data collection at the 32 sites. They will provide access to the ART facilities and program data, technical oversight and ensuring adherence to protocol. They will ensure that all persons involved in the conduct of the study 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.

CDC investigators will not be involved in data collection activity and neither will they have access to identifiable information of the subjects. However they are involved in the project deign, protocol development and will provide technical oversight. They will also participate in analyses, interpretation and report writing of de-identified data.

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 Synopsis

Title	Outcome evaluation study for ART "Test and Start." - Nigeria multi-Center ART Study (NCAS)
Purpose	To determine treatment outcomes and 12-month retention on antiretroviral treatment (ART) of human immunodeficiency virus (HIV)-positive adults initiated on ART immediately after identification/diagnosis of HIV, irrespective of baseline CD4 count or clinical staging.
Study Design	A mixed quantitative (retrospective cohort analysis) and qualitative (key informant interviews) study design. Relevant patient information will be abstracted from patient's records using a data abstraction tool specially designed for this purpose (Appendix 1). Interview-administered questionnaire (Appendix 2) will be used to obtain information on providers' perspective of factors contributing to attrition.
Study population	The study population will be a random sample of study eligible patients: HIV-positive individuals aged 15 years and above initiated on ART between the beginning of October 2015 and end of September 2016 at any of the study sites.
Study Duration	Estimated start date for data collection is 2nd October 2017. Total duration in the field will be approximately two months.
Study Sites	The study will be conducted in all health facilities in 8 local government authorities (LGAs) randomly selected from 32 scale-up LGAs. To achieve the required sample size, the number of patients randomly selected from each site will be based on probability proportional to size sampling procedure.
Primary Objectives	• To determine proportion of patients with viral load suppression at 24 weeks after initiation of ART, using the "Test and Start" approach • To determine the 12-month retention rate of adults initiated on ART immediately after diagnosis of HIV. • To determine the rates of lost to follow-up, transferred out, and mortality at 12 months after initiation of ART • To determine the factors associated with treatment failure and attrition among persons living with HIV (PLHIVs) initiated on ART immediately (within two weeks) after diagnosis of HIV. • To determine providers' perspectives of factors contributing to attrition.

1. Background

In 2013, an estimated 35 million people were living with human immunodeficiency virus/acquired immunodeficiency syndrome (HIV/AIDS) worldwide, with sub-Saharan African having the highest burden with 24.7 million people living with HIV (1). In Nigeria, it is estimated that 3.2 million persons are living with HIV (PLHIV)(1). Nigeria is among the 15 countries which account for 75% of the 2.1 million new infections, as of 2013 and is among the six nations that are facing the triple threat of high HIV burden, low ART coverage, and little or no decline in new HIV infections (1).

To increase access and coverage, the Government of Nigeria, with support from the United States (U.S.) President's Emergency Plan for AIDS Relief (PEPFAR), as well as other international and domestic donors, has dramatically scaled up antiretroviral treatment (ART) services in Nigeria. At the end of 2015, Nigeria had over 700 facilities providing ART services, and over 750,000 PLHIV initiated on ART. Despite the laudable efforts in scaling-up, ART coverage in Nigeria has remained at 21 percent, which is considerably lower than that of other countries in sub-Saharan Africa (1).

In 2014, the Federal Ministry of Health (FMOH) in Nigeria published a revised Integrated National Guidelines for HIV Prevention, Treatment, and Care (2). The country's new guidelines were adapted from the 2013 World Health Organization (WHO) consolidated guidelines. A key recommendation of the Nigerian Guidelines was that PLHIV with a CD4+ cell count less than 500 cells per microliter (µL) are eligible for ART, irrespective of clinical staging, with priority for persons with CD4+ cell count less than 350 cells per µL.

There is evidence that promoting more testing for HIV and encouraging immediate treatment of individuals found HIV positive, could 'eliminate' the epidemic and decrease ART costs in the long term (3). A large international, randomized study involving HIV-infected, ART-naïve adults with CD4+ counts of more than 500 cells/µL, reported that the immediate initiation of ART was superior to delay of treatment until the CD4+ cell count declined to less than 350 cells/µL (4). Beneficial effects of immediate ART were observed in both serious AIDS-related and serious non-AIDS-related events (4). Furthermore, there was no apparent increase in the rate of adverse effects in individuals immediately initiating ART (4).

A study in Ivory Coast in which patients with HIV type 1 infection and CD4+ count of less than 800 cells/µL were randomly assigned to one of four treatment groups: deferred ART (ART initiation according to WHO guidelines), early ART (immediate ART initiation), deferred ART plus isoniazid preventive therapy (IPT), or early ART plus IPT, reported that immediate ART and six months of IPT independently led to lower rates of severe illness than did deferred ART and no IPT (5).

A mathematical modelling exercise completed in South Africa using hypothetical assumptions relating to the South African population reported that 'universal voluntary HIV testing and immediate ART (regardless of baseline conditions) combined with established prevention strategies could significantly reduce the size of the epidemic (6). However, other modelling exercises reported that the impact of Test-and-Treat approach on HIV incidence will depend on the particular epidemiological setting, including sexual partner networks (concurrency, heterogeneity, and mixing), uptake of HIV testing, linkage to care, and ART coverage, among other factors (3, 7-9).

We hypothesize that implementation of universal HIV testing in communities with high HIV prevalence, followed by immediate ART initiation of all persons testing HIV positive, regardless of immunological or clinical staging, will improve outcomes on ART and help the country achieve epidemic control.

1.1 Aim

The primary goal of this study is to determine treatment outcomes and 12-month retention on ART for adult patients initiated on ART immediately after identification/diagnosis of HIV, irrespective of baseline CD4 count or clinical staging and their associated factors at selected Local Government Areas (LGAs) in Nigeria between October 2015 and September 2016.

1.2 Objectives

- To determine proportion of patients viral load (VL) suppressed 24 weeks after initiation of ART, using the "Test and Start" approach

- To determine the 12-month retention rate of adults initiated on ART immediately after diagnosis of HIV.
- To determine the rates of lost to follow-up (LTFU), transferred out, and mortality at 12 months after initiation of ART
- To determine the factors associated with treatment failure and attrition among PLHIVs initiated on ART immediately after diagnosis of HIV.
- To determine providers' perspective of factors contributing to attrition

1.3. Key Questions

What proportion of patients initiated on ART immediately after HIV diagnosis had VL suppression at 24 weeks post-initiation on ART? The Nigerian integrated national guidelines for HIV prevention, treatment, and care defines VL suppression as less than 400 HIV ribonucleic acid (RNA) copies/milliliter (mL).

- What proportion of PLHIV are alive and on ART at 12 months, following HIV diagnosis and "Test and Start"?
- What proportion of PLHIV initiated on ART immediately after diagnosis of HIV were LTFU?
- What proportion of PLHIV transferred out, died, or stopped ART?
- What are the site and patient level factors associated with treatment failure and attrition of patients initiated on ART immediately after diagnosis of HIV?

1.4 Study Hypothesis

This study is predominantly a non-comparative review where simple information, such as virologic failure, retention, and attrition rates in patients offered "Test and Start", will be reported. However, we plan to study some factors that may affect these rates. We hypothesized that these factors may not be different among subjects who are retained in treatment or care as compared with those who have been lost to care or treatment. We hypothesize as follows:

- The level of adherence, number of missed drug pick up appointments, baseline CD4+ cell counts, and patients' socio-demographic characteristics are not different in those virally suppressed, and those with treatment failure. 24 weeks? 12 months?
- That baseline socio-demographic characteristics, such as age, sex, educational status, and employment status are not different in those retained, and those lost to attrition.
- That baseline clinical characteristics, such as CD4+ cell count, haemoglobin concentration, creatinine, weight and TB and HBV co-infection rates are not different in population lost to attrition, and those retained on ART.
- There is no difference in the median time to attrition by facility type or clinical and sociodemographic characteristics of patients.

In this study the level of significance $\alpha=0.05$. Where we observe a difference, the difference will be considered of statistical significance and we will not accept the null hypothesis if the p-value is less than 0.05. To reduce the probability of a type 1 error, we will use Bonferroni correction to reduce the size of our critical α when making multiple comparisons among groups.

2. Methods

2.1 Background on study population

Nigeria is a lower-middle-income country (Gross Domestic Product per capita: $6,400.0 (US dollars)), with a current population estimate of 181,562,056 (population demographics: 49% female, 51% male; 54% rural, 46% urban)(10). Nigeria has 36 states and an administrative capital called the Federal Capital Territory. (10). The States in Nigeria are divided into smaller administrative units called LGAs. There are 774 LGAs in Nigeria; each LGA is managed by a Local Government Council (11). Nigeria's HIV epidemic is generalized, with national HIV prevalence rates for

adults aged between 15 and 49 years estimated to be around 3.2 percent (1). There is significant variation in HIV prevalence across the states and LGAs in Nigeria; estimates range from 0.6 percent in Ekiti State to 15.2 percent in Rivers State (12). To achieve epidemic control in Nigeria, the U.S. PEPFAR team in Nigeria developed a plan for the fiscal year 2016 (October 2015 to September 2016) to work in partnership with the Government of Nigeria (See Appendix 3) and the Global Fund to achieve epidemic control in 32 high-burden LGAs. While continuing to support those already on ART in U.S. government (USG)-funded programs. This plan involves the implementation of "Test and Start" strategy, in which individuals testing HIV positive are initiated on ART without delay.

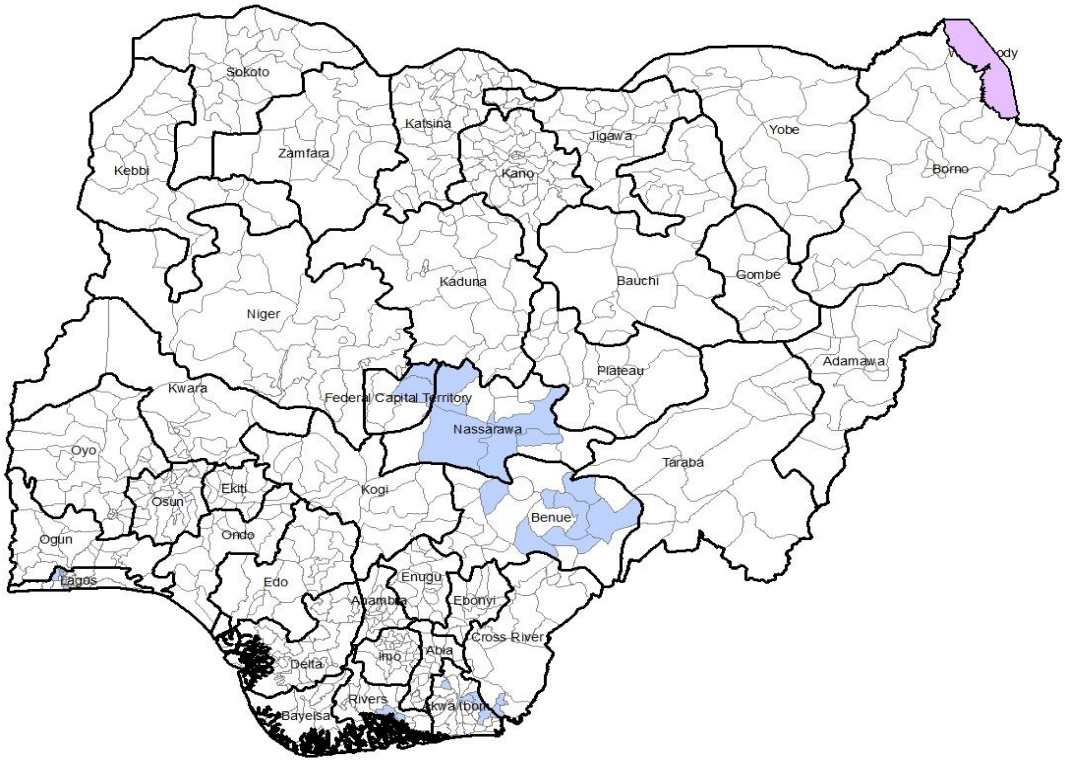

Figure 1: Map of Nigeria with areas highlighted in blue representing scale-up LGAs for epidemic control (32 LGAs)

2.1.1 Procedures for ART initiation and implementation of Test and Start:

In the 32 scale-up LGAs, starting from October 2015, patients identified HIV positive were to be initiated on ART immediately after being diagnosed, irrespective of their clinical or immunological status. Other than being initiated on ART immediately after diagnosis, patients in the 32 LGA were to be managed in accordance with Nigerian Integrated National Guidelines for HIV Prevention, Treatment, and Care. As part of the routine care, patients were to receive a unique number, have their sociodemographic, and clinical information entered in the ART Register and ART Card. Clinicians would take a comprehensive clinical and social history and should perform a full physical examination for every HIV-positive patient initiating ART. Baseline and follow-up investigations were to be done in accordance with the Nigerian guidelines.

To promote retention in HIV care, and timely initiation of ART, expedited counselling would be given to all patients. The first counselling session would be done on the day of enrolment in HIV care, and the 2nd session one week later ("week 1"). 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 would be planned and the patient initiated on ART at week 2.

As part of the routine care, patients would be provided co-trimoxazole prophylactic therapy if the patient was symptomatic or had a baseline CD4<350cells/µL, and IPT (after routine symptom screening excluding 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 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 (CRAG should be done if CD4<100cells/µL), Hepatitis B surface antigen hemoglobin concentration, creatinine, and urine dipstick (if applicable)
    - Provide first counselling session
    - Give 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 cotrimoxazole prophylactic therapy (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/Assistant provides routine adherence support counselling before dispensing ARVs
    - Enter further relevant information in the patient care booklet during every 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 booklets
    - 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/Assistant provides routine adherence support counselling before dispensing ARVs

Patient Follow-up and Care after ART Initiation

- Standard follow-up at the two weeks, eight weeks and three months as 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 would 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 workers at facilities that might not have clinical mentors attached to them would continue receiving technical support from a distance.

2.2 Study Design

This study will be cohort analysis of patients initiated on ART immediately after diagnosis of HIV between October 2015 and September 2016. We will utilize a combined quantitative (retrospective cohort analysis) and qualitative (key informant interviews) study design. Although our analysis will be done retrospectively, the patients' clinical data will have been entered prospectively into relevant clinical forms and ART card at the various sites.

Sources of Data: Study data will come from several sources, including electronic or paper-based as follows:

- Adult ART patient registers at HIV care and treatment facilities.
- Client folder/ART cards reviewed at selected sites.
- Review of pharmacy records (worksheets and daily registers).
- Review of laboratory records, if CD4 counts are not recorded in the charts.
- Interviews with health care workers at each site to collect site-specific data.

2.2.1 Study population

The study populations are two groups of adult patients. The first are those newly identified HIV-positive initiated on ART immediately after diagnosis irrespective of clinical or immunological status, and the second are pre-ART patients previously diagnosed HIV positive but started on ART irrespective of current eligibility status during the study period. The term "immediately" in this study, means started on ART within two weeks of HIV diagnosis irrespective of current eligibility status as per current national guidelines. All pre-ART and newly diagnosed patients initiated on ART regardless of their current eligibility status or within two weeks of HIV diagnosis will be considered eligible for the study.

2.2.2 Inclusion Criteria

- All adults aged 16 years or older at the time of ART initiation at one of the eligible sites, who initiated ART immediately after diagnosis of HIV infection on or after October 1, 2015, regardless of treatment outcome at the time of chart abstraction will be eligible for inclusion.
- All pre-ART patients, aged 16 years or older at time of ART initiation, previously diagnosed HIV positive but initiated on ART irrespective of their current eligibility status during study period.
- To ensure data for analysis of 12-month retention, the cohort initiated on ART between October 2015

and September 2016 will be included in the study (Data abstraction will begin October 2017).

2.3. Sample Size Considerations

2.3.1. Adult Cohort Study Sample Size

Sample Size Required to Answer Key Question: What factors are associated with retention and attrition 12 months after ART initiation?

In the ART outcomes study, we will investigate factors associated with attrition and retention at 12 months post-ART initiation. Sample size calculations discussed below will be used for 12-month retention and attrition as the outcomes of interest.

Attrition: Attrition will be defined as patients who initiated ART, who have died, been lost to follow-up, or stopped ART indefinitely (all patients who discontinued treatment and do not wish to re-start ART) by 12 months after ART initiation.

Retention: Patients retained on ART will be defined as patients who are alive and on therapy at 12 months after initiation of ART. Patients who are documented to have transferred out of each facility will be excluded from this group, while patients transferring into a facility will be included in the appropriate cohort of the year initiated on ART. Previous studies in Africa reported the average retention rate of adults enrolled in ART programs is approximately 80% at 12 months of follow-up (13). In this study, we use a conservative estimate of 75% based on routine program data. If the 12-month retention rate of adults in ART care in Nigeria ART program is found to be 75%, the ratio of patients in retention to attrition will be 3:1.

Virologic Failure: A study in South Africa reported a virologic failure prevalence rate of 19% (14). A nationally representative dataset from the National ART Program in Nigeria suggests a treatment failure rate of 20.6%. Factors previously reported to be associated with virologic failure include: poor adherence, missed drug pick-up appointments, low baseline CD4 count at ART initiation, and prior virologic failure (15). In this study we will assume a virologic failure rate of 25%.

2.3.2. Sample Size Calculation for Adult ART Cohort

The study is designed to answer specific questions about a cohort of adult patients on ART using “Test and Start” in 32 LGAs. Hence, the sample size calculation that will provide the data to answer these questions is adopted. We assumed the following:

- That proportion of patients on ART with viral suppression, 24 weeks after ART initiation is 75%.
- The proportion of patients alive and on treatment, 12 months after ART initiation is 75%
- 95% confidence interval (CI) and a precision of 5%.
- Anticipate a 20% attrition rate (selected IDs without medical records (charts))
- Because of sampling size technique that may result in clustering of sampling, a design effect of 3.0 is applied.

Table 2: Precision of 95% Confidence Intervals (CI) around Primary Proportion of Interest (Calculated using StatCalc – EPI INFO®)

Estimated Retention Rate	Design Effect	Finite Population Correction Factor Used?	95% CI	Sample Size Required	Sample size corrected for 20% attrition
75%	3.0	No	± 2.5%	3,432	4,289

2.4 Selection of study LGA

Due to funding constraints, probability proportionate to size random sampling was used to select 25% (8) of the 32 LGAs (Appendix 4) for inclusion in the study.

2.5 Selection of Study Sites and Participants

2.5.1 Health Facilities

Sites that will be included in this study will have the following criteria:

- Located in the one of the 8 scale-up LGAs implementing "Test and Start" selected for the study.
- Implementing "Test and Start" for adult patients
- Have at least 50 patients initiated on ART at Annual Progress Report (APR) 15
- Started ART services on or before October 2015

2.5.2. Defining Sample Frame of Sites

All sites in the selected LGAs meeting inclusion criteria will be included in the study (see Appendix 5)

2.5.3 Selection of Study Sites and Participants

Multi-Stage Sampling Strategy

- **Stage 1 - LGA Clusters:** We randomly selected 8 LGAs out of the prioritized 32 LGAs (see Appendix 4) using probability proportionate to size.
- **Stage 2 -** All sites in the 8 selected LGAs were selected (see Appendix 5).
- **Stage 3 - Specifying Number of Medical Records to be Selected at Each Selected Clinic**
  - We multiplied sample size by site selection probability to determine the number of patient records to select within each site **(**see Appendix 5).
  - We will us simple random sampling to select the required number of patient records at each site.
  - A sample frame of all patients meeting inclusion criteria will be created using patients' unique identification number in Microsoft excel.
  - *the sample frame will be divided by the sample size for the site to provide the interval for systematic sampling of charts which will be used to select subsequent charts after the first ID until the number required from that site is complete*
  -

2.5.4. Study Confounders/Limitations:

We anticipate that missing charts and data may be a major limitation in this study. If a selected, eligible medical record is unavailable for review at the time of the site visit, clinic staff will be present during the abstraction, to determine whether the record has been removed for patient tracking or other purposes, and the record will be retrieved, when possible. The study team will make every effort to locate all selected records. If retrieving a patient chart for review is not possible, the next medical record on the list of randomly ordered unique identification numbers will be selected, until the quota for that site is reached. We anticipate that about 20% of the selected IDs will have missing charts.

Record of the number of missing charts and charts removed for patient tracking will form part of the report generated by this evaluation. Also, using a data abstraction form, we will abstract as much information on patients with missing charts from the ART register, pharmacy, and laboratory records as is possible. In a sub-analysis, we will attempt to define if charts are missing at random or if a pattern of "missingness" can be detected. We will compare those with charts to those with missing charts to see if the groups differ socio-demographically or behaviourally depending

on the breath of information accessible from the existing registers. This information will be used to define if the problem of missing charts biases our findings in any way. All information will assist the FMOH to generate recommendations for improvement in record keeping and filing so that patient care is optimized. We also anticipate that some sites may not routinely collect some information that the study requires. The information will be obtained as much as possible through key informant interviews.

2.5.5 Selection of the Health Care Worker to be Interviewed

During each site visit, the health care worker who has been involved in providing ART care at the clinic (pharmacy nurses and doctor) for the longest period will be identified. We will also, identify individuals who are regarded by clinic manager to be the most **knowledgeable** about the adult ART program at the site, who are available, and willing to be interviewed. We will interview a minimum of one health care worker in each site until we interviewed a minimum of 40 health care providers.

3. Data Quality Assurance, collection and Management

3.1 Data Quality Assurance

The protocol engaged the services of the University of Maryland office in Nigeria, the Maryland Global Initiative Corporation (MGIC) for the implementation of this study. Staff from this office with guidance and supervision from the Division of Epidemiology and Prevention, Institute of Human Virology, University of Maryland 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, Institute of Human Virology, University of Maryland School of Medicine. For best quality assurance with improved adherence to protocol, data completeness and accuracy, a stakeholders' committee (implementing partner working group) will be created to supervise the study implementation.

3.1.1 Implementing partner working group, the Implementation Dissemination Evaluation Alliance (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 implementing partners (IPs) in Nigeria. Through the IDEA working group, each IP will contribute a point-of-contact (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, sites activity during data abstraction and data transferred to UMD MGIC. This working group will have representatives of CDC, Nigeria 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, Nigeria and the FMoH will however not be involved in the data collection supervision.

3.1.2 Training

Data abstractors and the supervising IDEA group will be trained on the survey objectives and t their roles in the survey, as well as the need for good quality data. The abstractors and data manager who are trained with hands-on experience on data collection, capturing, storage and human subject protection will be required to take refresher CITI training on confidentiality and human subject protection. They will receive internal 2 days training on data security form the University of Maryland School of Medicine. Supervisors will undergo a four-day, central-level training. The IDEA group members will be required to take the Collaborative Institutional Training Initiative (CITI) training on human subject protection.

3.1.3 Field supervision

During the data abstraction, the IDEA group members supervising data collection at the sites will supervise abstractors' handling of chart selection, confidential records, data de-identification, entry into the mobile device and review 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.

3.2. Data Collection

The contract research organization's (UMD 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 test and start program started at different calendar times at the selected sites. Data will be abstracted in batches as participants at different sites complete the 12 months observation period. Site selection for data abstraction will thus be guided by the program start date, number of patients that completed the12 months follow up or number of patients per month that will be completing their follow ups up to September 30, 2017. Site unable to enrol the minimum number of patients (sample size for the site) as of October 31, 2016 will be substituted with another site from the same LGA that had enrolled sufficient number by this date. The IP POCs will introduce UMD MGIC team of abstractors to the site's PEPFAR program manager and supervise the data abstraction. The site program manager together with ART clinic staff provides access to the site's data and relevant registers.

Our preliminary assessment indicated that almost all the selected sites have moved from paper based medical records keeping to electronic medical record (EMR) platforms. The UMD MGIC team of abstractors are familiar with the various EMR platforms used by the different IPs and are currently comparing the data abstraction tool to the various EMR forms to identify data elements not captured in the EMRs that would require manual abstraction 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. The total number of patients enrolled in the program at a site will constitute the sampling frame for the sample required from that site. Systematic sampling with selection interval defined by the ratio of sampling frame to the site sample size will be used to select IDs for medical chart review. IDs with missing charts will be replaced. A mobile tablet with SurveyCTO Collect android app will be used for data collection. This device is GSM data (3G) capable with 512MB of RAM, 8GB of internal storage memory and an external storage 32GB Micro SD Card. It is also GPS compatible and has WiFi 802.11b/g/n capacity.

De-identification and Study identification: Data entered into the abstraction form on the device will not include patient's name, phone number, fax numbers, email and physical addresses, health insurance number, biometric identifier or photographic images if any. Enrollment ID will be generated and assigned during abstraction. It includes prefix 2 digit site code, patient's hospital record and 1 digit abstractor's code. E.g., 0114553 identifies patient with hospital number 1455 enrolled from site 01 by data abstractor number 3. Medical record numbers will be retained but re-coded 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. The same device will be used to collect qualitative data through key informant interviews of health care providers at the ART clinics.

3.2.1 Training of Abstractors

Before beginning data collection, all data abstractors will undergo a 3-5 day training on the protocol, forms, and study procedures. UMD MGIC in collaboration with CDC and FMOH will conduct all 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. The abstractors will be required to attest that they will not disclose any information they read in the charts (see Appendix 6).

Also, as part of the training, UMD 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.

3.2.2 Data abstraction operational procedures

Charts used for the routine collection of data on adult patients on ART at HIV care and treatment sites have been reviewed and should provide all the data needed for completion of the data abstraction tool (Appendix 1).

Occasionally, the following problems may occur: A chart of a selected patient who is recorded in the ART register cannot be located, even after requesting assistance from the attending clinic staff. These data will form part of the report to the FMOH. The next chart on the randomly ordered list of ART charts will then be selected for inclusion in the study. Because it is difficult for data abstractors to determine if weights, CD4 counts, VLs, haemoglobin values, or alanine aminotransferase (ALT) values are eligible for inclusion in 6 and 12-month outcome analyses, we will attempt to collect data on **all** follow-up weights, CD4 counts, VLs, haemoglobin values, and ALT values, along with the date of information recorded in the patient chart. All weights should be recorded in kilograms, haemoglobin levels in grams/deciliter, and VL in RNA copies/mL.

3.2.3 Variables Collected During Data Abstraction

A list of data to be abstracted is recorded below. The data abstraction tool is documented in Appendix 1.

- **Outcome of ART and Date of Outcome**
  - Still alive and on ART (retained on ART). We will record the date of the most recent visit to the health care facility to see the health care provider or pick up medicines.
  - Died during ART and date of death.
  - LTFU during ART (has not attended the health care facility in the 90 days from date of missed appointment to see a healthcare provider or pick up medicines.) We will record the date of the most recent visit to the health care facility to see the health care provider or pick up pills.
  - Transferred out to another facility during ART with documentation of the date of transfer.
  - Stopped ART care voluntarily 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 ART care.). We will record the date of stopping ART.
  - Where applicable, what was the reason for stopping ART, and what was the recorded cause of death?
- **Support services**
  - Referral for support services: nutrition, prevention with positives (PwP), OVC, psycho-social support services.
  - Counselling.
  - Did the patient receive adherence counselling before ART initiation?
  - Did patient receive PwP counselling at any stage during care (include the date of first counselling)?
- **Demographic Data**
  - Date of birth (month and year only), age at enrolment into HIV care, gender; village, town, or city of residence at HIV care initiation; marital status, educational level reached at the time of enrolment into HIV care, employment status at the date of enrolment into HIV care
- **HIV Diagnosis Information**
  - Date of first HIV diagnosis recorded in the chart,
- **ART Initiation Visit**
  - Weight, haemoglobin, CD4 count, VL, clinical stage, co-trimoxazole prescription, and ART regimen at ART initiation.,
- **Most Recent ART Visit**
  - Weight, clinical stage, co-trimoxazole prescription, and most recent VL at most recent visit.
- **Regimen Changes and Drug Substitutions**

- Was the patient's regimen changed and, what was the reason for changing the regimen?
- Was a drug substituted and, what was the reason for the drug substitution?

- **Follow-up Information**
  - Dates of all follow-up appointments and weights post-ART initiation.
  - Dates and values of all CD4 counts, VL, haemoglobin levels, serum creatinine, and ALT results after ART initiation
- **Adverse Events and Opportunistic Infections during ART**
  - The occurrence of adverse reactions related to ART medication. Immune Reconstitution Inflammatory Syndrome and hepatitis are the events of interest.
  - The presence of opportunistic infections after ART initiation.
- **Adherence and Drug Dosages**
  - To calculate a proxy for patient adherence, we will calculate the total number of days that any patient selected for chart review was late to pick up ARVs from the pharmacy during the first six months after ART initiation. This will require review of the clinic's pharmacy register.
- **PwP (Positive Health, Dignity, and Prevention)**
  - Did the patient receive a PwP) package at the most recent visit (PEPFAR PwP indicator). A PwP package consists of:
    - Assessment of sexual activity and provision and usage of condoms (and lubricant) and risk reduction counselling.
    - Assessment of partner status and provision of, or referral for, partner testing.
    - Assessment for STIs and (if indicated) provision of, or referral for STI treatment and partner treatment
    - Assessment of family planning needs and (if indicated) provision of contraception, or safer pregnancy counselling, or referral for family planning services
    - Assessment of adherence and (if indicated) support or referral for adherence counselling
    - Assessment of need and (if indicated) referral or enrolment in community-based program, such as home-based care, support groups, and post-test-clubs.

3.2.4 Information Collected During the Interviews with Health Care Workers

In addition to variables extracted from the chart, qualitative data, as determined from interview responses by health care providers at ART clinics, will be used to define:

- Availability of human resources to facilitate adult ART and TB care and treatment:
  - Number of health care workers who have been trained to prescribe ART, are prescribing ART, and have been trained in TB diagnosis and treatment services and are providing these services.
- HIV diagnostic tests and protocols at the site.
- The most frequent sources of referral to HIV care services.
- Working conditions at the ART delivery site and health care worker satisfaction with the working conditions.
- Drug availability at selected sites.
- Availability of support services, including nutritional and psychosocial care at selected sites.

- Network of services: Hub and Spoke model, tracking referrals to support services such as nutrition counselling, PwP, psycho-social support, and adherence counselling

The interview form is documented in Appendix 3. About 40 ART clinic health care providers will be interviewed. Selection of health care providers for the interview will be proportional to the number of patients enrolled on ART at the site or clinic.

3.2.6 Review of Referral Registers and/or Forms

- 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.

3.2.7 Review of Laboratory Register

- If CD4 counts, haemoglobin levels, or VL are missing from the charts, the laboratory register at the clinic where all the results are recorded will be reviewed in an attempt to complete as much of the data abstraction form as possible.

3.2.8 Review of Pharmacy Register

- Once data abstractors have completed reviewing the appropriate number of charts at selected sites, the data abstractors will review the pharmacy register in order to determine a proxy for adherence for each chart reviewed as part of study. Because review of pharmacy records will occur at the end of each day at a time suitable for the pharmacist, and because no personal identifiers such as name or clinic registration number will be abstracted onto the data abstraction forms, a "study register" which links the patient's name to the unique study number will be created during chart review and will be destroyed as soon as the pharmacy register has been reviewed. The study register will at no time leave the care of the study team.

3.3 Chart Abstraction logistics and Planning

- Three teams of three data abstracters and one facilitator will be identified for each state. Each team of three abstractors and one facilitator will visit a subset of clinics selected for study.
- Prior to arrival at the clinic, the clinic manager, the local health authority, the State Health Authority and the State AIDS Control Agency will have been informed of the purpose and timing of the visit.
- When the team arrives at the clinic with a copy of an introductory letter from the FMOH, the abstractors will first meet with the clinic manager who will bring in the clinic and medical records staff to orient staff about the objectives of the evaluation.

3.4 Data Management Plan

Data collection and handling: A mobile tablet with SurveyCTO Collect android app will be used for the collection of abstracted data and information obtained through interviews. Trained study staff will de-identify and abstract patient level data at facility level, obtain consent and administer questionnaires to the health care providers. Data completeness and accuracy are 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 entered into the Excel spreadsheet on the collection device are transferred into a desktop computer and SurveyCTO central server at the UMD MGIC office. 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 UMD MGIC office, and in secured SurveyCTO server for electronic data. All electronic data are stored in 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. Lead investigator and study staff will have access to the data through the data manager accessible to the investigator and key study personnel. SurveyCTO stores 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 UMD MGIC and can be made available on a week 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 IDEA at the UMD 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 3% 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 or 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 system. Data shared in this study will not contain enrolment IDs.

Table 3: Data Handling and Management-UMD MGIC Team Members Roles

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

4. Data Analysis Plan

Data will be collected in this study with the aid of SurveyCTO software on a mobile device. Data collected from chart extraction will be weighted and we will control for the design of the survey. Data analysis will include frequencies, chi-square tests for categorical variables, and t-tests for continuous variables. As part of an initial descriptive analysis, a table will summarize the frequencies of demographic, immunologic, and clinical characteristics of patients at ART initiation.

Data obtained from key informant interviews will be examined as the interview are conducted to identify better and easier ways to elicit and interpret health provider response that best describe their motivations, perspectives and recommendations for the test and start program. Two ART program analysts will manually review, organize and code data into categories of outcomes or end points that address the evaluation objectives and highlight health providers' perspective on successes and barriers of the test and start program. Reasons for program success may provide insight on good treatment outcomes deduced from the quantitative data while information on important barriers may explain otherwise. Health care providers' recommendations on how to improve uptake of the test and start treatment strategy may help decision making better. Analyst will look for repetitive trends, similarities and differences between trends in participants' responses. And, assess relationships between trends and how these relationships provide additional information to the findings from the quantitative data.

Primary Analysis: The primary analyses needed to answer the key questions of this study are listed below.

4.1 Determining Virologic Failure, Retention Rates, and Weight Gain at 12 Months of ART Follow-up

The proportion of patients with viral suppression after 24 weeks initiating "Test and Start" will be reported. Additionally, the proportion of patients who are alive and on ART at 12 months will be reported with appropriate 95% CIs. In addition, of those not retained in ART at the time points of interest, the proportion documented to have died, been lost to follow-up, or stopped ART along with appropriate 95% CIs, will be reported. For those patients who are retained on ART, 12 months after ART initiation, we will calculate the median gain in CD4 count and weight from baseline and report these medians with appropriate inter-quartile ranges. Of these patients retained at 12 months of ART, we will determine the proportion with missing CD4 counts at the time points of interest. Kaplan-Meier survival curves will be used to graphically illustrate patient retention on ART over time. The event of interest will be attrition, which for this study is defined as died, LTFU, or stopping ART. Patients who transferred out of care at each facility will be excluded from this analysis.

4.2 Secondary Analyses

In a secondary analysis, we will calculate adjusted and unadjusted rate ratios for all patient-level characteristics with respect to virologic failure and outcomes of patient retention, weight gain, and median CD4 increase by 12 months of therapy. These values will be presented in table format. Our analysis will account for the complex study design, and clustering in the sample. We will also apply a finite population correction factor $\sqrt{(1-f)}$. Where f=n/N, n=sample size and N=total population. However, because N is huge, we expect that f will approach zero. Furthermore, since our sample size is large we expect our standard error to be low as well.

4.3 Potential Biases

No bias in data collection is anticipated, however, the retrospective nature of the evaluation makes it difficult to control for rates of missing data. We will explore various methods to manage the problem of missing data. These methods may include maximum likelihood estimation, multiple imputations, and the pattern mixture approach.

4.4 Data Flow

Three separate databases will be created, using SurveyCTO software, with separate databases created for the data from chart abstraction during study and a third database created for interview-generated data. The coordinating team will send aggregate data reports (from the national sample, not site-specific) to the ART sites that are involved with the evaluation. However, all original data will remain at the central level.

4.5 Quality Control

Trained data entry clerks, who will be hired by implementing partner, will double-enter data from the abstraction forms and interview sheets into the electronic database. The database will have built-in checks that will not accept erroneous values.

4.6 Determining Risk Factors Associated with Retention and Attrition 12 months after ART Initiation:

Amongst other variables, we will investigate the association between low baseline CD4 count (<200 cells/µL), type of HIV-infection, poor adherence, type of initial ART regimen, TB infection at ART initiation, and attrition at 12 months of ART follow-up. To define the significance of each risk factor for attrition we will calculate adjusted and unadjusted odds ratios through bivariate and multivariate analyses and report these odds ratios with appropriate 95% CIs.

4.7 Data Ownership, Disposition and Results Dissemination

The database will be co-owned by the Nigerian FMOH and UMD. After data entry, data collection forms will be stored in a locked cabinet at the UMD MGIC office in Abuja. Hard copies of forms will be kept for three years. After the expiration date, the paper forms will be shredded. At the conclusion of the evaluation, the evaluation implementing partner working group will work with FMOH, CDC, Nigeria 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, conferences and seminars, and will be published in reputable peer review journals. A final evaluation report will be produced in alignment with the PEPFAR ESoP requirements and posted (in English) on a publically accessible website within 90 days of clearance

5. Human Subjects and Informed Consent

5.1 Chart Review and Pharmacy Register Review

5.1.1 Informed Consent

We are requesting a waiver of informed consent for medical record abstraction for this study. The waiver is appropriate because: (1) the studies are retrospective in nature, involve no more than minimal risk to human subjects, and no personal identifiers will be collected; (2) the studies will not adversely affect the rights and welfare of the subjects; (3) the studies could not practicably be carried out without the waiver because it is not possible to track down and obtain consent from selected clinic patients; and (4) if tracing of patients to their homesteads was attempted, this might reasonably constitute a violation of privacy and confidentiality.

5.1.2 Benefit for Program

We do not anticipate that all patients included in the studies will directly benefit from the results of this evaluation. However, it is rational to expect that the majority of patients included in this program evaluation, those who remain alive and on ART, will indirectly benefit from the assessment through improvements made in the quality of the HIV care and treatment program. Improvements in the program are, however, dependent on a number of other variables, including the availability of financial, human, and other resources. Results of the study will be shared with all the sites and key stakeholders in the country.

5.1.3 Confidentiality

No personal identifiers that can be traced back to clinic patients, such as patient name or clinic registration number will be collected during chart extraction. There is a potential risk of loss of confidentiality since data abstractors will be reviewing medical records. To reduce risk of loss of confidentiality, data abstractors will be trained on the importance of maintaining confidentiality of patients whose charts are reviewed and will sign a document indicating their agreement to maintain this confidentiality. Hard copies of the data extraction forms will be kept in a locked cabinet, the key to which will be held by the PI. Hard copies of the data extraction forms will be kept for three years after the construction and cleaning of the electronic database (or after the end of the study). At the expiration date, the paper forms will be shredded. The data, once computerized using the SurveyCTO data entry tool, will be kept by the investigators on personal computers with password-protected login screens. The data will be analysed and interpreted in a collaborative manner, under the leadership of the PI.

5.2. Interviews

The health care workers providing ART services at the study site will be approached by our trained interviewers (who are also the data abstractors) through the site program manager. The site program manager is responsible for coordinating the interviewers' activity at the site including access to data and clinic staff. The interviewers will request the site manager to inform the clinic 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 clinic staff to find out if they are interested in the study and will like to learn more about it. Those who indicate 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.

5.2.1 Informed Consent

Before initiation of interviews with health care workers, we will request written, informed consent. The consent form will be read to the participant assuring confidentiality of responses and lack of negative consequences from participation in the study. The consent form will be read in English. One copy of the informed consent form will be kept by the health care worker and one copy will be kept by the PI who is not a direct or indirect supervisor of any of the health care workers.

5.2.2 Benefit for Program

All results will be used to inform program planning and improvement. Improvement of the program is however dependent on the availability of appropriate human, financial, and other resources.

5.2.3 Confidentiality

All interviews will be confidential. The name of the person interviewed will at no time be recorded on the interview sheet. The signed informed consent will be kept separate from the completed interview sheets and stored by the PI who is not a direct or indirect supervisor of any of the health care workers. No supervisor of the interviewee will be present during the interview, and the results of the interview will not be shared with supervisors of the health care providers. Data abstractors and facilitators will be trained on confidentiality and data security. The interviewers will sign a document indicating their intent to maintain this confidentiality.

5.3. Institutional Review Board (IRB) Approval

The final protocol will be submitted to the National Health Research Ethics Committee in Nigeria, and the CDC Division of Global HIV and TB (DGHT), for review and approval before the implementation phase starts.

6. Study timeline and budget

	2016		2017											
Activity	7 to 11	12	1	2	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 in Nigeria and Atlanta														
Hiring of data abstractors														
Training of data abstractors and IDEA														
Establish program start dates at the selected sites														
Pilot data abstraction and collection tools at three sites														
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														

The budget and the budget justification for this activity are part of a larger cooperative agreement between UMD and CDC for the SHIELD grant. However, the total cost of test and start evaluation is estimated at $289,000

7. References

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8.0 Appendices

Appendix 1: ART Data Abstraction Tool

Participant identifier: NCAS/../../… __ __ A __ __ __ Name and type of Facility: _____

Abstractor's Name: _____ Date of Abstraction: D D / M M / Y Y

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

9. Did patient start ART at a different clinic BEFORE transferring into this clinic?	☐ **No** *(skip to question 12)* ☐**Yes,** **if yes: *date of transfer in:*** ____/_____/_____ ☐ **Missing**
10. If patient is a "**transfer in**", enter the dates of HIV ART initiation at previous facility *(if available)*.	**ART Initiation:** D D **/** M M **/** Y Y ☐ **Missing**
11. Name of the ART regimen initiated at previous facility?	_____/_____/_____☐ **Missing**
B. CLINICAL INFORMATION	
12. Date of first confirmed HIV Positive test:	D D **/** M M **/** Y Y ☐ **Missing**
14. Patient height:	_____ **Meters** ☐ **Missing**
15. Patient weight at start of ART:	_____ **kg** ☐ **Missing**
16. Date eligible for ART:	D D **/** M M **/** Y Y ☐ **Missing**
17. Date ART started:	D D **/** M M **/** Y Y (cannot be missing)
18. Eligibility criteria for ART: *(check all that apply)*	☐ **Clinically only** ☐ **CD4+cell count** ☐ **Missing** ☐ **HIV positive test** ☐ **Other, specify**_____
19. CD4+ cell count at start of ART:	_____ **cells/mm^3** ***Date of test:*** D D **/** M M **/** Y Y ☐ **Missing**
20. Clinical stage at start of ART:	☐ **Stage I** ☐ **Stage II** ☐ **Stage III** ☐ **Stage IV** ☐ **Missing**
21. Functional status at start of ART:	☐ **Working** ☐ **Ambulatory** ☐ **Bedridden**

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

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

C. ART REGIMEN

28. 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)** 1a. d4t-3TC-NVP 1b. d4t-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				1c. TDF-3TC-NVP
D D / M M / Y Y				1d. TDF-3TC-EFV
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. ART INTERRUPTIONS AND ADVERSE EVENTS

29. Any history of stopping ART 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**
30. If patient **stopped ART**, 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**
31. Any documented adverse events to ART that patient developed?	☐ **Yes** ☐ **No** ***If Yes, check all that apply*:** ☐ **Severe rash** ☐ **IRIS** ☐ **Anemia** ☐ **Hepatitis** ☐ **Neuropathy** ☐ **Renal Impairment** ☐ **Other, specify:**_____

E. FOLLOW UP STATUS

32. 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 ART**

4 = Lost to follow-up **5 = Transferred out** **6 = Restarted ART** **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?	
33. Pre-ART counseling	☐ **Yes, *No. of times*____** ☐ **No** ☐ **Missing**
34. Counseling at ART initiation	☐ **Yes, *No. of times*____** ☐ **No** ☐ **Missing**
35. Any adherence counseling during follow-up	☐ **Yes, *No. of times*____** ☐ **No** ☐ **Missing**
36. Does patient attend a support group?	☐ **Yes** ☐ **No** ☐ **Missing**

	If yes, please specify:_____
37. Support services used by the patient since initiation of ART (*check all that apply*)	☐ **Home-based care** ☐ **Nutritional support** ☐ **Community based support groups** ☐ **OVC** ☐ **Psychosocial services** ☐ **Other, please specify:**_____ ☐ **Not using any support services** ☐ **Missing**
38. Does patient use condoms?	☐ **Always** ☐ **Most of the time** ☐ **Occasionally** ☐ **Does not use condoms** ☐ **Not sexually active** ☐ **Not assessed** ☐ **Missing**

G. PHARMACY REGISTER

39. List dates of **ALL** ARV collected, please record date refill given, ARV regimen (use ARV codes from question 28), and number of days for which ARV 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

40. 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/YY		DD/MM/YY		DD/MM/YY		DD/MM/YY
2		DD/MM/YY		DD/MM/YY		DD/MM/YY		DD/MM/YY		DD/MM/YY
3		DD/MM/YY		DD/MM/YY		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

41. Hepatitis B status	☐ **Antibody positive** ☐ **Antigen positive** ☐ **Negative** ☐ **Unknown** ☐ **Missing**
42. Hepatitis C status	☐ **Positive** ☐ **Negative** ☐ **Unknown** ☐ **Missing** **Date of test:** D D / M M / Y Y
	D D / M M / Y Y

43. Date of last clinic visit:	
44. Patient's outcome at the last visit?	☐ **Died, d*ate of death:*** *D D* **/** *M M* **/** *Y Y* ☐ **Alive, on ART** ☐ **Transferred out, *date of transfer out:*** *D D* **/** *M M* **/** *Y Y* ☐ **Stopped ART, *date of voluntarily stopping care:*** *D D* **/** *M M* **/** *Y Y* ☐ **Lost to follow up**
45. If patient died, what was the documented cause of death?	☐ **Pneumonia (not Pulmonary TB/PCP)** ☐ **Cryptococcal meningitis** ☐ **Acute diarrhoea** ☐ **Chronic diarrhoea** ☐ **Pulmonary TB** ☐ **Extrapulmonary TB** ☐ **Other, specify:**_____ ☐ **Unknown** ☐ **Missing**

If additional space is needed for **question 32,** please use the space below

Continuation from page 4, question 31			
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**	
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**	
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**	

If additional space is needed for **question 39,** please use the space below

Continuation from page 5, question 39

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		
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		
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		
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		

If additional space is needed for **question 40,** please use the space below

Visit #	**CD4+ cell count(/μL)**	**Date**	**VL (copies/mL)**	**Date**
13		DD/MM/YY		DD/MM/YY
14		DD/MM/YY		DD/MM/YY
15		DD/MM/YY		DD/MM/YY
16		DD/MM/YY		DD/MM/YY
17		DD/MM/YY		DD/MM/YY
18		DD/MM/YY		DD/MM/YY
19		DD/MM/YY		DD/MM/YY
20		DD/MM/YY		DD/MM/YY
21		DD/MM/YY		DD/MM/YY
22		DD/MM/YY		DD/MM/YY

23		DD/MM/YY		DD/MM/YY
24		DD/MM/YY		DD/MM/YY
25		DD/MM/YY		DD/MM/YY
26		DD/MM/YY		DD/MM/YY
27		DD/MM/YY		DD/MM/YY
28		DD/MM/YY		DD/MM/YY
29		DD/MM/YY		DD/MM/YY
30		DD/MM/YY		DD/MM/YY
31		DD/MM/YY		DD/MM/YY
32		DD/MM/YY		DD/MM/YY
33		DD/MM/YY		DD/MM/YY
34		DD/MM/YY		DD/MM/YY
35		DD/MM/YY		DD/MM/YY
36		DD/MM/YY		DD/MM/YY
37		DD/MM/YY		DD/MM/YY
38		DD/MM/YY		DD/MM/YY
39		DD/MM/YY		DD/MM/YY
40		DD/MM/YY		DD/MM/YY
41		DD/MM/YY		DD/MM/YY
42		DD/MM/YY		DD/MM/YY
43		DD/MM/YY		DD/MM/YY
44		DD/MM/YY		DD/MM/YY
45		DD/MM/YY		DD/MM/YY
46		DD/MM/YY		DD/MM/YY
47		DD/MM/YY		DD/MM/YY
48		DD/MM/YY		DD/MM/YY

49		DD/MM/YY		DD/MM/YY
50		DD/MM/YY		DD/MM/YY
51		DD/MM/YY		DD/MM/YY
52		DD/MM/YY		DD/MM/YY
53		DD/MM/YY		DD/MM/YY
54		DD/MM/YY		DD/MM/YY
55		DD/MM/YY		DD/MM/YY

Appendix 2: Interview for Health Care Provider

Hello, my name is ……and I am working with the United States Centers for Disease Control and Prevention and the Federal Ministry of Health to find ways in which services delivered from this clinic and others like it in Nigeria might be improved. As part of this evaluation, we are interviewing health care providers at HIV care centers for HIV-infected adults to: learn more about the successes of the ART services provided to patients, and how to improve ART services as the program expands.. Participation in this study is completely voluntary. Any information you give will be kept confidential.

Are you willing to participate in this 25-30 minutes interview?

Yes: Go ahead to obtain consent

No:Thank respondent for his or her time and end it here.

IINFORMED CONSENT FOR PARTICIPATION IN ART TEST AND START EVALUATION

Principal Investigator: name and contacts

You are invited to participate in an evaluation study on HIV anti-retroviral therapy (ART) service delivery. Please take time to review or listen to this consent as it is being read to you and ask any questions you may have with the study staff. Participation in this study is voluntary. You may take time to make your decision about participation 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.

PURPOSE OF STUDY

HIV is a leading cause of illness and dealth in this envoronment.. The success of 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 perpective of health care service providers on the ART test and start treatment approach, what works well and what needs improvement upon as the program expands... You are invited to participate in this study because you are an HIV health care provider. About 30 HIV health provider volunteers are expected to participate in this study.

PROCEDURES

If you take part in this study, you will be asked to participate in an interview. The interview will last for about 30 minutes You will be required to respond to questions concerning your work, work place, patients coming to seek for care, care delivery and support services.This interview has no follow ups.

POTENTIAL RISKS/DISCOMFORTS

Some of the questions may make you feel uncomfortable.. 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.

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 transmissions in the community..

ALTERNATIVES TO PARTICIPATION

Your alternative is to not take part. If you choose not to take part, your work as ART service prover will not be affected.

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

PAYMENT TO PARTICIPANTS
You will not receive 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 provided. A list linking your names to the codes will be kept separate from the interview notes and will be destroyed at the conclusion of the study. Any responses included in the final report will be kept anonymous.. We cannot promise complete secrecy. Organizations that may inspect the information ayou provided include the IRB, the CDC, Nigeria and the Federal Ministry of Healh.. 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 participation in this study is voluntary. You do not have to take part in this evaluation. You are free to withdraw your consent at anytime. Refusal to take part or to stop taking part in the study will involve no penalty nor affect your job in anyway.. You will receive all the benefits entitled to you in this program. If you decide to stop taking part, or if you have questions, concerns, or complaints related to the study, please contact the investigator, at 080 ……..

CAN I BE REMOVED FROM THE STUDY?

The person in charge of the study or the sponsor can remove you from the studywithout your approval. We will notify you if this happens. You will have chance to ask questions.

Signing this consent form indicates that you have read this consent form (or have had it read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this study. You will receive a copy of this signed consent form.

If you agree to participate in this study, please sign your name below.

_____

Participant's Signature

Date:_____

_____

Investigator or Designee Obtaining Consent Signature

Date:_____

_____

Witness (for illiterate or those who cannot sign)

Date:_____

Interview for Health Care Provider

Instructions for conducting interviews

The interviewer should not be the direct or indirect supervisor of the care provider since this may bias the responses.

Interviews should be conducted in a quiet, private location.

Interviewers should avoid remarks, body language, or questions that may bias interviewee responses.

The interview will be conducted in English or a local language in which the care provider is fluent. The reading level is *Flesch-Kincaid Grade Level 7.4.*

Interviews are entirely voluntary and potential interviewees may choose not to participate at any time. Interviews will be conducted during work hours with prior approval from the head of the clinic. It will be necessary for the head of the clinic to give consent for one of the adult ART providers to conduct the interview. The actual responses will not be made available for review by the head of the clinic. Instead, general themes which might allow for improvement of the ART program will be extracted from the interview responses. These general themes will be reported to all ART delivery sites.

Questionnaire for Health Care Provider giving the Interview at the Adult HIV Clinic

Type of Position:

Doctor	☐	Nurse	☐	Other	☐

Type of Facility:

*Urban	☐	**Semi-Urban	☐	***Rural	☐

*Urban = Within city limits of a city supporting >100,000 people

**Semi-Urban = Within 100 klms of the limits of a city supporting >100,000 people

***Rural = >100 klms from the limits of a city supporting >100,000 people.

*Primary	☐	Secondary	☐	Tertiary	☐

*Definitions according to MoH classification.

Human Resources:

At present, how many:

Adult patients (>15 years at HIV care initiation) are currently enrolled in HIV care at this site?	_____ pt's
	_____ pt's

At this clinic, how many health care workers:

Routinely, provide ART care to adults and adolescents?	_____ HCW's
Have been trained to provide ART care to adults and adolescents?	_____ HCW's
Have been trained to provide ART care to HIV-2 and dually infected adults and Adolescents?	_____ HCW's

Referral Sources:

What is the major referral source for adult patients presenting to this clinic (tick only one)?

Adult ward	☐	PMTCT services/ ante-natal care services.	☐	Home Based Care	☐
Outpatient department	☐	HIV counseling and testing unit	☐	Other	☐
Maternal Obstetric Unit	☐	TB clinic	☐		

Is Cotrimoxazole currently prescribed to all HIV-1 and HIV-2 infected adults? __Y__N_

If not, what criteria are used to define HIV-infected patients eligible for co-trimoxazole?

_____

_____

Before ART initiation are:

	Yes	No
HIV-1 infected patients routinely screened for TB	☐	☐
HIV-2 infected patients routinely screened for TB	☐	☐
Dually infected patients routinely screened for TB	☐	☐

If yes to any of the above, what method is used to screen HIV infected adults for TB?

If the HIV-infected adult's result for a TB screen is positive, where are adults referred for TB diagnosis?

_____

If diagnosed with active TB, where do adults receive TB therapy? _____

If found TB negative how do they access isoniazid prophylactic theraphy (IPT) against TB?

Clinic Conditions:

Are HIV-infected adult patients, regardless of HIV type, who are enrolled in HIV care or ART, seen at this clinic on any day of the week or only on specified days?

Mon	☐	Tues	☐	Wed	☐	Thurs	☐	Fri	☐	Sat	☐	Sun	☐	Any day	☐

Are adult patients, not enrolled in HIV-care or on ART seen at this clinic on any day of the week or only on specified days?

Mon	☐	Tues	☐	Wed	☐	Thurs	☐	Fri	☐	Sat	☐	Sun	☐	Any day	☐

(For questions below, please review the clinic outpatient register)

At this clinic, in the previous month, the:

Number of out-patients, regardless of HIV status, seen	_____pts
Number of HIV-infected adult out-patients, regardless of HIV type, seen	_____pts
Number of HIV-infected adult out-patients, regardless of HIV type, enrolled in HIV-care or ART, seen	_____pts

On days that you work at this clinic, what is the time that:

You start seeing patients in the morning?	___h____
You stop seeing patients in the evening?	___h____

In your opinion, do you think doctors, working at this clinic are satisfied with the working conditions?

Yes, all doctors are satisfied	☐	Some doctors are satisfied	☐	No doctors are satisfied	☐

Please list as many reasons as possible for the answer given _____

In your opinion, do you think most nurses, working at this clinic are satisfied with the working conditions?

Yes, all nurses are satisfied	☐	Some nurses are satisfied	☐	No nurses are satisfied	☐

Please list as many reasons as possible for the answer given _____

Which of the following tools are available to you for management of adults on ART?

A scale to weigh patients	☐	A dosing schedule for Cotrimoxazole for adult patients	☐	Electricity	☐
A scale to measure the height/length of patients	☐	Running water	☐	Gloves	☐
A dosing schedule for ART in adult patients	☐	Soap	☐	Sharps containers	☐

Support Services:

Is there a support group for adults receiving ART? __Yes__No

Where is the support group held?

_____. It is _____kms from the ART clinic.

What methods do you routinely use to promote adherence of adults on ART: During treatment preparation:

	Yes	No
Are friends/family members designated as treatment supporters?	☐	☐
Is there intensive HIV education for patient and supporter	☐	☐
Registration in the HIV care register	☐	☐
Follow-up tracing if patients default	☐	☐
Home based care programs	☐	☐
Any other methods to promote adherence during pre-ART care?_____		

During ART treatment:

	Yes	No
Registration in the ART register?	☐	☐
Pill counting?	☐	☐
Treatment diaries?	☐	☐
Patient self-reported compliance?	☐	☐

Follow-up tracing if patients default?	☐	☐
Any other methods to promote or assess adherence during ART care?_____		

Adherence and retention (Source: Medical Director or Charge Nurse)

1) What would you suggest as the 3 most important interventions to improve 12 month retention of ART patients in your facility? (**Ask as open-ended question first. Place 1, 2, 3 in appropriate places per response. If difficulty in answering, show list and go through all potential responses then ask to answer.)**

_____Decrease time required for patients to spend at clinic for appointments

_____Provide multiple-month refills for stable patients (how many months? _____)

_____Provide services closer to where patients live

_____Hire additional staff dedicated to care and treatment of HIV patients

_____Improve lab services: (tick all that apply)

- ❑ results turnaround time
- ❑ range of tests available
- ❑ collection times
- ❑ sample transport vs. patient referral to lab

_____Improve staff treatment of HIV patients (e.g., decrease discrimination)

_____Provide family centered ART services (e.g., pediatric, adolescent, and adult)

_____Improve overall service quality (provide examples: _____)

_____Eliminate patient fees

_____Ensure patients start ART before they become very sick

_____Other (specify): _____

Appendix 3: Letter of approval to implement “Test and Start”

FEDERAL MINISTRY OF HEALTH
OFFICE OF THE HONOURABLE MINISTER

C.5438/S.1/Vol 1/89 — 11th March, 2016

Shirley A. Dady,
Coordinator,
U.S. President's Emergency Plan for AIDS Relief (PEPFAR)

Dear Shirley,

Re: Request to Implement "Test and Start" and decongest large volume sites

I bring you felicitations from the Federal Ministry of Health and express our appreciation for the support provided by the United States President's Emergency Plan for AIDS Relief (PEPFAR) towards the effective control of HIV/AIDS in Nigeria.

2. I refer to your letter on the above request for approval to commence the implementation of the new WHO guideline, otherwise tagged "Test and START" which recommended that i) antiretroviral therapy (ART) should be initiated in everyone living with HIV at any CD4 cell count; and ii) the use of daily oral pre-exposure prophylaxis (PrEP) is recommended as a prevention choice for people at substantial risk of HIV infection as part of combination prevention approaches, in the 32 PEPFAR scale-up LGAs listed in your letter.

3. Having reviewed your request, I wish to convey my approval for you to proceed. This approval is in further consideration of the convincing evidence that informed this recommendation including the HPTN 052, the START trial and the TEMPRANO trial, all showing that early treatment more than halves risks of serious illness and death, and almost entirely eliminates risks of transmitting the virus.

4. However, I wish to reiterate that this is not an ethics approval, and should you wish to carryout any activity other than just implementation of this strategy, we expect that you would seek authorization including ethics approval as may be necessary in line with global best practices and national requirements.

5. Please accept the assurances of my esteemed regards.

Prof. Isaac F. Adewole, FAS, FSPSP, DSc(Hons)
Honourable Minister of Health

Federal Secretariat Phase III, Ahmadu Bello Way, Central Business District, Abuja.
Tel: 0812 725 6638. Email: hmh@health.gov.ng Website: www.health.gov.ng
P.M.B. 083 Garki Abuja.

Appendix 4: List and number of PLHIV in 32 scale-up LGAs

S/N	Sub National Unit	PEPFAR Partner	Total PLHIV	APR 15 Current on Treatment[1]	Expected # current on ART at APR 16
1	ak IkotEkpene Local Government Area	FHI360	14,324	3,272	8,098
2	ak Okobo Local Government Area	FHI360	14,825	578	4,844
3	ak Uruan Local Government Area	FHI360	11,897	1,446	2,085
4	ak Oron Local Government Area	FHI360	10,779	3,774	6,431
5	ak Uyo Local Government Area	FHI360	26,480	3,757	6,989
6	be Buruku Local Government Area	IHVN	9,329	2,600	5,455
7	be Gwer West Local Government Area	CIHP	8,684	1,806	4,699
8	be Katsina-Ala Local Government Area	CIHP	17,608	564	11,369
9	be Konshisha Local Government Area	IHVN	10,202	252	5,462
10	be Logo Local Government Area	CIHP	14,990	5,533	7,603
11	be Tarka Local Government Area	CIHP	4,740	2,485	3,101
12	be Ushongo Local Government Area	IHVN	12,995	253	4,648
13	cr Calabar South Local Government Area	FHI360	14,714	1,746	5,425
14	cr Calabar-Municipal Local Government Area	FHI360	8,920	4,680	6,035
15	fc Abuja Municipal Local Government Area	IHVN	84,103	19,947	43,211
16	fc Bwari Local Government Area	IHVN	18,082	4,341	10,109
17	la Agege Local Government Area	FHI360	5,711	280	1,829
18	la Ajeromi-Ifelodun Local Government Area	FHI360	20,381	2,565	8,368
19	la Alimosho Local Government Area	APIN	24,544	559	8,120
20	la Apapa Local Government Area	FHI360	3,761	298	1,856
21	la Ifako-Ijaye Local Government Area	APIN	13,836	570	4,736
22	la Ikeja Local Government Area	APIN	5,873	3,401	3,405

23	la Mushin Local Government Area	APIN	52,824	7,618	22,333
24	la Surulere Local Government Area	FHI360	4,944	224	2,408
25	na Doma Local Government Area	IHVN	7,638	1,901	4,418
26	na Karu Local Government Area	IHVN	13,617	4,119	13,924
27	na Lafia Local Government Area	IHVN	24,115	6,957	13,926
28	na Nasarawa Local Government Area	IHVN	13,133	184	6,375
29	na Obi Local Government Area	IHVN	13,087	268	6,364
30	ri Eleme Local Government Area	FHI360	4,922	0	1,088
31	ri Obio/Akpor Local Government Area	FHI360	9,170	4,442	5,475
32	ri Port Harcourt Local Government Area	FHI360	13,561	3,144	4,485
	Subtotal		**513,789**	**93,564**	**244,674**

[1]**APR 15 Current on Treatment:** Totals are for all facilities in the LGA.

Appendix 5: LGAs and Sites Selected for Study with Associated Patient Selection Probabilities

S/N	STATE	LGA	FACILITIES	APR15 Tx_CURR	No. of patients to be sampled	Selection Probability
1	Akwa Ibom	Uyo	University of Uyo Medical Centre	164	13	0.0036544
2	Akwa Ibom	Uyo	University Teaching Hospital	3,515	269	0.0783235
3	Akwa Ibom	Uyo	Uyo Base Primary Health Centre	70	5	0.0015598
4	Benue	Buruku	General Hospital Buruku	1,393	107	0.0310397
5	Benue	Buruku	Mbagen Community Hospital - Abwa	1,207	92	0.0268951
6	Benue	Gwer West	Fr. Mathias Clinic	541	41	0.0120549
7	Benue	Gwer West	General Hospital Naka	1,265	97	0.0281875
8	Cross River	Calabar South	Dr Lawrence Henshaw Memorial Hospital	1,683	129	0.0375017
9	FCT	Abuja Municipal Area Council	Asokoro District Hospital	4,166	319	0.0928294
10	FCT	Abuja Municipal Area Council	Custom Staff Clinic	188	14	0.0041891
11	FCT	Abuja Municipal Area Council	Evangelical Church of West Africa (ECWA) Medical Center	272	21	0.0060609
12	FCT	Abuja Municipal Area Council	Federal Staff Hospital - Gwarimpa	77	6	0.0017158
13	FCT	Abuja Municipal Area Council	Federal Staff Hospital - Jabi	434	33	0.0096707
14	FCT	Abuja Municipal Area Council	Garki General Hospital	1,412	108	0.0314631
15	FCT	Abuja Municipal Area Council	Gwarimpa General Hospital	1,124	86	0.0250457
16	FCT	Abuja Municipal Area Council	Karshi General Hospital	660	50	0.0147065
17	FCT	Abuja Municipal Area Council	Maitama General Hospital	2,851	218	0.0635278
18	FCT	Abuja Municipal Area Council	Massan Clinic Limited	59	5	0.0013147
19	FCT	Abuja Municipal Area Council	National Hospital - Abuja	4,657	356	0.1037702
20	FCT	Abuja Municipal Area Council	National Institute For Pharmaceutical Research - Idu	2,502	191	0.0557511
21	FCT	Abuja Municipal Area Council	Nyanya General Hospital	285	22	0.0063506
22	FCT	Abuja Municipal Area Council	Pigba Medical Center	52	4	0.0011587
23	FCT	Abuja Municipal Area Council	Ruz Medical and Diagnostic Centre	109	8	0.0024288
24	FCT	Abuja Municipal Area Council	Sisters of Nativity Hospital (SON) - Jikwoyi	721	55	0.0160658
25	FCT	Abuja Municipal Area Council	The Crown Hospital	63	5	0.0014038
26	Lagos	Ikeja	Lagos State University Teaching Hospital	3,248	248	0.072374
27	Lagos	Ikeja	Ojodu Primary Health Care	149	11	0.0033201
28	Lagos	Mushin	Lagos University Teaching Hospital (LUTH)	7,342	561	0.1635991
29	Lagos	Mushin	Mushin General Hospital	272	21	0.0060609
30	Rivers	Obio/Akpor	Obio Cottage Hospital	311	24	0.0069299

31	Rivers	Obio/Akpor	University of Portharcourt Teaching Hospital	4,086	312	0.0910468
			Total	**44,878**	**3,431**	

Appendix 6: Statement of Intent to Maintain Confidentiality

I ……, will at all times maintain the confidentiality of the patients whose charts are reviewed, and the health workers, who are interviewed, as part of this evaluation. At no time will I disclose the names of patients whose charts are reviewed, or any information within the charts. At no time will I disclose the names of health workers interviewed, or any details of the interview. Charts will be reviewed in a private location. If there are questions related to the chart review, these will be discussed with the team facilitator or site manager in a private location. No names will be written on the data abstraction forms or on the interview sheets. The study register will be destroyed as soon as the pharmacy register has been reviewed. Once the evaluation is complete, names of patients, or data within individual charts, or details of interviews, will not be discussed with anyone.

Signed by:……

Place:……

Date:……

Witness 1:……

Witness 2:……